



# FDA Qualification for Equipment and Utilities of the Revlon production site in Pla de Santa Maria

**Master thesis presented by Christian-Aleix Sanromà Ortiz**  
to obtain the Master's Degree in Chemical Engineering from the Universitat  
Rovira i Virgili

Company Supervisor: Eduard Ibañez  
URV Tutor: Josep Basco

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## **EXECUTIVE SUMMARY**

Revlon, a company dedicated to the sale of cosmetic products and fragrances, decided in 2020 to focus on an organizational strategy to sell different products made at the Pla de Santa Maria plant in the United States. This resulted in having to adapt different parts of the production plant to meet the requirements of the corresponding legislations to sell this product to the United States. From here, it is begun this great project of the company Revlon, where a small part that is based on the qualification of different equipment and services is shown in this final project of master, in order to obtain the certification of the food and drug administration to produce and sell these types of products in the United States, along with the study of improving the cleaning process of the reactors. Regarding the qualifications, a total of 15 elements are chosen to qualify for this project. These 15 elements are mainly focused on equipment in the production area, on the services used and on the new equipment to be purchased. To perform the qualifications, a series of sequential steps are followed for each item to be qualified, the steps to be followed are different depending on whether the item is existing or a new purchase. For existing equipment, the qualification is begun by performing a risk analysis to assess whether the machine can damage the product, this risk analysis is performed both theoretically and by going down to the production plant. Then, it is continued with the installation qualification protocol, where all the technical information verified in plant and different documents and procedures that have to do with the equipment to qualify in question are introduced and finally, if it is an equipment, the qualification is ended with the operational qualification protocol, where different tests are thought and performed to verify that the equipment works as stipulated by the manufacturer, and if they are services after the operational qualification, the functional qualification is performed, which is based on evaluating the service for a year in the operating conditions established by the company and see that its operation is constant. For new equipment or services, it is started by making user requirements noting all the characteristics of the new element and send them to the interested suppliers, once the offers are sent to you, the design qualification is performed where it is evaluated that all the aspects that have been requested are in the offer, from there, with the different offers the equipment or system is purchased, and in case of equipment, to verify that they work, a test is performed in the vendor's factory and once it is observed that it works, it is installed and the tests are performed in the Revlon company in order to verify that everything works correctly. From there, the installation qualification is followed by the operational qualification and finally, depending on the case, the functional qualification. After the completion of this project, all the stages of the qualified elements have progressed favorably to be completed in a short period of time and thus be ready to be evaluated and obtain their certification. Regarding the cleaning improvement study, the current cleaning has been evaluated, and from there, improvements have been thought to apply to this same cleaning, and then two improvement proposals have been thought replacing this current cleaning by a cleaning using steam and another cleaning using an automatic system. The adaptation of the factory and the improvement of the cleaning system of the reactors is a future bet that will cause an improvement in the quality of production, due to all the control that will be had to produce, and in the number of daily productions, since, if the cleanings are faster, new productions will be able to be started before. All this, in the long term, is an increase in profits for the company, although the initial investment is very high.

## **NOMENCLATURE**

<b>Abbreviation</b>	<b>Meaning</b>
RA	Risk Analysis
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
URS	User Requirement Specifications
DQ	Design Qualification
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
FDA	Food and Drug Administration
GMP	Good Manufacturing Process
CIP	Clean-In-Place
SAS	Sterile Access System
HVAC	Heating Ventilating Air Conditioned
QMS	Quality Management System

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## **1. INTRODUCTION**

The company Revlon, in 2020/2021 decided to take a strategic vision to transfer the products marketed in the United States of skin care, which were made by a third-party company in the United States, to the production plant of Pla de Santa Maria, based on the successful experience that has been had in the production plant of Pla de Santa Maria with the products Charlie, Mitchum Aerosol, Coty's Cutex, EA Fragrance. For this reason, the company decided to design a project to improve long-term strategic capacity and cost, increase the production volume of the Pla de Santa Maria plant, maximize production savings, and develop a more flexible and lower cost supply chain. The implementation of this project will result in a total of several million dollars in annual savings, even though the initial investment is large. The strategic impact will be internal sourcing that will create technical capabilities that are key to continuing to grow the skin care business in a more efficient and financially sound manner, capabilities to develop proprietary technology and products, capabilities to minimize the complexity and resources associated with product handling, and finally, gain greater control over the quality and performance of our products.

For this reason, Revlon, as it moves to producing products that were made in the United States, has the objective of adapting the factory to be able to obtain FDA certification to market a product in the field of skin care products in the professional area in the United States. In addition, the products that Revlon would have to manufacture and market, as they are cosmetics, are marketed and catalogued as OTC products in the United States. OTC products are medicines that do not require a medical prescription to be purchased and consumed by people. For this reason, the certification sought is related to the FDA, since cosmetics are classified as drugs.

All these FDA inspections are based on what are called GMP regulations. These standards require the production of high-quality products with all relevant information on how the product has been manufactured. Moreover, these standards are based on the idea that the traditional quality system is not sufficient and that these controls at the end of the processes are not enough to ensure the quality of the product. For this reason, the GMP standards determine which are all the correct steps in the manufacturing process to ensure the quality of the product at each step of the manufacturing of the product that you end up getting at the end of the process.

To obtain the final validation of the process, first the equipment must be qualified separately, and finally the whole process must be validated by carrying out a manufacturing process for the specific product. In other words, to guarantee compliance with GMP regulations, it is necessary to qualify all the equipment and installations that belong to the specific product.

Figure 1.1 is shown the 3 main stages for the final validation of a process to obtain OTC products. The validation of the process for obtaining an OTC product is based on collecting and observing data, from the design phase of the process to its production and sale, which establishes evidence that a product with guaranteed quality can be obtained. The stages involved in this validation are 3.

- Stage 1 → Process design
- Stage 2 → Process qualification
- Stage 3 → Continuous process verification

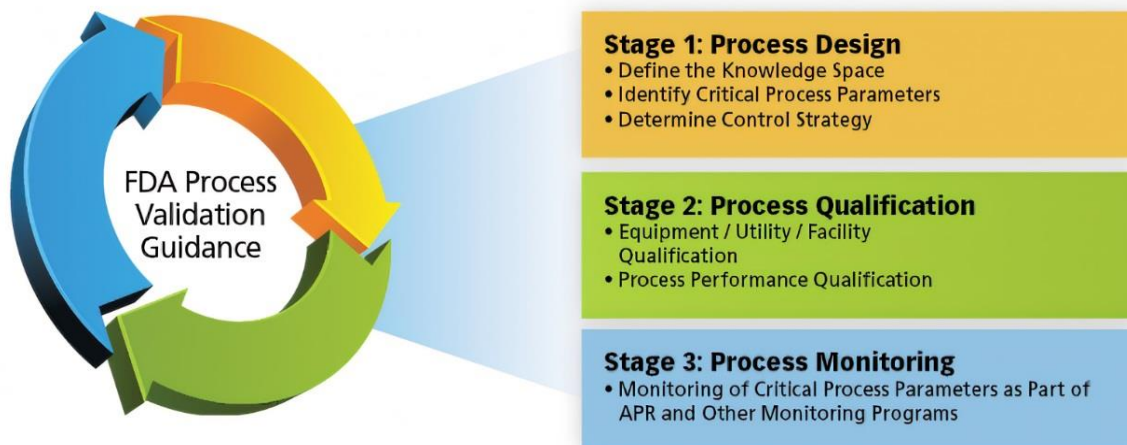


Figure 1.1 FDA process validation steps.<sup>1</sup>

Looking at Figure 1.1 and as mentioned above, the focus of this project is on stage 2, where the equipment and utilities involved in the production of the OTC product are qualified. In this stage 2 of the process validation, the process design is studied to evaluate and establish whether it is capable of continuous and repeatable commercial manufacturing. This stage has two main parts: the first is the design of the facilities and the qualification of the equipment and utilities, which is the focus of this project, and the second is the qualification of the process performance. This second stage is very important since it must be satisfactorily contemplated to be able to commercialize the product obtained.

Regarding the qualification of equipment and facilities to obtain FDA certification, the main idea to obtain this certification is to perform IQ, OQ and PQ. The IQ, OQ and PQ are 3 independent procedures used in the qualification of the equipment to verify and test the critical elements of the mechanical and electrical part, piping and the control system that these are installed correctly, the equipment that is in the field agrees with the theoretical requirements and that it operates correctly under load. This allows demonstrating that the installed equipment offers a high level of quality ensuring that all production processes produce products that meet the quality requirements. In addition to this, a risk analysis of each piece of equipment is also performed to find possible threats and try to reduce them by applying an improvement. These parts are explained in more detail in the following subsections.

Within this stage, the cleanings are also validated to obtain the FDA certificate. This aspect of cleaning validation is not part of the project, but a part that is considered and carried out in the project is the study of the improvement of the cleaning of one of the equipment that is qualified, in this case the cleaning of the reactor. The introduction of the reactor cleanliness is observed in subsection 1.6.

<sup>1</sup> Campbell, C. (2014). FDA 2011 Process Validation Guidance: Lifecycle Compliance Model. *PDA Journal of Pharmaceutical Science and Technology*, 68(2), 185–191. <https://doi.org/10.5731/pdajpst.2014.00972>

### **1.1. Risk Analysis**

A risk analysis is a tool to prevent possible failures by predicting potential threats that affect the performance and functionality of equipment or processes. A risk analysis will not prevent any failure from occurring, but it will be useful to have a realistic picture of the positive and negative points of an equipment or system, and, for this reason, certain changes can be applied, and certain contingency plans can be made in case any error occurs.

Once this is known, it is commented that there are two types of risk analysis: qualitative risk analysis and quantitative risk analysis.

On the one hand, qualitative risk analysis is based on a written definition of uncertainties, an assessment of the extent of the impact and plans of measures to be taken in the event of a negative event occurring.

On the other hand, quantitative risk analysis is based on building a risk model using deterministic statistics to assign numerical values to the risk of something affecting the equipment or system.

Once introduced what risk analysis is and what types of risk analysis there are, the type of risk analysis that is performed to assess the risks of equipment, system or processes is explained. The risk analysis that is performed is called Failure Mode and Effects Analysis (FMEA) where it is one of the most common tools of root cause analysis. This root cause analysis allows to analyze failures and resolve them. This is not a specific method, but a set of tools that may be used to analyze different failures that can be safety, production, processes, equipment or systems. Within this root cause analysis, can be found among others the 5Ws analysis, the failure trees, the Ishikawa diagram, FMEA or data analysis.

The Failure Mode and Effects Analysis (FMEA) is divided into two parts, the first part is the identification of the failure mode and consequently the possible root cause, and the second part is the evaluation of the effect of the same failure. This analysis can be functional, process or performed in the design phase of the project.

The objective of the FMEA analysis is to improve the quality, reliability and safety of the element under analysis. However, there are different benefits to perform an FMEA, these benefits can be to perform a safer and more reliable work method, analyze the possible failure mechanisms and their impact, identify the failure points and check the integrity of the system, check the effect of changes and adjustments in certain procedures, a faster resolution of failures and the definition of criteria for tests and checks to introduce in the preventive maintenance of equipment or systems.

Known this, the different process steps that are followed to perform an FMEA analysis are explained.

1. Initially describe the process flow to be analyzed by specifying stages and their sequence.
2. Identify potential failures (failure modes) following the expected sequence of the process.
3. Identify the immediate effect of each failure.
4. Estimate the severity (S) of the effect according to the established criteria.
5. Estimate the probability of occurrence (P) of the failure according to the established criteria.
6. Identify the control mechanisms capable of detecting the failure: probability of detection (D) according to the established criteria.

7. Calculate the RPN (Risk Priority Number) for each cause as the product of severity, probability of occurrence and probability of detection ( $RPN = S \cdot P \cdot D$ ).
8. Assess the level of risk and its acceptability based on the RPN and severity.
9. Identify and implement corrective measures to eliminate the risk or reduce its level to acceptable limits.
10. Recalculate the RPN to verify that the risk has been reduced to an acceptable level.

Once the process steps for carrying out an FMEA analysis are known, the following is a guide to define the classification criteria for the different estimation factors used. Specifically, a distinction is made between the different classification criteria to be applied in two different areas such as manufacturing processes and qualifications/validations. The table 1.1 shows the severity criteria, table 1.2 the probability criteria and table 1.3 the detectability criteria.

Table 1.1 Severity criteria

Severity	Manufacturing	Qualification/Validation
Critic (4)	It affects the quality of the product with a clear risk to the worker's health and this may lead to a product recall with a direct impact on the marketing authorization.	Failure of a functionality causing irrecoverable damage to the product or process data.
High (3)	It affects the quality of the product and may cause non-harmful reactions in the patient and, therefore, a return of the product.	Failure of a functionality with hardly recoverable damage on the product or process data.
Medium (2)	It does not directly affect the quality of the product and may result in customer dissatisfaction and, consequently, a complaint.	Failure of a functionality with a recoverable damage on the product or on the process data. May significantly affect the performance of the equipment.
Low (1)	It does not directly affect the quality of the product and is little noticed by the customer.	Failure of a functionality, there is no significant or critical damage to the product. May slightly affect equipment performance.

Table 1.2 Occurrence probability

Probability	Manufacturing	Qualification/Validation
Very High (4)	Can be produced very easily	Can be produced very easily
High (3)	May occur occasionally	May occur occasionally
Medium (2)	Rarely will occur	Rarely will occur
Low (1)	Remote probability of occurrence	Remote probability of occurrence

Table 1.3 Detectability criteria

Detectability	Manufacturing	Qualification/Validation
Very Low (4)	The failure is not detected until it occurs.	The equipment or system does not have mechanisms capable of detecting the failure.
Low (3)	The failure can be detected by the client before the product consumption	The failure could be detected in periodic manual checks.
Moderate (2)	The failure can be detected in quality controls performed on the product before it is marketed.	The failure could be detected with items that are included in a routine check.
High (1)	The defect is detected when it occurs	There are automatic control mechanisms that monitor where failures may occur.

Finally, the table 1.4 shows the acceptability criteria and the level of risk obtained at the end of the analysis in each of the sections.

Table 1.4 Acceptability criteria and the level of risk

Risk Level	Control Action	Value
High	Unacceptable risk requiring immediate control action.	$RPN > 12$
Medium	Requires evaluation of possible control or mitigation actions.	$12 \geq RPN \geq 8$
Low	Acceptable risk that does not require control action	$RPN \leq 7$

Once all these steps have been completed, the FMEA analysis can be considered as finished and the different aspects to be introduced to improve the equipment or system can be evaluated to mitigate the risk at very low levels.

**1.2. Installation Qualification protocol**

Installation qualification is a process that verifies by documenting that an equipment or system has been delivered, installed and configured correctly according to all current regulations. In the IQ there must be all the necessary tests to be able to verify its correct installation in accordance with all the specified equipment, and above all, with the user's requirements.

The requirements for a correct IQ are based on verifying and comparing the characteristics designed for the equipment against those installed in certain points to be considered. These main tests and processes that are performed to verify in the IQ are shown in the following points:

- Verify the design review, where it is observed that the equipment drawings agree with the existing installation, that all equipment components are identified in the drawings and that the control elements are accessible for reading and manipulation.
- Verify the components of the equipment, where it is necessary to check that all the elements of the equipment or system are correctly identified, the material that is in contact with the product is adequate and certified, and that the supply of services for the machine or system are correctly identified and adequate for its correct use.

- Verify the system and the control elements, where the control elements must be checked and calibrated with their calibration certificate and with a correct traceability, and the control system has to check the installation of the software and have a record of the firmware versions to have it all registered.
- Verify that you have all the documentation of the equipment or system, such as drawings, operation manuals, technical specifications of the measuring elements, welding reports, etc.

Everything specified that the IQ must have been introduced in a template made by the company, which can be minimally modifiable depending on the equipment or system, to have a checklist and have all the information introduced in the same document and to be easier when it is looked for all the documents related to the equipment or system in question.

To sum up, the IQ means that everything related to the operation of the machine has been read, understood and that the equipment has been correctly installed, with its correct material conformity, but that it has not yet been started up and is not working.

### **1.3. Operational Qualification protocol**

Operational qualification is a process in which documented tests are performed to ensure that the equipment and systems work as defined in the functional design phase and operate within the range established by the manufacturer. In the operational qualification the equipment is put into operation, that is, after the IQ has been performed where the equipment is calibrated and all the documentation is in order, it is necessary to know if the equipment or system works within the operating margins given by the manufacturer, therefore certain tests are established to be performed to the equipment or system.

The requirements for a correct OQ are based on verifying and performing certain tests to observe that the machine works according to the manufacturer's design characteristics. As an objective, the OQ is used to verify that the equipment or system is operating correctly according to the design specifications, is used to verify and document that the equipment or system is operating within the conditions established by the manufacturer and according to the requirements of the company and is used to perform different tests to ensure that the equipment or installation is suitable for its use. These possible main tests and processes that are performed to verify in the OQ are shown below:

- Verify temperature control systems, both control elements and alarms.
- Verify pressure control systems, both control elements and alarms.
- To verify the systems that control the speed of the motors, both the control elements and the alarms.
- Control equipment and interfaces with operators.
- Testing of equipment or system valves.
- Testing of flows in a system.
- Testing of product packaging.

As shown, there are an infinite number of tests that can be performed on an OQ depending on the machine or system is being qualified. Everything specified that the OQ must have been entered in a template made by the company, which can be minimally modifiable depending on the equipment or system, to have a checklist and have all the information of the tests performed

to verify the proper functioning of the equipment or system and be easier when defending in front of an inspector that the machine or system that has been qualified is working properly.

In short, the OQ means that the equipment has been started up and is working, and that different tests have been performed to verify that the machine is working according to the manufacturer's specifications, testing at the limits of its working range and seeing that everything is working properly.

#### **1.4. Performance Qualification protocol**

Performance qualification is a process that is based on verifying the performance of the equipment or system that meets all the requirements established in the URS and that the operating cycles are constant over time and within the working environment in which the machine or system has been installed. This process is the one that must comply with GMP standards.

The PQ protocol is very similar to the OQ, but the difference is that in the PQ the tests that are performed are in the usual working conditions of the factory. That is, the equipment or system is subjected to the conditions during batch production.

This final protocol is important because you observe the complete machine or system in operation and in this way, can be discovered certain faults that may have the equipment as shown below.

- Generation of excessive vibration or noise due to the failure of two individual elements that vibrate and produce resonance.
- Excessive heat production due to a bad adjustment between parts of the equipment or system.
- Generation of a pressure difference due to an open or closed valve.
- Failure of any of the transmitters that does not allow to have a proper process monitoring.
- A combination of failures of individual parts causing the equipment or system to malfunction.

As mentioned above, the tests to be performed for the PQ are the same as in the OQ, depending on the machine, but they are performed in the usual working conditions of the factory during a certain established time. It must be clear that the PQ is performed in the systems, in the equipment the qualification is stopped in the OQ and then the validation of the process is performed with the usual working parameters to produce a particular formula.

As in the other protocols, everything specified that the OQ must have been entered in a template made by the company, which can be minimally modifiable depending on the equipment or system, to have a checklist and have all the information of the tests performed to verify the proper functioning of the equipment or system in the usual working conditions.

Summarizing, the PQ means that the equipment is already working with a certain time, and that different tests have been performed to verify that the system works according to the process conditions established by the company. It is important to know that PQ should not be confused with final validation or cleaning validation. The PQ is independent for a system and the validation is for all equipment with a specific production process for a specific formula.

## **1.5. Protocols for New Equipment**

Once explained the main part on which the FDA equipment qualification process is based, it is proceeded to introduce other protocols that are focused when new equipment purchases are made and must be performed before the RA, IQ, OQ and PQ processes. These protocols that apply to new equipment are introduced below.

### **1.5.1. User Requirements Specifications**

The URS is basically a document that describes all the needs that the company has for a specific operation. It would be all the requirements, both technical and documentary, that a machine or system must have for the company when it wants to buy a new equipment or system. The URS is the first point that is drafted when it is wanted to buy equipment and when it is required to validate it, and these URS is drafted by the company, since it will be the final user of the equipment or system and must comment the needs that it has. The URS is not intended to be a technical document; readers with a general knowledge of the system should be able to understand everything it says in a URS.

In short, the URS is generally a planning document, created when a company is thinking about acquiring equipment or machinery and is trying to determine the specific needs they require for their process.

### **1.5.2. Design Qualification**

The design qualification is a process that, once you have obtained the offers from the suppliers, it is the point of observing if all the offers you have matched the URS that has been generated for the machine or system. In other words, the DQ is a process that is based on verifying the design you have stipulated in the URS and observing if everything you have asked for is entered.

To sum up, the DQ is a common part of new equipment or system purchases, where design reviews are documented to ensure that quality has been considered in the design phase of the equipment, i.e., it defines all the functional and operational characteristics of the equipment.

### **1.5.3. Factory Acceptance Test**

The FAT is a process that is based on performing an inspection that includes static and dynamic testing of major parts of the complete equipment or system to support the qualification of the equipment or system. The tests performed in the FAT should detail everything that is specified in the URS of the machine and verify that everything is working properly as specified. Since the FAT is performed at the supplier's facility, its main purpose is to verify that the machine is functioning properly in all specified aspects before it is shipped to the purchasing factory.

In summary, the FAT is a common part when purchasing new equipment or systems, and it is because once the URS and DQ have been performed and the equipment has been purchased, several tests are performed at the equipment manufacturer's facility to verify functionality and, most importantly, to verify that the machine complies with everything specified in the URS.

### **1.5.4. Site Acceptance Test**

The SAT is a process that follows the same methodology as the FAT, i.e., it is a process based on the performance of an inspection that includes static and dynamic tests of the main parts of the equipment or complete system to support the qualification of the equipment or system. The equipment, once the FAT has been performed and it has been verified that the equipment or system is working properly at the manufacturer's facilities, is assembled at the

company's factory and the SAT is performed. As the FAT is already performed at the company's facilities, its main purpose is to check that the control and safety systems are fully operational as specified before using them to operate the equipment itself.

In short, the FAT is a common part when buying new equipment or systems, because once has been verified that the FAT is working properly and the machine or system has been assembled in the company's facilities, are performed the necessary tests to verify that the machine or system works according to the specifications agreed in your company. From here, if it is verified that the FAT is all correct, you can start up the equipment or system.

Finally, for an equipment or system that is purchased new, once the SAT is done, which is the last step that differs from the qualification of an existing equipment to the qualification of a new equipment, you can go on to perform the main parts to finish the qualification of the equipment as a whole, that is, can be passed on to perform the RA, the IQ, the OQ and finally the PQ.

**1.6. Reactor Cleaning**

The cleaning of the reactor is an important step in the production process, because if the equipment is not properly cleaned after producing a product, when the next product is going to be produced in the same equipment, cross contamination may occur, and this would result in the rejection of an entire production. For this reason, it was decided to conduct an improvement study.

The reactor cleanliness improvement study relates to the reactor that is chosen to qualify to produce the OTC product, but this improvement would be the same for all professional packaging reactors.

Currently, reactor cleaning must be performed before 8 hours of the next production run and is divided into 6 steps, where one of them is optional:

1. **Previous cleaning** → Initially, pressurized water or manual cleaning with a brush and detergent is applied to remove product residues from the reactor walls and stirrer.

The reactor is then filled with deionized water at 80 °C and left stirring for a certain time. Depending on the type of product produced, the reactor is filled to a greater or lesser extent and the water is left stirring inside the reactor. The following table shows the pre-cleaning conditions according to the type of product manufactured and whether detergent needs to be applied at the next stage or not.

Table 1.6 Previous cleaning according to the product manufactured

Type of product	Osmotized water quantity	Need detergent?
Shampoo	25 % of reactor	No
Equave	25 % of reactor	No
Mask and conditioners	50 % of reactor	Yes
Supermasks	100 % of reactor	Yes
Oils	100 % of reactor	Yes
Serums	100 % of reactor	Yes
Fibers, Ryellis and creams	100 % of reactor	Yes
Specific shampoo	100 % of reactor	Yes

2. **Auxiliar equipment's disconnection and cleaning** → Then, while the reactor is stirring deionized water inside, the auxiliary equipment used during reactor unloading, filter, hoses and pump, are disconnected and taken to the cleaning room for cleaning.  
The filter is manually cleaned with detergent and disinfectant for a certain time established for each one. Once this is done, it is rinsed and left to dry.  
The hose and pump are cleaned using pump cleaning equipment.
3. **Foaming agent application** → Once the previous cleaning has been completed, the reactor is rinsed with tap water.  
The valve at the bottom of the reactor is then left open and a foaming agent is applied with MobyFoam equipment to all internal surfaces of the reactor, and then the foaming agent is allowed to stand for a certain specified time.
4. **Foam rinsing** → Then, when the foaming agent rest time has elapsed, with the valve at the bottom of the reactor open, tap water, which is tap water with an addition of sodium hypochlorite, is applied to the reactor to evacuate the remains of the foaming agent until no foam is observed inside the reactor.
5. **Application of peracetic solution (Optional)** → This section is optionally performed according to the planning for the next production in the reactor.  
If the reactor is not used within the next 8 hours and to improve the disinfection of the reactor, introduce a peracetic solution on all inner surfaces of the reactor for a certain period.  
Once finished, before using the reactor again, if it has been left wet with peracetic, rinse it with tap water for a few minutes to allow production.
6. **Cleaning completion** → Once all the steps have been completed, close the lid and place biowraps on the reactor drain valve, leaving it open, as well as on all the fixed connections. Once this is done, the cleaning of the reactor is finished.  
For the cleaning of the reactor, it must be considered that the Dirty Hold Time must be less than 8 hours and the Clean Hold Time must be 8 hours if peracetic acid is not applied.

Once this is explained, this is the current cleaning process that the company has for the professional manufacturing reactors. From there, an improvement study is carried out and are intended to apply alternatives to improve it.

## **2. SCOPE OF THE PROJECT AND OBJECTIVES**

### **2.1. Scope of the Project**

After an introduction on this aspect, this project is based on qualifying the equipment involved in the production of a product with a specific formula that once validated the entire process can be marketed in the United States. In this scope, during the qualification of each piece of equipment, all the machines are carefully observed, their operation is understood and observed, and finally, the qualification is started. Once the qualification is started, if during the process irregularities or certain points of improvement are observed, they must be solved and applied in order to be able to continue the qualification and reach the final stage. Furthermore, this project has focused on a study task for the improvement of one of the main parts of the process of obtaining the OTC product, which is the cleaning of the reactor that makes the product.

Finally, considering all that has been commented in the introduction, the FDA project that Revlon is carrying out is to qualify all the equipment and systems, both existing and new, as shown in table 2.1, which shows the 27 equipment, systems, and rooms to be qualified to adapt the factory and obtain FDA certification. As shown, there is a large amount of equipment and systems to be qualified, for this reason, in the scope for the chemical engineering project, the qualification has been focused on certain equipment and services, and those that are not in this scope, are introduced in the industrial engineering project. Furthermore, in the scope of the chemical engineering project the study for the improvement of the FDA reactor cleanliness is added, which is finally carried out considering that it can be used for all the professional manufacturing reactors.

Table 2.1 All elements to be qualified

Element number	Zone	Area/Equipment/System
1	Sampling Area	HVAC Sampling Area
2	Weighting Area	HVAC Weighting Area
3	Weighting Area	HVAC Weighting Cleaning Area
4	Weighting Area	Washing machine
5	Weighting Area	Weighting Area scales 1, 2 & 3
6	Utilities	Veolia reverse osmosis
7	Utilities	Astramatic reverse osmosis
8	Utilities	Distribution loops
9	Utilities	Compressed air
10	Manufacturing Area	HVAC Manufacturing Area
11	Manufacturing Area	Kettle (Reactor)
12	Manufacturing Area	Melter
13	Manufacturing Area	Kettle (Reactor) pilot plant
14	Manufacturing Area	Melter pilot plant
15	Manufacturing Area	Manufacturing cleaning system
16	Manufacturing Area	One use bag
17	Manufacturing Area	Filters
18	Manufacturing Area	Neumatic pump
19	Filling & Assembling Area	Neumatic pump
20	Filling & Assembling Area	HVAC Filling & Assembling Area
21	Filling & Assembling Area	Filling machine

22	Filling & Assembling Area	HVAC Filling & Assembling cleaning Area
23	Filling & Assembling Area	Washing machine
24	Filling & Assembling Area	Dynamic scale
25	Filling & Assembling Area	Metal detector
26	Warehouse	Warm room
27	Warehouse	Cool room

Observing the total number of equipment, as the scope of the project in general was too wide to perform in this project, a total of 15 equipment and systems were selected to be introduced in this master's degree final work together with the study of the improvement of the reactor cleanliness.

As it is observed, in this project the utilities have been introduced, such as the two water systems and the compressed air, and the equipment more related to the manufacturing, such as the scales in which the weighing of the raw materials for the manufacturing is performed, the reactor for the manufacturing of the OTC product, the discharge filters, one of the climatic chambers to see its qualification style and finally the cleaning tanks used for the reactors. And as a new part, the new equipment, the new areas are out of this scope.

Over the months and with the work of various departments, this scope of the overall project has varied according to the functions to be performed. For this reason, the final scope and the theoretical planning to follow already defined is shown in the following table.

Table 2.2 Tasks planning for this project

Element	Element task	Initial date	Final date
Weighting Area scales 1, 2 & 3	-	20-12-2021	31-03-2022
-	RA	20-12-2021	17-01-2022
-	IQ	18-01-2022	04-02-2022
-	OQ	28-02-2022	31-03-2022
Astramatic reverse osmosis	-	17-11-2021	31-03-2023
-	RA	17-11-2021	04-02-2022
-	IQ	07-02-2022	28-02-2022
-	OQ	01-03-2022	31-03-2022
-	PQ	31-03-2022	31-03-2023
Distribution loops	-	17-11-2021	31-03-2023
-	RA	17-11-2021	04-02-2022
-	IQ	07-02-2022	28-02-2022
-	OQ	01-03-2022	31-03-2022
-	PQ	31-03-2022	31-03-2023
Veolia reverse osmosis	-		
-	URS	01-04-2022	08-04-2022
-	DQ	N/A	N/A
-	FAT	N/A	N/A
-	SAT	N/A	N/A
-	RA	N/A	N/A
-	IQ	N/A	N/A
-	OQ	N/A	N/A
-	PQ	31-03-2022	31-03-2023

Compressed air	-	17-11-2021	01-02-2023
-	RA	17-11-2021	13-12-2022
-	IQ	14-12-2022	10-01-2022
-	OQ	11-01-2022	31-01-2022
-	PQ	01-02-2022	01-02-2023
Kettle (Reactor) and One use Bag	-	9-02-2022	08-04-2022
-	RA	9-02-2022	25-02-2022
-	IQ	28-02-2022	16-02-2022
-	OQ	17-02-2022	31-03-2022
Manufacturing cleaning system	-	15-03-2022	07-04-2022
-	RA	15-03-2022	23-03-2022
-	IQ	24-03-2022	07-04-2022
Two washing machines	-	01-12-2021	30-09-2022
-	URS	01-12-2021	18-02-2022
-	DQ	18-02-2022	11-03-2022
-	FAT	01-07-2022	21-07-2022
-	SAT	21-07-2022	05-09-2022
-	IQ	06-09-2022	16-09-2022
-	OQ	19-09-2022	30-09-2022
Dynamic scale	-	01-12-2021	30-09-2022
-	URS	01-12-2021	18-02-2022
-	DQ	18-02-2022	11-03-2022
-	FAT	01-07-2022	21-07-2022
-	SAT	21-07-2022	05-09-2022
-	IQ	06-09-2022	16-09-2022
-	OQ	19-09-2022	30-09-2022
Metal detector	-	01-05-2021	30-09-2022
-	URS	01-05-2021	18-02-2022
-	DQ	18-02-2022	11-03-2022
-	FAT	01-07-2022	21-07-2022
-	SAT	21-07-2022	05-09-2022
-	IQ	06-09-2022	16-09-2022
-	OQ	19-09-2022	30-09-2022
Cool room	-	24-01-2022	
-	RA	24-01-2022	
-	IQ		
-	OQ		
-	PQ		
Reactor cleaning study	-	31-01-2022	
-	RA	31-01-2022	14-02-2022
-	Evaluate the actual cleaning Study and implementation of improvements	15-02-2022	04-03-2022
-		07-03-2022	28-03-2022

	in the actual cleaning		
-	Evaluate steam cleaning	29-03-2022	08-04-2022
-	Evaluate the CIP cleaning	11-04-2022	25-04-2022
-	Comment and evaluate the different proposals	26-05-2022	09-05-2022

As shown in the planning table, there has been a change of ideas and new adaptations from the beginning of the project to the current state. As noted, there is equipment that has been removed from the qualification after a pilot production was carried out and it was observed that it was not necessary, such as the filters and the reactor melter, which after the test was carried out, it was observed that the product was very liquid and the melter was not necessary, since the materials were not very fatty.

Once this is known, the scope of the project is already established with its corresponding timing with respect to the tasks for FDA certification, the study of the improvement of the cleaning of the professional reactors was within this period of time that is observed and was done at certain times together with the process engineer.

## 2.2. Objectives

After an explanation of the scope of the project and the time stipulated to perform each of the tasks, the main objectives at the time of this project are observed.

The main objectives of this project are:

- Perform in the appropriate manner and following the stipulations set by FDA the qualification of the equipment selected in the scope of the project that goes into the production of the OTC product.
- Performing this qualification, observe possible improvements in the facilities or equipment to be able to introduce them and make everything work in a more optimal way.
- Verify that all equipment has the proper documentation and that the operation stipulated in the documentation is in accordance with the actual operation of the machines.
- Evaluate and study the current cleanliness of the reactor.
- Study possible improvements to be introduced and evaluate different options to be implemented for a more efficient cleaning of the reactor.

As shown, these are the main objectives of the project to be achieved during my internship at Revlon.

### **3. ROLE IN THE COMPANY**

#### **3.1. Company**

##### **3.1.1. Introduction**

Revlon is an American multinational company where it is a leading global beauty company with a lot of iconic brands that transform the lives of women and men around the world, and it sells its products in 150 countries and has many locations in big cities around the world. Revlon is in the cosmetics, fragrance, skin care and personal care industries and its headquarter is in New York. Moreover, the company has more than 7500 employees and with assets of 3024 million dollars and revenues of 2334 million dollars.

##### **3.1.2. History**

Revlon was founded in New York in 1932 by two brothers, Charles Revson and Joseph Revson, with the chemist Charles Lachman. They began the business with a single product, a nail enamel, that it was revolutionary.

Some years later, in 1937, Revlon brought different shades of nail enamel to market using pigments instead of dyes and they began to be sold in stores and beauty salons. In only 6 years Revlon became a multimillion company. Two years later, in 1939, Revlon introduced lipstick into product portfolio and in 1940 it offered a complete manicure line and different lipsticks.

After several years manufacturing, in 1955, Revlon started to expand the business globally and it began marketing its products abroad. In 1962, when Revlon landed in Japan, it already had subsidiaries in several countries. Revlon's entry into the Japanese market was carried out following the same strategy that was used in the different countries and instead of adapting its advertisements and using Japanese models, Revlon used the same standard advertising and the same models that were used in United States. For this reason, the Asian customers loved the American style and the sales in 1962 increased dramatically.

After a while, in 1970, Revlon made history by being the first beauty company to use an African-American model in one of its advertisements. In the same year, Revlon acquired the Mitchum company, which was based on a line of deodorant, and in 1971 launched a shampoo and conditioner called Flex. In 1973, Revlon launched the Charlie fragrance, where the model Charlie Shelley was used to promote the fragrance. This fragrance produced a huge increase in sales and became the number one fragrance in the world. In 1979 Revlon acquired Henry Colomer and launched Revlon Professional.

In 1985 Revlon was sold to MacAndrews & Forbes, owned by Ronald Perlerman, where his daughter is the current president. In 1991 the company introduced ColorStay lipstick which became the first non-transfer lipstick. In 1995 American Crew was born as the men's personal care category, where it is the global leader in men's personal care. In 1996 Revlon went public on the New York stock exchange as a public company and in 1997 launched Age Defying, an anti-aging makeup line.

In the year 2000 Revlon sold its professional products division to Beauty Care Professional Products Luxembourg and continued production. In 2011 it acquired a manufacturer of nail products called Mirage Cosmetics. In 2013 it acquired Colomer Group and reunited with its professional products division. Colomer Group in this case is the former owner of the factory where I am doing my internship in Pla de Santa Maria which in 2013 was bought by the company Revlon and is its current name. In 2015 Revlon bought the British fragrance management company CBBBeauty. In 2016 Revlon announced the purchase of its competitor Elizabeth Arden, a high-level skin care cosmetics and fragrance company, and from there comes its current name Beautyge and its current logo. In the same year 2016 Revlon completes the global acquisition of Cutex, which is a famous nail polish remover brand and in 2017 the Elizabeth Arden part launched White Tea which is a fragrance for women. Finally, in 2018 Revlon announced the appointment of Debra Perelman, the daughter of Ronald Perelman, to the CEO position and became the first female CEO where she remains to this day leading the company in all its areas.

### **3.1.3. Goals and Benefits**

Revlon is committed to the health, safety and well-being of its employees around the world and to creating a safe, respectful and inclusive workplace.

Revlon recognizes that the world in which it operates is complex and diverse, and championing an inclusive culture is essential to collective success. For this reason, employees are encouraged to be creative, bold and entrepreneurial. The company believes in continuous learning and development, from its newest employees to our most senior executives, and its commitment to talent development includes employee mobility through the mobility of employees across the company.

which includes employee mobility across brands, geographies, and functions. In addition, they foster a company culture that values boldness, creativity, and a passion for beauty, and encourage employees to bring their authentic selves to work every day.

They also value diversity and believe that an inclusive workplace that values and celebrates their differences is essential to long-term growth and success. Furthermore, they believe that continuous learning and professional development are essential to building a strong and successful workforce, and their commitment to talent development includes global mobility of employees across brands, geographies, and functions, building the next generation of leaders.

Regarding Revlon's benefits, they are committed to building a community of healthy and satisfied employees and believe that good health should extend to all aspects of their lives. The company offers comprehensive medical, dental, vision, and mental health coverage, as well as wellness incentives and more.

Next, Revlon offers a periodic energy recharge, meaning the company offers paid time off for vacations, company and floating holidays, summer hours and even your birthday. In addition, the company recognizes that life goes on well beyond your career, so it offers savings and investment programs to help you reach your financial goals and provide peace of mind when planning for your future.

In addition, Revlon believes in and values learning, education and professional development, which is why it promotes a culture of learning and supports personal and professional development and offers tuition reimbursement for qualifying courses and advanced degree programs. In addition, we strive to create an environment that respects and appreciates the family.

Finally, they are committed to creating a diverse and inclusive culture in which all employees have the freedom to celebrate their authentic and unique selves and encourage employees to give back to their communities and share their time and talents in the communities where they live and work.

#### **3.1.4. Brands and Products**

Revlon has a large group of brands and, respectively, a wide variety of products for its customers.

The two major brand groups are Revlon and Elizabeth Arden, which is where the name of the current company, Beautyge S.L., comes from. In terms of the products that each of the brands have, Revlon has a strong reputation for trend-setting color and beauty authority products in the world of color cosmetics. And since 1932, Revlon has provided consumers with innovative products of high quality, performance and glamour. Elizabeth Arden, meanwhile, has a broad portfolio of prestige beauty brands with products related to skin care, color and fragrances.

Once commented the two great brands that the company has by which the current name comes out, Revlon has other great brands that generate great products.

One of these brands is Almay, Almay is a brand that manufactures makeup products that enhances your skin features, and each shade is made to highlight your unique beauty.

Another great brand is American Crew, which is the world's leading official supplier of men's grooming products, with strong endorsement from stylists, to enhance men's confidence in their day-to-day lives.

Another great brand is CND, which is a world leader in professional nail and beauty care. CND is all about perfectly polished nails with an unwavering commitment.

The Cutex brand is another great brand that owns Revlon where it manufactures products for nails. Cutex is synonymous with nail polish remover all over the world, where it now offers a complete range of products that find you an innovative solution for your nails, hands and feet.

Another great brand is SinfulColors where its main products are nail polish. SinfulColors is the brand for those who want to paint their nails outside the lines with outrageous, innovative, trendy and eye-catching colors.

Mitchum is another of the great brands that Revlon has, the main products of this brand are antiperspirants and deodorants. Over the years, Mitchum has become a global brand offering a range of powerful antiperspirants for both women and men, easily recognizable by its green packaging. Mitchum's goal is to provide maximum efficacy against sweat and odor with its highest level of active ingredient.

Britney Spears Fragrances is another brand, this brand is one of the largest and most iconic celebrity portfolios in the world. Britney's many best-selling and award-winning fragrance products invite consumers to experience the world of an inspirational idol.

On the other hand, Christina Aguilera Fragrances is another brand with celebrity fragrance product collection where it celebrates sensuality, glamour and feminine power.

Another brand is Elizabeth Taylor Fragrance where it celebrates the glamour and elegance of Elizabeth Taylor, the legendary actress, activist, humanitarian and international celebrity. This brand manufactures fragrance products of the legendary actress.

John Varvatos is another of Revlon's great brands. This brand is a perfumery that knows no limits, driven by freedom and creativity. Its inspiration comes from the most precious and rare materials in nature.

On the other hand, the AllSaints fragrance collection is another brand that Revlon has, and this one pays homage to the brand's codes.

Finally, Juicy Couture is the last of the great brands that has a lifestyle brand of glamorous, irreverent and fun design, which brings the style and attitude of Los Angeles to girls all over the world. Discover couture in your everyday with an element of surprise.

Finally, apart from the big brands that Revlon has, Revlon also has smaller brands related to the cosmetics world such as Alfred Sung, Charlie, Crème of Nature, Curve, D:FI, Ed Hardy, Eksperience, Gatineau, Giorgio, Grey Flannel, Halston, Intercosmo, Jean Nate, Jennifer Aniston, Lucky You, Mariah Carey, Orofluido, PureIce and Wildfox.

## **3.2. Internship Description**

### **3.2.1. Specific Tasks Description**

During my internship at Revlon, I was working as a project engineer in the engineering and maintenance department.

My internship as a project engineer was based on the realization of the project of this master's thesis. That is, the internship was based on the qualification of the equipment and utilities of the production plant in Pla de Santa Maria for the FDA.

Explained this, the functions as project engineer related to this project were based, first of all, on compiling the technical information of the different machines and services that would be used to produce the OTC product, understanding all the information that had been found and, if necessary, contacting the supplier of the equipment or services to provide more information about them, and from there, carrying out the risk analysis. In addition, if necessary, also made work instructions for certain equipment or system, basically instructions for performance and maintenance of equipment, and in addition, once you had all the relevant information, the whole process of readings, revisions, and signatures in the web document management QMS was managed.

The risk analysis was carried out in the following way; Initially, with the information collected, a theoretical risk analysis was carried out, and once it was done, the equipment was taken to the plant and observed, and with the help of the person in charge of the machine, the operation of the machine was correctly understood, and from here, the risk analysis was reviewed and the corresponding modifications were made to have it in an ideal form.

Then, once the risk analysis had been carried out, the installation qualification protocol was filled in with the information collected from the machine.

In this protocol, the locations where the information of the drawings of the equipment or installation to be validated (going to the field to verify that the drawing is in the factory), the operation and instruction manuals of the equipment, the list of spare parts, the information of the measuring equipment and the welding reports were entered, all this considering whether the information was available or not, depending on the case of validation. Then, the type of control and the acceptance ranges given by the machine, the year of manufacture of the equipment and the electrical specifications of the machine were also entered. Then, different technical data of the possible equipment that has the machine or systems were introduced, for example, in the water treatment system, in the whole system find pumps, membranes, EDIs.... Well, all this information of these elements is introduced in this section. Next, the services (water, compressed air, electricity and steam) used by the machine or system and their specifications were entered. Next, the parts of the equipment or system that are in contact with the product and how it has been verified are entered, and finally, a list of standard operating procedure (SOP) related to the machine or system being validated is entered.

Then, once the installation qualification protocol was done with all the information collected from the machine, it is proceeded to perform the operation qualification protocol. In this protocol, another of the functions that I performed as a project engineer was that, once read and observed all the information of the machine or system, for the operation protocol went to the factory and observed the operation of the equipment, from here were thought critical points that had the equipment or system and certain tests were thought and how to perform them to verify the operation of the equipment in its maximum and minimum ranges of functionality of the equipment. Once they were thought of, they went and tested the equipment to verify its functionality.

In this protocol of operation of the installation were introduced the critical points thought of the machine or system and that could be displayed on the PLC screen, then were introduced certain functional verifications of the equipment related to these critical points, making the machine or system to work the maximum and minimum values that allows, and finally, write down all the alarms that may have the system and in the verification cause these alarms to verify that they work properly. That is to say, all this you have the protocol with all the commented subjects pointed out and then you go to the factory, and you verify that the machine or the system fulfills it.

Finally, once the operation qualification protocol is completed, the last step to the qualification the machine is the performance qualification protocol.

In this performance protocol, which is very similar to the operation protocol, a table was introduced to perform different functional verification tests, but this time these tests are with the performance of the equipment or installation in a standard way, that is, with the conditions under which these machines or systems normally work.

Once all these points were completed, all the aspects for the FDA qualification were obtained, and the next step is validating each equipment and then, the products to be manufactured can be sold in the United States.

On the other hand, one of the steps to obtain the FDA certification was to qualify the reactor that manufactures the product for the FDA and in this qualification process, another of the tasks that I have done as a project engineer in these practices is the study of improvement of the

reactor cleaning process. In this work, there was a lot of contact with the process engineer of the manufacturing part since he was the expert in the subject of reactor cleaning. At this point, we took the information and the cleaning procedure of the professional reactors, went to see in situ how it worked, and from here, were carried out the necessary calculations to observe the cost and the time it took to perform it. From here, meetings were held with the process engineer and improvements and certain alternatives were proposed. Once this was established, the calculations were made and the viability of the application of the alternatives was observed with him, different possible tests were carried out and finally, final results were obtained and discussed with him to see the best option and possible implementation in the plant.

### **3.2.2. Communication and Complexity of Work**

Regarding communication at work, related to this project, it was observed that both with the same colleagues in the engineering and maintenance office when asking for information about equipment or system, to resolve certain questions about machine operation, etc. As with each department which corresponded to the machine to qualify asking for any kind of help, it has been necessary and at the same time useful to develop the work in a more enjoyable and faster way, and to understand and learn about each part of the process being performed. This aspect of communication, I could see that it was closely related to the complexity and difficulty that I would find when performing each task. If the communication was good and fluid, the complexity of the work decreased.

The following is an explanation of the work channels that were most followed in the development of the activities.

The department with which I had the most communication was the GMP/QA department, which is the department in charge of good manufacturing practices and instead of verifying that the final product is of good quality, they verify that each section of the production process until the product is of high quality. For this reason, it was the department with which I had the most communication.

The communication flow was based on assigning which machine would start to qualify within the engineering and maintenance department, once the machine was chosen, the risk analysis was started, once the risk analysis was done, contact was established with the department where the machine in question was located, the departments that were contacted according to the machines to be qualified were the maintenance department and the manufacturing department, and a field review of the risk analysis was carried out. The GMP/QA department was then contacted, and a meeting was held to review the risk analysis and approve it. Once approved, the IQ was performed, following the same communication process and then the OQ and finally the PQ, following the same communication flow in each case.

Apart from following this communication flow with the different departments, there was also a weekly meeting with the engineering department, with my tutor, and with the GMP department to review how the validation process was going and how it was evolving. And from time to time, I held meetings with the process engineer from the manufacturing side to discuss the aspects of improving the cleanliness of the professional reactors.

### **3.2.3. Adequacy of the Internship to the Company's Goals**

Certain tasks as a project engineer meant that had to be in the plant for a certain amount of time and, at the same time, that I had to comment on any possible improvements that it was observed during my stay. In addition, the function I had to perform meant that had to be in contact with different departments of the company and this was closely related to the company's objectives of continuous improvement and inclusion of workers.

## **4. APPROACH**

The approach of this project is based on understanding the process that the company follows to obtain a final product, then, to see how it is applied in the FDA all the parts involved in the process of obtaining the product and perform the qualification of each facility and equipment, and finally, in one of the parts that is involved in the validation, an improvement study is conducted to show different alternatives and thus choose the most beneficial.

### **4.1. Process to Obtain a Product**

In this section the procedure followed by the company to obtain the final product and thus commercialize it is commented.

Initially it is necessary to understand that to produce any product in any type of factory follows and complies with the well-known rule of the 4 Ms, depending on the site can reach 6 Ms. These 4 Ms are people, materials, machines and methods.

The first point, which is about people, is considered the most critical and the most important when it comes to production. This factor refers to the motivation, training and desire of the worker to manufacture the product and work on a daily basis.

The second point of materials is based on the raw materials that are necessary to produce a product and that for the selection of these raw materials take into account the factors of cost, quality, availability, reliability with suppliers and the amount of raw material that is spent in a production. From there, the best supplier is selected to obtain minimum production cost and profit maximization.

The third point is about the machines of the factory, these machines are the equipment that are used in the production of the product to be obtained. To know if the equipment that is used is adequate for the process, you have to observe if the type of machine that is used is good for the product and materials that are used, if the machines cost a lot of money, if they have enough capacity for what you have planned to produce, if there are spare parts nearby and you do not have to order them on the other side of the world with a very long delivery time, if the machine is easy and understandable to use and finally, if the machines that are used are efficient and do not make you lose money because of the great consumption that they have.

Finally, the fourth point is about methods, this is related to the techniques that are used to convert raw materials into final product. Raw materials are made through a series of stages to be transformed and finally obtain the final product to be marketed.

Once this explanation is understood, it is established a supply of this project related to the machines of these 4 Ms. To better understand the production process of Revlon in the professional area, it is explained in figure 4.1, where 5 major groups are observed

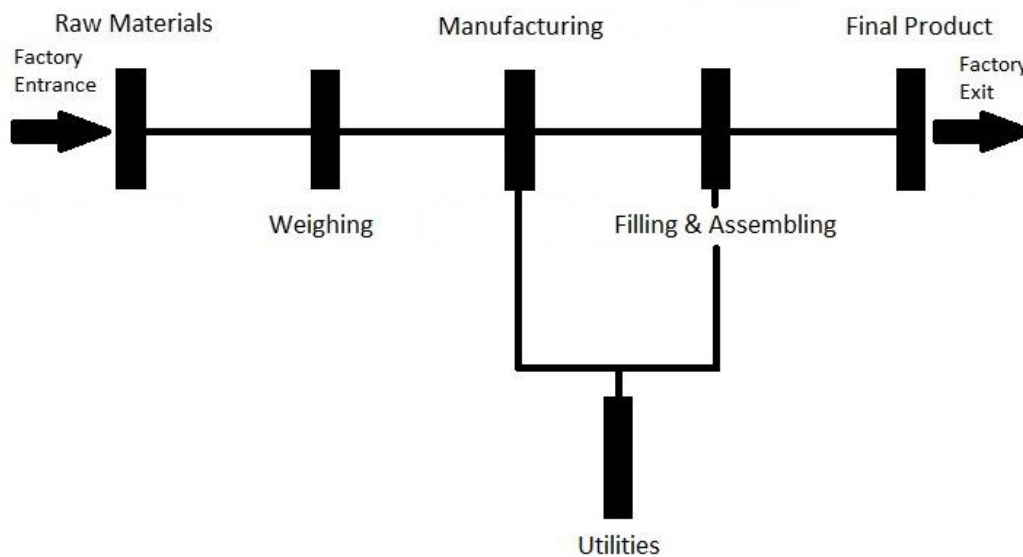


Figure 4.1 Division of the 5 main groups for obtaining a product.

The material has a specific flow to follow during the production process in the company's professional area.

The production process starts when the raw material enters the factory through specific docks located near the weighing room. All types of raw materials are received, both those used in the professional field and those used in mass consumption, aerosols and fragrances.

Then, a quality test of the raw material is carried out to check that the materials are obtained in good conditions and with the requested specifications. After the test, if the raw materials are suitable, they are stored in the raw materials warehouse and are ready for use when needed.

Then, when they are to be manufactured, they go to the next stage and are sent to the weighing room to obtain the weights according to the formula of the product to be made.

Once the raw materials are weighed, they are transferred to manufacturing. Professional manufacturing is a hall where the products are manufactured in the reactors. This room is filled with reactors of different volumes in order to produce as required. In the manufacturing stage, the raw materials, previously weighed, are introduced into the reactor and the products are made. Once manufactured, a diaphragm pump is connected to the discharge valve and the product is introduced into single-use plastic bags called C-packs. Once the product transfer is finished, the plastic bag with the product inside is transferred to the packaging area, and the reactor is cleaned.

In filling and assembling there are different types of filling machines, jars, bottles, tubes... Once the product is ready, the pump is connected to the containing bag and to the corresponding filling machine, and the hopper is filled. From this point on, once the hopper is filled, the product is packed into the appropriate container, weighed, and placed in boxes to finally obtain the final product for commercialization. Once the filling and assembling is finished, the final product is stored in the finished product warehouse.

Related to utilities, they are marked in this way in figure 4.1 because they are fully related to the manufacturing and filling and assembling sections. As utilities, electricity is left aside, since electricity is necessary throughout the factory and without it nothing would work, but in this section, it is divided into two groups. On the one hand, the services that are in direct contact with the product, which are compressed air and osmosis water. On the other hand, the utilities that are not in contact with the product, which are steam and cooling water. The utilities that are in contact with the product, the compressed air is used in all the electrovalves, but moreover, it is used to seal the tubes, since the packaging machine works with hot air to seal the tubes. Regarding the osmotized water, it is used for the cleaning of the reactor, melter and packer and moreover, depending on the formula, the osmotized water is used as raw material to obtain a specific product. The services that are not in contact with the product, both steam and cooling water are mainly used to heat or cool the reactors of the plant. The steam is also used to heat the hot chamber of the factory to obtain an improvement in the manufacturing process, heating some raw materials.

Once the production process has been explained, figure 4.2 shows a more detailed and enlarged scheme of 4.1, according to the explanation given.

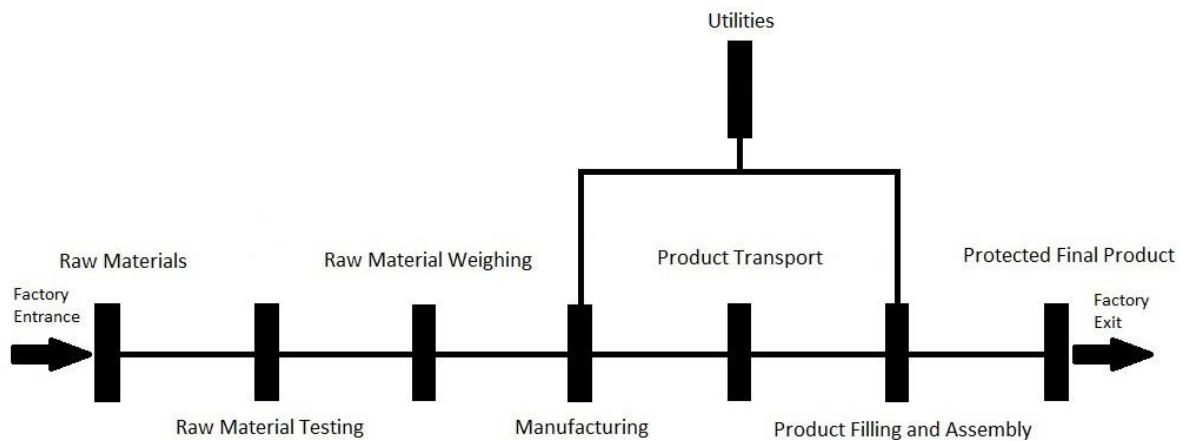


Figure 4.2 Process detailed scheme.

#### 4.2. FDA Application

Once the process to obtain a product is explained and understood, the knowledge on figure 4.2 is expanded, and figure 4.3 is obtained with all the equipment, rooms and instruments involved in the manufacture of a professional product. Of all these equipment's and rooms there are some specific ones that are in the supply of the project, which are those of the FDA, and most of these equipment's are those that are in contact with the product in order to be protected and to obtain a good quality at the end of the whole process.

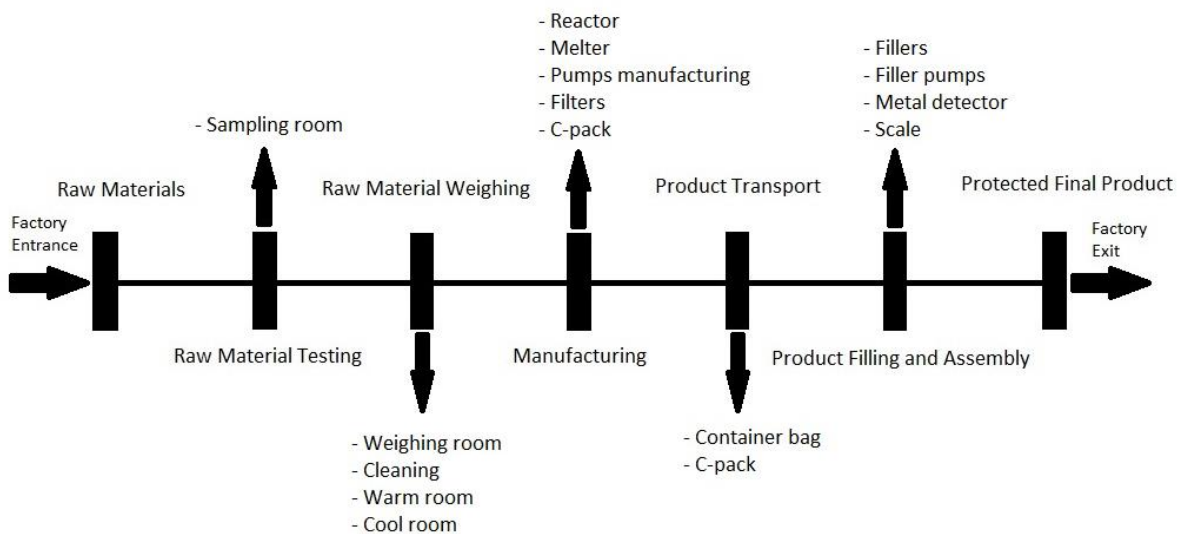


Figure 4.3 Equipment and room to obtain a product.

The process flow is discussed above. Initially, the raw materials arrive at the two assigned docks of the factory, are unloaded, and pass to the sampling room. In the sampling room, the relevant tests are carried out to verify the quality of the raw materials for good production.

Once sampled, they are stored in the raw material warehouse, and depending on the raw material, they are introduced into the hot chamber to be dehydrated and easier for production.

When it is produced, the raw materials are taken from the warehouse and transferred to the weighing room. In the weighing room, each raw material is weighed according to the formula needed for production. Once everything has been weighed, the raw materials are left in the temporary warehouse waiting to be moved to the production area where the reactors are located.

Then, the raw materials are moved to the production area and are introduced into the reactor, either manually or by attaching a pneumatic pump to load the reactor. The melter is used or not depending on the formula, the function of the melter is basically for formulas with waxes or with very viscous elements. Once all the raw materials are introduced into the reactor, a set point temperature is established, and the turbine and the scrapers are activated to generate the product. Once finished, a pneumatic pump is attached to the discharge mouth and the product is placed in a single use holding bag. Once unloaded, the reactor is cleaned so that if other products are to be manufactured there is no cross contamination.

Once the product is in the C-pack, it is moved to the packaging area and the bag is placed in the packaging machine to be used. Then, the pneumatic pump is attached to the bag and the other part to the packaging machine, and the hopper begins to be loaded for packaging. Each time the products come out, they are weighed to know the quantity that is introduced and finally, they are introduced in boxes, put on pallets and stored in the warehouse of finished products ready to be marketed. Once all the product that has been produced in the reactor has been packaged, the packaging machine is cleaned so that if other products have to be packaged there is no cross-contamination.

Once the process for obtaining a product is known, it is known that, in order to obtain the FDA certification, once the scope of all the machines that will be included in the qualification is established, the existing machines that have to be qualified and the machines that have to be

purchased new in this chemical engineering project are observed. Regarding the machines to be purchased new, these have varied throughout the project and have not been established until the end.

As mentioned above, the qualification of the equipment is divided into existing equipment and new equipment. Depending on whether the equipment is existing or new, the procedures to be carried out are different, but the main part to obtain the FDA qualification, which are the IQ, OQ and PQ, are in both areas. The detailed explanation is explained below

#### 4.2.1. Existing Equipment

On the one hand, the explanation of all the existing equipment that has been taken into account for the qualification, and the process that has been followed to have everything in order to obtain the FDA certification is carried out.

Regarding the existing equipment and facilities that have been selected as scope in the project, it can be seen in section 2 of the project, have been the following, where next to it there is the explanation of each one of them because it has been selected to qualify.

- **Compressed Air system** → Compressed Air is a service that is used for all the valves in the factory, but it has been selected mainly because the filler machine that fills the product, at one point of it, blows and heats the tube with compressed air, for this reason it has been decided to validate this section.
- **Osmotized Water system** → Osmotized water is a main element since it is used as raw material for many production formulas. In this case, it has not been selected for this reason, since the OTC formula to be used does not have osmotized water, but it has been decided to qualify it for a future formula to be used, since a large percentage of formulas use water as raw material.
- **Weighing scales 1, 2 & 3** → The weighing scales are equipment used to weigh the raw material to be used to manufacture the OTC formula, for this reason it has been decided to qualify them to verify that everything works correctly in production.
- **Kettle R-3514** → The R-3514 kettle is an important part of the qualifications because it is the machine that, once all the weighed raw materials have been introduced, makes the emulsion and obtains the product to be filled. For this reason, it has been decided to include it in the area to be qualified, since it is necessary to verify that the manufacturing system and the obtaining of the final product are carried out correctly and adequately.
- **Cleaning system tanks** → The tanks of the cleaning system are an important part of the process because once the production of a specific product has been carried out, to manufacture again with that reactor, cleaning must be carried out to avoid cross-contamination. For this reason it has been qualified, since it has to be verified that the tanks, pipes and pumps that carry the different cleaning elements to the reactor are working properly.
- **Cool Room** → The cold room is another equipment that is not essential for the qualification, but it has been made because inside it stores explosive products that can explode above a certain temperature. This room is not related to the production process of the OTC product, but it has been decided to validate it for the future if it is decided to reprimand the FDA project for the fragrance area. For this reason, it has been decided to qualify the cold room to ensure that it meets all the requirements and performs its function correctly.

Once all the existing equipment to be qualified and its reasoning have been explained, the general procedure to be followed to qualify an existing equipment is explained.

The procedure followed for existing equipment is shown in figures 4.4 and 4.5.

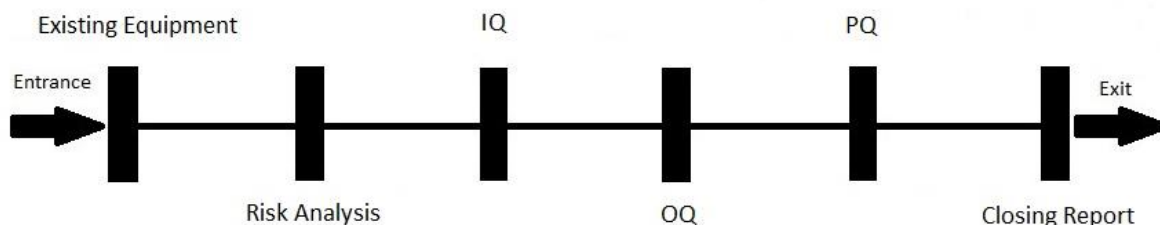


Figure 4.4. Existing equipment procedure.

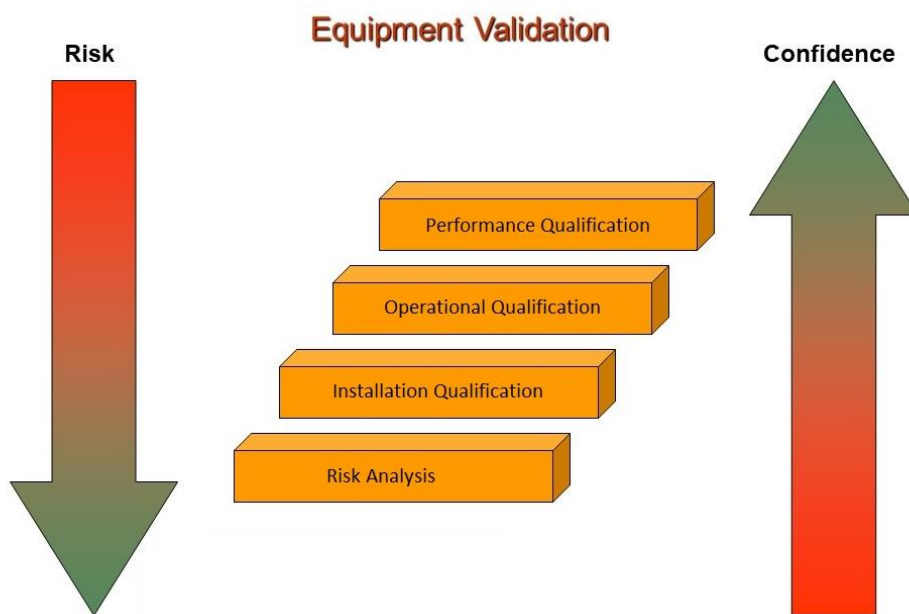


Figure 4.5. Existing equipment procedure<sup>2</sup>.

As shown in the two previous figures, for an existing equipment it is based on following the procedure shown in the images.

<sup>2</sup> *Equipment Validation / Facility Qualification / Material Qualification*. (2021, 12 mayo). PresentationEZE. <https://www.presentationeze.com/presentations/product-and-process-validation/product-and-process-validation-full-details/equipment-validation/>

Initially, the equipment to be qualified is chosen, and information on how the equipment or system works is read and obtained to get a general idea of its operation and to facilitate subsequent tasks.

Straightaway, a theoretical risk analysis is performed, which is based on the identification, analysis and evaluation of the factors that may influence the manifestation of the risk, so that with the information obtained it is possible to evaluate the type and dimension of the risk to quantify and counteract it, all this by performing the risk analysis only with the theoretical information of the machine or equipment. Once this theoretical risk analysis has been carried out, the field risk analysis is carried out to make corrections and add aspects that had not been considered in the theoretical one. This step is very important, because with the help of a technician who explains the complete operation of each machine or system, it allows you to understand it better and perform a more in-depth risk analysis than the one that had been performed.

Once the risk analysis has been performed and approved by certain managers, the IQ of the equipment or system is performed. The IQ is about collecting as much information as possible from the system to verify the integrity of the machine. It is based on taking the mechanical and electrical drawings of the machines and verifying that everything in the drawing was in the plant, reviewing the most general and critical points. Then, the operation manuals are looked for or instructions are made to verify that, if a new operator wants to use the machine, with the manuals or instructions that are available, he can do it. A list of spare parts is also made, to verify if there is any breakdown that the most critical parts are available for replacement.

All the technical documentation of the instrumentation that the equipment in question may have been also entered, together with the calibrations of these instruments that are carried out annually. Another thing that is put is the welding certification of the equipment in question, there were equipment's that did not have this report and it had to be done. Also the different services that the machine uses and the specification they arrive with are introduced, and finally a certification of materials corroborating that the material with which the equipment is made is the one that was observed, and as in some other case, if this certificate was not obtained, some concrete test had to be carried out to verify that the material was the one stipulated in the documents. Finally, the threads and certain other elements are marked and verified as sanitary and from here, with all this documentation introduced in a template made by the company, the IQ is evaluated to be approved.

Once the IQ has been performed and approved by certain managers, the OQ of the equipment or system is performed. The OQ is about verifying the functionality of the machine, that is, it is based on verifying that with the theoretical parameters that the manufacturer gives you about the machine, it can operate correctly. In this case, the OQ is based on performing tests to verify the operation of both the PLC and the control panel of the equipment or system and perform tests to verify the operation of the machine within the manufacturer's ranges. With this in mind, for each machine or system, certain tests have been designed, both for the PLC and for the operability of the equipment, to verify the operation of the equipment, observing the typical value and then forcing the equipment to work at the maximum and minimum values. Once these tests are performed, the most critical or common alarms that the equipment has are also noted and from here, the machine is forced to cause these alarms to verify the correct operation in case of equipment failure. Finally, once all the established tests had been carried out and with

all this documentation entered in a template created by the company, the OQ was evaluated for approval.

Once the OQ is done and approved by certain responsible persons, the PQ of the system is done, in the case of the equipment, the qualification ends in the OQ and then the validation of the process with the characteristics of the OTC formula continues. In this case, for an equipment, the qualification would be ready so that now that it wants to be accredited for the FDA, the inspector gives the approval, and it is apt to produce OTC products and commercialize them in the United States.

For the systems, the PQ procedure is based on following the same steps as in the OQ, but with the range of values validated by the company. In the PQ the same tests are performed as in the OQ, but instead of observing the operational values of the range marked by the manufacturer, the values of functionality that you want that system to work are observed, and this range of values is stipulated by the company. Then, once the OQ is done and approved, the same tests are performed for the PQ, observing the range of functional values of the system during one productive year.

Once the PQ is completed and approved, the qualification process of the system is finished, and it can be ready to be accredited by the FDA when the inspector gives the go-ahead to produce OTC products and market them in the United States.

After explaining the process of qualifying an equipment and an existing system with all the steps to be carried out, all the existing equipment that has been qualified is discussed. Of these existing equipment's, their basic operation and all the steps followed to obtain the qualification of the equipment in question are explained. All existing equipment that has been qualified is shown in the following sections.

#### ➤ **Compressed Air System**

The compressed air system is a system that has four compressors, a compressed air storage tank, six filters, three dryers and finally a dry air storage tank and a dry air tank for packaging. All these elements are used to obtain compressed air at 7 barg for instrumentation and to perform tasks in the factory where this type of air is needed. In addition, after the dry air tank there is a deviation of this compressed air where it passes through 3 more filters and a smaller dryer and finally to a reducer to obtain a much cleaner air which encounters the product, this air is called PIG air.

The operation of the air system is based on air being drawn in from outside and compressed through four compressors to 7.5 barg and sent to a compressed air storage tank. Next, there are three dryers in parallel, where before entering each of the dryers, the air passes through a filter where it is required so that debris and other contaminants do not block the condensate trap and dryer heat exchangers, then enters the dryers where they are designed to ensure the supply of high-quality compressed air with minimum maintenance. Next, the compressed air exiting each of the dryers passes through a filter and is directed to a dry air storage tank. Finally, once the air is in the dry air storage tank, air is supplied at 7 barg for the instrumentation of different equipment and for parts of the factory where pressurized air is required, all this passing through different pressure transmitters to ensure that the air required is at 7 barg pressures. At the 7 barg compressed air outlet, there is a bypass with 3 filters, a smaller dryer, and a pressure reducer at 4 barg for the PIG air that is in contact with the product.

Regarding the approach taken to perform the qualification, initially a narrower scope is chosen to perform the qualification only with the compressed air generated for instrumentation and for the factory, but finally, to cover more scope and qualify everything, the entire compressed air system is chosen, eliminating two filters and two dryers to be removed to modify aspects of the factory to adapt certain parts for FDA certification. Once the scope is established, all the information present in the compressed air system is collected and the risk analysis is performed. Once the risk analysis is done, it is taken down to the plant to modify certain aspects and to observe how it works so that it could be better understood. Once the risk analysis is finished, it is proceeded to perform the IQ with the information initially collected and if certain documents are missing, they are requested to the supplier. In addition, the information of the various main equipment that make up the compressed air system is searched in the plant, in the equipment directly. Once all the documentation is entered into the IQ and finalized, the OQ is performed. To perform the OQ, the basic tests are performed to corroborate that the compressors are working properly, such as performing the off and on, and putting a pressure gauge at the outlet of the compressors to verify that 7.5 bars out. The main tests, but are obtained from the company that comes to evaluate the air quality annually, where this observes the humidity in the air and the number of oils and particles that have. From here, the OQ could be completed and advance to the PQ. In the PQ is established to leave the system in operation for 1 year and take data from time to time to verify that the values are within the established range. Once this is done, the compressed air system should be qualified and ready to obtain FDA certification.

#### ➤ **Osmotized Water System**

The complete osmosis water system is divided into two parts, the generation of demineralized water and the distribution loops. In the demineralized water generation part, two generation systems are observed, one from the Veolia company and the other from the Astramatic company. On the other hand, of the distribution loops, 3 distribution loops are observed that move and go throughout the plant with different points of use. In this case, the focus is on the Astramatic osmosis equipment

The operation of the osmosis water system is based on mains water is introduced into a preliminary tank and from here there are two branches that each go to a different demineralized water generation unit. From here, each generation equipment works according to the demand of osmotized water that the plant has, where normally almost always works both at the same time due to the high demand of water. In this generation equipment there are several stages, where the main stage is that the water passes through reverse osmosis membranes to demineralize the water, and finally passes through equipment called EDIs that deionize the water and thus the final conductivity of the water obtained is very low. Once the water is out of this generation equipment, it is sent to the distribution loops. The distribution loops mainly have two 50 m<sup>3</sup> tanks to accumulate demineralized water, UVA equipment and ozone generators. During the week, as the factory is operating, demineralized water is supplied to the plant with the UVA equipment active to eliminate the ozone in the water, and on weekends, as the plant is shut down, the ozone generators are activated to introduce ozone into the distribution loops so that the water is in continuous movement with ozone inside to prevent the growth of microbiological contaminants. From these distribution loops that go through different points of the plant, when there is demand at a point of use, the valve is opened, and demineralized water can be supplied.

Regarding the approach to perform the qualification, a scope of the Astramatic osmosis water generation with the distribution loops is chosen, the Veolia osmosis water generation has been qualified, but no task has been performed because the machine is newer and when it was installed in the factory all the necessary documents for the qualification were already performed by Veolia itself and for this reason it is not necessary to perform neither the IQ nor the OQ. Once the scope is established, all the information present in the osmosis water system is collected and the risk analysis is performed. Once it is done, it is taken down to the plant to modify certain aspects and to observe how it works to better understand it. The risk analysis considers the entire system, i.e., osmosis water generation, both Astramatic and Veolia, and the distribution loops. Once the risk analysis has been completed, the IQ is carried out with the information initially collected and, if certain documents are missing, they must be requested from the supplier. In addition, the information of the various main equipment that make up the osmosis water system is sought in the plant, directly from the equipment. This IQ of the osmosis water has been divided in two due to the dimensions of each part, one IQ for the Astramatic generation equipment and one IQ for the distribution loops. Once all the documentation for the two IQs has been entered and finalized, it is proceeded to perform the OQ. In the OQ, the same procedure is followed as in the IQ and two OQs are performed, one for the Astramatic generation equipment and one for the distribution loops. To perform the OQs, different basic tests are carried out to check that both the water generation and its distribution through the plant are working correctly and that the water flow and its velocity is correct. From here, the OQs can be completed and advance to the PQ. In the PQ, it is established to leave the complete system in operation for 1 year, here with the two water generations and their distribution loops, and to take data from time to time to verify that the values are within the established range. Once this is done, it is intended to have the osmosis air system qualified and ready to obtain FDA certification.

➤ **Weighing scales 1, 2 &3**

The weighing scales are 3 scales of different load capacities, one up to 35 kg, one up to 60 kg and the largest up to 1500 kg, which are located inside box A of the weighing room.

The operation of the scales is based on weighing, depending on the amount of raw material needed to produce a particular formula, the different raw materials of a particular formula in order to be sent to the professional manufacturing area and manufacture a product.

Regarding the approach used to perform the qualification, a scope is chosen for the three scales located inside box A of the weighing room. Once the scope has been established, all the information on the scales is collected, which is basically the operating manuals, and a risk analysis is performed. Once the risk analysis is done, it is taken down to the plant to modify certain aspects and to observe how they work to better understand them. Once the risk analysis is finished, the IQ is carried out with the information initially collected and if certain documents are missing, they must be requested from the supplier. Once all the documentation has been entered in the IQ and finalized, the OQ is performed. To perform the OQ, basic tests are performed to corroborate that the scales are working properly, and basically, the OQ tests performed are the same as those performed when the scales are calibrated annually. From here, the OQ can be completed, and the qualification can be finalized. In this case, as the scales are equipment, it is not necessary to perform the PQ to obtain FDA certification and the OQ would complete the qualification.

➤ **Kettle R-3514**

The R-3514 reactor is a unit consisting of a vertical cylindrical body with a volume of 500 L, closed to the atmosphere at the top by a hinged lid with hermetic seal and a diffuser-type bottom. Under vacuum and is used as a mixer is worked this equipment

The operation of the R-3514 reactor is based on introduce the necessary raw materials according to the cosmetic formula, creating a vacuum inside the 500 L mixing boiler and starting up the equipment. Then, with the help of the heating jacket and the two-agitation equipment, the final product to be obtained is produced in a stipulated time. Once the manufacturing process is finished, all the product is transferred from the reactor to the container bag so that it can be filled in the filling machine. All the reactors go together with their melters, but in this case for this application and according to the FDA formula, it has been decided to eliminate the melter that goes together with this reactor.

Regarding the approach to perform the qualification, a scope is chosen, as previously mentioned, of the R-3514 reactor without its melter because it is removed since it will not be used for this FDA project. Once the scope is established, all the information present in the R-3514 reactor is collected and the risk analysis is performed together with the part of the single-use containment bag. Once it is done, it is taken down to the plant to modify certain aspects and to observe its operation to better understand it. Once the risk analysis is finished, it is proceeded to perform the IQ with the information initially collected and if certain documents are missing, they have to be requested to the supplier, but in this case, it is more complicated since the reactor is more than 30 years old and probably all the information that the supplier was already delivered. In addition, the information of the various instruments contained in the R-3514 reactor is looked for in the plant, directly on the equipment. Once all the documentation is entered in the IQ and finalized, the OQ is performed. To perform the OQ, the basic tests are carried out to corroborate the correct operation of the reactor, basically tests of the reactor integrity, the operation of the reactor agitators, the correct heating, cooling, and maintenance of the temperature of the heating jacket and that it performs a correct vacuum. From this point, the OQ can be completed, and the qualification can be finalized. In this case, as the reactor is a piece of equipment, it is not necessary to perform the PQ to obtain the FDA certification and the OQ would complete the qualification and it would be qualified. From here, the validation of the manufacturing process would be performed, where the reactor would be tested with the specific characteristics of the OTC formula.

➤ **Cleaning system tanks**

The tanks of the cleaning system to be qualified are three, the deionized water tank at 80 °C, the mains water tank (chlorinated water) and the peracetic acid tank. These tanks are used for another part of the factory, but are also used for the cleaning of the reactors, where there are connections from these three tanks to all the professionally manufactured reactors in order to introduce the fluid inside the reactor.

The operation of these tanks is based on a tank with a booster pump and piping. From there, when one of the fluids is required from the tank to the reactor, the demand is made and fed to the reactor.

Regarding the approach taken to perform the qualification, a scope is chosen, as previously mentioned, of three tanks, the 80 °C deionized water tank, the mains water tank (chlorinated water) and the peracetic acid tank, with their corresponding pumps and the piping that transports the fluid. Once the scope is established, all the information present in the tanks is collected, and in this case, it is not very complicated since it is a fairly new installation and the risk analysis is performed. Once the risk analysis is done, it is taken down to the plant to modify certain aspects and to observe its operation to better understand it. Once the risk analysis is finished, it is proceeded to perform the IQ with the information initially collected and if certain documents are missing, they must be requested from the supplier. Once all the documentation is entered in the IQ and finalized, the qualification process is stopped here and the OQ is not performed because the functionality tests of the tanks for cleaning fall within the scope of the cleaning validation and this is done by another department. Once this is done, the tanks that will be used for the cleaning of the reactor to make the formula of the product that will be sent to the United States will be qualified and ready to obtain FDA certification.

### ➤ Cool Room

The cool room is a climatic room with a temperature of 7°C. To cool the room to these conditions, one unit is installed outside the building and two units are located inside the cool room. The outdoor unit sends the cooling power to the two units inside the chamber through refrigerant gas. The cold room is located in an ATEX zone and for this reason, it has a LEL detector installed with a safety interlock with the refrigeration equipment to be able to stop it in case of detection of flammable vapors.

The operation of the cool room is because the air conditioning system of the cool room is started from the outside of the cool room. Once the air conditioning system is turned on, to achieve the required conditions in the cool chamber, the equipment outside the chamber sends the cooling power to the two units inside through copper pipes. Once the heating power has reached the interior of the room, the room is cooled to obtain a temperature of 7°C±3°C.

Regarding the approach that is performed to perform the qualification, a scope of the cold room is chosen, basically the dimensions of the room and cold generation equipment. Once the scope is established, all the information present in the cold equipment of the cold room is collected and the risk analysis is performed. Once the risk analysis is done, it is taken down to the plant to modify certain aspects and to observe the cold room and see how everything is located in the field. Once the risk analysis is finished, the IQ is carried out with the information initially collected and if certain documents are missing, they must be requested to the supplier. Once all the documentation has been entered in the IQ and finalized, the OQ is performed. To perform the OQ, a temperature mapping is performed with different measuring equipment distributed throughout the room to verify that at all points of the room the temperature is similar and is within the range marked by the manufacturer of cold generation equipment. Once the mapping is done and with the results evaluated and the critical point obtained with the empty room without materials inside, the OQ can be completed and move on to the PQ. In the PQ the procedure is similar to the OQ, a temperature mapping is performed, but in this case with the entire chamber loaded to observe how the temperature affects with materials inside, taking into account the range is established by the flammability of the product, since there are products that above a certain temperature are flammable and can cause a quite dangerous risk. Once the temperature mapping of the PQ is done and verified that everything is working properly, the cold room is intended to be qualified and thus be ready to obtain FDA certification.

As can be seen, these are all the existing equipment with the approximations made to perform the different qualifications in the Pla de Santa Maria plant that have been selected to qualify and to obtain the FDA validation. Once this was done, as several months had already passed and the scope and budget were more established, the next step was to explain the approach taken and the new equipment purchased to improve the plant and obtain this FDA certification.

#### 4.2.2. New Equipment

On the other hand, once known and established all the existing equipment that will be qualified to obtain the FDA certification, an explanation is made of all the new equipment that has been considered and that will be purchased for the qualification and the process that has been followed to have everything to obtain the FDA certification.

Regarding the new equipment and facilities, can be seen in section 2 of the project, where it is observed that most of them are facilities to adapt certain parts of the factory to obtain FDA certification and produce OTC products. All the parts that are new areas, there is a design done by another engineer of the company, but it does not fall within the scope of this project, and the qualification of these areas is done in the other project. The scope of this project includes the equipment to be purchased to improve the factory in the production of the OTC product. The equipment to be purchased are basically three that are explained below, and this part of the qualification is done as much as possible, since at this time the purchase has not yet begun, and this will be done later.

- **Osmotized Water System** → Osmotized water is a main element since it is used as raw material for many production formulas. In this case, it has not been selected for this reason, since the OTC formula to be used does not have osmotized water, but it has been decided to qualify it for a future formula to be used, since a large percentage of formulas use water as a raw material. A plus it acts as a secondary element, since it is not a raw material, but it is used for cleaning the reactor and ends up encountering the product indirectly. As can be seen in this section, there is also an osmosis system, and this is because the company currently has one that has been mentioned in the existing equipment, and furthermore, it has purchased another osmosis equipment to continue producing more deionized water. In the project and in the results this new equipment is differentiated as Veolia Osmosis, and the existing equipment as Astramatic osmosis.
- **Dynamic Scale and Metal Detector** → The scale and the metal detector are two pieces of equipment that follow the tube packaging machine, the scale is used to ensure that the weight of all the tubes is uniform with a very small margin of variation, and the metal detector is used to ensure that inside the tubes there is no metal piece that escapes from the machine, for this reason, as it is introduced in the whole process of the production of the OTC product, it is necessary to qualify it.
- **Weighing area and filling area washing machine** → The washing machine is a special thermodisinfector machine for cleaning different laboratory utensils that is incorporated in the cleaning rooms of the weighing area and the filling area. As the cleaning rooms are a requirement to obtain the FDA certification, when these cleaning rooms are made, it is also thought of this equipment for cleaning the different materials, for this reason it has been decided to qualify this section.

Once all the equipment and installations to be installed and qualified and their reasoning have been explained, the general procedure to be followed to qualify new equipment is explained.

The procedure to be followed for new equipment to be installed is shown in figures 4.6 and 4.7.

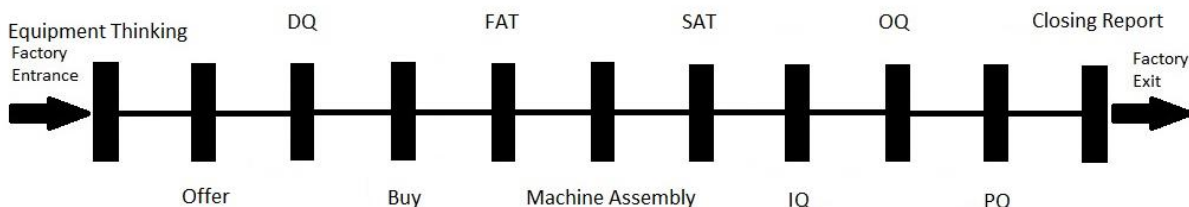


Figure 4.6. New equipment procedure.

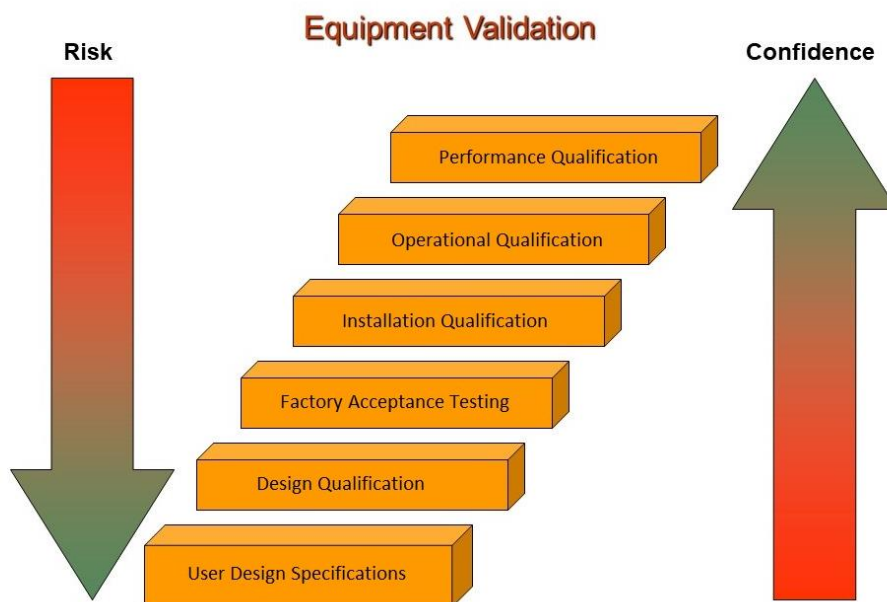


Figure 4.7. New equipment procedure<sup>3</sup>.

As shown in the two previous figures, for a new equipment it is based on following the procedure shown in the images.

Initially, the idea is there, and it has been proposed what equipment is wanted to buy to install in the factory. Once the idea of the equipment is there, all the requirements are written and all the technical specifications that you want it to have in a document, this document is called URS. The URS is a document that forms the basis for the purchase of a new equipment,

<sup>3</sup> *Equipment Validation / Facility Qualification / Material Qualification*. (2021, 12 may). PresentationEZE. <https://www.presentationeze.com/presentations/product-and-process-validation/product-and-process-validation-full-details/equipment-validation/>

moreover, it describes the technical requirements in all aspects of any equipment that the organization decides to acquire for its productivity.

Once the URS is drafted and signed by the different departments involved in the purchase of the new equipment, the next step is to ask for bids from different suppliers, basically to see the price difference and finally choose the option with the best value for money.

Then, once different offers are available and finally the best is chosen according to the company, the next step is to perform the design qualification, DQ. The DQ is a common part in the qualification of new equipment, and it is a document where all the design reviews that are noted in the URS are collected and verified in the final equipment to demonstrate that all the quality aspects have been considered in this initial phase. In other words, the DQ is established as a process of verifying the design of the equipment to comply with product quality requirements and GMPs.

Once the DQ is corroborated and everything is in accordance with the URS, the equipment is purchased. Once the machine has been purchased, the FAT is performed. The FAT is since, once the machine has been purchased, different functionality and operability tests are carried out at the customer's facilities to verify that everything works correctly.

Then, once the FAT has been approved and it has been verified that everything is working correctly, the machine is assembled at the company's facilities and the SAT is carried out. The SAT is a process that is equivalent to the FAT but is carried out at the company's facilities, i.e., the FAT is a process in which once the machine is assembled in the company, various tests are carried out, both functional and operational, to check that everything is working correctly and to give the approval for the machine to start and be established in the production process.

Once the SAT is done, the procedure is the same as with the existing equipment and facilities, the IQ is done, once approved the OQ is done and finally the PQ in systems, in equipment the OQ is finished.

Once the PQ is finished and approved for the systems and the OQ for the equipment, the qualification process is finished and it can be ready to be accredited by the FDA, the inspector will give the approval and it will be ready to produce OTC products and commercialize them in the United States.

After explaining the process of qualifying a new equipment or facility with all the steps to be taken, it is proceeded to comment on all the new equipment or facilities that have been qualified. The basic operation of these new equipment is explained, as well as all the steps followed to obtain the qualification of the equipment in question. All the new equipment that has been qualified is shown in the following sections.

#### ➤ **Osmotized Water System**

The complete osmosis water system is divided into two parts, the generation of demineralized water and the distribution loops. In the demineralized water generation part, two generation systems are observed, one from the Veolia company and the other from the Astramatic company. On the other hand, of the distribution loops, 3 distribution loops are observed that move and go throughout the plant with different points of use. In this case, the focus is on the Veolia osmosis equipment

The operation of the osmosis water system is based on the fact that mains water is introduced into a preliminary tank and from here there are two branches that each go to a different demineralized water generation unit. From here, each generation equipment works according to the demand of osmotized water that the plant has, where normally almost always works both at the same time due to the high demand of water. In these generation equipment's there are several stages, where the main stage is that the water passes through reverse osmosis membranes to demineralize the water and finally is passed through equipment called EDIs that deionize the water and thus the final conductivity of the water obtained is very low. Once the water is leaving this generation equipment, it goes to the distribution loops where it has been previously explained in the osmosis section of the existing equipment. From these distribution loops that go through different points of the plant, when there is demand at a point of use, the valve is opened, and demineralized water can be supplied.

Regarding the qualification approach, the procedure previously mentioned for new equipment is followed. Initially, the URS is carried out so that it is approved by all the people in charge and from here offers are requested to different suppliers. Once the offers are received, the DQ is carried out, verifying that everything that has been established and approved in the URS is in accordance with the offers obtained for the osmosis equipment. Once the bids have been evaluated, the best option is chosen. The FAT is made and once accepted, the equipment is installed in the factory and the SAT is performed. From here, the IQ is done directly, and once the IQ is done with all the documentation provided by the suppliers, the OQ is done. Finally, once the OQ is done, the PQ is done. In the PQ it is established to leave the complete system in operation for 1 year, here with the two water generations and their distribution loops, and to take data from time to time to verify that the values are within the established range. Once this is done, it is intended to have the complete osmosis system qualified and ready to obtain FDA certification.

#### ➤ **Dynamic Scale and Metal Detector**

The scale and the metal detector are two pieces of equipment that are followed by the tube filler, the scale is used to ensure that the weight of all the tubes is uniform with a very small margin of variation, and the metal detector is used to ensure that no metal piece is introduced inside the tubes that escapes from the machine.

The operation of this equipment is to be coupled to the tube filling machine and while the tubes are coming out, they pass over the dynamic scale, which will have a stipulated weight that the tubes have to have, and if the weight is correct within the established margins, it continues to be filled, if not, it is rejected, and then, once passed the scale, pass between the metal detector to detect if inside the tube can be seen fallen some metallic element of the machine, and like the previous one, if it detects something metallic, the tube is rejected, if it does not detect anything, it continues to be packaged and thus can be sold.

Regarding the approach to make the qualification, the procedure previously mentioned for new equipment is followed. Initially, the URS is made so that it is approved by all the people in charge and from this point on, offers are requested to different suppliers. The offers obtained from different suppliers, in this case, there are as a set, that is, the scale and the metal detector together, or with separate equipment. Once the bids are in, the DQ is performed verifying that everything that has been established and approved in the URS agrees with the bids obtained for the equipment. Once the bids are evaluated, the best option is chosen. The FAT is made and

once accepted, the equipment is installed in the factory and the SAT is performed. From here, the IQ is done directly, and once the IQ is done with all the documentation provided by the suppliers, the OQ is done. Finally, once the OQ is done, the equipment is qualified and ready to obtain FDA certification.

➤ **Weighing Area and Filling Area Washing Machine**

The washing machine that is introduced in the weighing cleaning area and in the filling cleaning area is to facilitate the work of cleaning certain utensils that are used in either of the two areas.

The operation of the washing machine is similar to a domestic one, but the size is bigger. It is based on introducing all the utensils to be washed inside the machine, choose the washing program to be used and press start, and after a certain time, take out the clean utensils.

Regarding the approach used to make the qualification, the procedure previously mentioned for new equipment is followed. Initially, when it is known that a cleaning room will be introduced inside the two areas mentioned above, it is already thought of introducing a washing machine to facilitate the cleaning work. Once this is known, the URS is made to be approved by all the people in charge and from this point on, offers are requested to different suppliers. Once the offers are received, the DQ is carried out verifying that everything that has been established and approved in the URS agrees with the offers obtained for the washing machine. Once the bids are evaluated, the best option is chosen. In this case, the FAT and SAT are not considered because it is a very simple machine, similar to a domestic one, and it is installed directly in the factory. As the installation is also very simple, if a problem occurs, it can be uninstalled and repaired. From here, the IQ is done directly, and once the IQ is done with all the documentation provided by the suppliers, the OQ is done. In this aspect, being a very simple equipment the OQ is very fast, as there is not much variety of tests to be performed on the equipment. All the tests performed in the OQ have to agree with most of the specifications introduced in the URS. Finally, once the OQ is done, the equipment is qualified and ready for FDA certification.

#### **4.3. Reactor Cleaning Study**

Once the approach for the qualification of the equipment and systems involved in the process of obtaining the OTC product for FDA certification has been explained, the approach for the cleaning of the reactor and the melter is explained.

Initially, it is considered that the melter that goes next to the reactor of the FDA project is eliminated, and inside the manufacturing room, the reactor and the pilot melter and the manufacturing reactor are placed. Considering that, the cleaning study is focused on the manufacturing reactor, but the same steps could be followed for the melter, since the melter is similar to a reactor, but smaller.

The different steps to perform a current reactor cleaning are explained in the introduction, in section 1.6. Knowing how the reactor cleaning is performed, it is thought to approach the improvement study following different steps.

Initially, a risk analysis of the current cleaning is evaluated and carried out, considering the process and the raw materials that are introduced into the reactor. From here, it is observed the time it takes to perform the cleaning, the cost of performing the current cleaning and finally the efficiency, i.e., if the microbiological results obtained after cleaning are adequate according to the microbiology department of the company. From here, the 3 different approaches for a possible improvement in the reactor cleaning process are explained.

#### 4.3.1. First Proposal

As a first proposal to improve the cleaning of the reactor, different options to modify the current cleaning to improve it are considered. In a cosmetic reactor cleaning, four main points are taken into account:

- **Reactor stirring** → Stirring during the cleaning process is important as it directly influences the penetration of the cleaning solutions into the reactor and the consequent disinfection.
- **Time** → Time is an important element because with more or less time, depending on the product to be cleaned from the reactor, the cleaning can be more or less effective.
- **Temperature** → This is another important point, since having an optimum temperature for cleaning can increase the efficiency of the cleaning process. It is important to know that each product has an optimum temperature range, and increasing the temperature will not improve the process, since increasing the temperature too much could generate reactions inside the product that would cause an adverse result and worsen the cleaning process. For the products manufactured by Revlon, the recommended working range is between 80 °C and 85 °C, which is the range for alkaline products.
- **Detergent** → The detergent may be the most important point, since it is the element that removes dirt and disinfects. According to each type of product that is manufactured, there is a specific concentration of detergent to be introduced to obtain the maximum efficiency, but from a certain concentration, the efficiency starts to decrease. For this reason, if we are below this maximum concentration, we need more time to clean and if the concentration is higher, we spend detergent unnecessarily.

Knowing these 4 main points for a good cleaning, is focused on the proposal to modify some of these points to try to improve the cleaning. These 4 main points are interconnected if any of them is modified, it is observed that the rest are changed: if the time is reduced, a higher temperature is needed, if the temperature is reduced, a higher agitation is needed and so on. The tests performed and the results obtained will be mentioned in section 5.

Then, once the approach towards a modification of the current cleaning to improve it has been made, two more proposals of different cleanings are made where at least the points of cost and time are observed, and if the test can be carried out in the factory, the efficiency is observed, considering the microbiological results.

### 4.3.2. Second Proposal

As a second proposal to improve the cleaning of the reactor, apart from using some of the stages of the current cleaning, is the use of steam and thus eliminating some other stage of the current cleaning. The procedure that would be carried out is explained in the results section. In the case of the time, it takes for the steam application part, a steam generation machine is chosen, and its characteristics are observed. From there, the liters per hour of steam generated by the machine are observed and a time of use of this stage is obtained. Related to the cost of the cleaning in this proposal, first of all the initial investment that would have to be made to buy the machine is observed, and then the amount of osmosis water needed to produce steam is observed, taking into account that the entire reactor is filled in both cases, and finally, the section on efficiency would be a point to test if the machine is purchased, but as it is a viable option and some steps are similar to the current cleaning, it is most likely that the efficiency would be similar to that of the current cleaning.

By making these points, the initial cost of the purchase of the machine is observed and then the cost and time for each cleaning performed with this proposal. From there, it is compared with the other options to see which is the most cost effective to use.

### 4.3.3. Third Proposal

As a third proposal to improve the cleaning of the reactor, apart from modifying some of the parameters of the current cleaning, is the installation of a CIP system. The procedure to be followed is explained in the results section. In the case of the time, it is taken for the complete CIP process, the time it is taken to carry out a CIP is established as a basis, depending on the reactors in the toilet building. From studying the CIP operation of the toilet reactors, the time is scaled to the professional reactors, considering that they have lower volumes, and the time it would take to perform a cleaning in one of the professional reactors is obtained. Regarding the cost of cleaning in this proposal, firstly, the initial investment that would have to be made is observed, it is considered that the different steps that the CIP has, all the water that is used is discarded, although this is not 100% and it depends on the conductivity that it has. Of the 5 steps that the CIP has, only the water from the first step is discarded, from the following steps the conductivity is observed, and if the conductivity has a certain value the water is stored and reused, but in this case, it is considered that all the water that is used is discarded. Then, as all the water is discarded, the cost of the different chemical agents that are used is considered, as well as the cost of producing the osmotized water and the cost of heating the different quantities of the chemical agents needed for cleaning

By carrying out these points, the initial cost of the purchase of the machine, or the adaptation of the current CIP to the professional manufacturing plant is observed, and then the cost and time for each cleaning that is carried out with this proposal. From there, it is compared with the other options to see which is the most cost effective to use.

## **5. RESULTS AND DISCUSSION**

In this section are shown the results and discussion of the qualification of the equipment and systems established in the scope of the project, and the results obtained and the different proposals with their pros and contras of the reactor cleaning.

### **5.1. FDA Application Results**

Once the procedure followed to qualify the equipment has been explained, the results obtained from the different equipment mentioned in the scope of the project and some points that have not been finalized due to the time of the project are shown below. It is commented that in several of the equipment's and instructions and forms to be filled in by the operators were made to complete different IQs. In addition, all the RAs, IQs and OQs together with the test results are attached in appendices. It will be observed that there are documents, RAs, IQs and OQs that are finalized but not signed due to the delay in the flow of signatures, if not in the case of the contrary in the explanation of the results it is commented that it remains to be finalized.

#### **5.1.1. Existing Equipment**

In this section are shown the results obtained from the qualification of the existing equipment that has been introduced in the scope of the project. The results of all the protocols are attached in the appendices.

##### **➤ Compressed Air System**

The results obtained from the compressed air system are divided, as in any of the existing equipment, into RA results, IQ results and OQ results. The results of the PQ have not been obtained since in order to finalize the qualification process of the system, data must be collected during a whole year from the approval of the OQ and for this reason, there was not enough time for all the data collection and to be able to present it in the term of delivery of the project.

All the protocols with the results obtained can be found in the appendix.

Initially, in the risk analysis of the compressed air system, a scope has been established which is the compressed air generation part, i.e., compressors, different storage tanks, dryers and filters. Once this is established, the RA is performed, and certain results are obtained.

The RA has been divided into risks associated with the installation of the compressed air system and risks associated with the operation.

In the risks associated with the installation, basically the risk is obtained as an inappropriate installation of the air system for different possible reasons, that the materials in contact with the air are not suitable and that the electricity service is not available to operate the equipment.

In the risks related to the operation, there are risks related to the switching on and off the equipment, the ability to obtain the established air pressure and risks related to the specific equipment mentioned above. In addition, risks related to the alarms that the equipment may have and to the quality of the air to be obtained at the points of use.

For each of these risks, values of severity, probability and detectability of the possible failure are entered according to a company instruction, and from here, multiplying the three values between them, a result is obtained, which is the risk level of each action. As can be seen in the attached document, all the results obtained have a medium or low risk level and this does not cause the application of quick changes to mitigate possible failures, but in the results obtained with a medium risk level, improvements are tried to be applied in order to reduce the result to a low risk level.

This RA and the risks mentioned are more related to the operation and functioning of the equipment than to other aspects, since the aim of the ratings is to verify that the equipment is functioning correctly.

Once commented the results obtained in the RA, it is proceeded to comment the results of the IQ.

In the IQ of the compressed air system, in the first table where it shows the main documentation of the system, it has been found and verified that the P&IDs match with what is in plant, and that the main elements of the electrical diagrams also match. In addition, to have operating manuals and operating instructions for the equipment to know how it works. In this case, a spare parts list is not necessary because maintenance contract is in place and when any of the equipment is broken, the suppliers come to repair it. Regarding the material and personnel flow plans, are not necessary since this is more related to the rooms and the circuit that people and materials must have in them. The specifications of the measuring instruments in this case are necessary and finally, the welding certificates do not apply because the equipment comes as a set and the connections between them are all straight and without elbows, that is why it has been decided that it does not apply. In the following points of the IQ are obtained inspection of the equipment, which is a table with the main data of the system, the type of control and electrical specifications, then there is a table with all the main characteristics of the equipment that make up the compressed air system. Next, it is shown if there are elements that are calibrated and the date of its next calibration, then the utilities needed by the compressed air system to operate, which in this case is only electricity. Next, if the materials encounter the product, and in this case does not apply because most of the air does not come into contact with the product, and the air that comes into contact with the product does not fall within this scope but this air falls within the scope of the equipment that needs it, since a filtration unit is introduced before use and thus is qualified. Finally, a table is shown with the operating, cleaning, and maintenance instructions of the equipment in question, as can be seen the main instruction was nonexistent and had to be done to proceed with the qualification. From here a table is shown with three GMP requirements for the installation and training of personnel for the operation of this air system. In most cases, a deviation is opened, as shown in the last point, since all training is obsolete and must be done again to train new operators.

Once the results obtained from the IQ are commented and approved, it is proceeded to the OQ.

In the OQ of the compressed air system, the approach was made to perform the tests and verify the operation of the different equipment and cause different alarms of the equipment to verify that it works, and waited for the visit of the supplier to perform the tests because they had to perform start and stop of the equipment and verify the quality of the air, and these tests are always performed by suppliers of compressed air equipment. In this case, there is only the approach and there are no results because it had to sign a new contract with the supplier and to come to perform the tests could be extended until the end of the year, so there is only the approach made.

Once the supplier came to perform the tests, the OQ would be finalized and the PQ would be carried out, taking data for a whole year. Finally, once the whole year has elapsed, the PQ is completed, and the equipment would be qualified and ready for FDA certification. Finally, the results obtained from the RA and the IQ protocol are shown in the appendix, and the testing approach for the OQ is not shown in the appendix due to it is not finalized.

### ➤ Osmotized Water System

For osmotized water, the focus is on the results of the Astramatic reverse osmosis and distribution loops.

As in the previous case, the results of the osmosis water system are divided into risk analysis results, IQ results and OQ results. The results of the PQ, as in the previous case, have not been obtained since to finalize the qualification process of the system, data must be collected during a whole year from the approval of the OQ and for this reason, there was not enough time for all the data collection and to be able to present it in the delivery term of the project.

Initially, to facilitate the completion of the RA, a scope of the RA of the Astramatic osmosis, Veolia osmosis and distribution loops was performed.

As in the previous case, the RA was divided into risks associated with the installation of the osmosis water system and risks associated with the operation.

In the risks associated with the installation, the risk is basically an inappropriate installation of the osmosis water systems for different possible reasons, that the materials in contact with the water are not adequate, that the electricity and compressed air services are not available to operate the equipment and the water service from outside to feed the reverse osmosis equipment and produce osmosis water, and finally, that the additives for the correct operation of the reverse osmosis systems are not available or are inadequately dosed.

In the risks related to the operation, risks related to the switching on and off the two reverse osmosis plants and the distribution loops, risks related to the specific equipment, such as tanks, filtration systems, pumps, ozone generators, UVA lamps... are obtained. In addition, risks related to the alarms and instrumentation that the equipment may have, with the quality of the water to be obtained, with the sanitizations performed by the osmosis and distribution loops and finally, certain risks related to the PLC, i.e., risks of user permissions to access, traceability of changes, backups, and data integrity.

As in all ARs, for these risks, values of severity, probability and detectability of the possible failure are entered according to a company instruction, and from here, multiplying the three values among them, a result is obtained, which is the risk level of each action. As can be seen in the attached document, all the results obtained have mostly a medium or low risk level and there are a couple of high risks. In most of the cases this does not cause to apply quick changes to mitigate the possible failures, but in the results obtained with a medium risk level, improvements are tried to be applied to reduce the result to a low risk level and in the case of the high-risk level, measures have to be applied to reduce this risk to the minimum in case the failure occurs.

As can be seen, this AR and the risks discussed are more related to the operation and functioning of the equipment than to other aspects, since the aim of the ratings is to verify that the equipment is functioning correctly.

Once the results obtained in the RA have been commented on, the IQ results are commented on.

In the IQ of the osmosis water system, the IQ is divided into two different IQs. An IQ for the Astramatic reverse osmosis and an IQ for the distribution loops, the IQ for the Veolia reverse osmosis is discussed below.

In the IQ for the Astramatic reverse osmosis, in the first table where the main documentation of the system is shown, is found and verified that the P&IDs and the distribution layout match what is in the plant, and that the main elements of the electrical schematics also match. In addition, to have operating manuals and operating instructions for the equipment to know how it works. In this case, in the spare parts list there are certain basic instruments such as gaskets... and everything related to SAP. Regarding the material and personnel flow plans are necessary,

since the additives to be introduced must have a flow, and this document had to be created because it was not done. The specifications of the measuring instruments in this case are necessary and finally, the welding certificates do not apply because all the pipes of the Astramatic osmosis plant are made of PVC. In the following points of the IQ, is obtained the inspection of the equipment, which is a table with the main data of the osmosis, the type of control and the electrical specifications, followed by a table with all the main characteristics of the equipment that make up the Astramatic osmosis system. Next, it is shown if there are elements that are calibrated and the date of their next calibration, then the utilities that the Astramatic osmosis system needs to operate, which in this case is electricity and compressed air, and the water from outside is to feed the equipment. Next, if the materials come into contact with the product, which in this case they do, because the water is used for various things and ends up touching the product or being part of it as raw material, it must be verified that the materials that are in contact with it are suitable. In this section, the materials in contact with the water are not so critical because the water is still being treated, when the water leaves the EDIs and goes to the storage tanks, at this point the materials are critical and should be considered. Even so, it is introduced that the materials in contact with the water are plastic, attaching the P&IDs made by the supplier that verifies it. Finally, a table is shown with the operating, cleaning, and maintenance instructions for the equipment in question. From here a table is shown with three GMP requirements for the installation and training of the personnel for the handling of this water system. In most cases, a deviation is opened, as shown in the last point, since all the trainings become obsolete and have to be done again to train new operators and, in this case, another deviation is opened because there are instructions that have to be updated.

In the IQ of the distribution loops, is followed the same procedure as for the Astramatic osmosis, in the first table where the main documentation of the loops is shown, is found and verified that the P&IDs match with what is in the plant, and that the main elements of the electrical diagrams also match. In addition, to have operating manuals and operating instructions for the equipment to know how it works. In this case, in the spare parts list there are certain basic instruments such as gaskets... and everything related to the SAP. Regarding the material flow and personnel drawings in this case are not necessary. The specifications of the measuring instruments in this case are necessary and finally, the welding certificates are also necessary because the water here is already deionized, and it is critical to know that the welds are made correctly and that the material in contact with the product is correct. In this issue of the welds throughout the project has been a problem because to count the welds it was necessary to have an isometric drawing, which had to be done, and from here to count all the welds of the loops. In the following points of the IQ, is obtained the inspection of the equipment, which is a table with the main data of the distribution loops, the type of control (the main one is the water conductivity and TOC) and the electrical specifications, then there is a table with all the main characteristics of the equipment that make up the distribution loops system. Next, it is shown if there are elements that are calibrated and the date of their next calibration, then the utilities that the distribution loops system needs to operate, which in this case is electricity and compressed air, and the water from the outside is to feed the equipment. In this section, the materials in contact with the water are more critical and it must be verified that are stainless steel, for this reason a metal detector was purchased, and different tests were performed to corroborate that the material is stainless steel 316. Finally, a table is shown with the operating, cleaning, and maintenance instructions of the equipment in question. From here, a table is shown with three GMP requirements for the installation and training of the personnel for the handling of this water system. In most cases, there is a deviation, as shown in the last point,

since all training is obsolete and has to be done again to train new operators and, in this case, there is another deviation because there are instructions that have to be updated.

Once the results obtained from the IQ were discussed, it was commented that it was all done, but not approved by the company's managers due to the issue of the welds mentioned above. It took some time to make the isometrics and then check all the welds was not done due to budget issues, so the welds of the critical path to the reactor were counted to evaluate them during the summer. Once the critical path welds have been analyzed, will be entered into the IQ, and can be approved and proceed to the OQ. Although the IQ is not 100% completed and approved, samples were taken from the OQ to advance the qualification work, but until the IQ was not approved, the OQ could not be finalized and the PQ could not be performed, for this reason the OQ data obtained are shown, but it could not be approved.

In the OQ, it is proceeded in the same way as in the IQ and perform an OQ for the Astramatic reverse osmosis and an OQ for the distribution loops.

In the OQ of the Astramatic osmosis, initially certain points of the control system are verified, such as switching on and off, an emergency shutdown and verifying that everything is switched on correctly, that the synoptic is correct, that it shows general information about the process... These points are verified, and it is observed that they work correctly, the issue of backups and traceability of changes is not done remotely, since the equipment is very old and it is explained that a routine control is performed which is noted the data on a sheet and if you make any change of parameter is recorded on the sheet as well. Regarding the operational verification of the equipment, it is verified when there is water demand of the plant and when a sanitization is performed, it is also performed when there is no water demand, but when there is no water demand the osmosis stops, but for a very short time and that means that it is always active and for this reason, it is not possible to take this type of data from the PLC. To control the Astramatic osmosis when there is water demand, a table is made, attached in the appendice, where certain critical data must be noted and must be within the operational range that marks each element. To verify the osmosis Astramatic when performing a sanitization, it is observed and noted in a file prepared for the OQ. In addition, the different alarms of the Astramatic osmosis are checked to verify that in case of any failure in any part of the process, an alarm is triggered. Once all the tests have been carried out and all the protocol has been verified, the OQ of the Astramatic osmosis is completed.

In the OQ of the distribution loops, the points to verify the control system are not considered, since the control of the Astramatic osmosis and the distribution loops is done with the same PLC and therefore this part is already checked in the Astramatic equipment. Regarding the operational verification of the equipment, it is verified when there is water demand of the plant and when there is no water demand, in this case sanitization is not performed by the distribution loops because when the factory is stopped, ozone is added to the tanks to eliminate the contamination that can be generated and when the factory is started, these ozone generators are turned off and the UVA lamps are activated to eliminate the ozone that may have the water and thus supply deionized water to the plant. Once this is known, the same procedure is followed as in reverse osmosis and data is taken when there is water demand from the outlet pressure of the 3 loops, the ozone in each loop, the UVA lamps in each loop and the TOC. With these data and the velocity and Reynolds number of the consumption points, which is shown in another attachment, the OQ of the distribution loops is finalized.

Once the two OQs are completed and approved, after the IQs are finalized, the PQ will be performed.

In this case the PQ would be performed for the Veolia reverse osmosis, the Astramatic and the distribution loops. The results in this case are not obtained for the same reason as the compressed air system, but in this case in the PQ instead of observing the operational range of the equipment, the same procedure would be followed and used as in the OQ, but the range would be changed to the desired by the company that has it stipulated in a procedure and thus observe for a year that the results obtained from the water are constant and with an adequate value. Finally, after one year of taking data after the approval of the OQ, the PQ would be finalized, and the qualification of the deionized water system would be finished.

In other words, once the welding issue was solved and the two IQs were approved, the OQs would be finalized, and finally, the PQ of the whole water system would be carried out to finalize the qualification. For this reason, the only results that are shown in the appendix are the RA and some data acquired for the OQ.

➤ **Weighing scales 1, 2 &3**

Regarding the weighing scales, the focus is on the results on the WI-22009, WI-22010 and WI-22011 scales, which is the nomenclature of the three scales in the factory.

The results obtained from the weighing scales are divided into risk analysis results, IQ results and OQ results. The PQ results are not shown because it is not necessary as it is an equipment.

All the protocols with the results obtained can be found in the appendix.

As in the previous case, the RA has been divided into risks associated with the installation of the scales and risks associated with the operation.

In the risks associated with the installation, the risk is basically an inappropriate installation of the scales for different possible reasons, that the materials in contact with the product are not suitable (in this case, weighing is done inside containers or bags and there is no direct contact with the scales, but this has also been taken into account), that the electricity services are not available to operate the scales and finally, that the scales are not correctly leveled and this causes an error in the weighing.

In the risks related to the operation, there are risks related to the turning on and off the scales, with the weight indication unit not giving erroneous results, with the transmission of the weight reading to the problem screen, with a bad calibration or non-calibration of the scales and finally, with an inadequate cleaning of the equipment that can contaminate the materials.

For each of these risks, values of severity, probability and detectability of the possible failure are entered according to a company instruction, and from here, multiplying the three values among them, a result is obtained, which is the risk level of each action. As can be seen in the attached document, all the results obtained have a low risk level and it is not necessary to apply actions to further reduce the risk if it is already at the lowest level.

This AR and the risks discussed are more related to the operation and working of the scales than to other aspects, since the purpose of the ratings is to verify that the scales are functioning correctly.

Once the results obtained in the RA have been commented on, the results of the IQ are commented on.

The IQ of the scales, being a measuring instrument, is not very complex. In the first table, no drawings or electrical installations of the scales are necessary. In this case, the most important point is the operation and instruction manuals to facilitate the handling and operation of the scales. The issue of spare parts list does not apply either, since due to the maintenance contract, if a scale breaks down, it is sent to the supplier for repair. In this case, although it is the qualification of the instrument, the plans associated with the material and the flow of people

are introduced to consider how the material moves inside the weighing room and what is the procedure before and after weighing. Next, the specifications of the scales are introduced to have technical information and finally, welding certificates are not necessary since the equipment comes compact and complete and does not have to be assembled or welded. In the following points of the IQ the inspection of the equipment is obtained, which is a table with the main data of the scales, the type of control and electrical specifications, in this case a table was made for each of the scales, then there is a table with all the main characteristics of the three scales. Next, it is shown if there are elements that are calibrated and the date of their next calibration, where the three scales that are calibrated annually have been introduced, then the services that the scales need to operate, which in this case is electricity. Next, if the materials encounter the product, which in this case they do not since the product does not touch the scale plate during weighing. Finally, a table is shown with the operating, cleaning, and maintenance instructions for the scales in question, most of the instructions were done, but the one for verification of the weighing scales had to be done to finalize the IQ. From here a table is shown with three GMP requirements for the installation and training of the personnel for the handling of this air system. In most cases, a deviation is opened, as shown in the last point, since all training is obsolete and must be done again to train new operators.

Once the results obtained from the IQ have been commented and approved, it is proceeded to the OQ.

In the OQ of the weighing scales, as in the other cases, the initial focus is on the verification of the control system, which in the case of the scales is very simple and it is only necessary to verify that they are turned on and off, that the few buttons on the scales perform their function and that the display shows the necessary information. Regarding the operational verification, to verify and qualify the scales the same tests that are performed in an annual calibration of the scales are performed, but in this case taking five different values within its range of weights and that at least one value is a minimum value, an intermediate value, and a maximum value of the weighing range of the scale. This is taken advantage of and when the suppliers who calibrate the scales came, were asked to bring different types of calibrated weights, and perform the tests themselves, and after several days they made a report which was attached to the OQ. To finalize the OQ, the tests of different alarms are performed to observe that in case of any error the alarm goes off.

Once the OQ is finished and approved, the scales are already qualified, since it is not necessary to perform the PQ because, as it is a piece of equipment, the OQ is the final qualification. In this case, the RA, IQ and OQ results are shown in the appendix.

#### ➤ **Kettle R-3514**

The results obtained from the R-3514 reactor system are divided, as in any of the existing equipment, into risk analysis results, IQ results and OQ results. As mentioned above, since it is a unit, the qualification ends in the OQ and then the validation of the process with the raw materials and the specific conditions for the OTC formula would be carried out.

All the protocols with the results obtained can be found in the appendix.

In relation to the scope, initially this reactor R-3514 had to be qualified together with the melter as each reactor, but after performing the pilot test of the production and observing the OTC product formula, it was thought to eliminate the melter from the qualification for the FDA since only the reactor would be used due to the fact that no wax raw materials were used and for this reason, the qualification is of the reactor R-3514 together with the container bag that stores the product.

As in the previous case, the RA has been divided into risks associated with the installation of the R-3514 reactor and risks associated with its operation.

In the risks associated with the installation, basically is obtained as a risk an inappropriate installation of the reactor for different possible reasons, that the materials in contact with the product are not adequate, which is an important point because the product is generated inside the reactor and if the reactor materials are not adequate can be contaminated the product, that the necessary utilities are not available for the correct operation of the reactor, in this case the necessary utilities are many, such as osmotized water, compressed air, PIG air, steam and as in all, electricity and finally, that the location of the reactor is not adequate and is located in an uneven way causing an inadequate operation.

In the risks related to the operation, there are risks related to the start-up and shutdown of the R-3514 reactor, risks related to the equipment, such as the reactor boiler, the reactor lid, the reactor stirring equipment.... Furthermore, there are risks on the jacket temperature control system, on the reactor control elements such as probes, vacuum gauges, displays... In addition, risks related to the reactor alarms and safety elements and risks related to the reactor cleaning where this can cause cross contamination. Finally, some risks related to the container bag that stores the product are also shown.

For each of these risks, values of severity, probability and detectability of the possible failure are entered according to a company instruction, and from here, multiplying the three values among them, a result is obtained, which is the risk level of each action. As can be seen in the attached document, all the results obtained have a medium or low risk level and this does not cause the application of rapid changes to mitigate possible failures, but in the results obtained with a medium risk level, improvements are tried to be applied to reduce the result to a low risk level.

As can be seen, this RA and the risks discussed are more related to the operation and working of the equipment than to other aspects, since the aim of the ratings is to verify that the equipment is working correctly.

Once the results obtained in the RA have been commented on, the results of the IQ are commented on.

In the IQ the current result is shown, since during the project it was decided to apply certain improvements, such as an automatic vacuum and change of certain valves, to facilitate the production in the reactor and these improvements must be documented in the IQ, and until are approved and implemented in the reactor, they cannot be documented in the IQ. For this reason, to finalize the IQ of the reactor it would be necessary to introduce the documentation of the different improvements that have been made and consequently it could be approved.

The IQ protocol was carried out to have it ready so that when the missing information was received, the protocol could be finalized quickly. At the moment, the current results of the IQ of the reactor are commented.

In the IQ of the R-3514 reactor, in the first table where the main documentation of the system is shown, it has been found and verified that the P&IDs and the drawings match with what is in the plant, and that the main elements of the electrical diagrams also match. In addition, to have operating manuals and operating instructions for the equipment to know how it works. In this case, there was no operating manual for the R-3514 kettle, and for this reason a very detailed instruction was made with all the aspects involved with the operation of the reactor in order to facilitate the work of the operators and to fill in the box in the table, since it is an important point. Continuing in the table, there was no list of spare parts for the reactor in particular and that was because it had nothing specific to the reactor itself, and if a valve or a probe was damaged, it was changed and it was a generic change, since probes, valves or other elements

are used generically in much equipment of the plant and therefore are not specific spare parts of the equipment. Next, material flow and personnel drawings are necessary, but not critical, as it is shown the flow of materials from the weighing area to the professional area. The specifications of the measuring instruments in this case are necessary to have information of what is in the reactor and finally, the welding certificates do not apply because the kettle is a 500 L element and comes without welding to be done by the company. In the following points of the IQ the inspection of the equipment is obtained, which is a table with the main data of the kettle, the type of control and electrical specifications, then there is a table with all the main characteristics of the reactor and the control system, which in this case is not a PLC but it is a control scheme with relays. Next, it is shown if there are elements that are calibrated and the date of their next calibration, which in this case are the temperature indicators and the load cell, then the utilities that the R-3514 reactor needs to operate, which in this case are all possible from the factory, water, air, steam, and electricity. Next, if the materials encounter the product, which in this case it happens, and it is observed and corroborated that the materials of the reactor and the agitators are 316 stainless steels. Finally, a table is shown with the operating, cleaning, and maintenance instructions of the equipment in question. From here a table is shown with three GMP requirements for the installation and training of the personnel for the handling of this reactor.

Once the IQ is done and waiting to add the documentation of the changes to finalize it, the OQ is started to verify the operability of the reactor.

In the OQ of the R-3514 reactor, as in the other cases, initially the control system is verified, where the reactor control is turned on and off, an emergency shutdown and that everything is restored correctly, that the buttons of the control system perform each one the function that belongs to it, that the screen shows the information and that it is readable. These points are verified, and it is observed that it works correctly, the issue of backups and traceability of changes is not performed remotely, since the equipment is very old and it is explained that since the control system is a button panel, these functions are not equipped. Regarding the operational verification of the reactor, data are taken from the reactor pressure to verify its integrity and that there are no leaks and to see that it always maintains the pressure below atmospheric pressure, the pressure of the jacket to observe that it is within the established parameters, the fast and slow speed of the scraper and thus with a tachometer to verify that the speeds are consistent with what the engine says, the same is repeated for the turbine. Data is also taken from the jacket when it heats up, to observe how long it takes to reach the established setpoint and see how the temperature is maintained, and finally, data is taken from the reactor temperature in the cooling to see how long it takes to cool and corroborate that it cools properly. Finally, the few alarms that the reactor has, are checked, which rather than alarms are lights that light up when a failure or error occurs. Once all these aspects have been checked, the OQ of the equipment is completed.

Once the OQ has been performed and approved, the equipment is qualified and then the process validation is performed. As can be seen, the OQ does not have all the tests performed because it is waiting for the changes to be introduced so that all the tests can be performed. That is, in the qualification of the reactor, the IQ and the OQ were prepared and filled in as much as possible and are waiting for the changes to be introduced so that the protocols can be finalized, and the qualification can be completed. Once this is done, the qualification would be finished quickly, and the equipment would be qualified and ready for FDA certification.

In other words, once the changes have been applied and the IQ has been approved, the OQ will be finalized, and the reactor qualification will be completed. For this reason, the only results that are shown in the appendix is the RA since the IQ and OQ are raised, but not finalized.

➤ **Cleaning system tanks**

The results obtained from the cleaning system tanks are divided, as in any of the existing equipment, into risk analysis results and IQ results. The OQ and PQ results have not been obtained because the operational part is verified when the cleaning process is validated, which is not within the scope of this project.

All the protocols with the results obtained can be found in the appendix.

In relation to the scope, the tanks of the cleaning system are five: hot deionized water tank, water tank (hyperchlorinated water), detergent tank, peracetic acid tank and reclaimed water tank. Of these five tanks in the cleaning system, three tanks are qualified, which are the ones used for cleaning the professional reactors. These tanks that are in the scope of qualification are the hot deionized water tank, the mains water tank and the peracetic acid tank.

Then, it is proceeded to comment on the results obtained from the RA.

The RA has been divided into risks associated with the installation of the cleaning tanks and risks associated with the operation.

In the risks associated with the installation, the risk is basically an inappropriate installation of the cleaning tanks for different possible reasons, that the materials in contact with the liquids are not suitable and that the electricity and compressed air service is not available to operate the equipment.

In the risks related to operation, there are risks related to equipment such as the tanks, the centrifugal pumps that distribute the fluids, the exchangers that heat the deionized water tanks and mains water, the pipes that distribute the fluid to the reactors and finally, certain control elements such as valves, level, and conductivity sensors.

For each of these risks, values of severity, probability and detectability of the possible failure are entered according to a company instruction, and from here, multiplying the three values among them, a result is obtained, which is the risk level of each action. As can be seen in the attached document, all the results obtained have a low risk level and this does not cause the application of quick changes to mitigate possible failures.

As can be seen, this RA and the risks discussed are more related to the operation and functioning of the equipment than to other aspects, since the purpose of the ratings is to verify that the equipment is functioning correctly.

Once the results obtained in the RA have been commented on, the IQ results are commented on.

In the IQ of the cleaning tanks in the first table where it shows the main documentation of the system of the tanks, it has been found and verified that the P&IDs and the drawings match with what is in the plant, and that the main elements of the electrical diagrams also match. Moreover, in this case the operation manuals and instructions are not necessary because its operation is very basic, when you need liquid from any of the tanks, you open the corresponding valve, and the liquid appears. In the case of the spare parts list, it does not apply because there are no specific spare parts for any of the tanks, but the elements that can be changed are of a generic nature. Regarding the drawings associated with the flow of material and personnel flow, in this case does not apply because they are static tanks and there is no movement of personnel or material to stipulate. Finally, welding certificates are needed because it is necessary to ensure that all piping connections are adequate since the fluid comes into contact indirectly with the product. Three tables are shown below with information on the three tanks to be qualified and the type of control for each one. Next, the physical characteristics of the tanks are shown in a table. Next, it is shown if there are elements that are calibrated and the date of their next calibration, then the services that the cleaning tanks need to operate, which in this case is electricity and steam for heating. Next, if the materials come in contact with the product, which,

in this case indirectly yes, to confirm and have a certification that they are 316 stainless steels. Finally, a table is shown with the operating, cleaning, and maintenance instructions for the equipment in question. From here a table is shown with three GMP requirements of the installation and personnel training related to the cleaning tanks.

Once the results obtained from the IQ are commented and approved, the qualification process of the three cleaning tanks is finalized. As mentioned above, the OQ and PQ are not required as they fall within the scope of the cleaning process validation, and the operability of the equipment falls in there. In this case, the RA and IQ results are shown in the appendix.

#### ➤ Cool room

The results obtained from the cold room are divided, as in any of the existing equipment, into risk analysis results, IQ results, OQ results and PQ results. In this case PQ has been performed because it is performed together with OQ. Theoretically in new rooms, OQ tests are performed when the room is empty and PQ tests are performed when the room is full of material. In this case, it is not possible to remove all the material inside the cold room, since there are raw materials that are flammable above a certain temperature and therefore, a maximum of 10 °C is the established value. For this reason, OQ and PQ are performed together, and their results are evaluated together.

All the protocols with the results obtained can be found in the appendix.

Related to the scope, it is the cold room, where it is mainly the refrigeration equipment of the room.

Unlike the other cases, in the AR it has been divided into risks associated with the installation of the cold room, risks associated with the installation of the refrigeration system and risks associated with the operation of the refrigeration system.

In the risks associated with the installation of the cold room, is obtained the risks of the cold room finishes, basically that the finishes of the floor, wall, ceiling, etc. are adequate to avoid accumulation of dirty and thus avoid possible contamination of the product, that the construction materials are not adequate, basically that the materials of the floor, walls, ceiling, etc. are adequate and in good condition, and that are in good condition. etc. are adequate and in good conditions to avoid a possible contamination of the product and finally, that the necessary utilities are not available for the correct operation of the cold room, in this case the necessary utilities are few, specifically electricity for the light inside the room.

In the risks associated with the installation of the refrigeration system, is obtained the risks of an inappropriate installation of the refrigeration system for different possible reasons and that the necessary services are not available for the correct operation of the refrigeration system, in this case the necessary services are few, specifically electricity for the operation of the refrigeration equipment.

In the risks related to the operation of the refrigeration system, is obtained risks related to turning on and off the refrigeration system, risks related to the regulation of the temperature of the chamber, this case is an important point because the temperature cannot be higher than 10 °C, risks associated with alarms and interlocks where they work properly in case of any failure inside the chamber and finally risks related to the refrigeration equipment in particular, such as the condenser, evaporators, air filters and temperature probe inside the chamber.

For each of these risks are entered values of severity, probability, and detectability of possible failure according to an instruction of the company, and from here, multiplying the three values between them, a final result is obtained which is the risk level of each action. As can be seen in the attached document, all the results obtained have a medium or low risk level and this does not cause the application of rapid changes to mitigate possible failures, but in the results

obtained with a medium risk level, improvements are tried to be applied in order to reduce the result to a low risk level.

As can be seen, this AR and the risks discussed are more related to the operation and functioning of the refrigeration equipment in the chamber, since the ratings are intended to verify that the equipment is working properly.

Once the results obtained in the RA have been commented on, the results of the IQ are commented on.

In the IQ of the cold room, in the first table where it is shown the main documentation of the room, a 3D scheme of the cold room has been made to know its distribution, since it did not have any, and had to be done, and were found and verified that the main elements of the electrical schematics also agree with what was found with the documentation. In addition, they have operating manuals and operating instructions of the refrigeration system equipment. In this case, spare parts list is not necessary because it has a maintenance contract that when any part of the refrigeration equipment breaks down, suppliers come to repair it. Regarding the flow of material and personnel plans are necessary because you must know how the material has to go inside the chamber for proper operation. The specifications of the measuring instruments in this case are necessary, which finally in this section is introduced information cooling equipment and temperature probe and finally, welding certificates do not apply because the cooling circuit comes all in one block and the connections between them are all straight and without elbows, so it has been decided that does not apply. In the following points of the IQ are obtained inspection of the equipment, which is a table with the main data of the system, the type of control and electrical specifications. Related to the type of control, as there was no information on this section, went to the equipment and tests were performed, and the temperature was lowered to 3 °C and it was observed that the refrigeration equipment was capable of cooling the room to this temperature and was chosen as a minimum since it was valid for our process, and as a maximum stipulated the ambient temperature because, for the process, the camera could not be above 10 °C, so it was taken as valid. Finally, after observing that, the operating range of the room was chosen as 3°C to 25°C. Next is a table with all the main information of the refrigeration equipment. Next, it shows if there are elements that are calibrated and the data of its next calibration, in this case the datalogger that obtains data from the temperature of the chamber, then the services needed by the refrigeration equipment to operate, which in this case is electricity and compressed air for the compressor of the refrigeration equipment.

Next, if the materials meet the product, and in this case does not apply because the raw materials inside the chamber are packaged and inside boxes and at no time comes into contact with the room. Finally, a table is shown with the operating, cleaning, and maintenance instructions of the cold room in question, the operating and maintenance instructions were nonexistent and had to be made in order to proceed with the qualification. From here, a table is shown with three GMP requirements for the installation and personnel training for the operation of this cold room refrigeration system. In this case, there are no open deviations due to having all the necessary documentation to perform the IQ.

Once the results obtained from the IQ are discussed and approved, the OQ is performed.

In the OQ of the cold room, it is divided as the previous ones, but with some different things. Initially, the control system of the cold room is verified, where basically it is observed that the equipment is turned on and off, that the display shows all the information correctly and that it is readable, that all the buttons on the control panel perform their function and finally, observe that once the setpoint of the chamber has been established, when the equipment cools and

reaches a specific temperature, the equipment stops, and when the temperature drops to a certain point, the equipment starts to cool. As can be seen, all the results are favorable.

Once the control system part has been checked, it is proceeded to verify the operational part. In the verification of the operational part, eight dataloggers are placed inside the chamber and temperatures are taken in two cases. The first case when the cold room is closed and there is no door opening, and the second case on days when the chamber is working normally.

For the two cases, the results are shown in the appendix inside the OQ, but the temperature variation and the placement of the dataloggers are shown below.

The figure below shows the placement of the dataloggers inside the cold room.

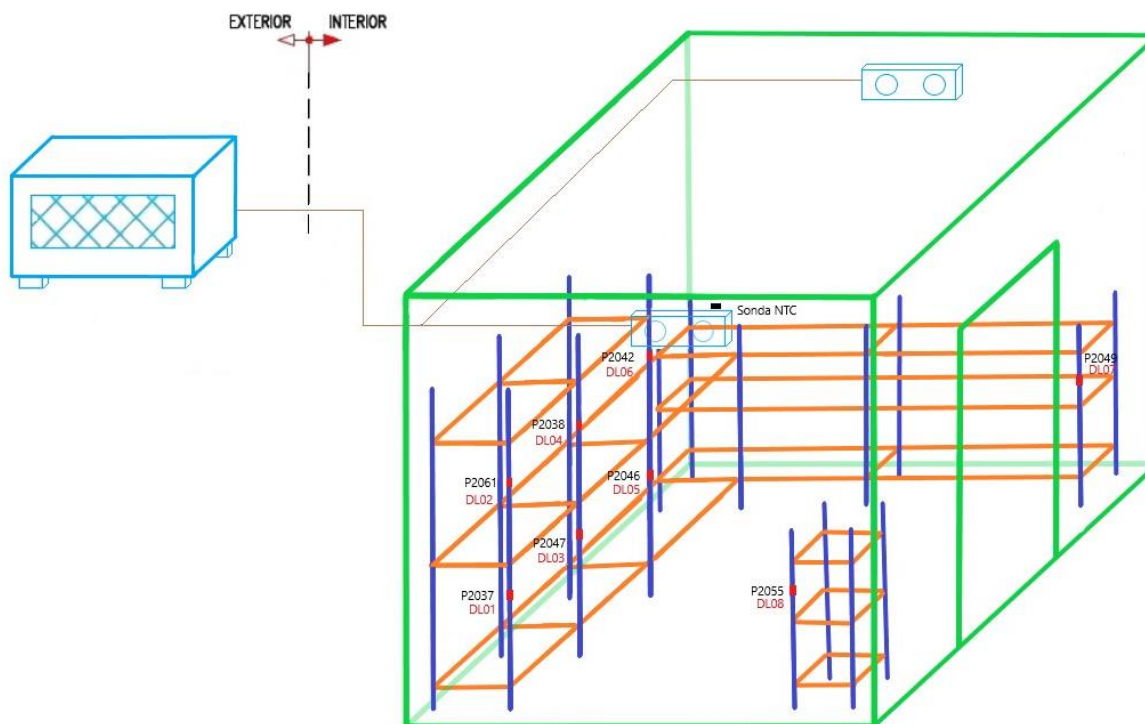


Figure 5.1 Placement of dataloggers inside the cold room.

Regarding the results obtained for the first case without opening the doors, it is observed that with a setpoint of 7 °C, the average results of each datalogger is around 9 °C, with minimums of 8.80 °C and maximums of 9.90 °C. As can be seen, although the cold air tends to go down, it can be observed that the results of the different dataloggers at different heights are quite similar and the temperature readings are very constant. It can also be commented that, although the temperature of the eight dataloggers is similar, the chamber must have small losses since the setpoint is 7 °C and the results obtained are 9 °C. Even with these small losses, as the results obtained are very similar, with little deviation and are within the range established by the company, which does not exceed 10 °C, they are considered acceptable. The following figure shows the evolution of the temperature for each datalogger introduced in the chamber in the first case.

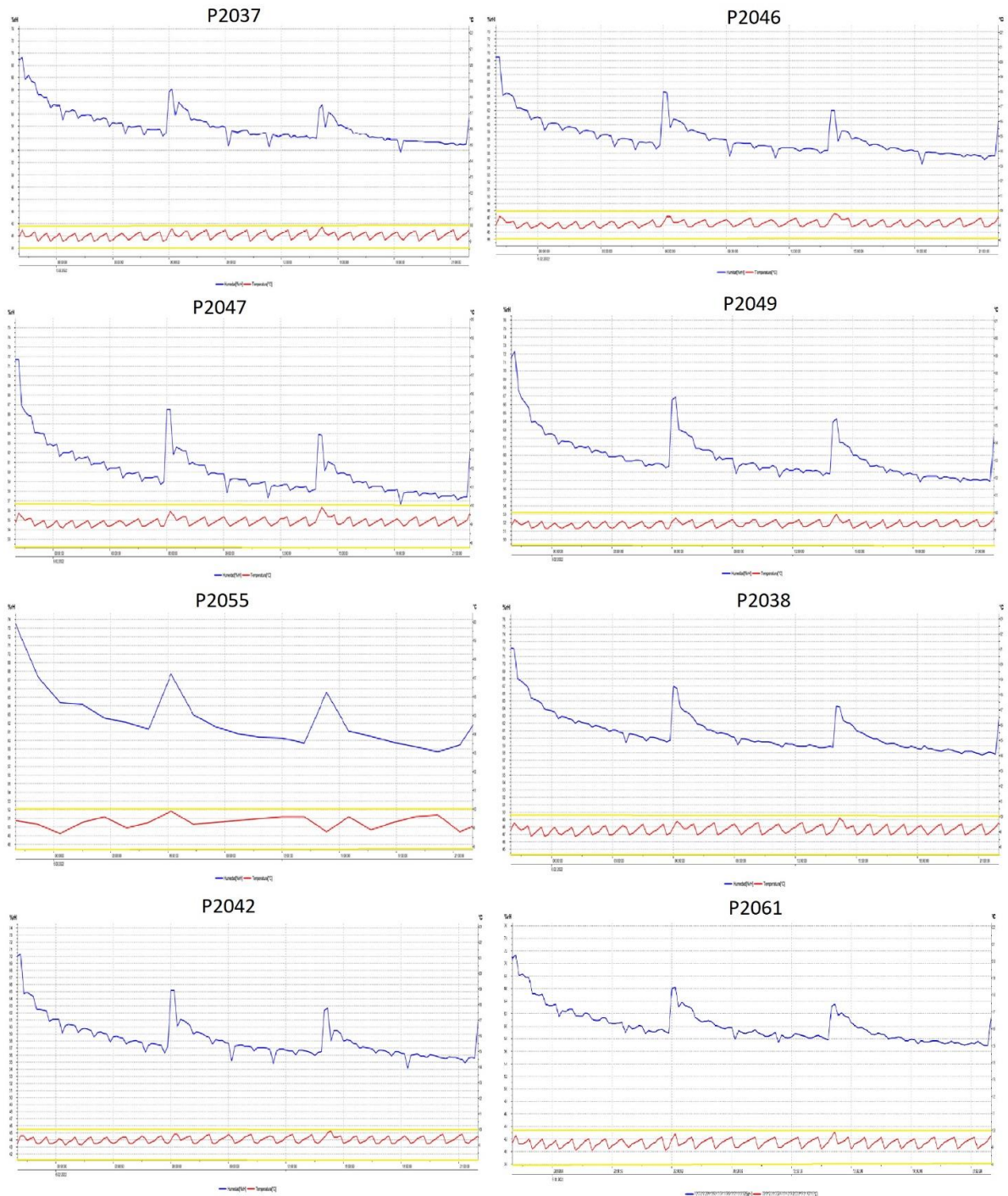


Figure 5.2 Temperature results about cool room operation without opening for 24h.

Regarding the results obtained for the second case in normal working days, it is observed that with a setpoint of 7 °C, the average results of each datalogger is around 9 °C, minimum of 8.70 °C and maximum of 10.30 °C. It is observed that the average temperatures of the dataloggers differ very little from the previous case, and that means that the cooling equipment of the chamber is working properly. As in the previous case, although the cold air tends to go down, it can be observed that the results of the different dataloggers at different heights are quite similar and the temperature read is very constant. As previously mentioned, although the

temperature of the eight dataloggers is very similar, the room must have small losses since the setpoint is 7 °C and the results obtained are 9 °C. Even with these small losses, as the results obtained are very similar, with little deviation and the maximum temperatures obtained, observing the graphs, they are very punctual moments that drop at a time of 10 °C, then the results can be considered acceptable. The following figure shows the evolution of the temperature for each datalogger introduced in the chamber in the second case.

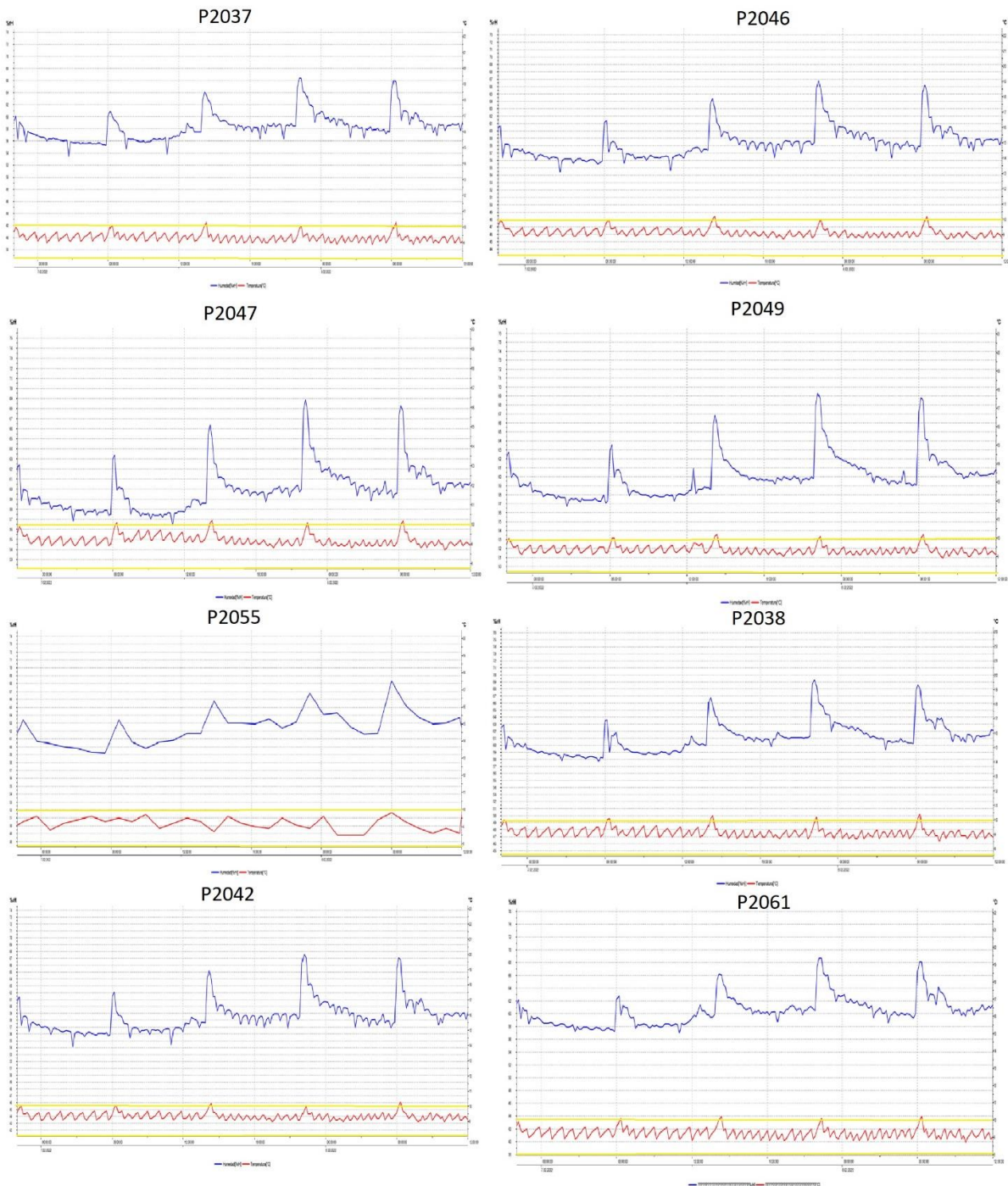


Figure 5.3 Temperature results about cool room operation for 2 days.

Once all temperatures have been verified, the alarm test would be performed to see that they work, but in this case as there is only one flammable detector and there is no other alarm, this test does not apply. The next point to perform is a power failure test, which in this case would disconnect the refrigeration equipment and let it reach room temperature, then the refrigeration equipment would be turned on again and the time it takes to cool the temperature back to the setpoint would be observed. In this case, this test could not be performed because having flammable raw materials that cannot be at a temperature above 10 ° C, you cannot reach room temperature inside the chamber and for this reason, the test could not be performed and puts a does not apply, and there is a brief explanation below the table. From here, the OQ ends with the personnel training record and with deviations if applicable. Finally, in the appendix there are attached the enlarged graphs of each datalogger to be able to better observe the results obtained and their evolution.

Once the OQ has been carried out and approved, the PQ will be carried out. As mentioned above, in this case the OQ and PQ are performed together because it is not possible to remove all the raw materials from the chamber. To perform the OQ and PQ correctly, the OQ would have to be performed with the chamber empty, without raw materials and the PQ would have to be performed with the chamber full, with raw materials. In this case, as the tests are performed with the chamber full of raw materials, it would be the PQ, but as the chamber cannot be emptied, it is considered that the OQ and PQ are performed together.

Known this, and having finished all the OQ tests, it is considered that the PQ is also performed, and the qualification of the cold room is completed in a favorable way. To finalize the 100% qualification and ensure its good performance, the same temperature mapping would be performed in summer, in the hottest week of the year, to see the behavior of temperatures in the summer season. Once this mapping is done, the qualification of the cold room will be finalized. In this case, the RA, IQ and OQ results are shown in the appendix.

### **5.1.2. New Equipment**

This section shows the results obtained from the qualification of the new equipment that has been introduced in the scope of the project. The results of all the protocols are attached in the attachments.

#### ➤ **Osmotized Water System**

The results obtained from the newly installed osmosis water system are those of the Veolia reverse osmosis.

In this case, the results obtained start from the realization of a URS, with all the technical requirements that are wanted for the realization of the osmosis plant. For this osmosis system equipment, the URS was already made in its day when it was purchased, but with a different format than the current one. For this reason, the existing URS was taken and changed to the current template.

Once the URS was completed, DQ was observed to compare these offers with the completed URS. The results obtained from the DQ are shown in the attachments, the one that was performed was the verification that the requirements that were written in the DQ were correct and fulfilled everything that was mentioned in the URS at the time and verify that it was performed properly. In this case, a DQ was made and in addition, a separate document called DQDOC was made, where in this document the verification of the different points such as P&ID, layout... In this case, the different current plans were observed, and it was verified that everything is as marked in the documents.

Then, the FAT was verified. Once the equipment was purchased, different tests of the installation and the control system were carried out at the Veolia company's facilities. In this case, it was not possible to check anything, since this section was carried out in the same company that supplied the osmosis water equipment. What could be observed is that there was no failure, and all the tests were in accordance and passed satisfactorily.

From here, once it was observed that the results of the FAT were satisfactory, it is proceeded to install the equipment at the Revlon factory. When the tube was installed, the SAT was performed, which is basically to start up the equipment and observe that the parameters are as established. In this case, it was observed that the results were favorable. To verify this, the equipment was stopped and started up and it was observed that everything worked correctly as specified. For this reason, it was possible to verify again its operation in plant.

Once the system was installed and working, the IQ was verified. The AR was already performed together with the Astramatic osmosis equipment and the distribution loops and everything is commented in this section, for this reason we will verify and check the IQ performed. In this case, the IQ performed follows a similar pattern, but not the same as the current one, since it does not use the Revlon template and the documentation to be reviewed is much more extensive. In this case, plans and electrical diagrams, list of all system components, verification of technical documentation such as operation manual, spare parts list..., verification of material certificates, verification of services, verification of pipe passivation, welding certificates, hydrostatic test, drainability check and finally, verification of the control system are verified. As can be seen, almost all the points are also in the IQ of the Astramatic osmosis, the only difference is that, in Veolia being a new equipment, the hydrostatic test is performed and documented, and it is verified that the passivation is correct because the system has stainless steel pipes. Once this was known, it was noted that all the documentation approved in this IQ was had and followed with the OQ check.

In the OQ, the results obtained differ in installation and in the control system, as is the case with the Astramatic osmosis equipment. In the case of Veolia, the verification of the control system is very similar to that of Astramatic, where the connection and disconnection of the equipment, management of the different menus on the display, user management, verification of alarms and several other things are verified. Regarding the verification of the installation, in this case the tests are somewhat different than if you have an equipment that has been in operation for many years, such as the Astramatic osmosis equipment. In Veolia we mainly verified that the system works within the parameters established by the instruments, as in the case of Astramatic, but the difference is that in this OQ the configuration of the parameters is verified and that there are customized configuration parameters for the equipment that require it. Knowing these steps, the same verifications were performed, and the result was favorable as in the case when the OQ was performed.

Finally, the PQ is performed, whereas mentioned above, the PQ of the equipment is performed by taking data from the equipment for a whole year and verifying that they are within the acceptance range established by the company. This PQ is performed together with the Astramatic osmosis equipment and the distribution loops, and when the OQ of the Astramatic osmosis and the OQ of the distribution loops are finished, the PQ of the whole system could be started and the qualifications of the three systems could be finished at the same time. In this case, the URS and DQ made to be adapted to the current format are shown. The rest of the protocols are not shown since they were reviewed and nothing extra was added to them, so are not attached.

➤ **Dynamic Scale and Metal Detector**

The results obtained for the scale and the metal detector in the filling and assembling area are based on the URS, with all the technical requirements related to the tubes to be filled and the characteristics required to obtain FDA certification.

Once the URS was made with the desired characteristics, different offers were requested to different suppliers to make a comparison.

Once the offers were received, the DQ was carried out to verify that all the offers obtained complied with the requirements set out in the URS. The DQ showed that all the offers received complied with the requirements established in the URS.

The results related to the URS and the DQ of the scale and metal detector are attached in the annex awaiting signature by the responsible parties.

The results obtained on the scale and metal detector were stopped here at the DQ, since the purchase of the equipment and the performance of the FAT, SAT, IQ and OQ would then proceed. Because the project was stalled for some time due to a budget mismatch, it was not possible to proceed with the purchase of equipment and the start of work until the entire budget was closed. For this reason, no further results could be obtained from the scale and metal detector for the tube line, and subtraction of the qualification steps will be performed later than the delivery of this project. In this case, the URS and DQ results are shown in the appendix since these protocols were the unique that was developed due to a budget mismatch

➤ **Weighing Area and Filling Area Washing Machine**

The results obtained for the cleaning machine for the weighing area and the packaging area are very similar to those obtained for the scale and the metal detector.

Initially, the results obtained are based on performing the URS with all the technical requirements related to the cleaning machine for the two cleaning rooms of the different areas.

Once the URS was made with the desired characteristics, different offers were requested to different suppliers in order to compare the different cleaning machines.

Once the offers were received, the DQ was performed to verify that all the offers obtained complied with the requirements established in the URS and it was observed in the DQ that all the offers received complied with the requirements established in the URS.

The results related to the URS and the DQ of the cleaning machine are attached in the annex waiting to be signed by the responsible parties.

The results obtained from the cleaning machines stopped here at the DQ, since the purchase of the equipment and the performance of the FAT, SAT, IQ and OQ would then proceed. As discussed in the previous case, because the project was stalled for some time due to a budget mismatch, it was not possible to proceed with the purchase of equipment and the start of work until the entire budget was closed. For this reason, it was not possible to obtain more results from the cleaning machines for the weighing and packaging areas, and the subtraction of the qualification steps will be done later after the delivery of this project. In this case, the URS and DQ results are shown in the appendix since these protocols were the unique that was developed due to a budget mismatch

## **5.2. Reactor Cleaning Results**

The results obtained for the reactor cleaning are shown below.

Initially, the results of the risk analysis performed related to reactor cleanup are discussed, where the result obtained is shown in the appendix.

In the risk analysis, a scope of the reactor cleanliness was performed based on all possible OTC ingredients to be introduced into the reactor and their probability to be soluble, their severity of failure on cleanliness related to toxicity data, allergens and whether it is pharmaceutical ingredient or not, and finally with the capacity of detection with visual inspection, to see if once the equipment is cleaned, residues are detected inside the reactor or not, and from here, observe the total of multiplying the probability, severity and detectability and see the capacity of transfer and adulteration of the OTC product for each specific ingredient.

In the risks associated with cleaning, basically as results are obtained that a total of six possible ingredients, by a bad cleaning can have a medium risk and adulterate the OTC product that is manufactured in the reactor, six other ingredients have a low risk by a bad cleaning and finally, there is an ingredient that has a high risk of causing adulteration and contamination by a bad cleaning.

When this RA was performed, it was possible to know the different raw materials that will be more difficult to clean from inside the reactor when the OTC product is made and from there, to be able to evaluate if the current cleaning is correct to remove all these ingredients from the reactor. Observing the different results of these ingredients that are used for other production formulas, it is observed that the current cleaning does allow to eliminate all the mentioned ingredients in a satisfactory way.

Furthermore, apart from the risk analysis carried out, as explained in the cleaning procedure of the professional reactors, one of the problems that can be found is that it is very manual and not very automated, and this can cause certain human errors when cleaning, and as will be observed later, a very long time to complete the cleaning of a professional reactor.

From here, it is proceeded to comment on the results and everything that has been obtained from the three proposals discussed in the section on the approach.

### **5.2.1. First proposal**

Considering the first proposal to improve the cleaning of the reactor mentioned in the approach section, the results obtained are commented.

Knowing what was commented in the approach, considering the 4 main points for a good cleaning of a cosmetic reactor, which are the agitation of the reactor, the time of each stage, the temperature, and the detergent to be used, the option of modifying some of these 4 points to improve the cleaning of the reactors in the professional area has been evaluated with the help of the manufacturing process engineer.

Initially, the possibility of reducing the times of the different cleaning stages was discussed to carry out the process more quickly and consequently produce faster in a reactor. Currently, the total time of the reactor depends on the dimensions of the reactor as such, since the stages of filling, detergent application... depend on the size of the reactor because filling a small reactor will take less time than filling a larger reactor. For this reason, the time range for a professional reactor cleaning is between 2 and 3 hours of procedure. Within these two or three hours many times depend, but the ones considered for a possible optimization are the times shown in the table below, where these times are the main ones for each of the stages to take into account for the cleaning.

Table 5.1 Time established for each stage of the reactor cleaning.

Stages	Stages tasks	Time
1 <sup>st</sup>	Introduce hot DI water into the reactor and leave it stirring.	1 h
2 <sup>nd</sup>	Leave the foaming agent inside the reactor.	30 min
3 <sup>rd</sup>	-	-
4 <sup>th</sup>	-	-
5 <sup>th</sup>	Peracetic acid water rinsing	2 min

Explained that these times are the most important, is talked to the manufacturing process engineer and is obtained the conclusion that these times were obtained some years ago through several tests performed by the Quality Assurance department, and for this reason these times cannot be modified. The different times that complete the 2 or 3 hours of the cleaning process are times related to human action, and in this case, with this cleaning process they cannot be optimized since they are related to the human factor.

For this reason, in this first test it can be concluded that the main times cannot be modified since were obtained as optimal a few years ago for the correct cleaning of the reactor and the remaining times cannot be modified because it is related to human action. Therefore, it is concluded that the main point of time cannot be modified for its optimization, since the main times have been optimized for several years.

Next, after evaluating the time, the temperature was considered. Regarding the temperature, is thought of increasing the deionized water temperature from 80 °C to 85 °C, which is the maximum for alkaline products, to see if it would increase the cleaning efficiency.

After talking to the process engineer and performing the relevant calculations, it was noted that increasing the temperature by 5 °C would not be worthwhile because increasing the temperature to improve cleaning efficiency and spending more money is not worth it if the efficiency obtained for each cleaning is already viable and no cross-contamination is obtained, there is no point in increasing the temperature to improve efficiency at all. In this case, it will have to be tested how much the efficiency increases if you increase the temperature, but what can be seen in the following table is that there is a cost overrun if the deionized water is heated from 80 °C to 85 °C depending on the reactor, from the smallest to the largest.

Table 5.2 Increasing water temperature cost overrun

Reactor	Cost overrun (€)
500 L	0,70
3.000 L	4,10

In the table, for the smallest reactors the additional cost to increase the temperature by 5 °C is 0,70 € per cleaning and for the largest reactors the additional cost is 4,10 € per cleaning. In the case of smaller reactors the additional cost is very small, but for large reactors the additional cost for each cleaning is already 4,10 €, and to have a somewhat higher cleaning efficiency to have to spend 4,10 € more per cleaning, with the large number of cleanings that are performed annually, this would be an inconsistent expense because if the efficiency of the current cleaning is already sufficient and there is no cross contamination, spending extra money to obtain greater efficiency if the existing one works properly is not feasible. If you increase the efficiency, you

reduce the chances of cross-contamination much more, but with the current cleaning it is already sufficient and there is no need to add this extra cost.

For this reason, in this second test it can be concluded that increasing the temperature of the deionized water to the maximum recommended temperature is not feasible, because the annual expenditure of money that would be produced to increase the cleaning efficiency by a small amount, if the current one is already working properly, does not pay off.

Next, after evaluating the time and temperature, it was considered to vary the agitation in the reactor.

In this case, no specific values were obtained because the cleaning is performed with slow agitation and the revolutions per minute established for each reactor were stipulated by the Quality Assurance department, where some time ago it was evaluated this point and obtained a specific number of revolutions per minute maximum to agitate the reactor so that the cleaning solutions could penetrate well. Furthermore, after discussing it with the process engineer, increasing the revolutions per minute would increase the cleaning efficiency, but it would not reduce cleaning times or costs, and for this reason it was left as it was.

Finally, as a final and most important point, the detergent to be used was evaluated.

At present, the detergent to be used is an alkaline foaming detergent obtained at 2,92 € per liter and with valid cleaning efficiency results according to the requirements set by the Revlon company. In this aspect, it was not possible to optimize the current detergent, since the quantities to be introduced to make the mixture and generate the foaming agent were established by the supplying company. What could be done to try to improve this aspect was to carry out tests with other detergents that met the cleaning requirements of Revlon and that were of lower cost than the current one. This case would produce a similar effect to that of varying the agitations, i.e., it would increase the efficiency, but would not reduce the cleaning time, but in this case, it would reduce the cleaning cost because the cost of the detergent would be lower.

Finally, a supplier was contacted to carry out tests with two different types of detergents. One is a non-foaming detergent for the cosmetic industry and the other is an alkaline foaming detergent like the one currently in use.

#### ➤ **Non-foaming detergent**

The test with the foaming detergent was carried out in a 600 L reactor to perform the test.

The test follows the same steps as the current cleaning, the only difference is that in the current cleaning the detergent is introduced with foaming agent and in this test the detergent is liquid, with a price of 3,89 € per liter, and a mixture is made with osmosis water. For this test, initially the reactor is flooded with osmosis water, but in this case, it is heated up to 75 °C because the dirt to be removed in this case has a flammability temperature of 83 °C and to ensure this it was heated up to 75 °C. Next, 300 L of osmosis water and 11 L of liquid detergent are introduced and stirred for 1 hour. Then, as in the actual cleaning, a rinse is carried out with tap water, peracetic acid is applied and the final rinse is carried out.

Known this, different samples were taken, two during the detergency phase, one after 10 minutes and one after 50 minutes, and one sample after the third stage of rinsing. These samples are shown below, noting that in the detergency phase the concentration and temperature are maintained within the recommended ranges and after rinsing the pH is observed.

Table 5.3 Results of the non-foaming detergent

Sample	Detergent concentration applied	Detergent concentration recommended	Temperature	Temperature recommended	pH
Sample 1 after 10 minutes of detergency	3,28 %	3-4 %	65,1 °C	60-80 °C	-
Sample 2 after 10 minutes of detergence	3,01 %	3-4 %	60,1 °C	60-80 °C	-
Sample 3 after rinsing	-	-	-	-	7

From this and the visual inspection of the reactor, it is concluded that the residue of the silicone-based product is satisfactorily removed by rinsing.

The results obtained to verify the effectiveness of the cleaning are within the recommended parameters. The advice to apply is to homogenize the detergent correctly before application.

After observing that with this first detergent the results are favorable, performing all the cleaning stages compared to the cleaning currently performed for a 600 L reactor, it is observed that the cost with this new detergent is 40 € higher for each cleaning and the time is 20 minutes higher, for this reason, in this case, it is concluded that the detergent gives better results in the case of efficiency, but as the cost and cleaning time are higher compared to the current one, the current detergent to be used is maintained.

The calculations of how to calculate the costs for each cleaning stage are explained in section 5.2.2.

➤ **New foaming detergent**

In this case, the test with the foaming detergent was performed in the FDA reactor.

The test follows the same steps as the actual cleaning, the only change being the application of the current foaming agent for the new one being tested. In this case, the foaming agent, priced at €4,50 per liter, is in contact inside the reactor for 20 minutes. For this test, the reactor is initially flooded with osmosis water, but in this case, it is heated up to 70 °C because these are temperature requirements set by the supplier for the product to be used. In this case, a sample is taken halfway through the detergent phase and at the end of rinsing. These samples are shown below, observing that in the detergency phase the concentration and temperature are maintained within the recommended ranges and after rinsing the pH is observed.

Table 5.4 Results of the new foaming detergent

Sample	Detergent concentration applied	Detergent concentration recommended	Temperature	Temperature recommended	pH
Sample 1 after 10 minutes of detergency	3,28 %	3-4 %	65,1 °C	60-80 °C	-
Sample 3 after rinsing	-	-	-	-	7

From this and from the visual inspection of the reactor, it is concluded that the residue of the product with polybutene component is satisfactorily removed by rinsing.

The results obtained to verify the effectiveness of the cleaning are within the recommended parameters. The advice to apply is to homogenize the detergent correctly before its application with the MobyFoam machine.

After observing that with this first detergent the results are favorable, performing all the stages of the cleaning compared to the cleaning that is currently performed for a reactor the FDA reactor, it is observed that the cost with this new detergent is 2 € higher for each cleaning, because the concentration of the foaming agent that is used is higher for its effective cleaning, and the time is reduced by 10 minutes, because the contact time inside the reactor is reduced by 10 minutes, normally it is 30 minutes and in this case it is 20 minutes, for this reason, in this case, it is concluded that the detergent gives better time results, but as the cleaning costs are higher than the current one and the efficiency is very similar to the current one, the current detergent to be used is maintained.

The calculations of how to calculate the costs for each cleaning stage are explained, as in the previous case, in section 5.2.2.

### **5.2.2. Second proposal**

Once the different points of the first proposal have been evaluated and seen that they cannot be further improved, an improvement proposal is established to replace some points of the current cleaning system with a different point.

For this improvement proposal, it has been based, as commented in the approach, with the total cleaning time, the cost of performing the cleaning and the efficiency of the cleaning. With these three points, a comparison has been made with the current cleaning and the new proposal.

Currently, the cleaning of the professional reactors is performed as explained in section 1.6, where it has mainly 5 stages to follow which are pre-cleaning, application of the foaming agent, rinsing of the foaming agent, application of the peracetic acid and final rinsing. From these 5 stages, the cost and time of each stage is calculated in order to obtain a total time and cost for each cleaning of the reactor, looking at the efficiency of the cleaning. These calculations were made for the FDA reactor, which is 500 L and for the largest reactor of the professional part, which is 3000 L. Once this was obtained, the calculations were made for the stages of the new proposal and a comparison was made.

Before commenting on the different stages of the current cleaning and those of the new proposal, it is commented how the production cost of the deionized water, the production cost of the steam for heating and the production cost of the mains water (hyperchlorinated water) were calculated. These three production costs were calculated because in any of the cleaning stages deionized water is used for cleaning and rinsing, steam is used to heat the different water tanks and mains water is used for rinsing.

#### **➤ Osmosis water production cost**

To calculate the cost of production of osmosis water, have basically been divided between the electrical cost of all the equipment to produce water and the cost of the chemical agents applied to the water. It is considered that there are two osmosis water generation systems, which are the ones mentioned in the qualification, and that the data have been taken from one and multiplied by two since they are almost identical.

The electrical cost of all the water production equipment is shown below. Initially, the following table shows all the equipment and their electrical consumptions taken from the technical data sheets.

**Table 5.5 Electrical power for all the equipment in the osmosis plant.**

Equipment	Electrical power
Initial pump	5,5 kW
Dosing pump	0,016 kW each one
P-77001	7,5 kW
P-77002	4 kW
P-77031	1,5 kW
P-77041	0,55 kW
Measuring elements	0,024 kW each one
PLC and gauges	0,015 W
EDI	1,5 kW each one

Looking at the table and knowing that there are 3 dosing pumps, 18 metering elements and 2 EDIs equipment, is obtained a total electrical power of 22,54 kW for each generation plant. Next, knowing that the maximum flow of osmosis water to be produced by each generation plant is 5.000 liters per hour and that the price of electricity is 0,319 € per kWh, then the price of electricity is divided by the liters per hour and a value is obtained. With this value obtained is multiplied by the electrical power of each generation plant, which in this case is 22,54 kW, and the cost of electricity consumption to produce osmosis water for each generation plant is obtained, where the result is 1,44 per cubic meter, which for the two plants is 2,88 per cubic meter. With this result it is said that the electrical cost to produce 1 liter of osmosis water is 2,88 €.

On the other hand, the cost of the chemical agents used in the production of osmosis water is based on the consumption of caustic soda, sodium bisulfite and an antifouling. The caustic soda is used to regulate the pH of the water, the sodium bisulfite is used to remove residual chlorine and the antifouling is used to avoid damaging the membranes.

For the calculation of the consumption of chemical agents, initially the regulation of the pump that doses the chemical agents is observed. It is observed that the caustic soda dosing pump is at 1,05 liters per hour, the sodium bisulfite dosing pump is at 0,56 liters per hour and the antifouling dosing pump is at 0,95 liters per hour. From there, these settings are divided by the percentage by which each chemical agent is diluted. The caustic soda is diluted at 10 %, the sodium bisulfite at 15 % and the antifouling at 6 % and with that is obtained chemical agent regulation values of 0,105 liters per hour of caustic soda, 0,084 liters per hour of sodium bisulfite and 0,057 liters per hour of antifouling. Then, with a feed water head to the equipment of 7,6 cubic meters per hour, the regulation of each pump is divided by this feed water head and a result of liters per cubic meter is obtained. Finally, the following formula is applied to obtain the cost for each of the chemical agents.

$$Cost \left( \frac{\text{€}}{\text{m}^3} \right) = \frac{\text{Water supply flow rate} * \text{Chemical agent cost} * \text{Consumption for m}^3}{\text{Osmotized water flow rate produced}} \tag{5.1}$$

From applying this formula, is obtained a result of the cost of consumption of each chemical agent for each water generation plant, for caustic soda is obtained a result of 0,018 € per cubic meter of water produced, for sodium bisulfite is obtained a result of 0,0037 € per cubic meter

of water produced and for antifouling is obtained a result of 0,084 € per cubic meter of water produced.

Known this, adding the electrical cost and the cost of the chemical agents for each osmosis water production plant, is obtained a value of 3,08 € per cubic meter of water produced. From here, the cost of the water purchased from the network in Pla de Santa Maria is added, which is 2,15 € per cubic meter, is obtained a result of the cost of production of osmosis water of 5,24 € per cubic meter produced. With this value it is possible to calculate the cost of osmosis water in the cleaning processes according to the liters that are spent.

➤ **Steam production cost**

To calculate the cost of steam production to know how much it costs to heat a tank, it has been calculated from an energy balance in a boiler. In the company there are two boilers that generate steam at 5 bars, a diesel boiler, and a gas boiler. From the energy balance of the boiler between the inlet water flow and the burning of diesel or natural gas, the following formulas are obtained.

$$Q_{steam} = m_{steam} * (h_{outletsteam} - h_{inletwater}) \tag{5.2}$$

$$Q_{fuel} = m_{steam} * HHV * \eta \tag{5.3}$$

From the two formulas the energies are equalized, and the fuel consumption is isolated. According to the above, the cost of steam per kilogram of steam produced can be obtained from the following formula.

$$Steam\ cost = \frac{(h_{outletsteam} - h_{inletwater})}{HHV * \eta} * Fuel\ cost * 100 + Chemical\ agents\ cost + water\ consumption\ cost + electrical\ energy\ cost + Operation\&\;Mantainance\ cost \tag{5.4}$$

Once this formula is known, the cost of steam production is obtained from the next part of the formula because it represents 90 % of the result and for this reason it is chosen as if the result were all from this formula.

$$Steam\ cost = \frac{(h_{outletsteam} - h_{inletwater})}{HHV * \eta} * Fuel\ cost * 100 \tag{5.5}$$

From this formula, with the data shown in the following table for each boiler, the steam production cost for each boiler is calculated.

Table 5.6 Values to calculate the steam production cost.

Element	Diesel boiler	Natural gas boiler
Enthalpy of the steam outlet (kJ/kg)	2.748,1	2.748,1
Enthalpy of inlet water (kJ/kg)	104,83	104,83
Steam capacity (kg/h)	3.100	3.000
HHV (kJ/kg)	42.705	38.627
Efficiency	90 %	93 %

Observing the previous table, the fuel consumption for each boiler and the steam production cost for each boiler are obtained with the formulas mentioned above and the results are shown in the following table.

Table 5.7 Steam production cost for each boiler.

Element	Diesel boiler	Natural gas boiler
Fuel consumption (kg(h))	21,32	22,07
Steam production cost (€/kg steam)	0,14	0,04

With these results, the sum of the two is made and the steam production cost of 0,18 € per kilogram of steam is obtained.

➤ **Mains water production cost (hyperchlorinated water)**

To calculate the cost of production of the mains water, it has been based on knowing the concentration of chlorine that is introduced in the mains water that arrives from the outside where the whole mixture is made in a tank of 10 cubic meters.

The concentration of color in the water is 5 ppm, from here, it is obtained that in tank of 10 cubic meters there are 50 grams of chlorine, that with its density is passed to obtain that there are 0,045 liters of chlorine. Knowing that the tank is 10.000 liters, it is known that the amount of mains water that is introduced is 9.999,955. Knowing that the price of tap water in Pla de Santa Maria is 0,00215 € per liter and that the price of sodium hypochlorite purchased by the company is 1,8 € per liter, the following formula is applied and the cost of producing hyperchlorinated water is obtained.

$$\text{Hyperchlorinated water cost} = (\text{Water supply cost} * \text{Quantity of water in the tank}) + (\text{cost of sodium hypochlorite} * \text{Quantity of sodium hypochlorite in the tank}) \quad (5.6)$$

From the formula, the production cost of hyperchlorinated water is 0,00216 € per liter.

Once it is known how the different production costs of the different elements used in the cleaning process were calculated, the new proposal is explained.

Initially, for the current cleaning, as mentioned above, the cost and time of each stage is calculated to obtain a total time and cost for each cleaning of the reactor, looking at the efficiency of the cleaning. The costs of each stage are mainly related to the amount of hot deionized water to be used, the amount of mains water to be used and the amount of peracetic acid to be used, and furthermore, the amount of steam used to heat the liters necessary for the cleaning of the reactor of deionized water, which is at 80 °C, and mains water, which is at 50 °C. The times of each stage are obtained presential, i.e., it was lowered to plant for two cleanings and all the times of each stage were noted. Known this, the following table shows the results obtained for the cost and time of cleaning for the 500 L FDA reactor.

Table 5.8 Results of each cleaning stage for the FDA reactor

Stage	Cost (€)	Time (min)
Stage 1 – Previous cleaning	11,25	70
Stage 2 – Foam agent application	3,86	43
Stage 3 – Foam rinsing	12,06	8
Stage 4 – Peracetic solution application	25,60	10
Stage 5 – Final rinsing	11,28	8

Looking at the previous table, the same calculations are performed, but for the larger 3.000 L reactor, where the results are shown in the following table.

Table 5.9 Results of each cleaning stage for the 3.000 L reactor

Stage	Cost (€)	Time (min)
Stage 1 – Previous cleaning	62,79	82
Stage 2 – Foam agent application	8,07	70
Stage 3 – Foam rinsing	38,37	15
Stage 4 – Peracetic solution application	61,45	22
Stage 5 – Final rinsing	37,59	15

Then, looking at all the results of each stage for the two reactors, the cost and cleaning time for each reactor is obtained in the table below.

Table 5.10 Results of the two reactors.

Reactor	Cost (€)	Time (min)
FDA reactor	64,04	139
3.000 L reactor	208,28	204

As can be seen, the cost and time of cleaning each reactor depends on its size, as the greater the volume, the greater the energy expenditure and the greater the cost of services to perform the cleaning, as well as the longer it takes. All this considering that the results of the efficiency of the cleaning carried out by the microbiology department of the company were favorable, as shown in the following table.

Table 5.11 Cleaning efficiency the two reactors.

Number	Sample ubication	Surface sampled (cm <sup>2</sup> )	Total allergens GC-FID method (ppm)	Total allergens GC-MS method (ppm)	Acceptable limit (ppm)	Result
1	Reactor Shaft Stirrer	25	0,05	0,05	354	Favorable
2	Reactor stirrer	25	0,389	0,05	354	Favorable
3	Reactor blade scraper	25	0,05	0,05	354	Favorable
4	Reactor lid	25	0,15	0,05	354	Favorable
5	Reactor discharge	25	0,695	0,261	354	Favorable
6	Reactor loading/unloading	25	1,607	0,387	354	Favorable
7	Reactor vent	25	0,275	0,05	354	Favorable
8	Reactor Walls	25	0,05	0,05	354	Favorable

Noting that the results of the cleaning efficiency for the two reactors are favorable, it is proceeded to evaluate the new proposal to improve the cleaning.

Regarding the other option for cleaning the professional reactors, it is based on maintaining the first stage that is performed in the current cleanings, which is the pre-cleaning stage, and then introducing a pressurized steam cleaning stage.

This steam cleaning stage would be carried out with equipment that would be purchased new. From there, the reactor cleaning would be completed.

The steam pressure cleaning stage was effective because the pharmaceutical industry uses a lot of steam for sterilization and the cleaning could be carried out in this way. This serious equipment with wheels to be able to be moved by the different reactors of the professional area and to be used with all of them. In addition, the pressure and steam flow that it would generate would be useful for the smaller reactors as well as for the larger ones, the only difference would be the time of steam application inside the reactor.

Known this, the cost and time of the two stages were calculated, considering that the steam application stage was obtained from the technical data of a machine that was selected as suitable for cleaning. From the second stage, with the amount of steam generated by the equipment and the volume of the reactor, a stipulated cleaning time was obtained, from hi was oversized to ensure proper cleaning. With this and with the amount of deionized water that the equipment would consume and the amount of steam that would be needed for sanitizing, which was double the reactor volume to ensure proper cleaning, a time and cost for this stage was obtained.

Commented this, in the following table is shown the results obtained for the cost and time of cleaning for the 500 L FDA reactor with this new proposal.

Table 5.12 Result for the second proposal for the FDA reactor.

Stage	Cost (€)	Time (min)
Stage 1 – Previous cleaning	11,25	70
Stage 2 - Steam pressure application	5,10	20

Looking at the table above, the same calculations are performed, but for the larger 3.000 L reactor, where the results are shown in the table below.

Table 5.13 Result for the second proposal for the 3.000 L reactor.

Stage	Cost (€)	Time (min)
Stage 1 – Previous cleaning	62,79	82
Stage 2 - Steam pressure application	19,09	75

Then, looking at all the results of each stage for the two reactors, is obtained the cost and cleaning time for each reactor of the new proposal in the table below.

Table 5.14 Results of the two reactors for the second proposal

Reactor	Cost (€)	Time (min)
FDA reactor	16,35	90
3.000 L reactor	81,88	157

The only section that would be missing to approve this cleaning proposal would be to observe its cleaning efficiency and see if it is within the standards set by the company. In this case, this could not be done because the equipment would have to be purchased and the necessary tests would have to be carried out. To be able to compare the proposals, since it is a pressurized steam that is used in the cleaning of pharmaceutical companies, it is considered that the cleaning efficiency would be favorable and would be within the values set by Revlon.

Finally, the following subsection shows the comparison.

➤ **Proposal comparison**

Observing the results obtained for the two cases, the two options are discussed.

The following figures compare the different stages for the reactor to be used for the FDA. The first image shows the total cost and time for each stage for the current cleaning system, and the second figure shows the same for the second cleaning option proposed.

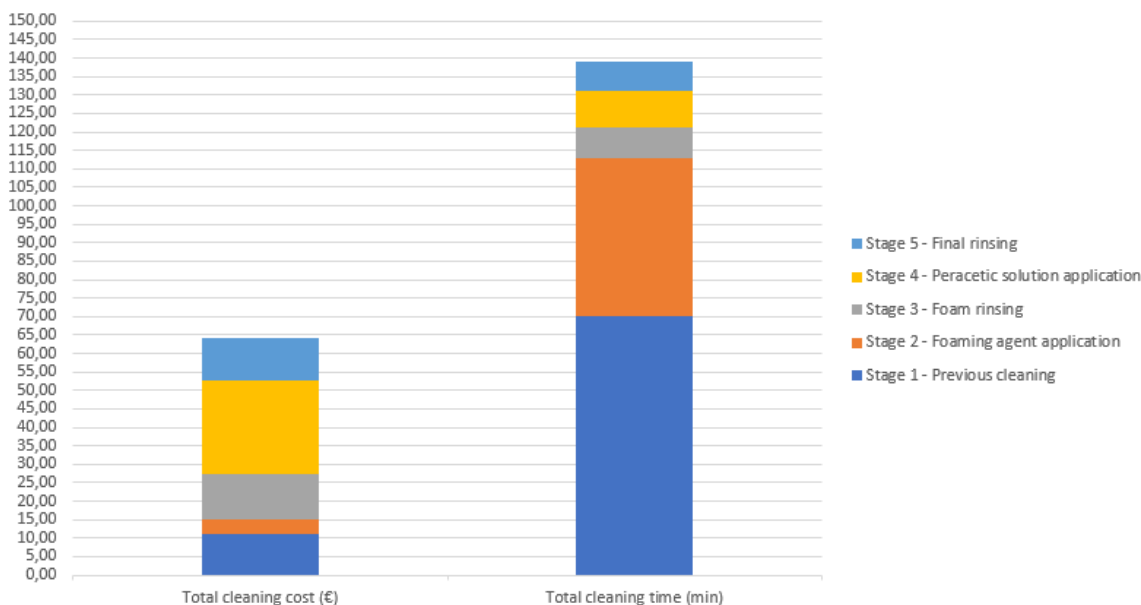


Figure 5.4 Results for the actual cleaning for FDA reactor.

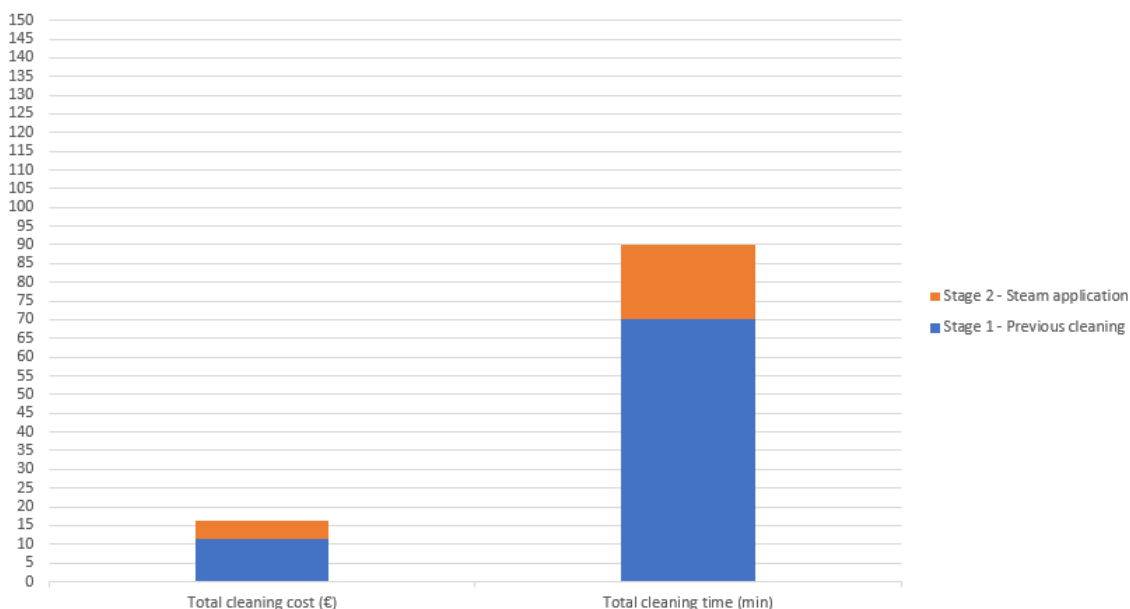


Figure 5.5 Results for the new proposal for FDA reactor.

The following figures compare the different stages for the largest reactor in the professional area. The first picture shows the total cost and time and of each stage for the current cleaning system, and the second figure shows the same for the second proposed cleaning option.

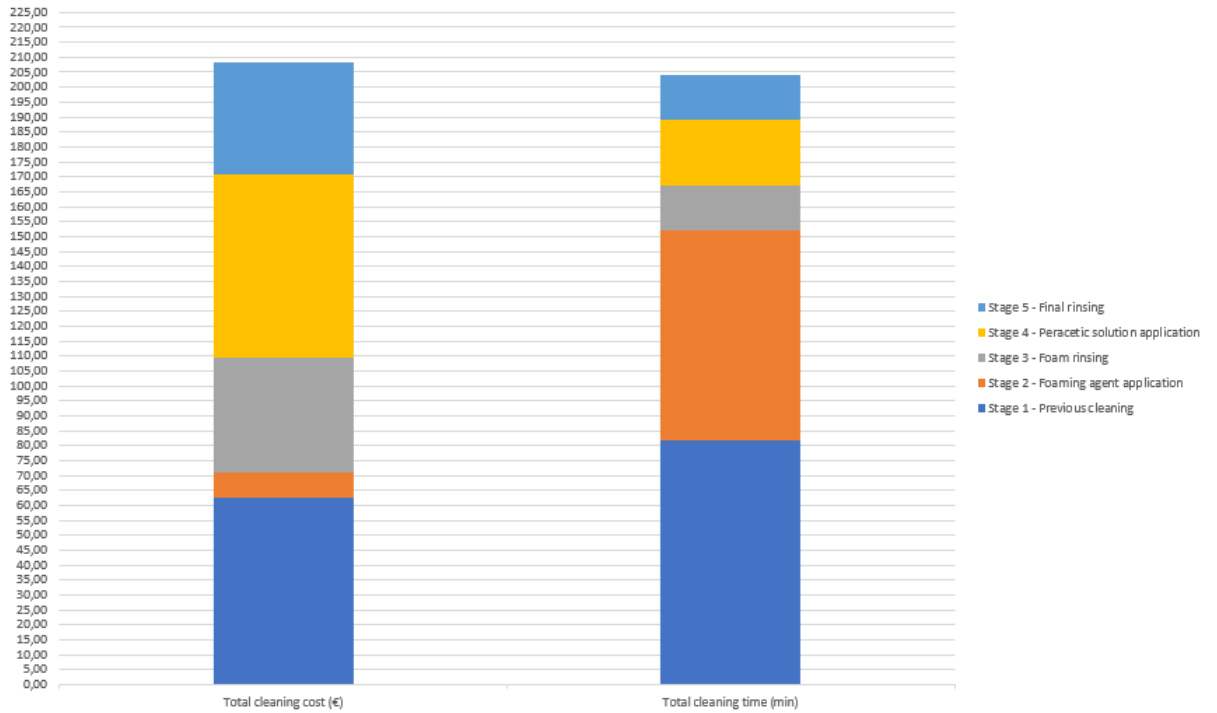


Figure 5.6 Results for the actual cleaning for 3.000 L reactor.

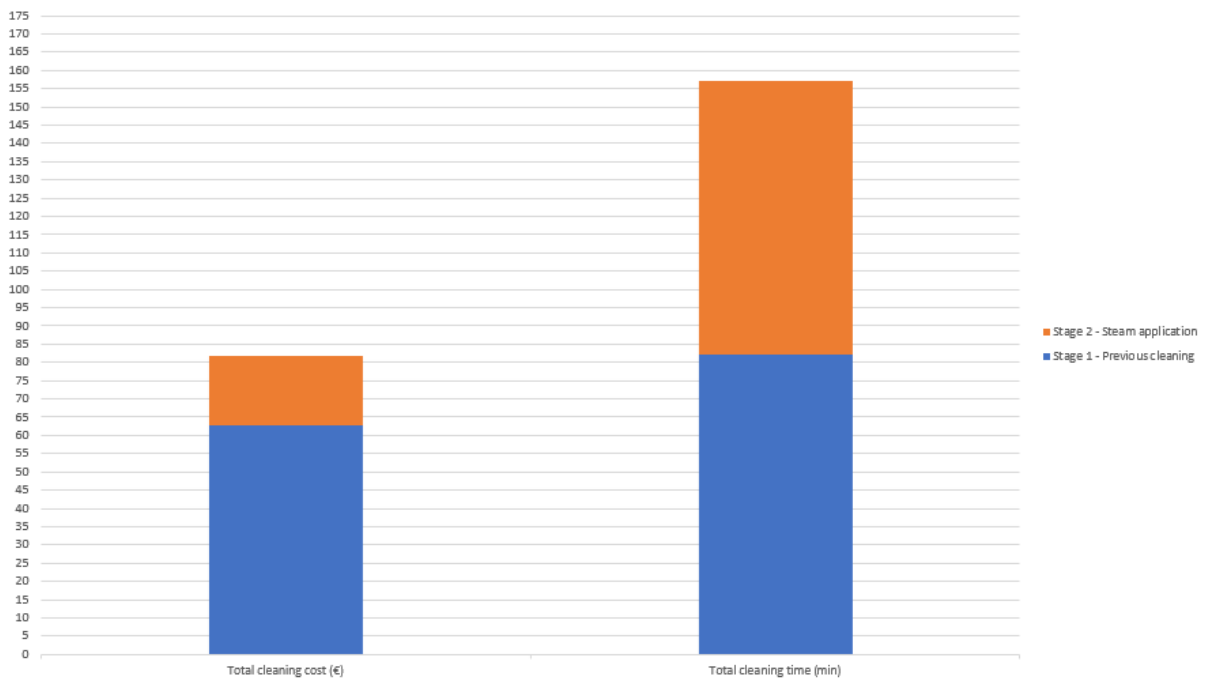


Figure 5.7 Results for the new proposal for 3.000 L reactor.

Once the results for the smaller FDA reactor and the 3.000 L reactor, which is the largest, have been observed, it can be seen in both cases that the proposed option of introducing pressurized steam would reduce the cleaning times, since in both reactors the cleaning time would be reduced by about 50 minutes, and in the case of the cleaning costs, with respect to the

FDA reactor it is reduced by about 48 € per cleaning and in the case of the 3.000 L reactor it is reduced by about 127 € per cleaning. As can be seen, in both cases of reactors, both the time and the cost of cleaning would be reduced, the only drawback is that in the new proposal would have to invest about 15.000 € to buy the equipment, and moreover, to verify that the effectiveness of the cleaning would meet the requirements of the company. To find out if the cleaning requirements are met, the supplier of the equipment could be contacted and asked if a pilot test could be carried out in a reactor and tests could be carried out to find out the microbiological results. If the cleaning requirements are met, investing around 15.000 € would be a viable option, since in the short term it would be profitable both economically and in terms of optimizing production time and being able to produce more, since cleaning would be carried out more quickly and another product could be produced more quickly in the same reactor.

If the pilot test did not achieve cost-effective cleaning efficiency results, another option has been proposed to be introduced to improve the cleaning of the reactors in the professional area.

### **5.2.3. Third proposal**

Once the different points of the first proposal have been evaluated, and in case the second proposal cleaning efficiency was not favorable, a third improvement proposal is established to replace the cleaning of the professional reactors.

For this proposal of improvement, it has been based, as commented in the approach, with the total time of the cleaning, the cost of carrying out the cleaning and the efficiency of the cleaning, all this first has been studied the cleaning in the toilet area and then it has been scaled for the reactors of the factory. With these three points, a comparison has been made with the current cleaning and the third proposal.

Initially, in the third proposal it is stated that a CIP system would be introduced for cleaning the reactors. A CIP system consists of circulating different cleaning solutions inside the reactor through different tanks and pipes, which is a closed circuit that is dictated by time sequences, marked by temperatures and different chemical agents. Known this, the CIP system of the toilet area reactors is evaluated and scaled up for the professional reactors.

First, it is commented that the CIP for the cleaning of the toilet area reactors is made up of 5 tanks. One tank is of water recovered from the previous cleaning to perform a first rinse, one tank of detergent, one tank of peracetic acid, one tank of beef water and one tank of deionized water. It is known that there are five stages for the cleaning of a toilet reactor. The first stage is a rinse with water recovered from other cleanings, then, as a second stage, the detergent is added, the third stage is a rinse of the detergent with tap water, the fourth stage is the addition of peracetic acid and finally, a rinse with hot deionized water is carried out. All these stages would complete the cleaning of a reactor with a CIP system, and as in the other proposals, the time of each stage and the cost of each stage has been calculated and consequently, it has been scaled to be able to introduce it in the professional reactors.

Regarding the CIP system, it is necessary to comment that the duration of the passage of the chemical agents inside the reactor is marked by the largest reactor of the toilet area and the rest of the reactors are cleaned with the same instructions, since the times and the pump impulsion capacity are always maintained for all the reactors. That is, in the case of the toilet reactor zone, the largest reactor is 10.000 L and the cleaning setpoints were stipulated for this reactor, but for the cleaning of the smaller reactors the same times are used. These times are shown in the following table, from these times, for each stage a time for reactor drainage and stage validation is added, which is 7 minutes.

Table 5.15 Times of CIP cleaning system for toilet area

Stage	Time (min)
Stage 1 – Recuperated water rinsing	5
Stage 2 – Detergent application	10
Stage 3 – Mains water rinsing	1
Stage 4 – Peracetic solution application	10
Stage 5 – Osmotized water rinsing	2

Once this was known, it is gone to the field and obtained the remaining times for each stage and then calculated the costs of each stage taking into account the same aspects as in the cleaning currently being carried out, which are related to the amount of hot deionized water to be used, the amount of mains water to be used, the amount of peracetic acid to be used and the amount of detergent to be used, the quantity of the chemical agents to be used was obtained from the head of the drive pump, which is fixed and from the time mentioned in the previous table, and, in addition, the quantity of steam used to heat the liters necessary for cleaning the reactor of deionized water, which is at 80 °C, and the mains water and detergent, which is at 50 °C.

After all the above, the table below shows the results obtained for the toilet reactor.

Table 5.16 Results of CIP cleaning system for toilet area.

Stage	Cost (€)	Time (min)
Stage 1 – Recuperated water rinsing	0,00	12
Stage 2 – Detergent application	96,40	17
Stage 3 – Mains water rinsing	3,60	8
Stage 4 – Peracetic solution application	54,95	17
Stage 5 – Osmotized water rinsing	15,17	9

From here, with the approximations made, the total cleaning cost and time for the toilet scrubbers is obtained.

Table 5.17 Final results of CIP cleaning system for toilet area.

Reactor	Cost (€)	Time (min)
Toilet area reactor	170,12	63

Once the cost and the total time fixed for a 10.000 L toilet reactor, which is the largest, is known, it is scaled for a reactor in the professional area and from here a comparison can be made with the results obtained from the actual cleaning.

The scaling for the professional reactors has been carried out considering a division factor of 3 for the times of stage 1, 2 and 4 stipulated in the CIP commented in table 5.18, in stages 3 and 5 the times have not been scaled since they are very small, and it has been decided to leave them as they were. This factor of 3 has been obtained from the division between the largest reactor in the toilet area on which the times of the CIP system are based, which is 10.000 L, and the largest reactor in the professional area on which the CIP to be introduced would be based, which is 3.000 L. Regarding the drainage and inter-stage check time, it has not been scaled up that much, but reduced to 5 minutes to be conservative.

Knowing these approximations, the following table shows the theoretical results that would be obtained if a CIP is installed in the professional manufacturing area.

Table 5.18 Results of CIP cleaning system for professional area.

Stage	Cost (€)	Time (min)
Stage 1 – Recuperated water rinsing	0,00	6,67
Stage 2 – Detergent application	32,13	8,33
Stage 3 – Mains water rinsing	3,60	6
Stage 4 – Peracetic solution application	18,31	8,33
Stage 5 – Osmotized water rinsing	15,17	7

From here, with the approximations made, the total cost and time that would be obtained from the cleaning for the professional reactors is obtained.

Table 5.19 Final results of CIP cleaning system for professional area.

Reactor	Cost (€)	Time (min)
Professional area reactor	69,23	36,33

Regarding the efficiency of the cleaning, the results are very similar to those commented in the current cleaning and being a cleaning system that is already in the plant, it can be verified that its efficiency falls within the parameters established by the Revlon company, and in this case, this cleaning system would be valid and suitable to be installed.

Finally, the following subsection shows the comparison with the cleaning system currently used in the professional area.

➤ **Proposal comparison**

Observing the results obtained, the current cleaning is compared with the implementation of the CIP cleaning system for the professional reactors.

The first figure shows the cost and total time of the current cleaning for the professional reactors, in this case the 3.000 L reactor has been chosen because the CIP parameters would be related to the largest reactor, which would be this one, and the second figure shows the figure with the implementation of a CIP system with the cost and the total theoretical cleaning time.

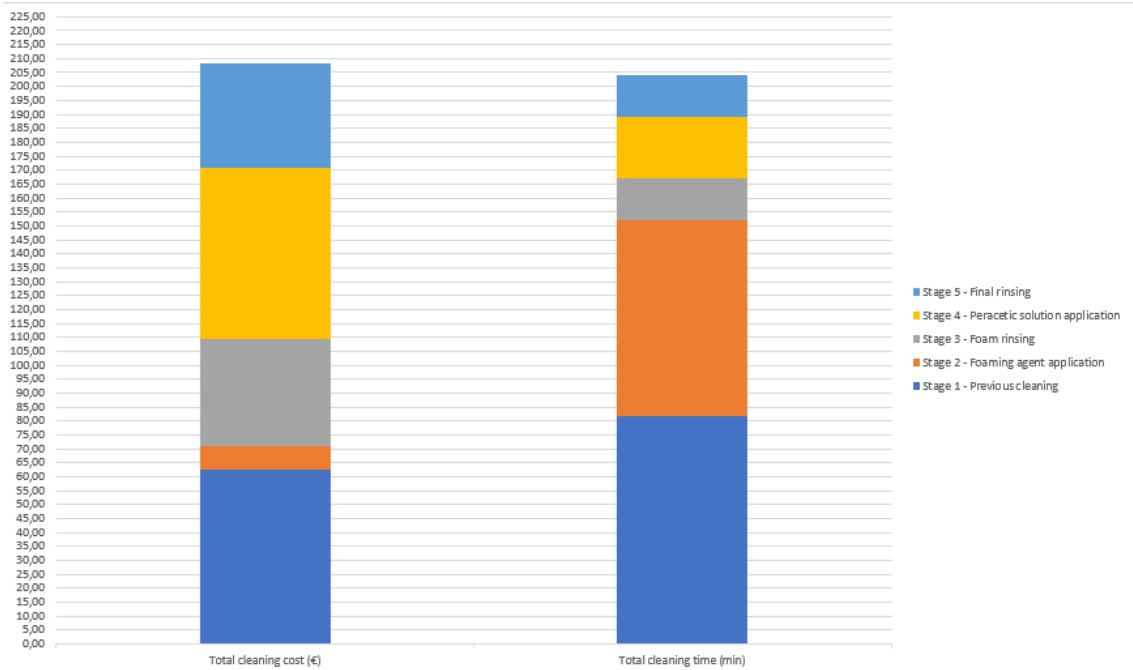


Figure 5.8 Results for the actual cleaning for 3.000 L reactor.

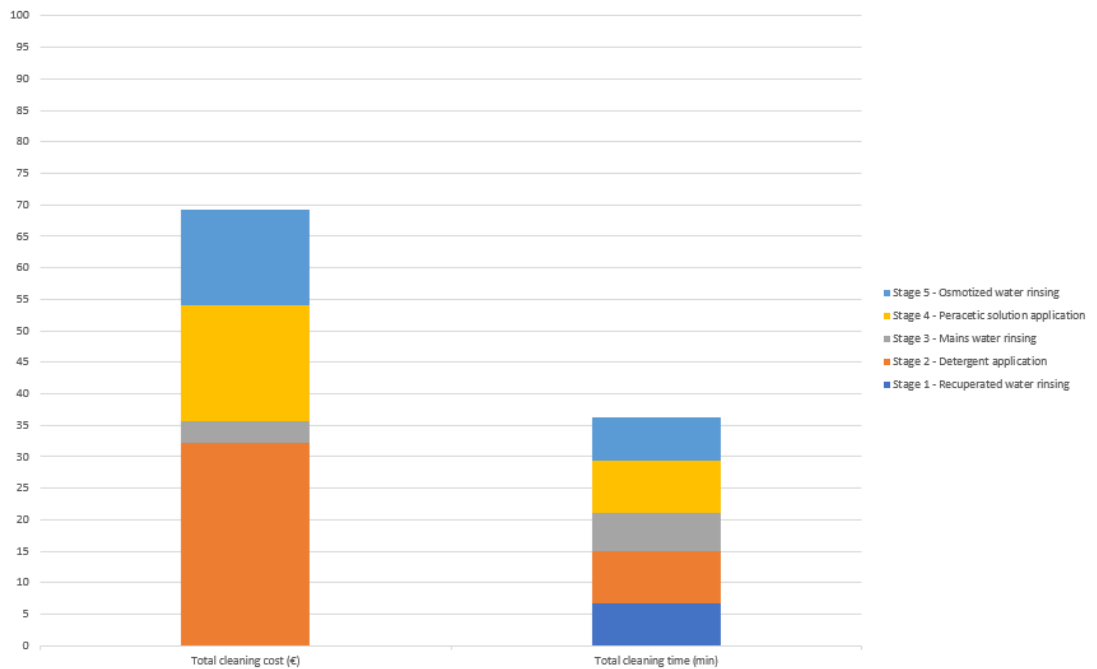


Figure 5.9 Results for the CIP cleaning for 3.000 L professional reactor.

Once observed the graphs, it is observed that the implementation of a CIP system for the cleaning of reactors causes a decrease in costs and time at the time of cleaning and that would be an advantage in the long run because the reactors could be cleaned more quickly and at the end could be produced again another product and that would increase the productivity of the reactors, since hours of work in front of products manufactured during the day would increase. Furthermore, it is observed that between one proposal and the other, the cleaning time is reduced by 167 minutes and the cost per cleaning by 139 €, obtaining the most profitable CIP system for cleaning.

Taking into account that the CIP system is already verified and its cleaning efficiency complies with the Revlon parameters, it would be a good option to improve the cleaning of the reactors, the only drawback is that an approximate investment of 100.000 € would have to be made for the installation of the different tanks containing the cleaning agents, but this initial investment would be profitable in a short time since there would be more time to produce products and consequently have more sales.

**5.3. Comparison between proposals**

Once the different options have been discussed, they are evaluated among them.

Initially, with the first proposal of the modification of different parameters that affect the cleaning of the reactor, it is observed that it is not possible to modify more because three parameters are already optimized and one of them was tested and it was observed that for cleaning cost or cleaning time it was better to keep the current detergent.

From here, a comparison is made for a 3.000 L reactor which is the largest of the current cleaning with the two proposals and a conclusion is obtained.

The following table shows the comparison of total cost, total time and cleaning efficiency values for a current professional reactor cleaning, a cleaning by purchasing the steam machine and a cleaning by implementing CIP.

Table 5.20 Cleaning summary for a professional reactor

Cleaning type	Cost (€)	Time (min)	Efficiency
Current cleaning procedure	208,28	204	Among the company requirements
Steam application procedure	81,88	157	To be verified
CIP implementation	69,23	36,33	Among the company requirements

Observing the table above, the more complex and modern the cleaning option is, the more costs and time are reduced. Assuming that the corresponding tests have been carried out and the steam application option is effective according to the company's parameters, can be commented on the results obtained.

Observing the results, the most reliable application and that over time will give better results in terms of time and cost optimization and increased productivity of the reactors because it will allow to produce more, is the option of implementing a CIP. The disadvantage is that an initial investment of 100.000 € must be made. If you do not want to spend a lot of money, can be purchased the steam machine for about 15.000 € and thus the cost and time for cleaning would be reduced somewhat more than doing the current cleaning, because as has been observed, the current cleaning, being very manual and that everything depends on human action cannot further optimize the parameters to improve the cleaning of the reactors.

As mentioned above, the cleaning of the melter is the same as that of the reactor and they are carried out in parallel.

Once all this has been commented, the study of improvement of the reactor cleaning is finalized by commenting on the most viable options to be applied in the company, all this discussed and commented with the manufacturing process engineer.

## **6. FUTURE WORK**

At the end of the project, for the different equipment and systems commented, the qualification has not been completed in all of them for different reasons, and in this section the reasons why the qualification has not been completed and the future work that remains to be done are commented. In addition, possible future qualifications of different equipment are discussed.

### **6.1. Existing Equipment**

The completion of the qualification of the existing equipment is related to the compressed air system, the osmosis water system (Astramatic reverse osmosis and distribution loops) and the R-3514 kettle.

#### **➤ Compressed Air System**

Regarding the compressed air system, to conclude, it remains that the new maintenance contract with the supplier is closed, and with the supplier and with the production coordination, to carry out the different tests proposed in the OQ, protocol already proposed, and that the protocol is completed. After the OQ, a whole year would be spent taking data, the same or very similar to those of the OQ, to perform the PQ. Finally, the qualification of the compressed air system would be finalized.

#### **➤ Osmotized Water System**

Regarding the osmosis water system, the main issue to be solved is the welding of the distribution loops, basically to know which number of welds to check and which procedure to follow. Once this is done, the welding reports would be entered in the corresponding section and the IQ could be finalized. When moving on to the OQ, many of the data collection has already been done, as shown in the annexes, and it would remain to force the Astramatic machine to work at its maximum and observe the flow rates at the osmotized water consumption points of the distribution loops plant. After the OQ, data would be taken for a whole year, the same as in the OQ, but with the range of values established by the company, to perform the PQ. Finally, the qualification of the osmosis water system would be finalized as follows

#### **➤ Kettle R-3514**

Regarding the R-3514 reactor, it remains that the final budget is established and so they can come to implement the improvements to the reactor, so these changes could be introduced in the IQ and finalize it. When moving on to the OQ, some data collection has already been done and the OQ protocol is already established, then with the improvements introduced all the tests could be performed and the OQ and the qualification of the equipment could be finalized. Then the validation of the process would be done by performing a manufacturing with the final formula of the OTC product, noting that all the values are within the ranges established by the company.

### **6.2. New Equipment**

Completion of the qualification of new equipment is related to Veolia reverse osmosis and the dynamic scale and metal detector and washing machines.

#### **➤ Osmotized Water System**

Regarding the osmosis water system, the last step is to take data during a whole year verifying that the values during a year are within the functional range established by the company, that is, the PQ together with the other osmosis water system.

➤ **Dynamic Scale, Metal Detector and Washing Machines**

Regarding the other new equipment to be purchased, the final budget has to be established in order to be able to select the most economical among the different offers obtained by the suppliers and, based on that, purchase the equipment and follow the protocols mentioned above, which are the FAT, SAT, IQ and OQ to finalize the qualification. The qualification of this equipment was related to the budget for its purchase and consequently its validation.

**6.3. Future Qualifications**

Regarding the possible future qualifications, as all of them would be related to the professional area, the company is considering a possible future qualification of other types of filling machines. Regarding the professional area, as this year all the elements have already been qualified, as a future option the company has in mind to qualify another type of filling machine, such as the jar filling machine, but this case is still in the air and nothing has been confirmed.

**7. CONCLUSIONS**

To conclude this project, after the company Revlon had the strategic vision to implement modifications in the plant and qualify their equipment to obtain FDA certification in the production center of Pla de Santa Maria, and thus be able to sell certain products in the United States, it is concluded that it is not an easy process to obtain certification and requires a lot of dedication and time.

As it has been observed to perform the qualification and subsequent validation of the manufacturing process, different guidelines must be followed and many aspects of the machines have to be verified so that everything is correct and suitable to obtain the FDA certification. A complicated point in this section is to obtain all the information and technical documentation of machines that have been working for years, and if at the time of installing the equipment the documentation was not requested at the time, this caused that several things had to be created or requested to the supplier and must verify that everything was the same as what was installed. In addition, it is necessary to verify that in the services all the installed equipment is the same as in the documentation, that the services that arrive are the appropriate ones and many other aspects to be introduced. In addition, to verify the equipment and systems, it was necessary to think about the type of tests to be performed to verify the operation of the equipment, and at the same time to perform and coordinate them with the production department, to verify that all the equipment works correctly. In addition to all this, the flow of revisions and signatures caused corrections and modifications in certain aspects of the ARs, as well as the IQ and OQ. Considering that there is certain equipment where the qualification has not been completed for certain aspects, it can be observed that in all of them it is well underway, and once the missing points in each equipment or system are finalized, the remaining information will be introduced in the protocol in question, and they can be finalized and ready for FDA inspection.

Regarding the improvement part, it can be concluded that the cleaning of the reactors is done in a very manual way, and if you want to improve you have to make an initial investment of money to reduce the time and cost of cleaning. Depending on the level of the initial investment to be made, this can lead to a faster cleaning process and to the reactors being ready in a shorter time to be able to produce earlier, i.e., to increase the daily production hours of each reactor.

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- INS-QA-016 *Technique FMEA (Failure Mode Effects Analysis)* Revlon
- Information extracted from the Revlon company's servers and SAP.
- Standard IEC 61511 – Functional Safety

## **9. APPENDICES**

### **9.1. Risk Analysis**

All risk analyses performed are shown in the appendix from page 81 to page 138 in the following order:

1. Compressed Air system
2. Osmotized Water system
3. Weighing scales 1, 2 & 3
4. Kettle R-3514
5. Cleaning system
6. Cool room
7. Reactor Cleaning

### **9.2. IO Protocols**

All IQ protocols performed are shown in the appendix from page 139 to page 257 in the following order:

1. Compressed Air system
2. Weighing scales 1, 2 & 3
3. Cleaning system
4. Cool room
5. Reactor Cleaning

### **9.3. OQ Protocols**

All OQ protocols performed are shown in the appendix from page 258 to page 320 in the following order:

1. Weighing scales 1, 2 & 3
2. Cool room
3. Some acquired data of Osmotized Water system

### **9.4. Documents for New Equipment**

The documents produced for the new equipment are shown from page 321 to the page 347 in the following order:

1. Dynamic scale and Metal detector
2. Weighing Area and Filling Area Washing Machine





### **9.5. Self-Evaluation Questionnaire**

The self-questionnaire is shown in the appendix from page 348 until the end of the report.

## Sistema de aire comprimido

### Análisis de Riesgos

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## 1. INTRODUCCIÓN

### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos del sistema de aire comprimido de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

El sistema de aire comprimido disponible en la planta de fabricación que REVLON dispone en el Pla de Santa María se instaló en el año 2010 y desde entonces ha estado operativo en las actividades de suministrar aire comprimido que se realizan en la planta de REVLON.

La creciente exigencia en las normativas y regulaciones vigentes establecen la necesidad de llevar a cabo la cualificación del sistema de aire comprimido.

### 1.3 Ámbito

Se incluyen en el ámbito del Análisis de Riesgos del sistema de aire comprimido de la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación del sistema de aire comprimido está formado por:

- ▶ Compresor L45 (K-74005), compresor L75RS (K-74006), compresor L80 (K-74007), compresor L75RS (K-74008) y compresor L07 (K-11001).
- ▶ Depósitos de almacenamiento
  - Depósito previo los secadores (D-74001).
  - Depósito de aire seco (D-74002).
  - Depósito de aire (D-74004).
  - Depósito de aire PIG (D-74005).
  - Depósito de aire (D-11001).
- ▶ Secadores (E-74001A, E-74001B, E-74001C, E-11001 y E-74004).
- ▶ Filtros (F-74008, F-74009, F-74010, F-74011, F-74012, F-74013, F-74014, F-74015, F-74016 y F-74016).
- ▶ Todas las líneas de distribución de aire comprimido hasta su punto de aplicación en la fábrica.

Quedan excluidos la cualificación prevista los siguientes apartados:

- ▶ Funciones de cualquiera de los componentes del sistema no incluidos en la utilización prevista en los procedimientos de uso

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

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### 2.1 Descripción del sistema

El sistema de aire comprimido es un sistema que dispone de cuatro compresores, un depósito de almacenamiento de aire comprimido, seis filtros, tres secadores y finalmente un depósito de almacenamiento de aire seco y un depósito de aire seco para envasado. Todos estos elementos se tienen para obtener aire comprimido a 7 bar para instrumentación y para realizar tareas de la fábrica la cual se necesite este tipo de aire. A más, hay 4 filtros más, un secador más, un reductor de presión y un depósito mas para obtener aire a 4 bares llamado aire *PIG*. También hay el aire comprimido del circuito de *Less*, que se basa en un compresor, un depósito de aire, un filtro y un secador para obtener aire a 7 bares para el circuito *Less*.

### 2.2 Funcionamiento del sistema

A continuación, se describe el proceso de obtención del aire comprimido.

El aire se capta del exterior y se comprime a través de cuatro compresores hasta 7,5 bares y se envía a un depósito de almacenamiento de aire comprimido. Seguidamente, hay tres secadores en paralelo, donde antes de entrar en cada uno de los secadores, el aire pasa por un filtro donde son necesarios para que los residuos y otros productos contaminantes no bloqueen el purgador de condensación ni los intercambiadores de calor del secador, seguidamente entra a los secadores donde están diseñados para garantizar el suministro de aire comprimido de alta calidad con el mínimo mantenimiento. A continuación, el aire comprimido al salir de cada uno de los secadores pasa por un filtro y se dirige a un depósito de almacenamiento de aire en seco. Finalmente, una vez el aire está en depósito de aire seco, se va suministrando aire a 7 bares para la instrumentación de diferentes equipos y para partes de la fábrica donde se requiera aire a presión, todo esto pasando por diferentes transmisores de presión para asegurar que el aire que se necesita se encuentra a 7 bares de presión. Si el aire se requiere para envasado profesional, antes de llegar al depósito de aire seco, el aire se desvía hacia otro depósito que hace de pulmón para así alimentar de aire comprimido a 7 bares el área de envasado profesional. Si el aire requiere mayor tratamiento para así poder estar en contacto con el producto, se realiza un desvío del aire a la salida del tanque del aire seco donde este aire pasa por cuatro filtros mas y per un secador, se reduce la presión a 4 bares y se almacena en un depósito de aire *PIG* para suministrar a la fábrica.

## 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos del sistema de aire comprimido se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DEL SISTEMA DE AIRE COMPRIMIDO</b>								
1.	Instalación del sistema de Aire Comprimido.	Instalación inapropiada del sistema de Aire Comprimido.	Funcionamiento inadecuado del sistema de Aire Comprimido.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de procedimientos de limpieza (IQ).</li> <li>Formación del personal (IQ).</li> <li>Planos, esquemas eléctricos y layouts actualizados (IQ).</li> </ul>
2.	Materiales de construcción (compresores, secadores, depósitos, conductos, etc)	Materiales en contacto con el aire no adecuados. Mantenimiento inadecuado	Posible contaminación del aire	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del sistema (IQ).</li> <li>Formación del personal (IQ)</li> </ul>
3.	Servicios (electricidad)	No se dispone de los servicios necesarios o estos no son adecuados	Imposibilidad de realizar las operaciones en el sistema de aire comprimido	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DEL SISTEMA DE AIRE COMPRIMIDO</b>								
4.	Encendido y apagado del sistema de Aire Comprimido	No es posible encender los equipos o apagar los equipos del sistema de Aire Comprimido manualmente	No pueden realizarse las operaciones para comprimir el aire Prolongación inadecuada del funcionamiento del sistema	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Esquemas eléctricos acordes a la instalación real (IQ).</li> <li>Encendido y apagado manual correcto (OQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
		Fallo del suministro eléctrico	El equipo no queda en posición segura  No es posible poner en funcionamiento de nuevo el sistema	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Las variables del equipo no se alteran (OQ).</li> <li>El equipo se enciende correctamente tras el fallo eléctrico (OQ).</li> </ul>
			Alteración de variables tras fallo eléctrico	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Comprobación de que las variables del equipo no se alteran (OQ).</li> <li>Sistema de gestión de alarmas (OQ).</li> </ul>
5.	Sistema de compresores	El sistema de compresores no es capaz de obtener el aire a una presión específica de 7 bar	Uso inadecuado del aire para fabricación e instrumentación	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación de la presión (OQ).</li> </ul>
6.	Depósito de acumulación de aire- D-74001	Sobrepresión	Expansión del depósito y posible ruptura	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Comprobación de que las sondas de presión no fallan (OQ).</li> </ul>
7.	Filtración del aire	Capacidad de filtración de aire inadecuado	Posible contaminación del aire por partículas y fallo en el secador	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Plan de mantenimiento preventivo del equipo (IQ).</li> <li>Verificación de la calidad del aire (OQ).</li> </ul>


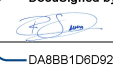
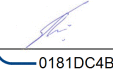

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
		Rotura de filtros	Contaminación del aire por partículas y fallo en el secador	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación de la calidad del aire (OQ).</li> </ul>
		Colmatación de filtros	No se alcanzan las renovaciones/horas requeridas	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
8.	Sistema de secadores	El sistema de secado no es capaz de eliminar la cantidad de agua que tiene el aire	Uso inadecuado del aire para fabricación e instrumentación	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Comprobación de que las sondas de presión no fallan (OQ).</li> </ul>
		Entrada de residuos y otros productos contaminantes.	Bloquear purgador de condensaciones e intercambiador de calor	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
9.	Depósito de acumulación de aire seco- D-74002, D-74004, D-1101 y D-74005	Sobrepresión	Expansión del depósito y posible ruptura	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Comprobación de que las sondas de presión no fallan (OQ).</li> </ul>
10.	Presión del aire que se obtiene del sistema	El sistema de Aire Comprimido no es capaz de generar aire con la presión requerida de 7 bar	Uso inadecuado de la instrumentación de la planta y de ciertos procesos productivos.	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento de los instrumentos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Instrumentos de regulación y transmisión calibrados (IQ).</li> <li>Sistema de alarmas (OQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
11.	Sondas de presión	Las sondas no funcionan en los cambios de proceso	Condiciones de servicio del aire no adecuadas	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Formación del personal (IQ).</li> <li>Registros de las sondas.</li> </ul>
12.	Alarmas y enclavamientos	El sistema de control no avisa de incidencias en el proceso	Condiciones de trabajo de la instalación no adecuadas	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
13.	Líneas de distribución de aire comprimido	Obstrucción de las líneas de distribución de aire.	Condiciones de servicio del aire no adecuadas para el producto	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Pequeña rotura de la línea y pérdida de presión desde la generación del aire hasta el punto de aplicación.	Condiciones de servicio del aire no adecuadas para el producto.	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
14.	Calidad del aire en el punto de uso	Calidad del aire comprimido inadecuada en el punto de uso	Posible contaminación del producto en punto de uso	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad del Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación del aire en el punto de uso (OQ).</li> </ul>

## Sistema de agua osmotizada: Pretratamiento, plantas Astramatic y Veolia y anillo de recirculación

### Análisis de Riesgos

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 Página: 1 de 13

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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos del sistema de tratamiento del agua de la planta productiva de Revlon, el Pla de Santa María, incluyendo en este el pretratamiento, los sistemas de osmosis Astramatic y Veolia y los anillos de recirculación.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

El sistema de agua osmotizada Astramatic se instaló en el año 2005 y desde entonces ha estado operativo para la purificación de agua de servicio en la planta de REVLON. En el año 2018 se realizó una sustitución de la osmosis Astramatic antigua por una nueva instalación de tratamiento de agua y en el año 2018 se instaló un nuevo sistema de agua osmotizada de Veolia. Los nuevos requerimientos de producto establecen la necesidad de llevar a cabo la cualificación del sistema de agua osmotizada.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos todo el sistema de tratamiento del agua situado en la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación del sistema está formado por:

- ▶ **PRETRATAMIENTO:**
  - Filtración
  - Adición de aditivos
- ▶ **SISTEMA OSMOSIS ASTRAMATIC (EQUIPO RO-1 GENERAL ASTRAMATIC) y SISTEMA OSMOSIS VEOLIA (EQUIPO RO-2 GENERAL VEOLIA):**
  - Tratamientos fisicoquímicos
    - Osmosis inversa
    - Electrodesionización
    - Intercambio iónico
  - Tratamientos microbiológicos posteriores
    - Radiación ultravioleta
    - Generador de ozono

- ▶ BUCLES DISTRIBUCIÓN (O ANILLOS RECIRCULACIÓN) EN ZONA DE PRODUCCIÓN
  - Radiación ultravioleta
  - Generador de ozono
  - TOC (Carbono Orgánico Total)

Quedan excluidos de la cualificación prevista los siguientes apartados:

- ▶ Funciones del equipo de análisis TOC, ver en los documentos **10271849 IQ/OQ TOC**.
- ▶ Funciones de cualquiera de los componentes del sistema VEOLIA, ver en los documentos **Veolia VMP proyecto 1750233125** del 13/11/17.

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

### 2.1 Tipos y usos del agua de fábrica

Mediante el sistema de tratamiento del agua se obtiene agua de fabricación. El agua de fabricación es utilizada como materia prima para la elaboración de producto granel, como disolvente de los agentes detergente y desinfectante del CIP, y para procesos industriales como generación de vapor, circuitos de refrigeración y humidificación del aire.

### 2.2 Funcionamiento del sistema

A continuación, se describe el proceso de obtención del agua de fabricación

#### PRETRATAMIENTOS:

Filtración:

- 1/ Filtros de arena/carbón activo, para eliminar sólidos en suspensión de gran tamaño (>10 µm), microorganismos, cloro y retener compuestos orgánicos.
- 2/ Filtros de cartucho, para retener sólidos de tamaño 1-50 µm y microorganismos. Es un tratamiento necesario y previo al sistema de ósmosis inversa, para proteger su correcto funcionamiento.

Adición de aditivos previa a la ósmosis:

- Agentes antiincrustantes
- Agentes neutralizantes del cloro
- NaOH: para aumentar el pH y eliminar la presencia de CO<sub>2</sub> en el EDI (electrodesionizador)

#### SISTEMA RO-1 ASTRAMATIC Y SISTEMA RO-2 VEOLIA: TRATAMIENTOS FISICOQUÍMICOS

- Ósmosis Inversa: utilización de membranas semipermeables con bombeo de alta presión, para la retención de sales disueltas, compuestos iónicos, materia orgánica e impurezas en suspensión. Después de la ósmosis inversa, el tratamiento sigue con una electrodesionización o bien con un intercambio iónico.

- Electrodesionización (EDI): retención de iones catiónicos/aniónicos mediante la acción de resinas de lecho mixto sometidas a un campo eléctrico.
- Tratamientos microbiológicos posteriores
  - Radiación ultravioleta
  - Generador de ozono

#### BUCLES DISTRIBUCIÓN (O ANILLOS RECIRCULACIÓN) EN ZONA DE PRODUCCIÓN

- Radiación ultravioleta
- Generador de ozono
- TOC

### 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos del sistema de agua purificada se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

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## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DEL SISTEMA DE AGUA OSMOTIZADA</b>								
1.	Instalación del pretratamiento y del sistema de osmosis inversa en Astramatic y Veolia.	Instalación inadecuada del sistema de purificación de agua.	Funcionamiento inadecuado del sistema de pretratamiento. Funcionamiento inadecuado del sistema de osmosis.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Acabados de la sala adecuados (IQ).</li> <li>Disponibilidad de procedimientos de limpieza (IQ).</li> <li>Formación del personal (IQ).</li> <li>Planos, esquemas eléctricos y layouts actualizados (IQ).</li> </ul>
2.	Materiales de construcción (tanques, bombas, conductos, filtros, membranas, válvulas, etc.) en Astramatic y Veolia.	Materiales inadecuados en contacto con el agua.	Posible contaminación química y/o microbiológica del agua purificada. Pérdida de eficacia del proceso.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de certificados de materiales en contacto con el agua (IQ).</li> <li>Disponibilidad de filtros y membranas (IQ)</li> <li>Procedimientos de uso y mantenimiento del sistema (IQ).</li> <li>Formación del personal (IQ).</li> <li>Plan de mantenimiento preventivo del sistema que incluye la gestión de filtros y membranas (IQ).</li> </ul> <p><u>Medida de control adicional a implementar:</u></p> <ul style="list-style-type: none"> <li>Registro fisicoquímico del agua</li> <li>Registro microbiológico del agua</li> <li>Procedimientos de sanitización de la instalación</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
3.	Servicios  (aire comprimido, electricidad)	No se dispone de los servicios necesarios o éstos no son adecuados.	Imposibilidad de realizar las operaciones en el sistema de agua osmotizada  Imposibilidad de bombear agua de pretratamiento.	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
4.	Aditivos (antiincrustante, bisulfito, sosa caustica) en Astramatic y Veolia.	Ausencia de diferentes aditivos en el sistema de osmosis.	Ineficiencia en el funcionamiento del sistema de osmosis	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de aditivos (IQ).</li> </ul>
		Especificación inadecuada de los aditivos en el sistema de osmosis.	Ineficiencia en el funcionamiento del sistema de osmosis.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Especificaciones de los aditivos (IQ).</li> </ul>
		Dosificación inadecuada de los diferentes aditivos en el sistema de osmosis.	Ineficiencia en el funcionamiento del sistema de osmosis.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Cantidades de los aditivos (IQ).</li> <li>Procedimiento de mantenimiento de los diferentes elementos de dosificación (IQ)</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DEL SISTEMA DE AGUA OSMOTIZADA</b>								
5.	Encendido y apagado del sistema de tratamiento (pretratamiento, Veolia, Astramatic, bucles de recirculación)	No es posible encender el equipo o apagar el equipo manualmente.	No pueden realizarse las operaciones de purificación del agua.  No pueden realizarse las operaciones de sanitización de la instalación.  Prolongación inadecuada del funcionamiento del equipo.	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>• Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Esquemas eléctricos acordes a la instalación real (IQ).</li> <li>• Encendido y apagado manual correcto (OQ).</li> </ul>
		Fallo del suministro eléctrico.	El equipo no queda en posición segura.  No es posible poner en funcionamiento de nuevo el sistema.	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>• Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Las variables del equipo no se alteran (OQ).</li> <li>• El equipo se enciende correctamente tras el fallo eléctrico (OQ).</li> </ul>
		Alteración de variables tras fallo eléctrico.		3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>• Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Comprobación de que las variables del equipo no se alteran (OQ).</li> <li>• Sistema de gestión de alarmas (OQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
6.	Depósito de ruptura en Veolia	Sobrellenado del depósito de ruptura	Revertir el flujo del agua	1	1	1	1 BAJO	<ul style="list-style-type: none"> <li>Comprobación de que las sondas de nivel no fallan (OQ).</li> </ul>
		Estancamiento del agua y falta de recirculación	Crecimiento microbiológico	3	3	1	9 MEDIO	<ul style="list-style-type: none"> <li>Programación de la recirculación (OQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Mantenimiento y Sanitización de la Planta de agua desmineralizada según las instrucciones INS-MI-002, INS-MI-003, INS-MI-004, INS-MI-005, INS-MI-006</li> </ul>
7.	Intercambiador en Veolia	Obstrucción de los tubos	Alteración en el proceso de calentar el agua.	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos mantenimiento del equipo (IQ).</li> </ul>
8.	Sistema de filtración y osmotización en Astramatic y Veolia.	Colmatación de filtros y membranas	Pérdida de eficacia en el proceso de filtrado	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación del caudal (OQ).</li> <li>Mantenimiento y Sanitización de la Planta de agua desmineralizada según las instrucciones INS-MI-002, INS-MI-003, INS-MI-004.01, INS-MI-005, INS-MI-006</li> </ul>
		Rotura de filtros y membranas	Contaminación del producto.	4	2	2	16 ALTO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Registro fisicoquímico del agua</li> <li>Registro microbiológico del agua</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
9.	Calidad del agua purificada en Astramatic y Veolia.	Sistema de osmosis no es capaz de generar agua con la especificación suficiente según el SOP-PR-006	Exposición en los procesos de fabricación de agua fuera de especificación.	3	2	2	12 ALTO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento de los instrumentos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Instrumentos de regulación calibrados (IQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Registro fisicoquímico del agua</li> <li>Registro microbiológico del agua</li> </ul>
10.	Alarmas y enclavamientos en Astramatic, Veolia y bucles de recirculación	El sistema de control no avisa de incidencias en el proceso	Condiciones de trabajo de la instalación no adecuadas, contaminación del producto	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
11.	Sondas de temperatura, caudal, nivel, presión y conductividad en Astramatic y Veolia.	Las sondas no funcionan en los cambios de proceso	Condiciones de trabajo de la instalación no adecuadas, contaminación del producto	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Formación del personal (IQ).</li> <li>Registros de las sondas.</li> </ul>
12.	Permisos de usuario en Astramatic y Veolia.	Usuarios básicos del sistema pueden hacer operaciones críticas	Mal funcionamiento del proceso Definición de los roles incorrectos	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Formación del personal (IQ).</li> </ul>
13.	Trazabilidad de cambios en programación Astramatic y Veolia.	No se almacenan cambios sustanciales en los cambios de las variables del proceso	Pérdida de información para la solución de problemas	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> </ul>
14.	Copias de seguridad en Astramatic y Veolia.	El sistema no es capaz de almacenar estados de variables del proceso	Pérdida de datos de proceso óptimos Falta de repositorio de copias de seguridad	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Formación del personal (IQ).</li> </ul>





Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
15.	Integridad de datos, solo usuarios registrados pueden manipular datos en Astramatic y Veolia.	Exposición de datos a personal no formado	Pérdida de datos de proceso	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Formación del personal (IQ).</li> </ul>
16.	Pruebas fisicoquímicas en Astramatic y Veolia	No detectar valores fuera de los límites establecidos para obtener agua purificada según los parámetros detallados en el SOP-PR-006  Mantenimiento inadecuado.	Exposición de los procesos de fabricación a agua contaminada	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Formación del personal (IQ).</li> <li>Registro de fisicoquímicos</li> </ul>
17.	Pruebas microbiológicas en Astramatic y Veolia.	No detectar presencia de microorganismos en el agua, debido a mal uso de las instalaciones o limpieza no adecuada.	Contaminación del producto por microorganismos.	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Formación del personal (IQ).</li> <li>Registros microbiológicos</li> </ul>
18.	Sanitizaciones en Astramatic y Veolia.	Proceso de desinfección inexistente o ineficaz	Pérdida de eficacia del proceso y contaminación del producto	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de limpieza y mantenimiento de equipos y salas (IQ).</li> <li>Mantenimiento y Sanitización de la Planta de agua desmineralizada según las instrucciones INS-MI-002, INS-MI-003, INS-MI-004.01, INS-MI-005, INS-MI-006</li> </ul>
19.	Depósitos de acumulación (D-77201 y D77202) de los bucles de distribución	Sobrellenado de los depósitos de acumulación	Revertir el flujo del agua	1	1	1	1 BAJO	<ul style="list-style-type: none"> <li>Comprobación de que las sondas de nivel no fallan (OQ).</li> <li>Sistema de gestión de alarmas (OQ).</li> </ul>
		Estancamiento del agua y falta de recirculación	Crecimiento microbiológico	3	3	1	9 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
20.	Bombas de recirculación de los bucles de recirculación	No funcionamiento o funcionamiento inadecuado de las bombas de recirculación	Incapacidad de recircular el agua y eso provoca estancamiento i posible crecimiento microbiológico	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>• Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> </ul>
21.	Generadores de ozono de los bucles de recirculación	No funcionamiento o funcionamiento inadecuado de los generadores de ozono	Condición del agua almacenada inadecuada, posible crecimiento microbiológico y contaminación del producto	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>• Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Verificación de sistema de control (OQ).</li> <li>• Sistema de alarmas (OQ).</li> </ul>
22.	Lámparas UVA de los bucles de recirculación	No funcionamiento o funcionamiento inadecuado de las lámparas UVA	Condición del agua para producción inadecuada, posible contaminación de producto.	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>• Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Verificación de sistema de control (OQ).</li> <li>• Sistema de alarmas (OQ).</li> </ul>
23.	Sondas de temperatura, caudal, nivel y conductividad en bucles de recirculación	Las sondas no funcionan en los cambios de proceso	Condiciones de trabajo de la instalación no adecuadas, contaminación del producto	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>• Verificación de sistema de control (OQ).</li> <li>• Sistema de alarmas (OQ).</li> <li>• Formación del personal (IQ).</li> </ul>
24.	Válvulas de elección de bucle o de envío de agua a proceso de los bucles de recirculación	No funcionamiento o funcionamiento inadecuado de las válvulas	Condiciones de trabajo de la instalación no adecuadas	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>• Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>• Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> <li>• Comprobación del funcionamiento de las válvulas (OQ)</li> </ul>

## Básculas de pesadas 1, 2 y 3

### Análisis de Riesgos

<b>Ref. Documento:</b>	MVP Rev 01
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Preparación	Preparado por	Cargo / Departamento	Firma	Fecha	
		Christian Sanroma	Project Engineer Internship	 <small>DocuSigned by:</small> <small>B3F6857A1121459...</small>	07 March 2022
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Aprobación	Aprobado por	Cargo / Departamento	Firma	Fecha	
		Eduard Ibáñez	Engineering Manager	 <small>DocuSigned by:</small> <small>0181DC4B2DC54B9...</small>	07 de marzo de 2022
		Josep Pena	Quality Assurance Manager	 <small>DocuSigned by:</small> <small>5EC558160682492...</small>	08 de marzo de 2022

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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos de las básculas de la sala de pesadas profesional de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

Las básculas 1, 2 y 3 de la zona de pesadas disponibles en la planta de fabricación que REVLON dispone en el Pla de Santa María, se instalaron en el año 2015 y desde entonces han estado operativas en las actividades de pesadas que se realizan en la planta de REVLON.

La creciente exigencia en las normativas y regulaciones vigentes establecen la necesidad de llevar a cabo la cualificación de las básculas de pesadas 1, 2 y 3.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos las básculas de pesadas 1, 2 y 3 de la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación del sistema está formado por:

- ▶ BÁSCULA 1 (WI-22009; 10217308): Báscula de hasta 35 kg.
- ▶ BÁSCULA 2 (WI-22010; 10217305): Báscula de hasta 60 kg.
- ▶ BÁSCULA 3 (WI-22011; 10217279): Báscula de hasta 1500 kg.

Quedan excluidos de la cualificación prevista de los siguientes apartados:

- ▶ Funciones de cualquiera de los componentes del sistema no incluidos en la utilización prevista en los procedimientos de uso.

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

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### 2.1 Descripción del equipo

Las básculas son equipos que se encuentran en el interior de la sala de pesadas de profesional.

En el box A se dispone de tres básculas debidamente calibradas e identificadas y donde en cada báscula se indica el rango de peso que se puede medir. Estas tres básculas son la WI-22009, la WI-22010 y la WI-22011.

### 2.2 Funcionamiento del equipo

A continuación, se describe el proceso de pesadas de las básculas.

Inicialmente, antes de realizar cualquier pesada se debe verificar el correcto estado de la báscula. La báscula se debe escoger en función de dos parámetros:

- ▶ La cantidad que deba pesarse para la orden.
- ▶ El recipiente que va a contener la pesada, de forma que la altura de la báscula y el recipiente no superen el codo del operario que realiza dicha pesada.

Una vez se tiene en cuenta estos aspectos, se introduce la cantidad que se quiera pesar a la báscula escogida y se obtiene el peso correspondiente. Seguidamente, se retira la cantidad pesada de la báscula y se deja preparada para la correspondiente fabricación para obtener producto.

Para el proceso de pesadas se utiliza el programa *Techest* para seguir la trazabilidad de este proceso y facilitar el proceso de pesadas en la fábrica. La explicación más extensa sobre la utilización del programa *Techest* se puede observar en el documento **VMP Rev.01**.

## 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos de las básculas de pesadas 1, 2 y 3 se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DE LAS BÁSCULAS DE PESADAS 1, 2 Y 3</b>								
1.	Instalación de las básculas de pesadas 1, 2 y 3	Instalación inadecuada de las básculas de pesadas	Funcionamiento inadecuado de las básculas de pesadas  Posible error en el proceso de fabricación y pérdida de producto	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de procedimientos de limpieza (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
2.	Materiales de las básculas de pesadas  (plato de carga de la báscula)	Materiales inadecuados en contacto con el producto	Posible contaminación química	1	1	2	2 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
3.	Servicios  (electricidad)	No se dispone de los servicios necesarios o éstos no son adecuados.	Imposibilidad de realizar las operaciones de pesaje en las básculas de pesadas 1, 2 y 3	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
4.	Nivelación de las básculas de pesadas 1, 2 y 3	Nivelación inadecuada de las básculas de pesadas	Funcionamiento inadecuado de las básculas de pesadas	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación semanal de las básculas según la instrucción correspondiente (IQ).</li> </ul>
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DE LAS BÁSCULAS DE PESADAS 1, 2 Y 3</b>								
5.	Encendido y apagado de las básculas de pesadas 1, 2 y 3	No es posible encender el equipo o apagar el equipo manualmente	No pueden realizarse las operaciones de pesaje  Prolongación inadecuada del funcionamiento del equipo.	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Encendido y apagado manual correcto (OQ).</li> </ul>
		Fallo del suministro eléctrico.	El equipo no queda en posición segura.  No es posible poner en funcionamiento de nuevo los equipos	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Las variables del equipo no se alteran (OQ).</li> <li>Los equipos se encienden correctamente tras el fallo eléctrico (OQ).</li> </ul>
		Alteración de variables tras fallo eléctrico.	Alteración de variables tras fallo eléctrico.	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
6.	Unidad de indicación de las básculas 1, 2 y 3	No indicación del peso o indicación errónea del pesaje	Incapacidad o dificultad en la lectura del pesaje que se realiza	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> </ul>





Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
7.	Conexión de las básculas 1, 2 y 3 con el ordenador	No transmisión de la lectura del peso en la pantalla del ordenador	Incapacidad de trazar los pesajes realizados	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> </ul>
8.	Limpieza de las básculas 1,2 y 3	Limpieza inadecuada que puede provocar entrada de líquido en el interior de la bascula	No funcionamiento o funcionamiento inadecuado de las básculas	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de los equipos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Procedimiento de limpieza de las básculas según la instrucción correspondiente (IQ).</li> </ul>
9.	Calibración de las básculas 1, 2 y 3	No calibración o mala calibración de las básculas 1, 2 y 3	Funcionamiento inadecuado y posible error en el proceso de fabricación y pérdida de producto	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de los equipos (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de los equipos (IQ).</li> <li>Certificados de calibración de las básculas (IQ).</li> </ul>

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## Reactor R-3514 y bolsa contenedora

### Análisis de Riesgos

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Preparación	Preparado por	Cargo / Departamento	Firma	Fecha
	Christian Sanromà	Project Engineer Internship	 B3F8857A1121459...	28 April 2022
Revisión	Revisado por	Cargo / Departamento	Firma	Fecha
	Rosa Gimeno	Quality Assurance Technician	 DA8BB1D6D927439...	02 May 2022
Aprobación	Aprobado por	Cargo / Departamento	Firma	Fecha
	Eduard Ibáñez	Engineering Manager	 0181DC4B2DC54B9...	03 de mayo de 2022
	Josep Pena	Quality Assurance Manager	 5EC558160682492...	05 de mayo de 2022

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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos del reactor R-3514 y la bolsa contenedora, que es el recipiente donde se guarda el producto, de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

El reactor R-3514 se instaló en el año 1985 y desde entonces ha estado operativo para la fabricación en la planta de REVLON.

Los nuevos requerimientos de producto establecen la necesidad de llevar a cabo la cualificación del reactor de la planta piloto.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos el reactor R-3514 situado en la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación del reactor R-3514 está formado por:

- ▶ Reactor (R-3514)
- ▶ Bolsa contenedora

Quedan excluidos de la cualificación prevista los siguientes apartados:

- ▶ Funciones de cualquiera de los componentes del sistema no incluidos en la utilización prevista en los procedimientos de uso.

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

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### 2.1 Descripción del equipo

El reactor R-3514 es una caldera reactor RUC-500 con un volumen de 500 L. Este equipo trabaja al vacío y sirve como mezclador.

El reactor RUC-500 consta de un cuerpo cilíndrico vertical, cerrado a la atmosfera por su parte superior por una tapa con bisagra y cierre hermético con junta y con un fondo inferior, tipo difusor.

El cuerpo cilíndrico, el fondo inferior, son de chapa de acero inoxidable AISI-304 y están envueltos por una camisa de acero inoxidable AISI-304, quedando entre ambas chapas un recinto cerrado por el que circula el fluido calefactor que permite el calentamiento de los productos contenidos en el recipiente. El cuerpo se refuerza exteriormente con un arrollamiento de perfil plano que aumenta la transmisión térmica.

La caldera reactor contiene productos cosméticos y en la camisa circula vapor que permite su calentamiento y agua que permite su refrigeración.

Finalmente, una vez realizado el producto se introduce en las bolsas contenedoras, que son equipos que se encargan de almacenar el producto para después introducirlo a la envasadora.

### 2.2 Funcionamiento del sistema

A continuación, se describe el proceso de fabricación en el reactor R-3514.

El sistema básicamente funciona introduciendo las materias primas necesarias según las formula del cosmético en el interior de la caldera de mezcla de 500 L y realizar la puesta en marcha del equipo, entonces con la ayuda de la camisa calefactora y de los dos equipos de agitación se va realizando el producto final a obtener en un tiempo estipulado.

Una vez finalizado el proceso de fabricación, se traspasa todo el producto del reactor a la bolsa contenedora para así poderlo envasar.

## 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos del reactor R-3514 se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DEL REACTOR DE LA PLANTA PILOTO</b>								
1.	Instalación del sistema del reactor R-3514	Instalación inadecuada del sistema del reactor R-3514	Funcionamiento inadecuado del sistema del reactor R-3514	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de procedimientos de limpieza (IQ).</li> <li>Formación del personal (IQ).</li> <li>Planos, esquemas eléctricos y layouts actualizados (IQ).</li> </ul>
2.	Materiales de construcción (reactor, conductos, bomba etc)	Materiales inadecuados en contacto con el producto	Posible contaminación del producto	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad del conocimiento de los materiales del equipo (IQ).</li> <li>Procedimientos de uso y mantenimiento del sistema (IQ)</li> <li>Formación del personal (IQ).</li> </ul>
3.	Servicios (agua ozmotizada, aire comprimido, aire PIG, vapor y electricidad)	No se dispone de los servicios necesarios o estos no son adecuados	Imposibilidad de realizar las operaciones en el sistema del reactor	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ)</li> </ul>
4.	Emplazamiento del sistema del reactor R-3514	Lugar de emplazamiento de la máquina esta desnivelado	Funcionamiento inadecuado del sistema del reactor	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del sistema (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DEL REACTOR DE LA PLANTA PILOTO, BOMBAS NEUMATICAS Y BOLSAS CONTENEDORAS</b>								

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
5.	Encendido y apagado del sistema del reactor R-3514	No es posible encender o apagar el sistema manualmente	No pueden realizarse las operaciones de fabricación del producto  Prolongación inadecuada del funcionamiento del equipo	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Esquemas eléctricos acordes a la instalación real (IQ).</li> <li>Encendido/Apagado correcto del reactor R-3514 (OQ).</li> </ul>
		Fallo del suministro eléctrico	El equipo no se queda en posición segura.  No es posible poner en funcionamiento de nuevo el sistema	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Las variables del equipo no se alteran (OQ).</li> <li>El equipo se enciende correctamente tras el fallo eléctrico (OQ).</li> </ul>
		Alteración de variables tras fallo eléctrico.	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Comprobación de que las variables del equipo no se alteran (OQ).</li> <li>Sistema de gestión de alarmas (OQ).</li> </ul>	
6.	Caldera de 500 L	Sobrellenado de la caldera de 500 L	Exceso de agua para el producto a obtener	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Comprobación que las sondas de nivel no fallan (OQ).</li> </ul>
		Fallo en la camisa de calefacción/refrigeración	Aumento de presión de la camisa de calefacción/refrigeración	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Sistema gestión alarmas de alta presión (OQ)</li> </ul>
		Aumento/Disminución de la temperatura de la camisa de calefacción/refrigeración	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Comprobación que las sondas de temperatura no fallan (OQ).</li> <li>Sistema gestión alarmas de alta temperatura (OQ)</li> </ul>	

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
			Mala distribución del calor/frío en la camisa de calefacción/refrigeración	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Registro de temperaturas en la camisa calefactora/refrigeración (OQ)</li> </ul>
		Fallo en la válvula manual de descarga a ras de fondo	Impedimento de la descarga del producto	1	2	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
7.	Tapa de vacío de la caldera reactor	Rotura tapa caldera reactor	Cierre y estanqueidad inadecuados de la caldera de 500 L	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> </ul>
		Abrir la tapa cuando los agitadores están funcionando	Posible contaminación del producto Posible lesión del operario debido al agitador activo	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Alarmas/Incapacidad de abrir tapa cuando los agitadores están activos</li> </ul>
8.	Equipo de agitación inferior de la caldera reactor	Fallo en el motor de agitación del rascador y de la turbina	Incapacidad de realizar la agitación lenta	2	2	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación del funcionamiento y de las velocidades del rascador y de la turbina (OQ).</li> </ul>
		Desajuste en las aletas de las palas de la turbina	Comunicación inadecuada del movimiento de rotación de las aletas de la pala a la mezcla	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Rotura de los rascadores y de la turbina	Incapacidad de que se produzcan recalentamientos locales y se mantenga una transmisión eficaz de calor o de refrigeración	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Pérdida de aceite de los motores de agitación	Posible contaminación del producto	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
9.	Sistema de control de temperatura de la camisa de calefacción/refrigeración de la caldera reactor	Fallo en el sistema de control automático de la temperatura	Control de temperatura de la caldera reactor inadecuado	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Sistema de gestión de alarmas por fallo de lectura en la sonda.</li> </ul>
10.	Elementos de control de la caldera reactor  (Sondas de temperatura, vacuómetro, visualizadores y controladores y PLC)	Fallo de la sonda de temperatura de la caldera reactor	Control de la temperatura del producto inadecuado y posible error en el resultado a obtener  Condiciones de trabajo inadecuadas, posible contaminación del producto	4	2	1	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Verificación del calentamiento del reactor y del mantenimiento de la correspondiente temperatura (OQ).</li> <li>Registros de las sondas.</li> </ul>
		Fallo del vacuómetro de la caldera reactor	Control del vacío de la caldera reactor inadecuado y posible error en el resultado a obtener	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación del vacío del reactor (OQ).</li> </ul>
		Fallo en los visualizadores y controladores de la caldera reactor	Control inadecuado de las revoluciones del equipo de agitación lenta y del equipo de agitación rápida	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento de la instalación (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Fallo en el PLC de todo el sistema	No se pueden realizar diversas funciones del sistema como la puesta en marcha, parada del sistema y el control de los diferentes procesos	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
11.	Elementos de seguridad de la caldera reactor  (Válvulas de seguridad, purgador de seguridad y micro de seguridad)	Fallo en el purgador de seguridad de la camisa calefactora/refrigeradora de la caldera reactor	Incapacidad de purgar el vapor y eliminar el aire de la camisa	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
12.	Alarmas y enclavamientos	El sistema de control no avisa de incidencias en el proceso	Condiciones de trabajo del sistema no adecuados, contaminación del producto	4	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
13.	Engrase de los rodamientos de la caldera reactor	No engrase o engrase inadecuado de los rodamientos de la torreta de agitación rápida y de la torreta de agitación lenta	Condiciones de trabajo del sistema inadecuadas	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
14.	Limpieza de la caldera reactor	No limpieza o limpieza inadecuada de la caldera reactor	Condiciones de trabajo del sistema inadecuadas  Contaminación cruzada de productos	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Procedimiento de limpieza y mantenimiento de equipos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Higienización de reactores según las instrucciones correspondientes (IQ).</li> </ul>
15.	Bolsa contenedora de producto	Exceso de producto en el interior de la bolsa  Temperatura muy elevada del producto en el interior de la bolsa	Posible rotura de la bolsa y fuga de producto al exterior	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimientos de uso de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Verificación de la temperatura y del enfriamiento del producto (OQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
		Cruce de mangueras en la descarga para uso de otras referencias	Posible contaminación del producto por mala colocación de mangueras	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>• Procedimientos de uso de la instalación (IQ).</li> <li>• Formación del personal (IQ).</li> </ul>
		Migración del material de la bolsa contenedora al producto	Posible contaminación del producto	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>• Certificado de migración de la bolsa contenedora (IQ)</li> </ul>

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## Sistema de Limpieza

### *Análisis de Riesgos*

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<b>Preparación</b>	Preparado por	Cargo / Departamento	Firma	Fecha
	Christian Sanromà	Project Engineer Internship		

<b>Revisión</b>	Revisado por	Cargo / Departamento	Firma	Fecha
	Rosa Gimeno	Quality Assurance Technician		

<b>Aprobación</b>	Aprobado por	Cargo / Departamento	Firma	Fecha
	Eduard Ibàñez	Engineering Manager		
	Josep Pena	Quality Assurance Manager		

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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos de tres tanques que se utilizan para la limpieza de los reactores de profesional, de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

Los tanques del sistema CIP que alimentan a los reactores de profesional para su limpieza se instalaron en el año 2015 y desde entonces han estado operativos para la limpieza de los reactores en la planta de REVLON.

Los nuevos requerimientos de producto establecen la necesidad de llevar a cabo la cualificación de tres tanques para la limpieza de los reactores. Estos tres tanques son: el tanque de agua desionizada caliente, el tanque de agua de red y el tanque de ácido peracético.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos los tanques del sistema CIP situado en la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación de los tanques de limpieza está formado por:

- ▶ Tanque de agua desionizada caliente (T-62001)
- ▶ Tanque de agua de red (T-62002)
- ▶ Tanque de ácido peracético (T-61001)

Quedan excluidos de la cualificación prevista los siguientes apartados:

- ▶ Funciones de cualquiera de los componentes del sistema no incluidos en la utilización prevista en los procedimientos de uso.

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

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### 2.1 Descripción del equipo

Los tanques de limpieza para los reactores de profesional son tanques de 8,5 m<sup>3</sup> con sus respectivas bombas de impulsión donde son parte del sistema CIP para los reactores de tocador, pero que tienen salida hacia la nave de profesional para su utilización durante la limpieza de los reactores.

### 2.2 Funcionamiento del sistema

A continuación, se describe el proceso de utilización de los tanques de limpieza para los reactores de profesional.

La limpieza de los reactores de fabricación profesional se realiza siguiendo pasos descritos en instrucciones. En la primera etapa se introduce agua desionizada caliente (aproximadamente a 80 °C), seguidamente se vacía el reactor y se aplica un espumante, que para los reactores de profesional es el detergente. A continuación, al cabo de un cierto tiempo, se aclara el espumante del reactor con agua de red, que es agua con cloro para el enjuague, y finalmente se introduce ácido peracético para terminar el proceso de desinfección. Los agentes de limpieza y desinfección que se utilizan para la higienización provienen de los 3 tanques de almacenamiento citados anteriormente y llegan hasta la nave de fabricación Profesional a través de tuberías hasta el punto de uso, cercano a los reactores. Cuando se necesita alguno de estos agentes de limpieza se conecta una manguera de la tubería (punto de uso) hacia al reactor y se abre una válvula para introducir el agente de limpieza dentro del reactor. Cuando ya se ha introducido la cantidad deseada, se cierra la válvula y se retira la manguera.

El detergente es introducido en un equipo independiente llamado equipo espumante MObyFoam que espraya el detergente en las superficies del reactor.

## 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos de los tanques de limpieza de los reactores de profesional se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DE LOS TANQUES DE LIMPIEZA</b>								
1.	Instalación de los tanques del sistema de limpieza	Instalación inadecuada de los tanques del sistema de limpieza	Funcionamiento y limpieza inadecuada de los reactores de limpieza profesional	3	2	1	<b>6</b> BAJO	<ul style="list-style-type: none"> <li>Formación del personal (IQ).</li> <li>Planos, esquemas eléctricos y layouts actualizados (IQ).</li> </ul>
2.	Materiales de construcción (tanques, bombas, tuberías, etc)	Materiales inadecuados en contacto con los agentes de limpieza que limpian los reactores	Posible contaminación del producto	3	2	1	<b>6</b> BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de conocimiento de los materiales del equipo (IQ).</li> <li>Procedimientos de uso y mantenimiento del sistema (IQ)</li> <li>Formación del personal (IQ).</li> </ul>
3.	Servicios (aire comprimido y electricidad)	No se dispone de los servicios necesarios o estos no son adecuados	Imposibilidad de realizar las operaciones en el sistema de limpieza	2	1	1	<b>2</b> BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ)</li> <li>Aire comprimido filtrado – mantenimiento</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DE LOS TANQUES DE LIMPIEZA</b>								
4.	Tanques de limpieza (T-61001, T-62001 y T-62002)	Sobrellenado de los tanques	Perdida de la mezcla a suministrar para la limpieza de los reactores	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Esquemas mecánicos y eléctricos acordes a la instalación real (IQ).</li> </ul>
		Posible grieta o rotura de los tanques	Perdida de la mezcla de los diferentes agentes de limpieza	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento del equipo (IQ).</li> <li>Formación del personal (IQ).</li> <li>Esquemas mecánicos y eléctricos acordes a la instalación real (IQ).</li> <li>Limpieza y desinfección de los tanques – frecuencia definida</li> </ul>
5.	Bombas centrífugas	Incapacidad de succión de las diferentes mezclas para la limpieza	Incapacidad de enviar los líquidos y de realizar el procedimiento de limpieza de los reactores al completo	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Sobrecarga en el motor	Posibles daños en el impulsor de la bomba e incapacidad de realizar el procedimiento de limpieza de los reactores al completo	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Perdida en el cebamiento de la bomba	Posibles daños en los sellamientos o en la tubería de aspiración donde esto provocaría la incapacidad de enviar los fluidos hacia el reactor	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ)</li> <li>Formación del personal (IQ).</li> </ul>
		Fallo en los sellamientos de la bomba	Posibles fugas de fluido hacia el exterior	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>


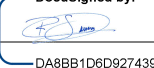
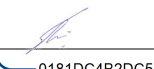
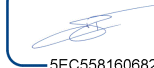
Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
		Fallo en el suministro eléctrico	Incapacidad de impulsar los agentes de limpieza hacia los reactores	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
6.	Intercambiadores de calor	Acumulación de suciedad en los intercambiadores de calor de los tanques de limpieza que están a cierta temperatura	Disminución de la eficiencia y aumento del consumo de los intercambiadores	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> </ul>
		Ubicación inadecuada y mantenimiento insuficiente	Funcionamiento incorrecto del intercambiador e incapacidad para calentar	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> </ul>
7.	Tuberías	Acumulación de suciedad en las tuberías	Incapacidad de suministrar los líquidos de limpieza al reactor	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Posible grieta o rotura de las tuberías	Incapacidad de suministrar los líquidos de limpieza al reactor	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ).</li> </ul>
8.	Elementos de control de los tanques de limpieza (Válvulas y sensores de nivel y conductividad)	Fallo en las válvulas para suministrar los líquidos de limpieza al reactor	Incapacidad de enviar los líquidos y de realizar el procedimiento de limpieza de los reactores al completo	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Fallo en los sensores de nivel de los tanques de limpieza	Incapacidad de lectura de nivel de los tanques y posible sobrellenado	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ)</li> <li>Calibración del equipo (IQ)</li> </ul>
		Fallo en los sensores de conductividad de los tanques de limpieza	Incapacidad de saber la concentración de la mezcla en el interior de los tanques	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de mantenimiento del equipo (IQ)</li> <li>Calibración del equipo (IQ)</li> </ul>
9.	Dosificación y dilución de ácido peracético de limpieza	Inadecuada o deficiente dosificación del ácido peracético	Posible contaminación de producto	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Formación del personal (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
10.	Válvulas y juntas	Fallo de válvulas entre distintas conexiones Degradación de juntas	Posible contaminación del ácido peracético o las distintas aguas Fuja de aguas o ácido peracético	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimiento de uso y mantenimiento del equipo (IQ)</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo del equipo (IQ).</li> </ul>

## Cámara fría

### Análisis de Riesgos

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	Eduard Ibáñez	Engineering Manager	 DocuSigned by: 0181DC4B2DC54B9...	12 de abril de 2022
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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos de la cámara fría de la nave de hidroalcohólicos de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

La cámara fría se instaló a finales del año 2017 y desde entonces ha estado operativa para el almacenaje de productos en la planta de REVLON.

Los nuevos requerimientos de producto establecen la necesidad de llevar a cabo la cualificación de la cámara fría.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos todo el sistema de la cámara fría situada en la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación de la cámara fría está formado por:

- ▶ La sala de la cámara fría.
- ▶ Sistema de refrigeración:
  - Condensadora
  - Dos evaporadores.
  - Presostatos de alta i baja presión.

Quedan excluidos de la cualificación prevista los siguientes apartados:

- ▶ Funciones de cualquiera de los componentes del sistema no incluidos en la utilización prevista en los procedimientos de uso.
- ▶ Los dataloggers para coger la temperatura del interior de la cámara fría.
- ▶ El detector LEL para los gases inflamables del interior de la cámara fría.

## 2. DESCRIPCIÓN DE LA INSTALACIÓN

### 2.1 Descripción del sistema

La cámara fría es una sala climática que tiene una temperatura de  $7^{\circ}\text{C}\pm 3^{\circ}\text{C}$ . Esta cámara tiene una superficie de  $35,4\text{ m}^2$  y un volumen de  $159,5\text{ m}^3$ .

Para conseguir las condiciones requeridas en la cámara fría se instaló una unidad ubicada en el exterior del edificio (condensadora) y dos unidades ubicadas en el interior de la cámara (evaporadores con sus respectivos ventiladores). La unidad exterior envía la potencia frigorífica a las dos unidades evaporadoras mediante gas refrigerante y a través de tuberías de cobre. La tubería a instalada es de tipo frigorífico forrada con Armaflex en su línea de aspiración para evitar en lo posible su condensación y degotamiento. La alimentación eléctrica se realiza a la unidad condensadora y esta la distribuye a los dos evaporadores.

Debido a que la zona donde está ubicada la sala climática es una zona ATEX, por seguridad, se instaló un detector LEL en la cámara que tiene un enclavamiento de seguridad con el equipo de refrigeración para poder pararlo en caso de detección de vapores inflamables.

### 2.2 Funcionamiento del sistema

A continuación, se describe el proceso que se realiza en la cámara fría.

Desde el exterior de la cámara se pone en funcionamiento el sistema de climatización de la cámara fría. Una vez encendido el sistema de climatización, para conseguir las condiciones requeridas en la cámara, la condensadora envía la potencia frigorífica a las dos unidades evaporadoras mediante gas refrigerante y a través de tuberías de cobre. Una vez llegada la potencia frigorífica a los evaporadores, se refrigera la cámara a través de los ventiladores que tienen los evaporadores para obtener una temperatura de  $7^{\circ}\text{C}\pm 3^{\circ}\text{C}$ .

Todo esto teniendo en cuenta que se esta en una atmosfera inflamable y si hay algún tipo de vapor inflamable el detector LEL activa el enclavamiento de seguridad.

## 3. METODOLOGÍA

Para la elaboración del Análisis de Riesgos de la cámara caliente se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DE LA CÁMARA FRÍA</b>								
1.	Acabados de la Cámara fría (suelo, paredes, techo, etc).	Acabados no adecuados	Posible contaminación del producto. Acumulación de suciedad.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Acabados de la sala adecuados (IQ).</li> <li>Disponibilidad de procedimientos de limpieza (IQ).</li> </ul>
2.	Materiales de construcción de la Cámara fría (suelo, paredes, techo, estanterías, etc).	Materiales inadecuados de la Cámara fría.	Posible contaminación del producto Mal mantenimiento del clima	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Materiales de construcción de la Cámara fría adecuados (IQ).</li> </ul>
3.	Servicios. (electricidad)	No se dispone de los servicios necesarios o éstos no son adecuados.	Imposibilidad de realizar las operaciones en la Cámara fría.	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ)</li> </ul>
<b>RIESGOS ASOCIADOS A LA INSTALACIÓN DEL SISTEMA DE REFRIGERACIÓN</b>								
4.	Instalación del sistema de refrigeración de la Cámara fría.	Instalación inadecuada del sistema de refrigeración.	Funcionamiento inadecuado del sistema de refrigeración.	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Documentación técnica de los componentes (IQ).</li> <li>Planos, esquemas eléctricos y layouts actualizados (IQ)</li> </ul>
5.	Servicios. (electricidad)	No se dispone de los servicios necesarios o éstos no son adecuados.	Imposibilidad de realizar operaciones de refrigeración con el equipo	2	1	1	2 BAJO	<ul style="list-style-type: none"> <li>Disponibilidad de servicios (IQ).</li> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
<b>RIESGOS ASOCIADOS AL FUNCIONAMIENTO DEL SISTEMA DE REFRIGERACIÓN</b>								
6.	Encendido y apagado del sistema de climatización	No es posible encender el equipo o apagar el equipo manualmente.	No se pueden realizar las operaciones de refrigeración de la cámara.  Prolongación inadecuada del funcionamiento de la cámara fría.	2	2	1	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Esquemas eléctricos acordes a la instalación real (IQ).</li> <li>Encendido y apagado manual correcto (OQ)</li> </ul>
		Fallo del suministro eléctrico	No es posible poner en funcionamiento de nuevo el sistema.  El equipo no queda en posición segura	3	1	1	3 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Las variables del equipo no se alteran (OQ).</li> <li>El equipo se enciende correctamente tras el fallo eléctrico (OQ).</li> </ul>
		Alteración de variables en la climatización tras fallo eléctrico.	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> <li>Comprobación de que las variables del equipo no se alteran (OQ).</li> <li>Sistema de gestión de alarmas (OQ).</li> </ul>	
7.	Regulación de la temperatura de la cámara.	Sistema de refrigeración no es capaz de regular la temperatura del aire.	El clima de la sala no es adecuado para el producto.  Degradación del producto almacenado.	2	2	2	8 MEDIO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de los instrumentos (IQ).</li> <li>Formación del personal (IQ).</li> <li>Instrumentos de regulación calibrados (IQ).</li> <li>El climatizador es capaz de regular la temperatura adecuadamente (OQ).</li> <li>Sistema de alarmas (OQ)</li> </ul>

Ítem	Elemento / Operación	Riesgo potencial	Impacto	G	P	D	Nivel Riesgo	Mecanismos de Control / Etapa de Verificación
8.	Alarmas y enclavamientos	El sistema de control no avisa ni actúa en caso de vapores inflamables.	Condiciones de trabajo de la cámara no adecuados.	4	1	2	8 MEDIO	<ul style="list-style-type: none"> <li>Verificación de sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
9.	Sondas de temperatura	Las sondas de temperatura no funcionan en los cambios de proceso	Condiciones de trabajo de la cámara no adecuados.	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Verificación del sistema de control (OQ).</li> <li>Sistema de alarmas (OQ).</li> <li>Formación del personal (IQ).</li> </ul>
10.	Condensador	El condensador no realiza el cambio de estado del refrigerante correctamente	<p>Funcionamiento inadecuado del sistema de refrigeración.</p> <p>Condensación de agua y contaminación del producto.</p>	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
11.	Evaporadores	Los evaporadores no realizan el cambio de estado del refrigerante correctamente y no envían el frío al interior de la cámara	<p>Funcionamiento inadecuado del sistema de refrigeración.</p> <p>Degradación del producto almacenado.</p>	3	2	1	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
12.	Filtros de aire	Capacidad de filtración de aire inadecuado	Posible degradación del producto almacenado	2	1	2	4 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de uso y mantenimiento de la instalación (IQ).</li> <li>Plan de mantenimiento preventivo del equipo (IQ).</li> </ul>
		Rotura de filtros	Posible degradación del producto almacenado	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> <li>Formación del personal (IQ).</li> </ul>
		Colmatación de filtros	No se alcanzan las renovaciones/horas requeridas	3	1	2	6 BAJO	<ul style="list-style-type: none"> <li>Procedimientos de mantenimiento de la instalación (IQ).</li> <li>Disponibilidad de Plan de Mantenimiento Preventivo de la instalación (IQ).</li> </ul>

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## Limpieza Reactor

### *Análisis de Riesgos*

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	Christian Sanromà	Project Engineer Intern		

<b>Revisión</b>	Revisado por	Cargo / Departamento	Firma	Fecha
	Rosa Gimeno	Quality Assurance Technician		

<b>Aprobación</b>	Aprobado por	Cargo / Departamento	Firma	Fecha
	Eduard Ibàñez	Engineering Manager		
	Josep Pena	Quality Assurance Manager		

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## 1. INTRODUCCIÓN

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### 1.1 Objetivo

El propósito de este documento es realizar el Análisis de Riesgos de la dificultad de limpieza de las materias primas en los reactores de profesional de la planta productiva de Revlon, el Pla de Santa María.

Los resultados obtenidos en el análisis de riesgos permitirán determinar el alcance y profundidad de las actividades de cualificación de forma que éstas permitan demostrar la correcta implantación de los mecanismos de control que mitigarán los riesgos identificados.

### 1.2 Antecedentes

La limpieza de los reactores de profesional en la planta de fabricación que REVLON dispone en el Pla de Santa María, ha estado operativas en las actividades de limpieza que se realizan en la planta de REVLON.

La creciente exigencia en las normativas y regulaciones vigentes establecen la necesidad de llevar a cabo la evaluación de los diferentes riesgos de la limpieza de los reactores.

### 1.3 Ámbito

Se incluye en el ámbito del Análisis de Riesgos las diferentes materias primas que se utilizan en las fórmulas para producir producto en la planta de fabricación que REVLON dispone en el Pla de Santa María (Tarragona).

El ámbito de la cualificación del sistema está formado por:

- ▶ Un total de 13 materias primas que se utilizan para obtener producto.

Quedan excluidos de la cualificación prevista de los siguientes apartados:

- ▶ Cualquiera de las materias primas no introducidas en este análisis de riesgos.

## 2. DESCRIPCIÓN

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### 2.1 Descripción

Todas las materias primas introducidas en el análisis de riesgo pueden ser usadas para la formulación y obtención final del producto OTC, por esta razón, como todos estos ingredientes pueden estar en la fórmula se realiza un análisis de riesgos de todos ellos para evaluar su dificultad en la limpieza de los reactores.

## 3. METODOLOGÍA

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Para la elaboración del Análisis de Riesgos de la limpieza del reactor se ha utilizado la técnica FMEA (Failure Mode Effects Analysis). Ver **INS-QA-014**.

## 4. RESULTADOS ANÁLISIS

			P	G				D	Total
Ítem	Ingrediente/Substancia	Categoría	Probabilidad de ocurrencia - Solubilidad	Datos de toxicidad (DL50-mg/kg)	Alergénico (límite <10 mg/kg)	Ingrediente farmacéutico activo	Total	Capacidad de detección- Inspección visual (detección de residuos)	Total-Producto de riesgo (transferencia y adulteración de productos OTC)
<b>RIESGOS ASOCIADOS A LA LIMPIEZA DE UN REACTOR DE PROFESIONAL</b>									
1.	Ingrediente 1	Lanolina	Insoluble	0	0	No	Baja	Baja	Baja
2.	Ingrediente 2	Ingrediente farmacéutico activo	Insoluble	0	0	Si	Media	Baja	Media
3.	Ingrediente 3	Ingrediente farmacéutico activo	Insoluble	0	0	Si	Media	Baja	Media
4.	Ingrediente 4	Petroquímico	Insoluble	0	0	No	Baja	Baja	Baja
5.	Ingrediente 5	Conservantes	Baja solubilidad	0	0	No	Baja	Media	Media
6.	Ingrediente 6	Vitaminas	Insoluble	0	0	No	Baja	Media	Media
7.	Ingrediente 7	Fragancias	¿?	0	>10	No	Alta	Alta	Alta
8.	Ingrediente 8	Pigmentos	Baja solubilidad	0	0	No	Baja	Baja	Baja
9.	Ingrediente 9	Pigmentos	Baja solubilidad	0	0	No	Baja	Baja	Baja
10.	Ingrediente 10	Conservantes	Insoluble	0	0	No	Baja	Media	Media
11.	Ingrediente 11	Aceites naturales	Insoluble	0	0	No	Baja	Baja	Baja




			<i>P</i>	<i>G</i>				<i>D</i>	<i>Total</i>
<i>Ítem</i>	<i>Ingrediente/Substancia</i>	<i>Categoría</i>	<i>Probabilidad de ocurrencia - Solubilidad</i>	<i>Datos de toxicidad (DL50-mg/kg)</i>	<i>Alergénico (limite &lt;10 mg/kg)</i>	<i>Ingrediente farmacéutico activo</i>	<i>Total</i>	<i>Capacidad de detección- Inspección visual (detección de residuos)</i>	<i>Total-Producto de riesgo (transferencia y adulteración de productos OTC)</i>
12.	Ingrediente 12	Aceites naturales	Insoluble	0	0	No	Baja	Baja	Baja
13.	Ingrediente 13	Vitaminas	¿?	0	0	No	Baja	Media	Media

## Installation Qualification Protocol (IQ)- COMPRESSED AIR


REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [IQ -ES0201SERAIRX74000\_COMPRESSED AIR]

### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		11.04.2022
Christian Sanromà	Project Engineer Intern		11.04.2022
Sabina Oaie	Quality Assurance Technician		20.04.2022

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		20.04.22
Eduard Ibañez	Project Engineering Manager		03.05.2022
Josep Pena	Europe Quality Assurance Senior Manager		20-IV-2022

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## 1. INTRODUCTION

Installation qualification (IQ), of newly installed or in-plant equipment, verifies that an instrument or unit of equipment being qualified has been installed and configured in accordance with the manufacturer's specifications or installation checklist.

In other words, the FDA definition of IQ provides a useful statement of the overall objective: to document that the "system or equipment has the necessary preconditions to perform as expected."

Knowing this, this document performs the installation qualification protocol for the Revlon production plant's compressed air generation.

## 2. OBJECT

The objective of this document is to carry out the installation qualification protocol of the compressed air generation and distribution until the consumption point of the Revlon production plant in Pla de Santa Maria.

The results obtained in the installation qualification protocol will allow to identify and document the equipment, verify the correct installation and observe if the critical components are installed correctly and according to the design documentation in order to demonstrate the correct implementation of the control mechanisms of the equipment.

## 3. DESCRIPTION

The compressed air system is a system that has four compressors, a compressed air storage tank, six filters, three dryers and finally a dry air storage tank and a dry air tank for filling. There is also a line coming out of the end of the compressor system, which is for the PIG air, and in addition, a compressor, a dryer and an air storage tank for the Less circuit. All of these elements are used to obtain compressed air at 7 bar for instrumentation and to perform tasks in the factory where this type of air is needed. The most important point to be considered in the air distribution line is in the filling machine.

## 4. QUALIFICATION REPORTS

### 4.1. EQUIPMENT/UTILITY IDENTIFICATION


*Pre-verify the protocol with the quality attributes associated with the respective installation or equipment. Available for review: operation manuals, approved service flowcharts, P&IDs (pipe diagram and instrumentation).*

Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code
Compressed air	Utilities	-	-	ES02-01-SER- AIR-X-74000

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

### 4.2. DOCUMENTATION


Check the availability of each document, review it for accuracy, and place it in a permanent location. All documents must be available, and their location identified.

Document Description	Availability	Location	Comments
Flow plans and diagrams according to the actual installation/equipment	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	→\\casiopea\Mantenimiento\DOCUMENTACION SISTEMAS\01-Edificio Principal\05-Servicios\74-AIRE COMPRIMIDO\100-P&ID → \\casiopea\Mantenimiento\DOCUMENTACION SISTEMAS\01-Edificio Principal\05-Servicios\74-AIRE COMPRIMIDO\020-Electric	-
Installation/Equipment Operations Manual	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	→\\casiopea\Mantenimiento\INGENIERIA\Legalizacions\Aire comprimit fábrica (2010)\MANUALS D'US I MANTENIMENT →\\casiopea\Mantenimiento\DOCUMENTACION MAQUINAS\SEC- SECADOR DE AIRE (E)\10271779_E-74001C_SEC-000010=SECADOR FRIGORIF. GRAL	-
Spare parts list	Yes No N/A <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	-	We have a maintenance contract that in case of any failure the technical service comes. That is why there are no spare parts.
Installation/equipment instructions	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	→\\casiopea\Mantenimiento\INGENIERIA\Legalizacions\Aire comprimit fábrica (2010)\MANUALS D'US I MANTENIMENT →\\casiopea\Mantenimiento\DOCUMENTACION MAQUINAS\SEC- SECADOR DE AIRE (E)\10271779_E-74001C_SEC-000010=SECADOR FRIGORIF. GRAL	-
Plans associated with material flow and personnel flow	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Measuring instruments and specifications (pressure indicator)	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\casiopea\Mantenimiento\DOCUMENTACION SISTEMAS\01-Edificio Principal\05-Servicios\74-AIRE COMPRIMIDO\030-Mecanic	-
Welding reports (certificate company, welding technician training...)	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Checked by:		Date:	11-04-2022

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

### 4.3. EQUIPMENT INSPECTION

Use appropriate documentation and visual inspection to field verify the information listed below to ensure that the installation complies with vendor's specifications and Revlon requirements.

Description	Specification/parameter to review	Field verification
Equipment/Installation	Compressed air	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	-	-
Serial number	-	-
Type of control and set point	Air pressure to the plant and instrumentation → Set point: 7 bar PIG air pressure → Set point: 4 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2010	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	Installed power → 288,12 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other specifications (...)	-	-
Checked by:		Date: 11.04.2022

### 4.4. MAJOR COMPONENTS LIST

Document information regarding system components to ensure that they meet vendor's specifications and Revlon requirements. Use the appropriate documentation and visual inspection to field verify the information.

Include in this list the PLC or software/hardware of the equipment such as software update and backups, signals, inputs, and outputs.

	Specification	Field Verification
<b>1. Compressor L45 - K-74005</b>		
Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	L45-7,5	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial Number	100008040/0003	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Total weight	1102 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Effective capacity	7,84 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Pressure among stages	7,5 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Suction pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Revolutions	3000 min <sup>-1</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	45 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>2. Compressor L75RS - K-74006</b>		
Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	L75RS-13A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial Number	CD10008532001	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Total weight	1800 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Effective capacity	7,84 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Pressure among stages	13 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Suction pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Revolutions	4050 min <sup>-1</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	75 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>3. Compressor L80 - K-74007</b>		
Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	L80-7-5A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial Number	CD10022813001	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Total weight	2010 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Effective capacity	14,72 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Pressure among stages	7,5 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Suction pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Revolutions	3000 min <sup>-1</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	75 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>4. Compressor L75RS - K-74008</b>		
Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	L75RS-13A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial Number	CD 10052711002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Total weight	1800 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Effective capacity	13,99 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Pressure among stages	13 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Suction pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Revolutions	3000 min <sup>-1</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	75 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>5. Air tank - D-74001</b>		
Manufacturer	SiCC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	90010284	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Reference	1002300048	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	900 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Minimum temperature	-10 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	120 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Service pressure	11 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Hydraulic pressure	16,5 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>6. Air dryer - E-74001A</b>		
Manufacturer	MTA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	DE140	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacture number	2200055520	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum absorption	6,5 A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	3,6 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Protection grade	IP22	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant type	R134A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant charge	2,35 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	70 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>7. Air dryer - E-74001B</b>		
Manufacturer	MTA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	DE140	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacture number	2200055520	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum absorption	6,5 A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	3,6 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Protection grade	IP 22	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant type	R134A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant charge	2,35 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	70 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>8. Air dryer - E-74001C</b>		
Manufacturer	MTA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	398998300001	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Minimum pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	14 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	65 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	3,02 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant type	407C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant charge	2,2 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>9. Dry air tank - D-74002</b>		

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Manufacturer	Fical	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	FIC-1000/10-M	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	093/96	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	01/0071/P2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	10 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service temperature	180 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Minimum service temperature	-10 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1000 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>10. Air filter - F-74008</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	PV-95	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z44334/0002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	VYON	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	3,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	40 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>11. Air filter - F-74009</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	FC-95	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z44334/0008	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	Coalescing filter	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	3,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	70 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>12. Air filter - F-74010</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Model	PV-95	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	N944869/0011	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	VYON	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	3,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	40 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>13. Air filter - F-74011</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	FC-95	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z241818/0041	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	Coalescing filter	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	3,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	70 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>14. Air filter - F-74012 and F-74013</b>		
Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	CF0198G2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	389553361015002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Port size	G2"	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Air flow rate	19,80 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Minimum service pressure	0 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Minimum service temperature	1,5 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service temperature	80 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>16. Air tank - D-74004</b>		
Manufacturer	IRUSA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Design pressure	11,77 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum working pressure	11,77 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	17,65 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1500 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>17. Air filter - F-74014</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	PV-30	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z445572/0009	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	VYON	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	40 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>18. Alumina Air Dryer - E-74004</b>		
Manufacturer	Novair-MTA S.A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	NDA-004/16	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	32535/05	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Construction year	2005	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Protection grade	IP 55	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	16 W	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum absorption	0,10 A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Ambient temperature	+ 45 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum working pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Fluid temperature	+ 45 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Dehydratant	Activated alumina	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Charge	67,76 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>19. Air filter - F-74015</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	PV-30	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z542799/0005	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	VYON	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>


## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	40 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>20. Air filter - F-74016</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	CA-30	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z442066/0002	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	Active Carbon	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1,6 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	30 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>21. Biologic Air filter</b>		
Manufacturer	Donald filtration	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Vessel type	P-EG-0027	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	1 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacturing year	2004	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>22. PIG Air tank - D-74004</b>		
Manufacturer	Depositos Coballes S.L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	V	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacturing number	223	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacturing year	1999	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Design pressure	8 kg/cm <sup>2</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	16 kg/cm <sup>2</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Design temperature	60 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Capacity	750 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Material	AISI 316	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>23. Compressor – K-1101</b>		

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR


Manufacturer	CompAir	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	L-07-13	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial Number	14093803829900901	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Total weight	190 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Effective capacity	0,69 m <sup>3</sup> /min	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Pressure among stages	13 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Suction pressure	1 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Revolutions	3000 rpm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	7,5 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>24. Air dryer – E-1101</b>		
Manufacturer	MTA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	DE018	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Manufacture number	2200041725	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum absorption	2,6 A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Installed power	0,4 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Protection grade	IP 22	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant type	R134A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Refrigerant charge	0,305 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	70 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>25. Air tank – D-11001</b>		
Manufacturer	SICC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type	500/7058	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Reference	0411247058	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	500 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Minimum temperature	-10 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum temperature	50 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Service pressure	11 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Hydraulic pressure	16,6 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>26. Air filter before Air dryer E-1101</b>		
Manufacturer	Tratecnica	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	PV-10	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	Z443684/009	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Constructive feature	VYON	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

Maximum service pressure	16 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Test pressure	24 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Volume	0,5 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Category	1	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Group	2	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date: 11.04.2022


### 4.5. MEASUREMENT EQUIPMENT WITHIN THE SYSTEM

*Examine all the elements of the system that are calibrated from time to time.*

Description of measurement equipment	Model	Last calibrated date	Next calibration date
PI-74403=PRESSION D-74003 AIRE SERVICIO	N/A	15/08/2022	15/08/2023
Checked by:		Date:	11.04.2022

### 4.6. UTILITIES VERIFICATION

*Examine connections by visual and/or flat inspection and, where necessary, test and ensure that the supply of each service is available as specified (check that the services are connected and meet specifications such as flow rate, pressure...)*

Service	Subminister	Specification	Field verification
Power Supply (electrical wiring)	Voltage	400 V AC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Water Supply	Operating pressure	-	-
Pneumatic Supply	Operating pressure	-	-
Checked by:		Date:	11.04.2022


## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

### 4.7. MATERIALS IN PRODUCT CONTACT

Examine the equipment to ensure that the type of material of construction is available as specified. In the "How Verified" column, the following abbreviations will be used:

*EF* - Physical examination – in the case of no certificate, a test will be performed.


*DOC* – Recorded from specific documents (provide document number) – check material certificate.

Part Description	Specification	How Verified
N/A	N/A	N/A
Checked by:		Date: 11-04-2022

**Note:** The air in the compressed air system that encounters the product is controlled and at each critical point of use there is a filtration unit to ensure that the quality of the air that comes into contact with the product meets the company's requirements.

### 4.8. LIST OF PROCEDURES (SOP)


Verify that the applicable SOPs are in place for Operation, Cleaning, Maintenance and Data Integrity.

SOP Description	SOP Number/ Version/ Title (QMS)	Expiry Date	Comments
Equipment Operation Procedure	INS-MI-044 Rev 01 (Revisión y Mantenimiento del Sistema de Aire Comprimido)	18/03/2025	-
Cleaning Procedure	-	-	See in INS-MI-044
Preventive Maintenance Program	INS-MI-044 Rev 01 (Revisión y Mantenimiento del Sistema de Aire Comprimido)	18/03/2025	-
	SOP-MI-001 Rev 02 (Mantenimiento Preventivo Correctivo) –	18/09/2022	
Control System (PLC)	INS-MI-044 Rev 01 (Revisión y Mantenimiento del Sistema de Aire Comprimido)	18/03/2025	-
Checked by:		Date:	11-04-2022

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – COMPRESSED AIR**

**4.9. cGMP COMPLIANCE**

Use the appropriate documentation and visual inspection to verify the information below.

Description	Field Verification
All product contact surfaces are accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Under/around the equipment is accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Welds, threads, and accessories of the equipment are sanitary	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by: 	Date: 11.04.2022

**4.10. PERSONNEL TRAINING**

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (Attachment 3).

**5. DEVIATIONS**

In the event of non-compliant results, record any deviations in FOR-QA-006: Deviation/Non-Conformity Registration. In the table below, list and monitor for corrective action and possible retesting.

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action
NC2022_011	Attendance control record for compressed air system personnel training is missing	Outstanding training to operators working on the compressed air system shall be performed and recorded.	

## 6. ATTACHMENTS

---

*The following table provides a list of each of the attachments associated with the protocol and serves as verification.*

<b>Attachment</b>	<b>Title</b>
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Conclusion Statement

*Other supporting documents can be attached during Installation Qualification if it's needed.*

**INSTALLATION QUALIFICATION PROTOCOL  
 (IQ) – COMPRESSED AIR**

**ATTACHMENT 1: TEST EQUIPMENT**

Document all test equipment that are used in the execution of this Installation Qualification. All test equipment must be in current calibration.

Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
N/A	N/A	N/A	N/A

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – COMPRESSED AIR**

**ATTACHMENT 2: DEVIATION REPORT FORM**

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

**ATTACHMENT 3: PROTOCOL TRAINING FORM**

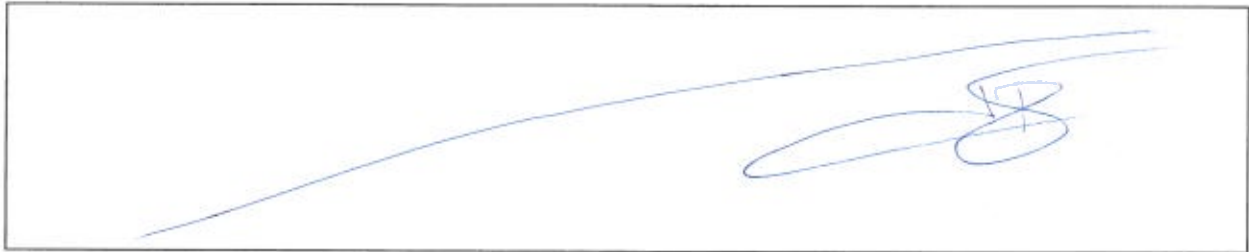
**Review that the staff involved has received appropriate training in FOR-RH-001: Control Assistance**

# INSTALLATION QUALIFICATION PROTOCOL (IQ) – COMPRESSED AIR

## ATTACHMENT 4: CONCLUSION STATEMENT

The Installation Qualification of the noted equipment stands complete. Any Deviations to the IQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.

Comments:



Final decision: Complies

Does not comply

Performed by:  Agus Barco

Date: 11-04-2022

Reviewed by:  Rosa M. Grieno

Date: 20.04.2022

Approved by:  Josep Pena

Date: 20-IV-2022

 Eouard  
IBANEZ




Date: 03-05-2022

## Installation Qualification Protocol (IQ)- WEIGHING SCALES 1, 2 & 3




REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [IQ -10217279-10217305-10217308\_WEIGHINGSCALES]

### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		24.03.2022
Christian Sanromà	Project Engineer Intern		24.03.2022
Sabina Oaie	Quality Assurance Technician		25.03.2022

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		31.03.2022
Eduard Ibañez	Project Engineering Manager		08.04.2022
Josep Pena	Europe Quality Assurance Senior Manager		30-III-2022

## Summary

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## 1. INTRODUCTION

Installation qualification (IQ), of newly installed or in-plant equipment, verifies that an instrument or unit of equipment being qualified has been installed and configured in accordance with the manufacturer's specifications or installation checklist.

In other words, the FDA definition of IQ provides a useful statement of the overall objective: to document that the "system or equipment has the necessary preconditions to perform as expected."

Knowing this, this document performs the installation qualification protocol for the Revlon production plant's weighing scales 1, 2 & 3.

## 2. OBJECT

The objective of this document is to carry out the installation qualification protocol of the weighing scales 1, 2 & 3 of the Revlon production plant in Pla de Santa Maria.

The results obtained in the installation qualification protocol will allow to identify and document the equipment, verify the correct installation and observe if the critical components are installed correctly and according to the design documentation in order to demonstrate the correct implementation of the control mechanisms of the equipment.

## 3. DESCRIPTION

The scales are equipment located inside the professional weighing room.

In box A there are three properly calibrated and identified scales, where each scale indicates the weight range that can be measured. These three scales are the WI-22009, WI-22010 and WI-22011.

## 4. QUALIFICATION REPORTS

### 4.1. EQUIPMENT/UTILITY IDENTIFICATION

*Pre-verify the protocol with the quality attributes associated with the respective installation or equipment. Available for review: operation manuals, approved service flowcharts, P&IDs (pipe diagram and instrumentation).*


Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code	Factory code
Scale 1	Weighing room	Sartorius EA35EDE-L	13508973	10217308	WI-22009
Scale 2	Weighing room	Acculab Exceleron ECL-60FEP- L0-EU	24592276	10217305	WI-22010

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

Scale 3	Weighing room	Sensocar SC10	706599	10217279	WI-22011
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### 4.2. DOCUMENTATION


*Check the availability of each document, review it for accuracy, and place it in a permanent location. All documents must be available, and their location identified.*


Document Description	Availability	Location	Comments
Flow plans and diagrams according to the actual installation/equipment	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Installation/Equipment Operations Manual	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\caslopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\10 BÁSCULAS PESADAS 1,2 Y 3\02 IQ\DOCUMENTACIÓN IQ\MANUALES	-
Spare parts list	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Installation/equipment instructions	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\caslopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\10 BÁSCULAS PESADAS 1,2 Y 3\02 IQ\DOCUMENTACIÓN IQ\MANUALES	-
Plans associated with material flow and personnel flow	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	SOP-PR-002 Rev.2 (Flujo de personas, materiales y producto)	-
Measuring instruments and specifications (scales)	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\caslopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\10 BÁSCULAS PESADAS 1,2 Y 3\02 IQ\DOCUMENTACIÓN IQ\MANUALES	-
Welding reports (certificate company, welding technician training...)	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Checked by:		Date: 24.03.2022	24.03.2022

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3


### 4.3. EQUIPMENT INSPECTION

Use appropriate documentation and visual inspection to field verify the information listed below to ensure that the installation complies with vendor's specifications and Revlon requirements.

Description	Specification/parameter to review	Field verification
Equipment/Installation	Scale 1 (WI-22009)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	Sartorius EA35EDE-L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	13508973	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type of control and acceptance ranges	Weighing range of the scale → The acceptance range is between 0 kg and 35 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	-	-
Electrical specifications	Maximum 16 VA; Typically 8 VA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date: 24.03.2022

Description	Specification/parameter to review	Field verification
Equipment/Installation	Scale 2 (WI-22010)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	Acculab Exceleron ECL-60FEP-L0-EU	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	24592276	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Type of control and acceptance ranges	Weighing range of the scale → The acceptance range is between 0 kg and 60 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2009	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	15,5 VA with battery charger circuit; 4 VA without battery charger circuit	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date: 24.03.2022

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

Description	Specification/parameter to review	Field verification
Equipment/Installation	Scale 3 (WI-22011)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	Sensocar SC10	-
Serial number	706599	-
Type of control and acceptance ranges	Weighing range of the scale → The acceptance range is between 0 kg and 1500 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	-	-
Electrical specifications	9-12 V DC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date: 24.03.2022

### 4.4. MAJOR COMPONENTS LIST

Document information regarding system components to ensure that they meet vendor's specifications and Revlon requirements. Use the appropriate documentation and visual inspection to field verify the information.

Include in this list the PLC or software/hardware of the equipment such as software update and backups, signals, inputs, and outputs.

	Specification	Field Verification
<b>1. Scale 1 (WI-22009)</b>		
Manufacturer	Sartorius	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	EA35EDE-L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Weighing capacity	35 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Readability	10 g	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Permissible tolerance	±2 g	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Tare range	35 kg	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Repeatability	10 g	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Linearity deviation	10 g	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Protection against foreign bodies and against water on platform	IP54	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>2. Scale 2 (WI-22010)</b>		
Manufacturer	Acculab	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>


## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

Model	ECL-60FEP-L0-EU	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Weighing capacity	60 kg	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Verification	5 gr	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Readability	10 gr	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Linearity	10 gr	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Load plate	Stainless steel	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Pollution degree	Degree 2	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<b>3. Scale 3 (WI-22011)</b>			
Manufacturer	Sensocar	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Model	SC10	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Weighing capacity	1500 kg	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Checked by:		Date:	24.03.2022

### 4.5. MEASUREMENT EQUIPMENT WITHIN THE SYSTEM

Examine all the elements of the system that are calibrated from time to time.

To see the calibration completed table, check the document FOR-MI-005.

Description of measurement equipment	Model	Last calibrated date	Next calibration date
Scale 1	Sartorius EA35EDE-L	15/08/2021	15/08/2022
Scale 2	Acculab Exceleton ECL	15/08/2021	15/08/2022
Scale 3	Sensocar SC10	15/08/2021	15/08/2022
Checked by:		Date:	24.03.2022

### 4.6. UTILITIES VERIFICATION

Examine connections by visual and/or flat inspection and, where necessary, test and ensure that the supply of each service is available as specified (check that the services are connected and meet specifications such as flow rate, pressure...)

Service	Subminister	Specification	Field verification
Power Supply Scale 1	Voltage	240 V AC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Power Supply Scale 2	Voltage	100 – 240 V AC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

Power Supply Scale 3 (electrical circuit)	Voltage	9-12 V DC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date:	

### 4.7. MATERIALS IN PRODUCT CONTACT

Examine the equipment to ensure that the type of material of construction is available as specified. In the "How Verified" column, the following abbreviations will be used:

*EF - Physical examination – In the case of no certificate, a test will be performed.*

*DOC – Recorded from specific documents (provide document number) – check material certificate.*

Part Description	Specification	How Verified
N/A	N/A	N/A
Checked by:		Date: 29.03.2022

### 4.8. LIST OF PROCEDURES (SOP)


Verify that the applicable SOPs are in place for Operation, Cleaning, Maintenance and Data Integrity.

SOP Description	SOP Number/ Version/ Title (QMS)	Expiry Date	Comments
Equipment Operation Procedure	<b>INS-MI-009 Rev. 02</b> <i>Operativa de puesta en marcha y uso de la sala de pesadas</i>	30/11/2024	-
Cleaning Procedure	<b>SOP-PR-012 Rev. 04</b> <i>Protocolo de limpieza y desinfección de equipos y utensilios, y despeje de zonas de producción</i>	8/12/2024	-
Preventive Maintenance Program	<b>INS-MI-046 Rev. 00</b> <i>Verificación/Calibración Básculas Pesadas</i> <b>SOP-MI-001. Rev 02</b> (Mantenimiento Preventivo Correctivo)	22/03/2025  18/09/2022	-
Control System (PLC)	-	-	-
Checked by:		Date:	24.03.2022

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

### 4.9. cGMP COMPLIANCE

Use the appropriate documentation and visual inspection to verify the information below.

Description		Field Verification	
All product contact surfaces are accessible and can be cleaned		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Under/around the equipment is accessible and can be cleaned		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Welds, threads, and accessories of the equipment are sanitary		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Checked by:		Date:	24.03.2022

### 4.10. PERSONNEL TRAINING

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (Attachment 3).

## 5. DEVIATIONS

In the event of non-compliant results, record any deviations in FOR-QA-006: Deviation/Non-Conformity Registration. In the table below, list and monitor for corrective action and possible retesting.

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action
NC2022_003	Instructions for cleaning and calibration/verification of box A weighing scales for IQ closure are missing.	The required instructions are carried out	
NC2022_008	The attendance control record for the training of weighing room scale personnel is missing.	Pending training for operators working in the weighing room will be carried out and recorded.	

## 6. ATTACHMENTS

---

*The following table provides a list of each of the attachments associated with the protocol and serves as verification.*

<b>Attachment</b>	<b>Title</b>
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Conclusion Statement

*Other supporting documents can be attached during Installation Qualification if it's needed.*

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 1: TEST EQUIPMENT**

Document all test equipment that are used in the execution of this Installation Qualification. All test equipment must be in current calibration.

Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
N/A	N/A	N/A	N/A

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 2: DEVIATION REPORT FORM**

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 3: PROTOCOL TRAINING FORM**

**Review that the staff involved has received appropriate training in FOR-RH-001: Control Assistance**

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – WEIGHING SCALES 1, 2 & 3

### ATTACHMENT 4: CONCLUSION STATEMENT

The Installation Qualification of the noted equipment stands complete. Any Deviations to the IQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.

Comments:

Final decision: Complies

Does not comply

Performed by:  ABEL BARRIOS


Date: 24.03.2022

Reviewed by:  ROSA GIMENO

Date: 31.03.2022

Approved by:  EDUARDO BONET

Date: 07.04.2022

	<b>INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM</b>
---	---

## Installation Qualification Protocol (IQ) - CLEANING SYSTEM

**REVLON LOCATION: EL PLA DE SANTA MARIA**

Document#: [IQ \_ *CLEANINGSYSTEM*]



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanromà	Project Engineer Intern		
Sabina Oaie	Quality Assurance Technician		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Josep Pena	Europe Quality Assurance Senior Manager		

## Summary

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## **1. INTRODUCTION**

---

Installation qualification (IQ), of newly installed or in-plant equipment, verifies that an instrument or unit of equipment being qualified has been installed and configured in accordance with the manufacturer's specifications or installation checklist.

In other words, the FDA definition of IQ provides a useful statement of the overall objective: to document that the "system or equipment has the necessary preconditions to perform as expected."

Knowing this, this document performs the qualification protocol of the installation of the professional cleaning system of the Revlon production plant, composed of the three different tanks, the acid tank, the hot deionized water tank and mains water tank and the piping.

## **2. OBJECT**

---

The objective of this document is to perform the installation qualification protocol of the professional cleaning system of the Revlon production plant in Pla de Santa Maria, composed of the three different tanks, the acid tank, the hot deionized water tank and mains water tank and the piping.

The results obtained in the installation qualification protocol will allow to identify and document the equipment, verify the correct installation and observe if the critical components are installed correctly and according to the design documentation to demonstrate the correct implementation of the control mechanisms of the equipment.

## **3. DESCRIPTION**

---

The cleaning of professionally manufactured reactors is carried out by following certain steps described in a set of instructions. In the different stages of this process, hot deionized water (approximately 80 °C) is introduced, then mains water is introduced, which is chlorinated water for rinsing and finally peracetic acid is introduced to finish the disinfection process. In this case, all these elements that are introduced come from different storage tanks that must be qualified to check their correct operation.

On the other hand, in this process the detergent is carried out in an independent equipment and therefore it is not necessary to qualify the detergent tank.

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 4. QUALIFICATION REPORTS

#### 4.1. EQUIPMENT/UTILITY IDENTIFICATION

Pre-verify the protocol with the quality attributes associated with the respective installation or equipment. Available for review: operation manuals, approved service flowcharts, P&IDs (pipe diagram and instrumentation).

Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code	Factory code
Hot deionized water tank	CIP	-	-		T-62001
Mains water tank	CIP	-	-		T-62002
Peracetic acid tank	CIP	-	-		T-61001

#### 4.2. DOCUMENTATION

Check the availability of each document, review it for accuracy, and place it in a permanent location. All documents must be available, and their location identified.

Document Description	Availability	Location	Comments
Flow plans and diagrams according to the actual installation/equipment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	→ \\casiopea\Mantenimiento\pedro g\ADG\040-Documentación\Pufos\XX-SIEMENS PCS7\CIP NUEVO - GRAU\DOCUMENTACION FINAL GRAU\Parte mecanica\DOCUMENTACION DIGITAL\PLANOS\EQUIPO CIP → \\casiopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\13 TANQUES LIMPIEZA\IQ\DOCUMENTACIÓN IQ\TANQUES CIP NUEVO\ELECTRICO	-
Installation/Equipment Operations Manual	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Spare parts list	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

Installation/equipment instructions	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Plans associated with material flow and personnel flow	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Measuring instruments and specifications	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\casiopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\13 TANQUES LIMPIEZA\IQ\DOCUMENTACIÓN IQ\TANQUES CIP NUEVO\INSTRUMENTACIÓN	-
Welding reports (certificate company, welding technician training...)	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\casiopea\Mantenimiento\DOCUMENTACION FDA\01 VALIDACIONES FDA 2021\07 Documentos validación\13 TANQUES LIMPIEZA\IQ\DOCUMENTACIÓN IQ\INFORME SOLDADURAS	-
Checked by:		Date:	

### 4.3. EQUIPMENT INSPECTION

Use appropriate documentation and visual inspection to field verify the information listed below to ensure that the installation complies with vendor's specifications and Revlon requirements.

Description	Specification/parameter to review	Field verification
Equipment/Installation	Hot deionized water tank	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	-	-
Serial number	-	-
Type of control and acceptance ranges	- Temperature → 75 °C to 85 °C - Level → 0 m <sup>3</sup> to 8,5 m <sup>3</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2015	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	-	-
Other specifications (...)	-	-
Checked by		Date:

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

Description	Specification/parameter to review	Field verification
Equipment/Installation	Mains water tank	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	-	-
Serial number	-	-
Type of control and acceptance ranges	<ul style="list-style-type: none"> <li>- Temperature → 45 °C and 55 °C</li> <li>- Conductivity → 0,05 µS/cm to 500 mS/cm</li> <li>- Level → 0 m³ to 8,5 m³</li> </ul>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2015	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	-	-
Other specifications (...)	-	-
Checked by:		Date:

Description	Specification/parameter to review	Field verification
Equipment/Installation	Peracetic acid tank	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	-	-
Serial number	-	-
Type of control and acceptance ranges	<ul style="list-style-type: none"> <li>- Conductivity → 0,05 µS/cm to 500 mS/cm</li> <li>- Level → 0 m³ to 8,5 m³</li> </ul>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2015	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	-	-
Other specifications (...)	-	-
Checked by:		Date:

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 4.4. MAJOR COMPONENTS LIST

Document information regarding system components to ensure that they meet vendor's specifications and Revlon requirements. Use the appropriate documentation and visual inspection to field verify the information.

Include in this list the PLC or software/hardware of the equipment such as software update and backups, signals, inputs, and outputs.

	Specification	Field Verification
<b>1. Hot deionized water tank</b>		
Manufacturer	GRAU	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Usable Volume	8,5 m <sup>3</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Tank temperature	80 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Inlet diameter	2000 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Thickness	5 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Height	4030 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Isolation thickness	48 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Construction material	AISI 316 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>2. Mains water tank</b>		
Manufacturer	GRAU	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Usable Volume	8,5 m <sup>3</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Tank temperature	80 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Inlet diameter	2000 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Thickness	5 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Height	4030 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Isolation thickness	48 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Construction material	AISI 316 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>3. Peracetic acid tank</b>		
Manufacturer	GRAU	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Usable Volume	8,5 m <sup>3</sup>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Tank temperature	80 °C	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Inlet diameter	2000 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Thickness	5 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Height	4049 mm	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Construction material	AISI 316 L	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date:

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 4.5. MEASUREMENT EQUIPMENT WITHIN THE SYSTEM

Examine all the elements of the system that are calibrated from time to time.

Description of measurement equipment	Model	Last calibrated date	Next calibration date
TT-62801=TEMPERATURA T-62002 AGUA CRUDA	-	15/08/2021	15/08/2022
TT-62800=TEMPERAT. T-62001 AGUA DESMIN.	EEX D IIC T6	15/08/2021	15/08/2022
Checked by:		Date:	

### 4.6. UTILITIES VERIFICATION

Examine connections by visual and/or flat inspection and, where necessary, test and ensure that the supply of each service is available as specified (check that the services are connected and meet specifications such as flow rate, pressure...)

Service	Subminister	Specification	Field verification
Power Supply	Voltage	400 V AC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Water Supply	Operating pressure	-	-
Pneumatic Supply	Operating pressure	-	-
Steam Supply	Operating pressure	5 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date:	

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 4.7. MATERIALS IN PRODUCT CONTACT

Examine the equipment to ensure that the type of material of construction is available as specified. In the "How Verified" column, the following abbreviations will be used:

**EF** - Physical examination – in the case of no certificate, a test will be performed.

**DOC** – Recorded from specific documents (provide document number) – check material certificate.

Part Description	Specification	How Verified
Hot deionized water tank	316 L Stainless Steel	DOC (\\casiopea\Mantenimiento\pedro g\ADG\040-Documentación\Pufos\XX-SIEMENS PCS7\CIP NUEVO - GRAU\DOCUMENTACION FINAL GRAU\Parte mecanica\DOCUMENTACION DIGITAL\PLANOS\EQUIPO CIP\DEPOSITOS CIP→ Document 20150064-A-ED0500)
Mains water tank	316 L Stainless Steel	DOC (\\casiopea\Mantenimiento\pedro g\ADG\040-Documentación\Pufos\XX-SIEMENS PCS7\CIP NUEVO - GRAU\DOCUMENTACION FINAL GRAU\Parte mecanica\DOCUMENTACION DIGITAL\PLANOS\EQUIPO CIP\DEPOSITOS CIP→ Document 20150064-A-ED0500)
Peracetic acid tank	316 L Stainless Steel	DOC (\\casiopea\Mantenimiento\pedro g\ADG\040-Documentación\Pufos\XX-SIEMENS PCS7\CIP NUEVO - GRAU\DOCUMENTACION FINAL GRAU\Parte mecanica\DOCUMENTACION DIGITAL\PLANOS\EQUIPO CIP\DEPOSITOS CIP→ Document 20150064-ED0500)
Checked by:		Date:

### 4.8. LIST OF PROCEDURES (SOP)

Verify that the applicable SOPs are in place for Operation, Cleaning, Maintenance and Data Integrity.

SOP Description	SOP Number/ Version/ Title (QMS)	Expiry Date	Comments
Equipment Operation Procedure	-	-	-
Cleaning Procedure	-	-	-
Preventive Maintenance Program	<b>SOP-MI-001</b> Rev 02 (Mantenimiento Preventivo Correctivo)	18/09/2022	-
Control System (PLC)	-	-	-
Checked by:		Date:	

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 4.9. cGMP COMPLIANCE

Use the appropriate documentation and visual inspection to verify the information below.

Description	Field Verification
All product contact surfaces are accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Under/around the equipment is accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Welds, threads, and accessories of the equipment are sanitary	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by: _____	Date: _____

### 4.10. PERSONNEL TRAINING

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (**Attachment 3**).

## 5. DEVIATIONS

In the event of non-compliant results, record any deviations in **FOR-QA-006: Deviation/Non-Conformity Registration**.

In the table below, list and monitor for corrective action and possible retesting.

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action
N/A	N/A	N/A	N/A

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### 6. ATTACHMENTS

---

The following table provides a list of each of the attachments associated with the protocol and serves as verification.

Attachment	Title
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Conclusion Statement

Other supporting documents can be attached during Installation Qualification if it's needed.

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### ATTACHMENT 1: TEST EQUIPMENT

Document all test equipment that are used in the execution of this Installation Qualification. All test equipment must be in current calibration.

Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
N/A	N/A	N/A	N/A

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### ATTACHMENT 2: DEVIATION REPORT FORM

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### ATTACHMENT 3: PROTOCOL TRAINING FORM

Review that the staff involved has received appropriate training in **FOR-RH-001: Control Assistance**

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – CLEANING SYSTEM

### ATTACHMENT 4: CONCLUSION STATEMENT

The Installation Qualification of the noted equipment stands complete. Any Deviations to the IQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.

Comments:

Final decision: Complies

Does not comply

Performed by: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_




Date: \_\_\_\_\_

## Installation Qualification Protocol (IQ)- COOL ROOM




REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [IQ -10272612\_COOLROOM]

### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		22.03.2022
Christian Sanromà	Project Engineer Intern		22.03.2022
Sabina Oale	Quality Assurance Technician		20.04.2022

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		23/03/2022
Eduard Ibañez	Project Engineering Manager		08/04/2022
Josep Pena	Europe Quality Assurance Senior Manager		23-III-2022

## Summary

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## **1. INTRODUCTION**

---

Installation qualification (IQ), of newly installed or In-plant equipment, verifies that an instrument or unit of equipment being qualified has been installed and configured in accordance with the manufacturer's specifications or installation checklist.

In other words, the FDA definition of IQ provides a useful statement of the overall objective: to document that the "system or equipment has the necessary preconditions to perform as expected."

Knowing this, this document performs the installation qualification protocol for the Revlon production plant's cool room.

## **2. OBJECT**

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The objective of this document is to carry out the installation qualification protocol of the cool room of the Revlon production plant in Pla de Santa Maria.

The results obtained in the installation qualification protocol will allow to identify and document the equipment, verify the correct installation and observe if the critical components are installed correctly and according to the design documentation in order to demonstrate the correct implementation of the control mechanisms of the equipment.

## **3. DESCRIPTION**

---

The cool room has a surface area of 35.4 m<sup>2</sup> and a volume of 159.5 m<sup>3</sup>.

To achieve the required conditions in the cold room, a unit located outside the building (condenser) and two units located inside the cold room (evaporators with their respective fans) were installed. The outdoor unit sends the cooling power to the two evaporator units by means of refrigerant gas and through copper piping. The piping to be installed is of refrigerant type, lined with Armaflex in its suction line to avoid condensation and degassing as much as possible. The electrical supply is made to the condensing unit and this distributes it to the two evaporators.

Since the area where the climatic room is located is an ATEX zone, for safety reasons, a LEL detector was installed in the chamber, which has a safety interlock with the refrigeration equipment to stop it in case of detection of flammable vapors.

## 4. QUALIFICATION REPORTS

### 4.1. EQUIPMENT/UTILITY IDENTIFICATION

Pre-verify the protocol with the quality attributes associated with the respective installation or equipment. Available for review: operation manuals, approved service flowcharts, P&IDs (pipe diagram and instrumentation).


Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code
Cool room	Warehouse	-	-	10272612

### 4.2. DOCUMENTATION

Check the availability of each document, review it for accuracy, and place it in a permanent location. All documents must be available, and their location identified.


Document Description	Availability	Location	Comments
Flow plans and diagrams according to the actual installation/equipment	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\caslopea\Mantenimiento\IED\FICI\CLIMATIZACIO-FDA- SAP 1241- SAP 1371\CLIMATIZACIO-SAP 1241- SAP 1371\Documentaci6\6383.95.HVAC\DOCS CAMARA FREDIA\Planos-Esquemas	-
Installation/Equipment Operations Manual	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	On paper → PROCool electronic panel manual (near the camera)	-
Spare parts list	Yes No N/A <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	-	We have a maintenance contract that in case of any failure the technical service comes. That is why there are no spare parts.
Installation/equipment instructions	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	On paper → PROCool electronic panel manual (near the camera)	-

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COOL ROOM

Plans associated with material flow and personnel flow	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	SOP-PR-002 Rev.2 (Flujo de personas, materiales y producto)	-
Measuring instruments and specifications (temperature detector)	Yes No N/A <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	\\caslopea\Mantenimiento\EDIFICIO\CLIMATIZACION-FDA- SAP 1241- SAP 1371\CLIMATIZACION-SAP 1241- SAP 1371\Documentación\6383.95.HVAC\DOCS CAMARA FREDA\Equip de fred	-
Welding reports (certificate company, welding technician training...)	Yes No N/A <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	-	-
Checked by:		Date:	22.03.2022

### 4.3. EQUIPMENT INSPECTION

Use appropriate documentation and visual inspection to field verify the information listed below to ensure that the installation complies with vendor's specifications and Revlon requirements.

Description	Specification/parameter to review	Field verification
Equipment/Installation	Cool room	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Model	-	-
Serial number	-	-
Type of control and acceptance ranges	Temperature inside the room → Acceptance range for room characteristics: 3°C a 25°C (See note below)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Equipment manufacturing year	2017	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Electrical specifications	Cooling equipment power → 14 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Other specifications (...)	-	-
Checked by:		Date:
		22.03.2022

**Note:** The range of acceptability of the equipment has been established by performing on-site tests.

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COOL ROOM


The set point was lowered to a value of 3°C, and it was observed that the equipment continued to cool and this value was established as the minimum, since it would be valid for our process.

The maximum value was set as room temperature because the test cannot be performed by raising the temperature, because if the temperature is higher than 10 °C can cause damage to the raw material, and as it was observed that up to 10 ° C if it cools, it was decided to set the room temperature as the maximum.

### 4.4. MAJOR COMPONENTS LIST


Document information regarding system components to ensure that they meet vendor's specifications and Revlon requirements. Use the appropriate documentation and visual inspection to field verify the information.

Include in this list the PLC or software/hardware of the equipment such as software update and backups, signals, inputs, and outputs.

	Specification	Field Verification
<b>1. Refrigerant equipment</b>		
Manufacturer	Pecomark	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Serial number	126297-41840332	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Reference number	UND BITZER USMBE 101 ECP	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Maximum pressure	28 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Low pressure	17 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Power	14 kW	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Gas	R134A/R404A/R448A	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Oil	Ester	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date: 22-03-2022

### 4.5. MEASUREMENT EQUIPMENT WITHIN THE SYSTEM


Examine all the elements of the system that are calibrated from time to time.

Description of measurement equipment	Model	Last calibrated date	Next calibration date
Data Logger TESTO (P2055)	175H1	22/06/2021	22/06/2022
Checked by:		Date:	22-03-2022

## INSTALLATION QUALIFICATION PROTOCOL (IQ) – COOL ROOM

### 4.6. UTILITIES VERIFICATION

Examine connections by visual and/or flat inspection and, where necessary, test and ensure that the supply of each service is available as specified (check that the services are connected and meet specifications such as flow rate, pressure...)


Service	Subminister	Specification	Field verification
Power Supply (electrical wiring)	Voltage	400 V AC	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Water Supply	Operating pressure	-	-
Pneumatic Supply	Operating pressure	7 bar	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:		Date:	22.03.2022

### 4.7. MATERIALS IN PRODUCT CONTACT

Examine the equipment to ensure that the type of material of construction is available as specified. In the "How Verified" column, the following abbreviations will be used:

*EF* - Physical examination – in the case of no certificate, a test will be performed.

*DOC* – Recorded from specific documents (provide document number) – check material certificate.

Part Description	Specification	How Verified
N/A	N/A	N/A
Checked by:		Date: 22.03.2022

### 4.8. LIST OF PROCEDURES (SOP)

Verify that the applicable SOPs are in place for Operation, Cleaning, Maintenance and Data Integrity.

SOP Description	SOP Number/ Version/ Title (QMS)	Expiry Date	Comments
Equipment Operation Procedure	INS-MI-042 Rev. 00 (Operativa de puesta en marcha y uso de la cámara fría)	11/03/2025	-
Cleaning Procedure	SOP-PR-011 Rev 05 (Limpieza de salas, suelos y estructuras)	16/06/2024	-

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – COOL ROOM**

Preventive Maintenance Program	SOP-MI-001 Rev 02 (Mantenimiento Preventivo Correctivo)	18/09/2022	-
Control System (PLC)	INS-MI-043 Rev. 00 (Revisión y mantenimiento de la cámara fría)	14/03/2025	-
Checked by:		Date:	22.03.2022

**4.9. cGMP COMPLIANCE**

Use the appropriate documentation and visual inspection to verify the information below.

Description	Field Verification
All product contact surfaces are accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Under/around the equipment is accessible and can be cleaned	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Welds, threads, and accessories of the equipment are sanitary	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Checked by:	Date: 22.03.2022

**4.10. PERSONNEL TRAINING**

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (Attachment 3).

**INSTALLATION QUALIFICATION PROTOCOL  
(IQ) – COOL ROOM**

**5. DEVIATIONS**

*In the event of non-compliant results, record any deviations in FOR-QA-006: Deviation/Non-Conformity Registration. In the table below, list and monitor for corrective action and possible retesting.*

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action

**6. ATTACHMENTS**

*The following table provides a list of each of the attachments associated with the protocol and serves as verification.*

Attachment	Title
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Conclusion Statement

*Other supporting documents can be attached during Installation Qualification if it's needed.*

**INSTALLATION QUALIFICATION PROTOCOL  
 (IQ) – COOL ROOM**

**ATTACHMENT 1: TEST EQUIPMENT**

Document all test equipment that are used in the execution of this Installation Qualification. All test equipment must be in current calibration.

Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
N/A	N/A	N/A	N/A

**ATTACHMENT 2: DEVIATION REPORT FORM**

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

**ATTACHMENT 3: PROTOCOL TRAINING FORM**

**Review that the staff involved has received appropriate training in FOR-RH-001: Control Assistance**

### CONTROL DE ASISTENCIA

ACCIÓN FORMATIVA: USO Y CONTROL DE TEMPERATURA EN CÁMARAS CLIMÁTICAS




FORMADOR: Ignasi Grau

LUGAR: Almacén

FECHA: 25/03/2022

HORARIO: 11-12h

NÚM. HORAS: 30 min

Núm.	Num. Empleado	NOMBRE	FIRMAS
1	8394	REBECA DÍAZ	
2	3136	JULIO MEDINA	
3	2821	MAGI FERÚ	
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

**OBSERVACIONES GENERALES:**

Operarios Almacén.

**INDICE DE CONTENIDOS:**

INS-MI-041 → Operativa de puesta en marcha y uso de la cámara caliente

INS-MI-041 → operativa de puesta en marcha y uso de la cámara fría

INS-WH-001 → Control T<sup>a</sup> y Humedad en Almacén

FOR-WH-004 → Control Temperatura Humedad Almacén.

**Firma Formador:**



JGASÍ GIMAU

**Fecha:**

25/03/2022

Código registro: FOR-HR-001

Rev 02

SOP relacionados: SOP-QA-001

SOP-HR-001

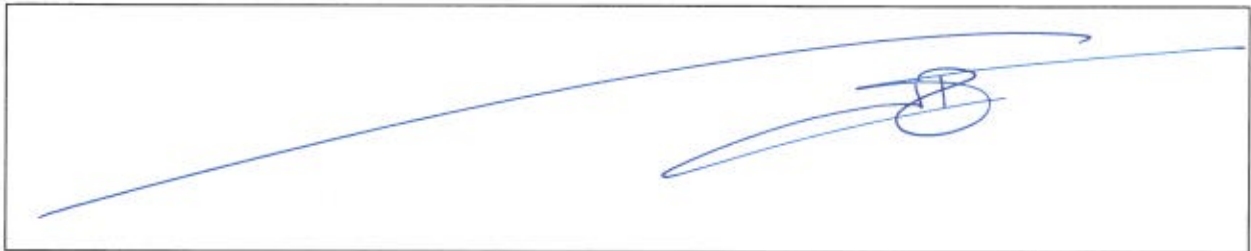


Código registro: FOR-HR-001  
Rev 02  
SOP relacionados: SOP-QA-001  
SOP-HR-001

ATTACHMENT 4: CONCLUSION STATEMENT

The Installation Qualification of the noted equipment stands complete. Any Deviations to the IQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.


Comments:



Final decision: Complies

Does not comply

Performed by:

 Adolfo Barrios

Date:

22.03.2022

Reviewed by:

 Eduardo Ibarra

Date:


07.04.2022

Approved by:

 Josep Tena

Date:

23-III-2022

	<b>OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 &amp; 3</b>
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## Operational Qualification Protocol (OQ)- WEIGHING SCALES 1, 2 & 3

**REVLON LOCATION: EL PLA DE SANTA MARIA**

Document#: [OQ -10217279-10217305-10217308\_ WEIGHINGSCALES]



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanromà	Project Engineer Intern		
Sabina Oaie	Quality Assurance Technician		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Josep Pena	Europe Quality Assurance Senior Manager		

## Summary

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# OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 & 3

## 1. INTRODUCTION

The Operational Qualification Protocol is a collection of test cases used to verify the proper functioning of a system. In other words, the FDA definition says that OQ is based on establishing confidence that process equipment and sub-systems are capable of consistently operating within stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined functional requirements, or that the system does what it's supposed to do.

Knowing this, this document performs the operational qualification protocol for the Revlon production plant's weighing scales 1, 2 & 3.

## 2. QUALIFICATION REPORTS

### 2.1. EQUIPMENT/UTILITY IDENTIFICATION

*Pre-verify the protocol with the quality attributes associated with the respective installation or equipment.*

Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code	Factory code
Scale 1	Weighing room	Sartorius EA35EDE-L	13508973	10217308	WI-22009
Scale 2	Weighing room	Acculab Exceleron ECL	24592276	10217305	WI-22010
Scale 3	Weighing room	Sensocar SC10	706599	10217279	WI-22011

### 2.2. PREREQUISITES

*Verify that the information and tasks listed in Table 2.2 are completed prior to OQ execution.*

Prerequisites	Initials/Date
The IQ closeout must have been signed prior to the execution of the OQ	
During IQ execution all deviation issues evaluated as having an impact on operation have been resolved and implemented	

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 & 3

### 2.3. CONTROL SYSTEM VERIFICATION OF EQUIPMENT

Identify and challenge critical controls and indicators associated with the equipment. Document in Table 3.1. Identify all the operations that the computer does and verify that they work.

Table 3.1		
Control	Function	Function Properly
<b>Control system switch on/off</b>		
Switch on/ Switch off the weighing scales	Verify that the manual start-up and shutdown of the equipment is working correctly	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
<b>Menu Management</b>		
Button's function	Verify that all keys on scales 1, 2 and 3 are working properly and performing their stipulated functions.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
<b>Data visualization</b>		
Display general process information shown by the display	Verify that the information is legible	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Checked by:		Date:

### 2.4. OPERATIONAL VERIFICATION OF EQUIPMENT

Identify critical operating parameters and verify equipment/system operations function as intended. Operating ranges and acceptance criteria must be verified for each parameter. Process should be challenged at the extremes of the critical process parameters wherever possible.

Table 4.1		
Control	Function	Function Properly
<b>Operating parameters</b>		
Weighing of the scale	Verify that the scale correctly measures the weight entered at the 5 different weights. Verify that the minimum and maximum weighing range of each scale works correctly with an error of 5 %.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Checked by:		Date:

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 & 3

### 2.5. ALARM VERIFICATION

List all alarms that contain the different parts of the computer. Existing equipment should list at least 10% of existing alarms, but for new equipment, if possible, request listing from the vendor for the relevant check.

Table 5.1		
Equipment	Alarm Device	Function Properly
Scale 1 (WI-22009)	<i>H</i> → Scale capacity exceeded	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 1 (WI-22009)	<i>L</i> → No load plate on the scale/Something is touching the load plate	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 1 (WI-22009)	<i>E 01</i> → Display overflow	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 1 (WI-22009)	<i>E 02</i> → Calibration parameter not met	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 1 (WI-22009)	<i>E 08</i> → Scale is not within the zero range	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 1 (WI-22009)	<i>E 22</i> → Weight too light, or no load on the scale	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 2 (WI-22010)	<i>oL</i> → The load exceeds the capacity of the scale.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 2 (WI-22010)	<i>uL</i> → Load plate is not in place/Something is touching the load plate	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 2 (WI-22010)	<i>dSPErr</i> → Display overflow	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Scale 2 (WI-22010)	<i>APPErr</i> → Weight too high or no sample on the scale with the application in use	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Checked by:		Date:

### 2.6. PERSONNEL TRAINING

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (**Attachment 3**).

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 & 3

### 3. DEVIATIONS

---

In the event of non-compliant results, record any deviations in **FOR-QA-006: Deviation/Non-Conformity Registration**.  
 In the table below, list and monitor for corrective action and possible retesting.

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action
N/A	N/A	N/A	N/A

### 4. ATTACHMENTS

---

The following table provides a list of each of the attachments associated with the protocol and serves as verification.

Attachment	Title
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Conclusion Statement

Other supporting documents can be attached during Installation Qualification if it's needed.

**OPERATIONAL QUALIFICATION PROTOCOL  
 (OQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 1: TEST EQUIPMENT**

Document all test equipment that are used in the execution of this Operational Qualification. All test equipment must be in current calibration.

Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
N/A	N/A	N/A	N/A

**OPERATIONAL QUALIFICATION PROTOCOL  
(OQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 2: DEVIATION REPORT FORM**

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

**OPERATIONAL QUALIFICATION PROTOCOL  
(OQ) – WEIGHING SCALES 1, 2 & 3**

**ATTACHMENT 3: PROTOCOL TRAINING FORM**

Review that the staff involved has received appropriate training in **FOR-RH-001: Control Assistance**

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – WEIGHING SCALES 1, 2 & 3

### ATTACHMENT 4: CONCLUSION STATEMENT

The Operational Qualification of the noted equipment stands complete. Any Deviations to the OQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.

Comments:

Final decision: Complies

Does not comply

Performed by: \_\_\_\_\_


Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_

Date: \_\_\_\_\_

	<b>OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM</b>
---	--

## Operational Qualification Protocol (OQ)- COOL ROOM

**REVLON LOCATION: EL PLA DE SANTA MARIA**

**Document#: [OQ -10272612\_COOLROOM]**



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanromà	Project Engineer Intern		
Sabina Oaie	Quality Assurance Technician		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Josep Pena	Europe Quality Assurance Senior Manager		

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## **1. INTRODUCTION**

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The Operational Qualification Protocol is a collection of test cases used to verify the proper functioning of a system. In other words, the FDA definition says that OQ is based on establishing confidence that process equipment and sub-systems are capable of consistently operating within stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined functional requirements, or that the system does what it's supposed to do.

Knowing this, this document performs the operational qualification protocol for the Revlon production plant's cool room.

It must be specified that because the cool room has been in use for some years and cannot be emptied and left without raw materials inside because this could affect the quality of the raw materials, for this reason the operational qualification (OQ) and performance qualification (PQ) are performed together, and the results and conclusions obtained are shown in this report.

## **2. OBJECT**

---

The objective of this document is to carry out the operational qualification protocol of the cool room of the Revlon production plant in Pla de Santa Maria.

The results obtained in the operational qualification protocol will allow to observe the operation of the cool room in different cases and to identify if the temperature is maintained within the range provided by the manufacturer and within the established range of the company to demonstrate the correct implementation of the control mechanisms of the equipment.

## **3. DESCRIPTION**

---

The cool room is a climatic room which is used to keep cold and not allow certain products to rise above a certain temperature due to their quality requirements.

The cool room is in the warehouse and inside it there is a temperature transmitter.

The operation of the cool room it is based on the set point at 7 °C, and when the temperature starts to rise, the refrigeration equipment is turned on to cool the room until it reaches a sufficiently low temperature and then the refrigeration equipment is stopped.

The range established by the company for the correct operation of the cool room is among 0 °C and 10 °C.

## **4. QUALIFICATION REPORTS**

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### **4.1. EQUIPMENT/UTILITY IDENTIFICATION**

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*Pre-verify the protocol with the quality attributes associated with the respective installation or equipment.*

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

Installation/ Equipment/ Control Panel (PLC)	Productive area	Model	Serial Number	SAP code
Cool room	Warehouse	-	-	10272612

### 4.2. PREREQUISITES

Verify that the information and tasks listed in Table 2.2 are completed prior to OQ execution.

Prerequisites	Initials/Date
The IQ closeout must have been signed prior to the execution of the OQ	
During IQ execution all deviation issues evaluated as having an impact on operation have been resolved and implemented	

### 4.3. CONTROL SYSTEM VERIFICATION OF EQUIPMENT

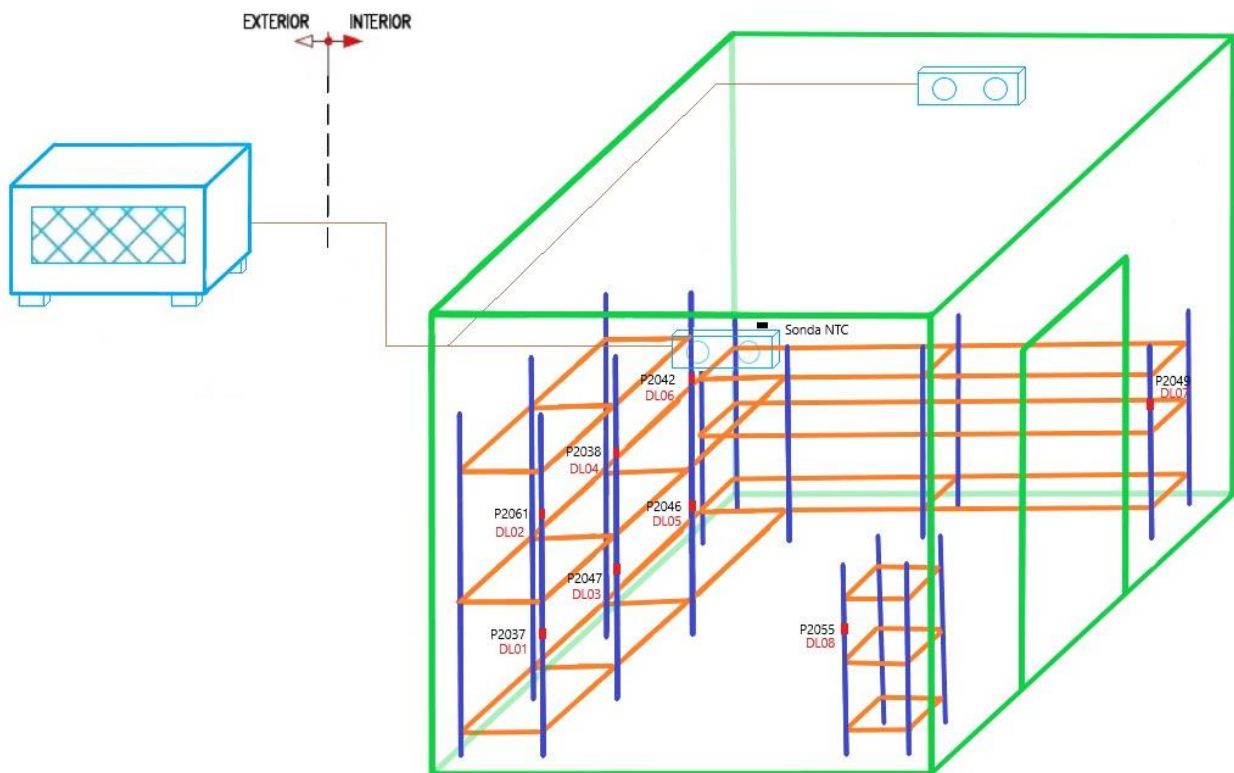
Identify and challenge critical controls and indicators associated with the equipment. Document in Table 3.1. Identify all the operations that the computer does and verify that they work.

Table 3.1		
Control	Function	Function Properly
Switch on/Switch off the system control and manual start-up and shutdown the cool room	Verify that the manual start-up and shutdown of the equipment is working correctly, and the control system starts to climatize the room	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Display general process information shown by the display	Verify that the information is legible	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Shows the correct operation of the different buttons of the control panel	Verify that the buttons on the control panel perform the function marked by the manufacturer and that they all function correctly.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Temperature control	Verify that the operation of the refrigeration equipment is adequate. With the set point established, observe that in the upper range the equipment is turned on, and that in the lower range the equipment is turned off.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Checked by:		Date:

## 4.4. OPERATIONAL VERIFICATION OF EQUIPMENT

Verify that the installation can control and maintaining uniform temperature. The complete area should be monitored for a period of at least one week using calibrated dataloggers of temperature (see Attachment 5). Add here a map of the climatic chamber with the locations of the dataloggers that will be used for the mapping:

The dataloggers in the lower zone (P2037, P2047 and P2046) are placed 1 meter above the ground, and the dataloggers in the upper zone (P2038, P2042 and P2061) are placed 3 meters above the ground. In addition, dataloggers P2049 and P2055 are located 1.5 m above the ground. In addition, dataloggers P2037 and P2047, P2047 and P2046, P2038 and P2061 and finally P2038 and P2042 are separated by 5.68 m.



In this case, it has been evaluated if the cool room was within the ranges established by the company using the 8 dataloggers.

The following two sections show the test without opening the cold room for 24h and the test of the normal operation of the cold room during two working days.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### ➤ Cool room operation without opening for 24H

Record the temperature results in a table like the one below. You can also add a temperature graph with the results.

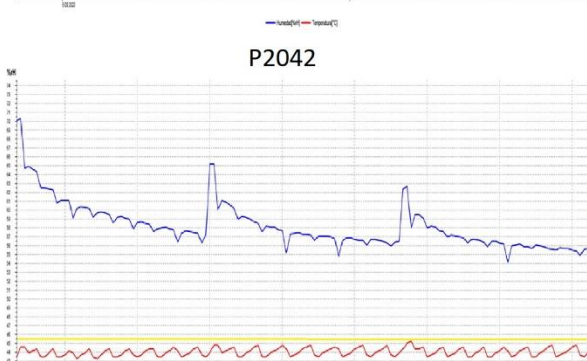
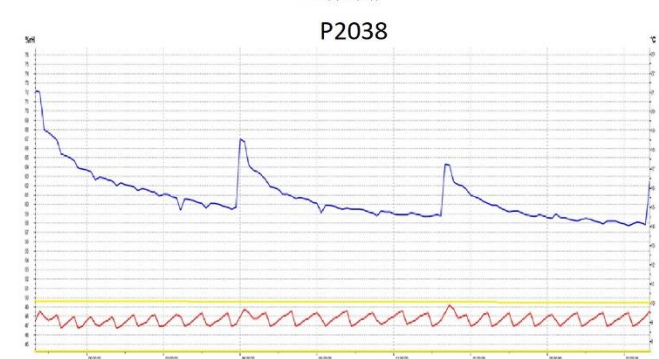
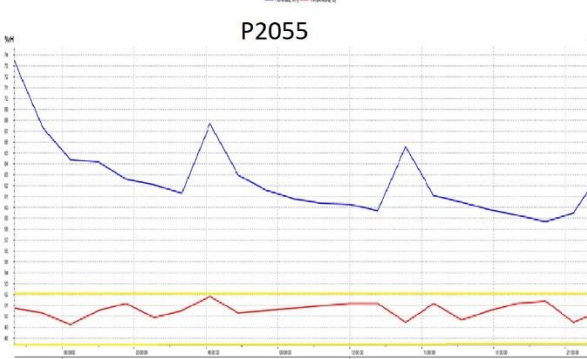
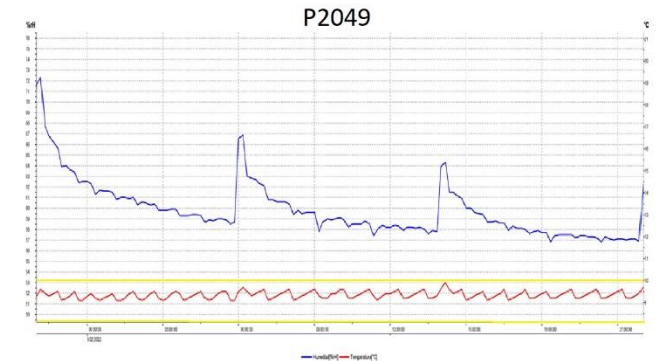
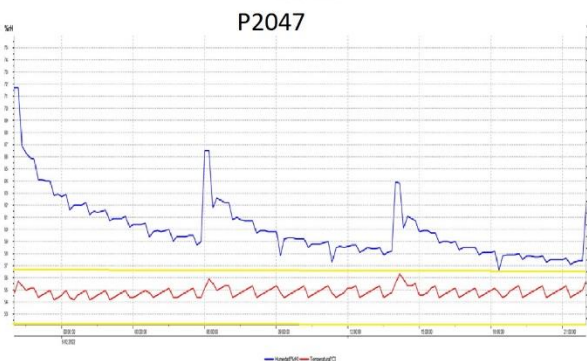
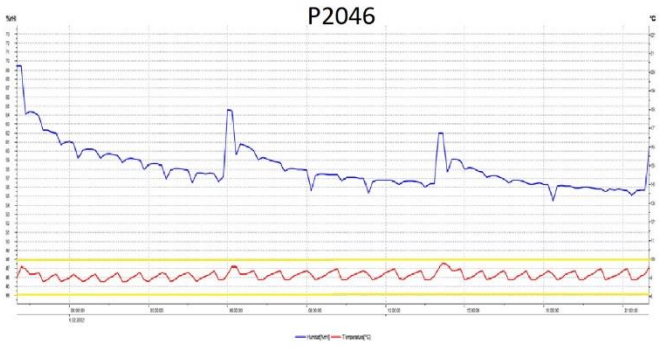
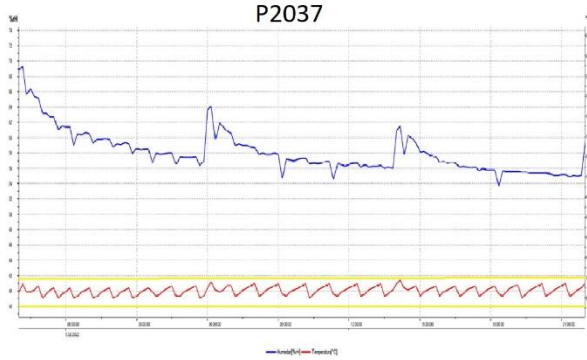
Table 4.1								
Set Point Temperature				7 °C				
DL number (Map)	DL ID number	SAP code	Min. Temp. Recorded (°C)	Max. Temp. Recorded (°C)	Mean temp. (°C)	Standard deviation	Pass/Fail	Date
01	P2037	10274327	9,00	9,90	9,37	0,21	Pass	
04	P2038	10270419	8,70	9,90	9,15	0,26	Pass	
06	P2042	10270414	9,00	9,90	9,35	0,20	Pass	
05	P2046	10274328	8,80	9,80	9,14	0,22	Pass	
03	P2047	10270425	8,80	9,90	9,13	0,20	Pass	
07	P2049	10270424	9,10	9,90	9,34	0,17	Pass	
08	P2055	10274347	8,70	9,90	9,32	0,32	Pass	
02	P2061	10274324	8,80	9,90	9,27	0,24	Pass	
<b>Mapping period starts at:</b>							Date:	
							Hour:	
<b>Mapping period ends at:</b>							Date:	
							Hour:	
<b>Checked by:</b>							Date:	
							Hour:	

As shown in Table 4.1 and in the tables obtained from all the dataloggers, the cool room remains within the range established by the manufacturer and, at the same time, within the established functional range. Therefore, it can be affirmed that the cool room is working properly and the equipment generates cold air within the range established by the manufacturer.

Annex 5 shows the graphs of each datalogger and some summaries of what can be observed in each of the results obtained.

Finally, after analyzing the results, it could be observed that all the points give similar values, but the point where the datalogger P2042 is located has been chosen as critical because it is an elevated position, where the cold air does not tend to go, and moreover, this point is located far from the cold generation, for this reason this position 6 has been chosen as critical point.

# OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### ➤ Cool room operation for 2 days

Record the temperature results in a table like the one below. You can also add a temperature graph with the results.

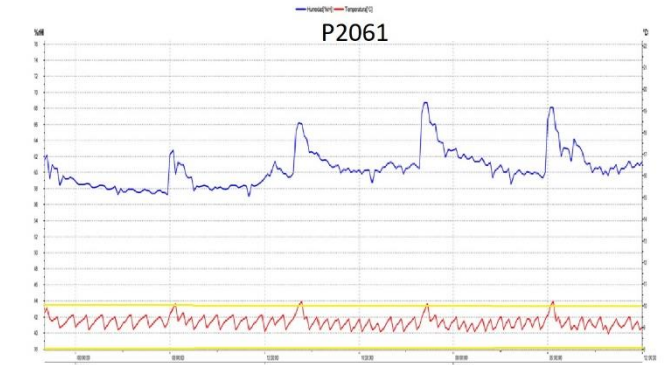
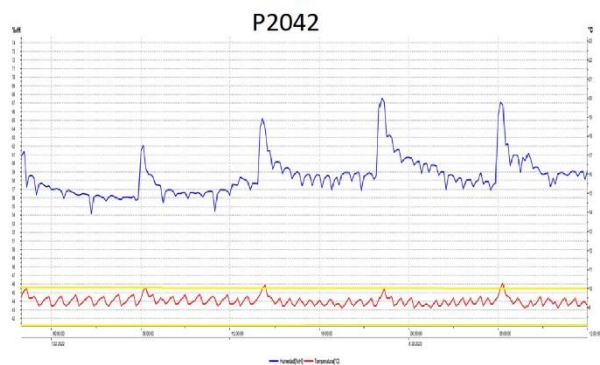
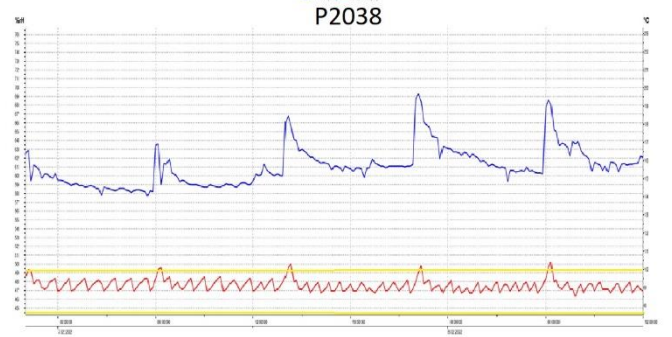
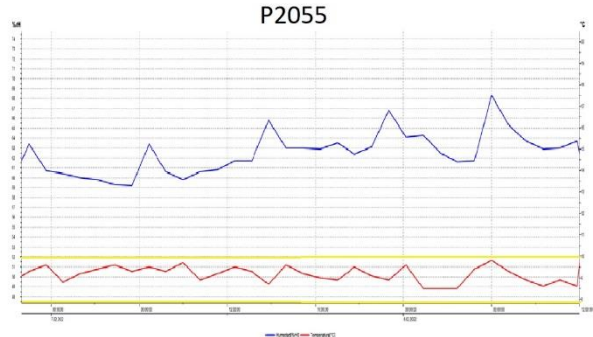
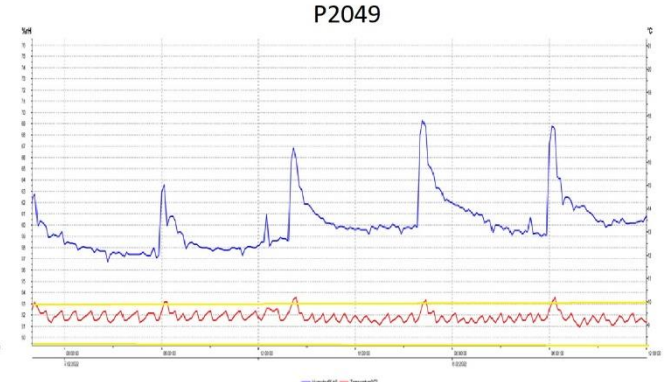
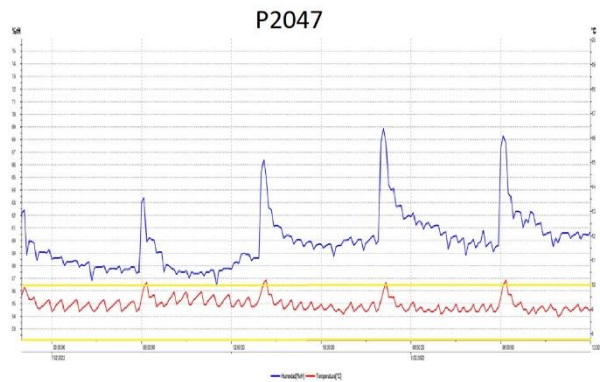
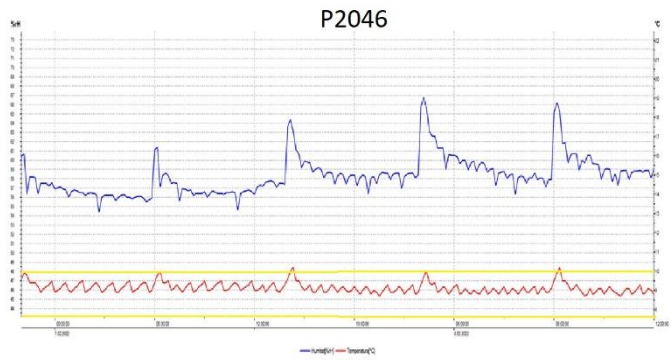
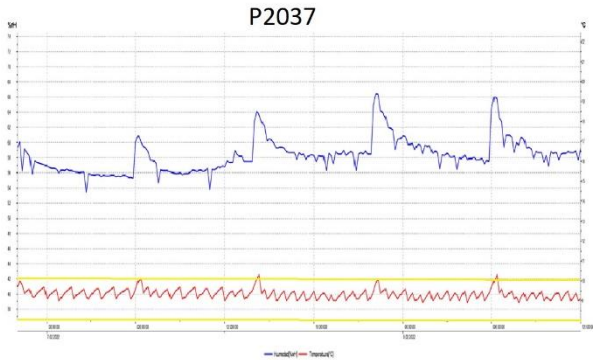
Table 4.2								
Set Point Temperature				7 °C				
DL number (Map)	DL ID number	SAP code	Min. Temp. Recorded (°C)	Max. Temp. Recorded (°C)	Mean temp. (°C)	Standard deviation	Pass/Fail	Date
01	P2037	10274327	8,90	10,30	9,34	0,25	Pass	
04	P2038	10270419	8,50	10,40	9,11	0,31	Pass	
06	P2042	10270414	9,00	10,30	9,35	0,23	Pass	
05	P2046	10274328	8,70	10,20	9,12	0,26	Pass	
03	P2047	10270425	8,70	10,20	9,18	0,27	Pass	
07	P2049	10270424	8,90	10,20	9,34	0,22	Pass	
08	P2055	10274347	8,50	9,80	9,14	0,34	Pass	
02	P2061	10274324	8,70	10,20	9,24	0,28	Pass	
<b>Mapping period starts at:</b>						Date: Hour:		
<b>Mapping period ends at:</b>						Date: Hour:		
<b>Checked by:</b>						Date: Hour:		

As shown in Table 4.2 and in the tables obtained from all the dataloggers, the cool room remains within the range established by the manufacturer and, at the same time, within the established functional range. Although the maximum temperature recorded overpasses the established range, this occurs only in a few pics, the other moments the temperature maintains constant. Therefore, it can be affirmed that the cool room is working properly and the equipment generates cold air within the range established by the manufacturer.

Annex 5 shows the graphs of each datalogger and some summaries of what can be observed in each of the results obtained.

Finally, after analyzing the results, it could be observed that all the points give more or less similar values, but the point where the datalogger P2042 is located has been chosen as critical because it is an elevated position, where the cold air does not tend to go, and moreover, this point is located in front of the door so that on working days, as the door is constantly opening and closing, the air tends to go through the door, for this reason this position 6 has been chosen as critical point.

# OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### 4.5. ALARM VERIFICATION

---

List all alarms that contain the different parts of the computer. For temperature alarm systems, there should be one high alarm test and one low alarm test. If the system also has an event alarm system – for example a door open alarm – this should also be tested.

Table 5.1			
Test	Operation	Function Properly	
N/A			
Checked by:		Date:	

The cool room does not have operation alarms, it only has a flammable gas detection alarm. Its operation works as is shown below.

- When the set maximum temperature is reached, which is the set temperature, the cooling equipment starts cooling the room.
- When the minimum temperature is reached, the cooling equipment stops cooling the room.

### 4.6. POWER FAILURE TEST

---

The objective of the test sequence is to establish and record:

- The length of time during which the installation can maintain the specified temperature range following a power failure – this known as the holdover time.
- How long it takes the installation to recover within the specified range once power is restored.

Datalogger ID number (SAP code)	Power off Time temp. was within range (hh:mm)	Power on Time to recover within range (hh:mm)
N/A	N/A	N/A
Checked by:		Date:

The power failure test has not been possible because the cold room stores critical raw materials, which if they exceed a certain temperature can be flammable and can be dangerous. For this reason, the room cannot be stopped and allowed to come to room temperature and then turn on the equipment and see how long it takes to cool the chamber, because it is dangerous for certain raw materials to be at room temperature.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### 4.7. PERSONNEL TRAINING

---

Review that the procedures have been read by the user. In case of new equipment, PQ will be reviewed (**Attachment 3**).

### 5. DEVIATIONS

---

In the event of non-compliant results, record any deviations in **FOR-QA-006: Deviation/Non-Conformity Registration**. In the table below, list and monitor for corrective action and possible retesting.

DOCUMENT#	DESCRIPTION	Corrective Actions/ Reasons corrective action is not required	Closing date of proposed action
N/A	N/A	N/A	N/A

### 6. ATTACHMENTS

---

The following table provides a list of each of the attachments associated with the protocol and serves as verification.

Attachment	Title
1	Test Equipment
2	Deviation Report Form
3	Protocol Training Form
4	Graphs Extracted from Dataloggers
5	Conclusion Statement

Other supporting documents can be attached during Installation Qualification if it's needed.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### ATTACHMENT 1: TEST EQUIPMENT

Document all test equipment that are used in the execution of this Operational Qualification. All test equipment must be in current calibration.

DL ID number	Description of measurement equipment	Serial/model number	Last calibrated date	Next calibration date
P2037	TESTO 175H1	40366070/606	22/06/2021	22/06/2022
P2038	TESTO 175-H2	38205524/707	22/06/2021	22/06/2022
P2042	TESTO 175-H2	38204747/706	22/06/2021	22/06/2022
P2046	TESTO 175-H2	38212673/801	22/06/2021	22/06/2022
P2047	TESTO 175-H2	38205732/707	22/06/2021	22/06/2022
P2049	TESTO 175-H2	20016413/309	22/06/2021	22/06/2022
P2055	TESTO 175H1	40371708/612	22/06/2021	22/06/2022
P2061	TESTO 175T1	44622244	22/06/2021	22/06/2022

**OPERATIONAL QUALIFICATION PROTOCOL  
(OQ) – COOL ROOM**

**ATTACHMENT 2: DEVIATION REPORT FORM**

In case of deviation/non-conformity you must fill in **FOR-QA-006: Deviation/Non-Conformity Registration**.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

### ATTACHMENT 3: PROTOCOL TRAINING FORM

Review that the staff involved has received appropriate training in **FOR-RH-001: Control Assistance**

#### **ATTACHMENT 4: GRAPHS EXTRACTED FROM DATALOGGERS**

In this attachment you can see all the graphs obtained from dataloggers and a short explanation of the results obtained.

The results of each graph follow the line shown in table 4.1 of the report. The first graph is that of datalogger P2037 and the last one is that of datalogger P2061.

In addition, each datalogger has 2 graphs of the results obtained.

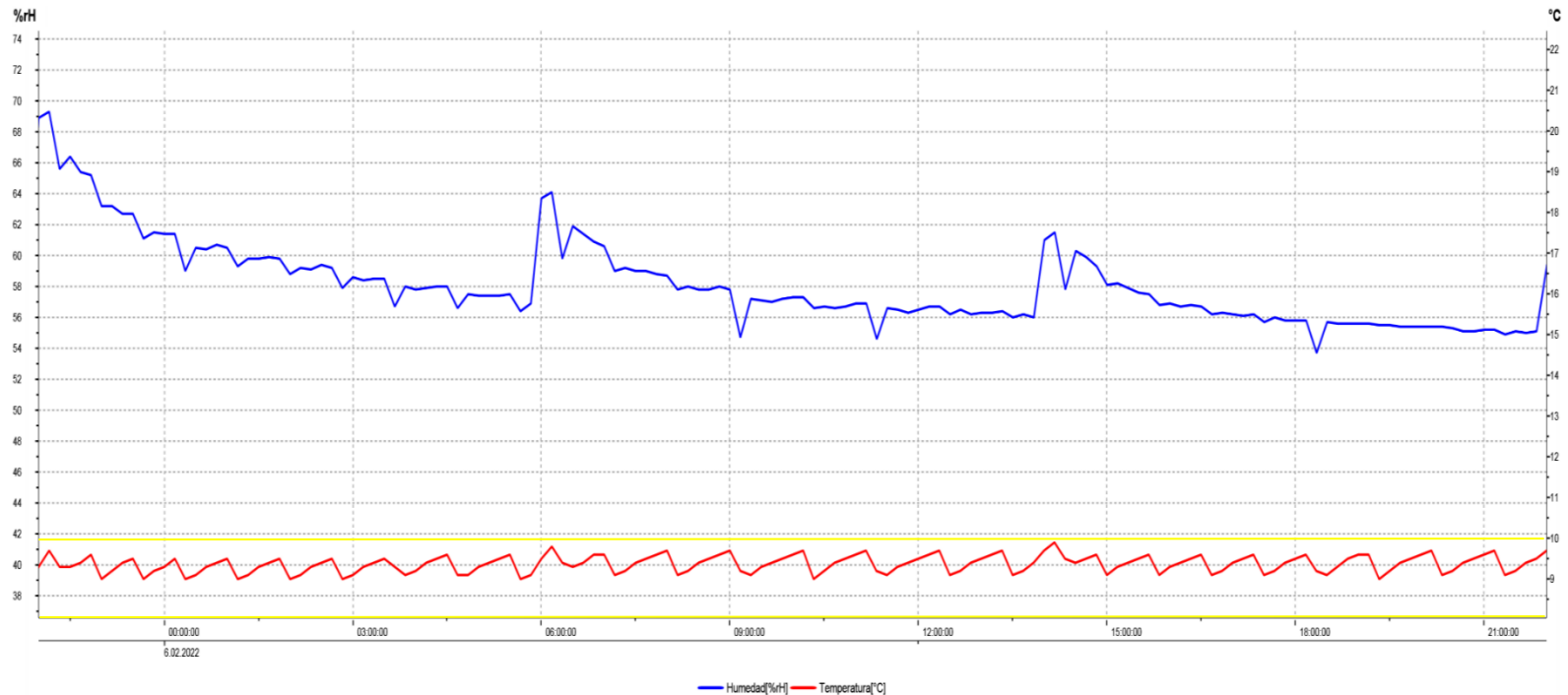
The first graph is without opening the doors of the room to be able to observe how it is maintained all the time at a constant temperature and close to the setpoint temperature that has been established.

The second graph shows the behavior of the temperature during the two working days, i.e., the factory works normally from Monday to Friday, with some Saturdays on demand, so it is more important to look at this graph. Therefore, it is important to observe the behavior of this equipment and verify that the temperature it generates inside the room is within the manufacturer's range and within the range established by the company.

Once this is explained, the graphs obtained for all the dataloggers at each point are shown below.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

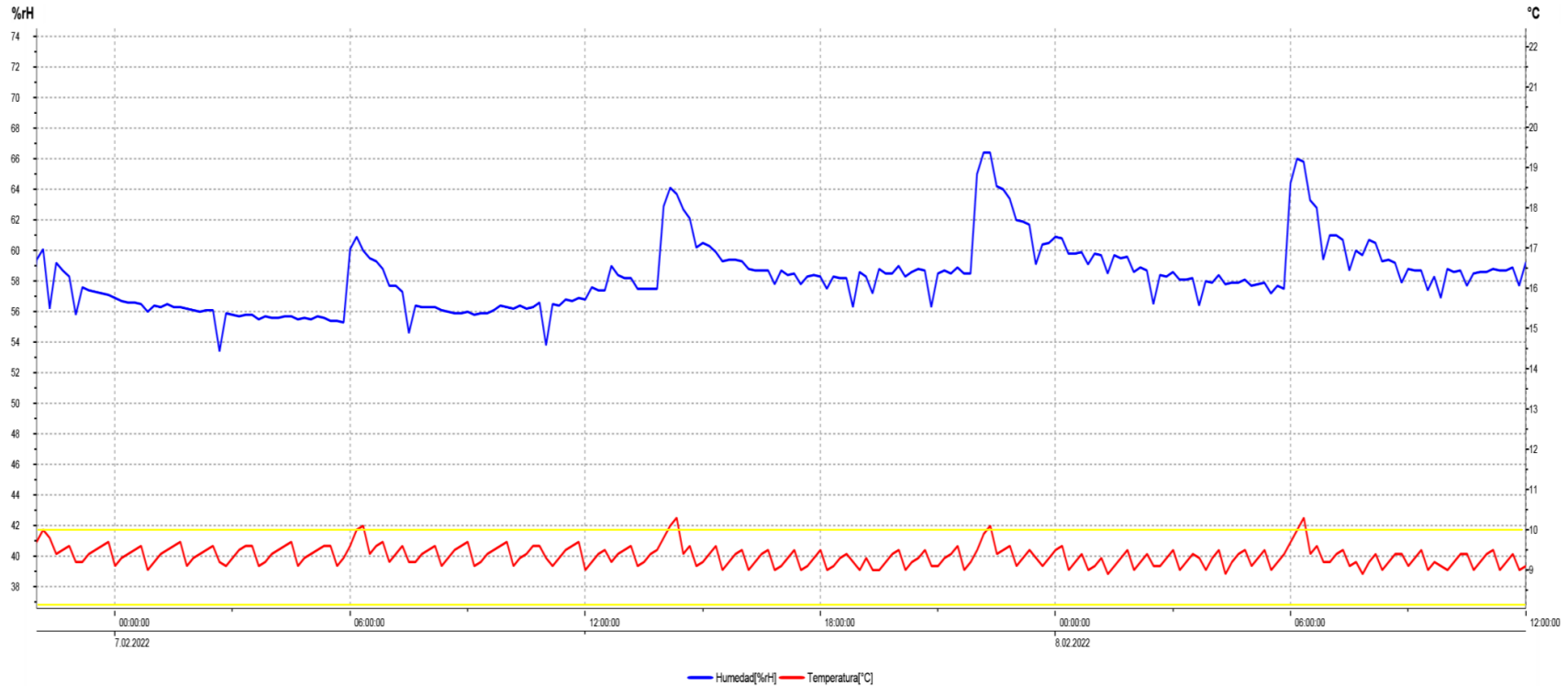
- **P2037**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9.5 °C, and with few temperature spikes, even though the cold room is closed.

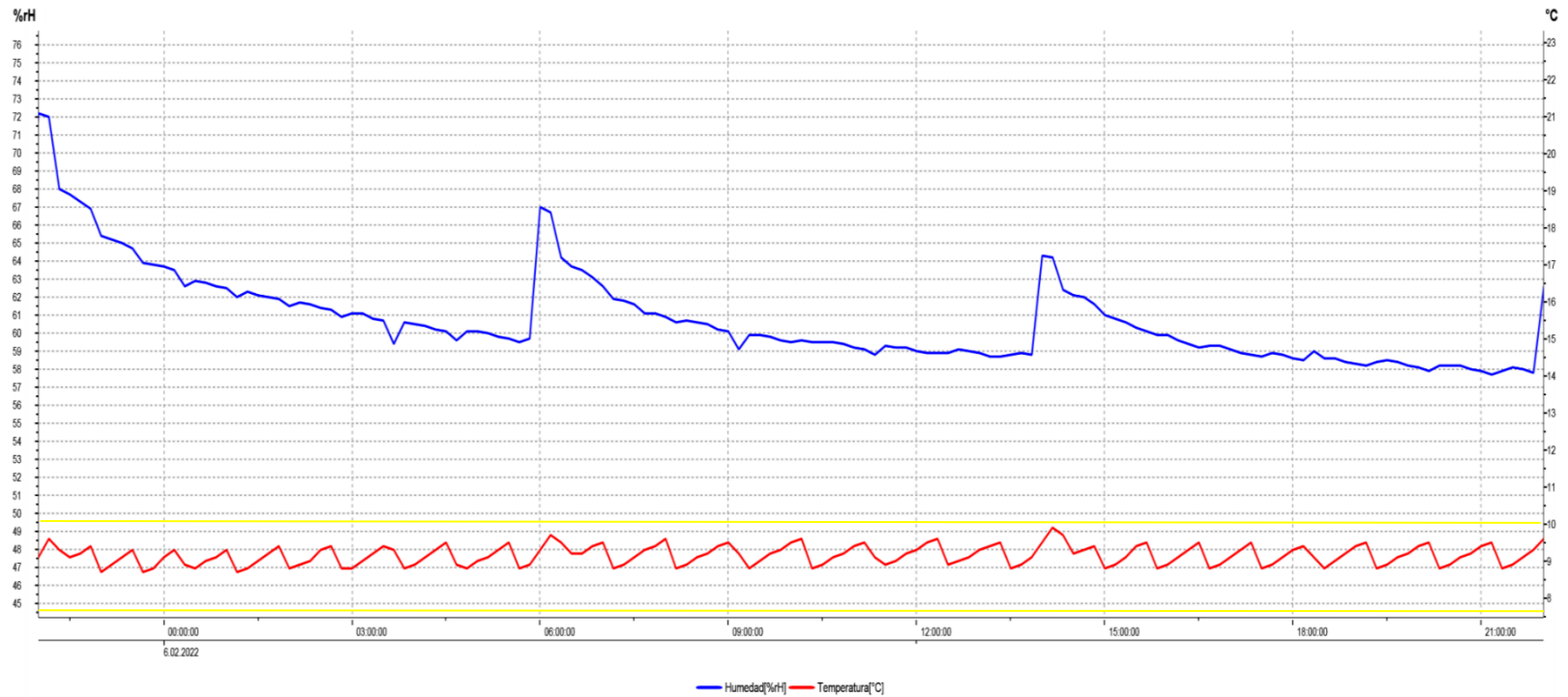
## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22. As can be seen, the room temperature remains constant, around 9.5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

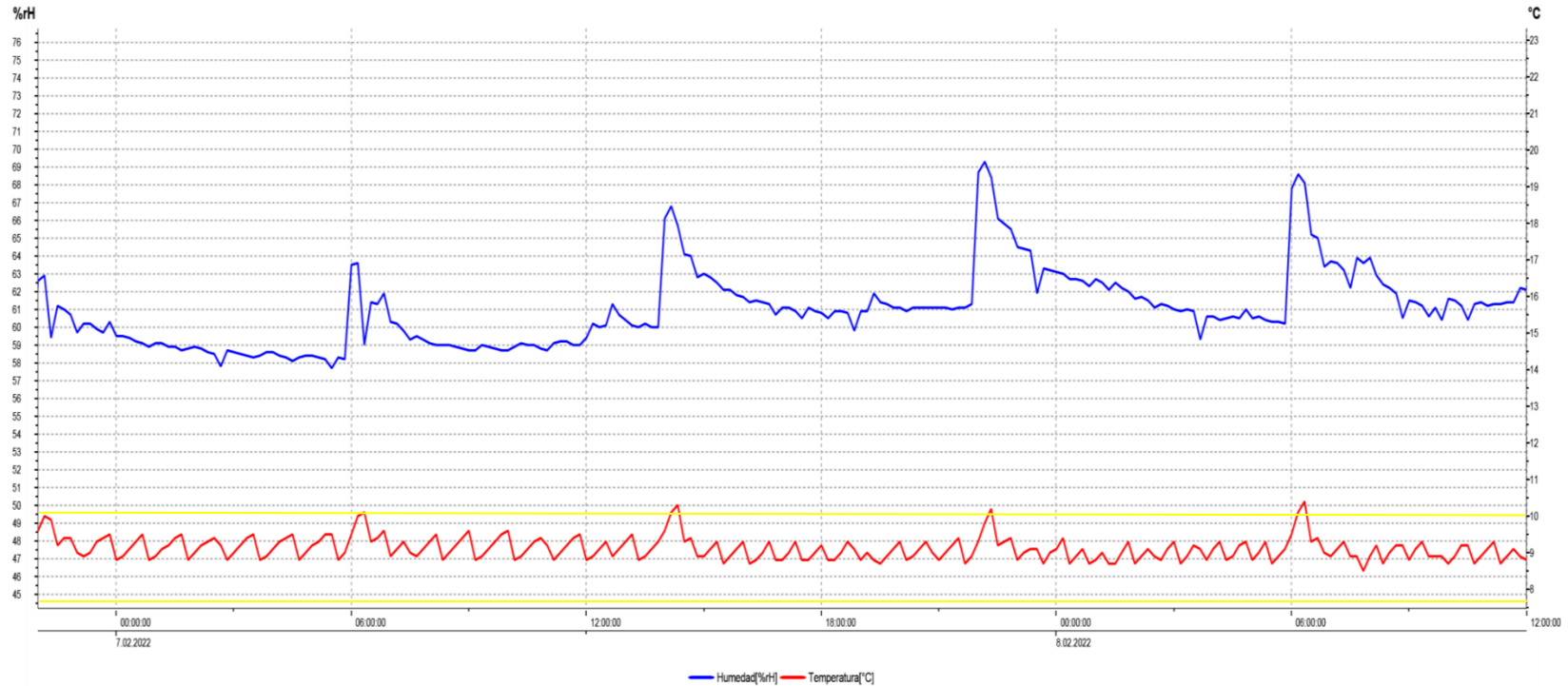
- **P2038**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

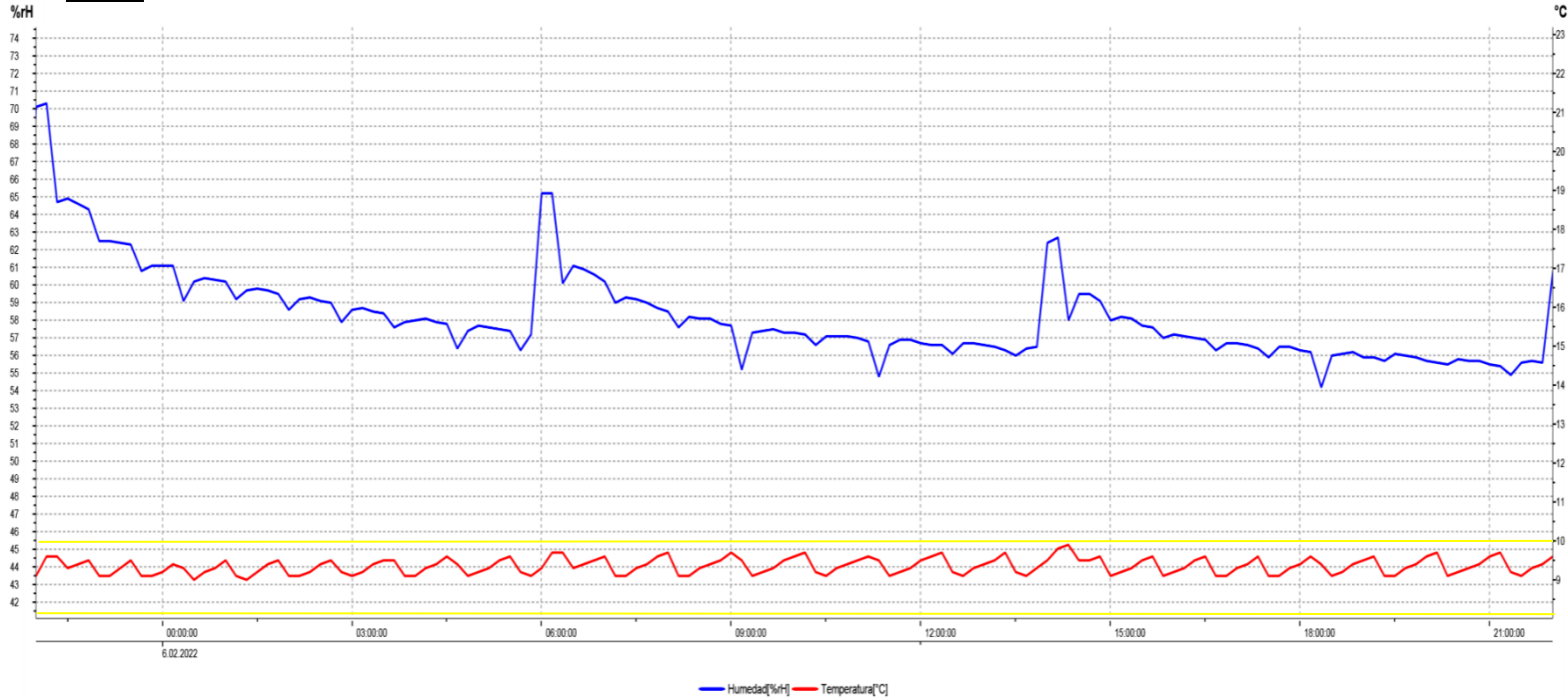
## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22. As can be seen, the room temperature remains constant, around 9 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains fairly constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

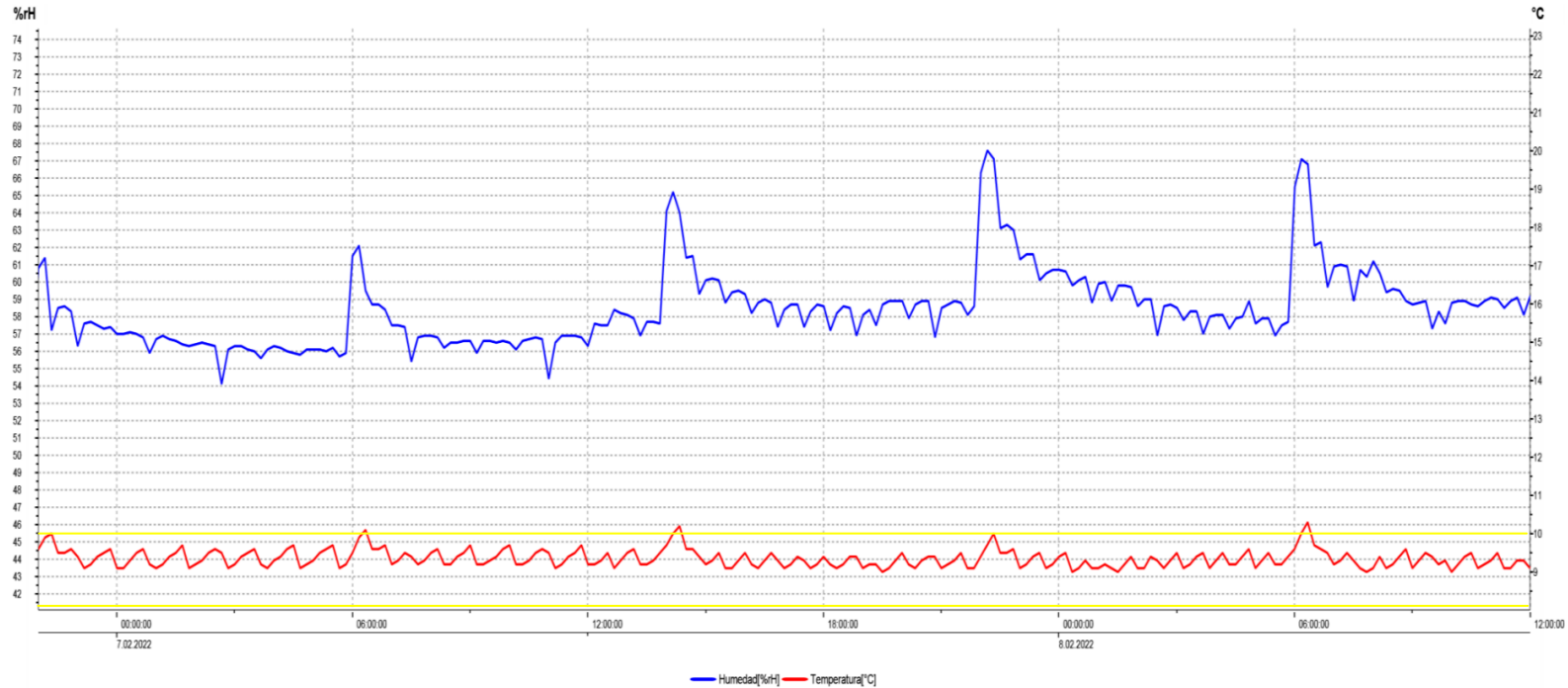
• **P2042**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

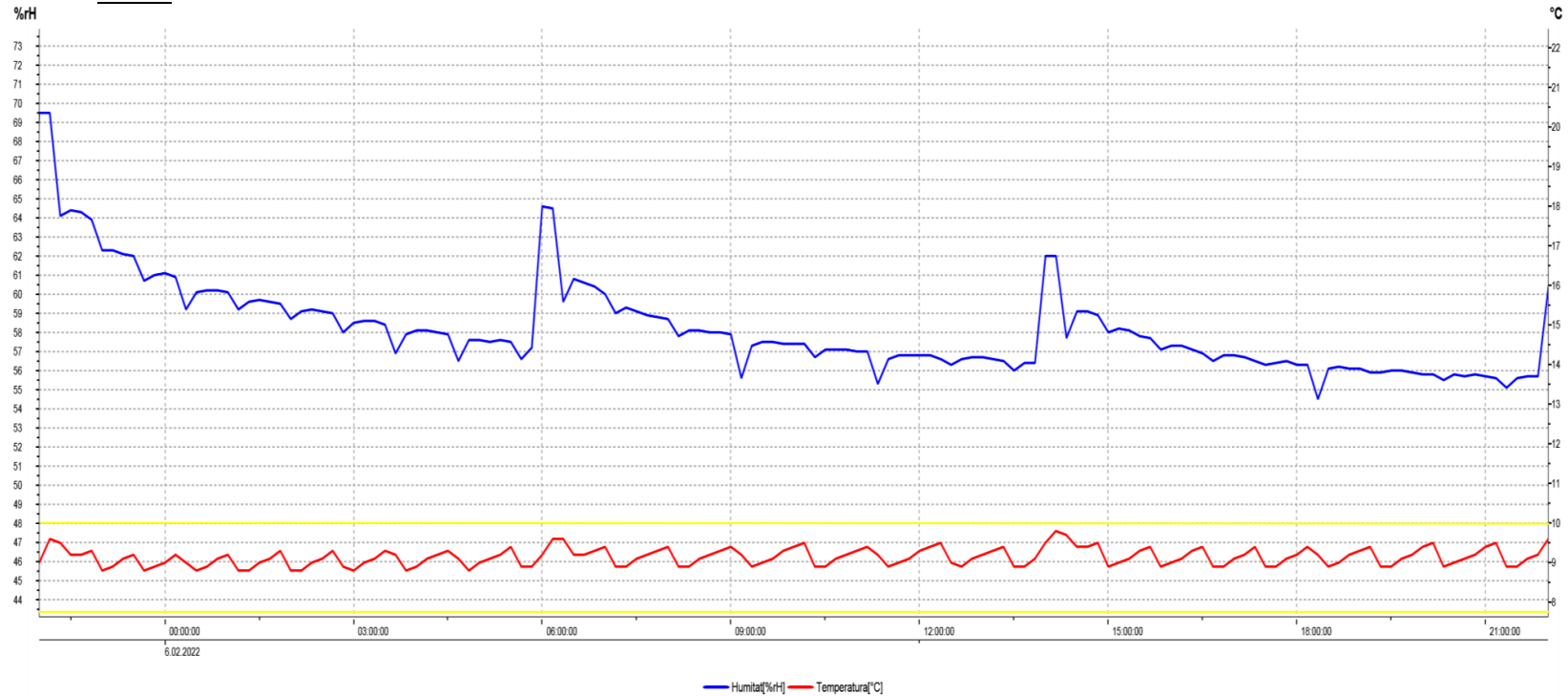
## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22. As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains fairly constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

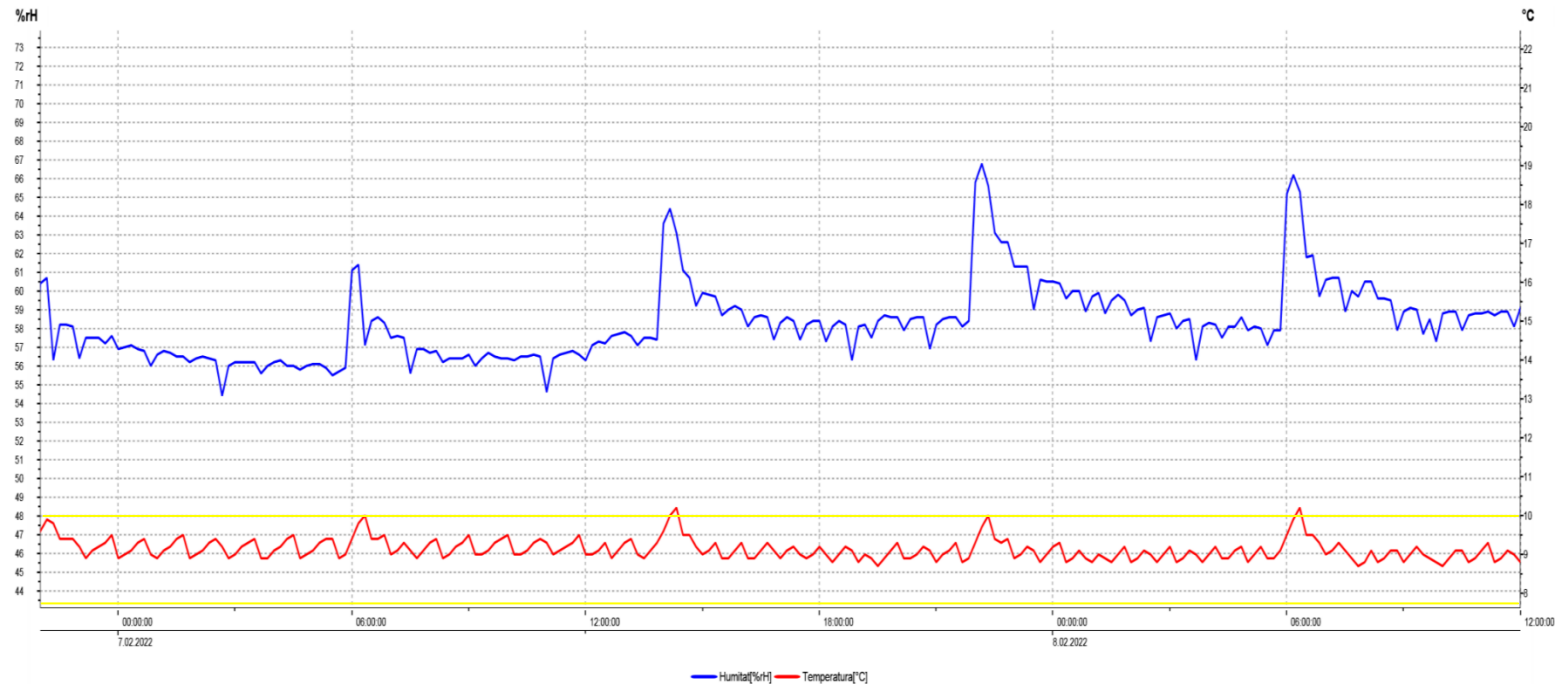
• **P2046**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

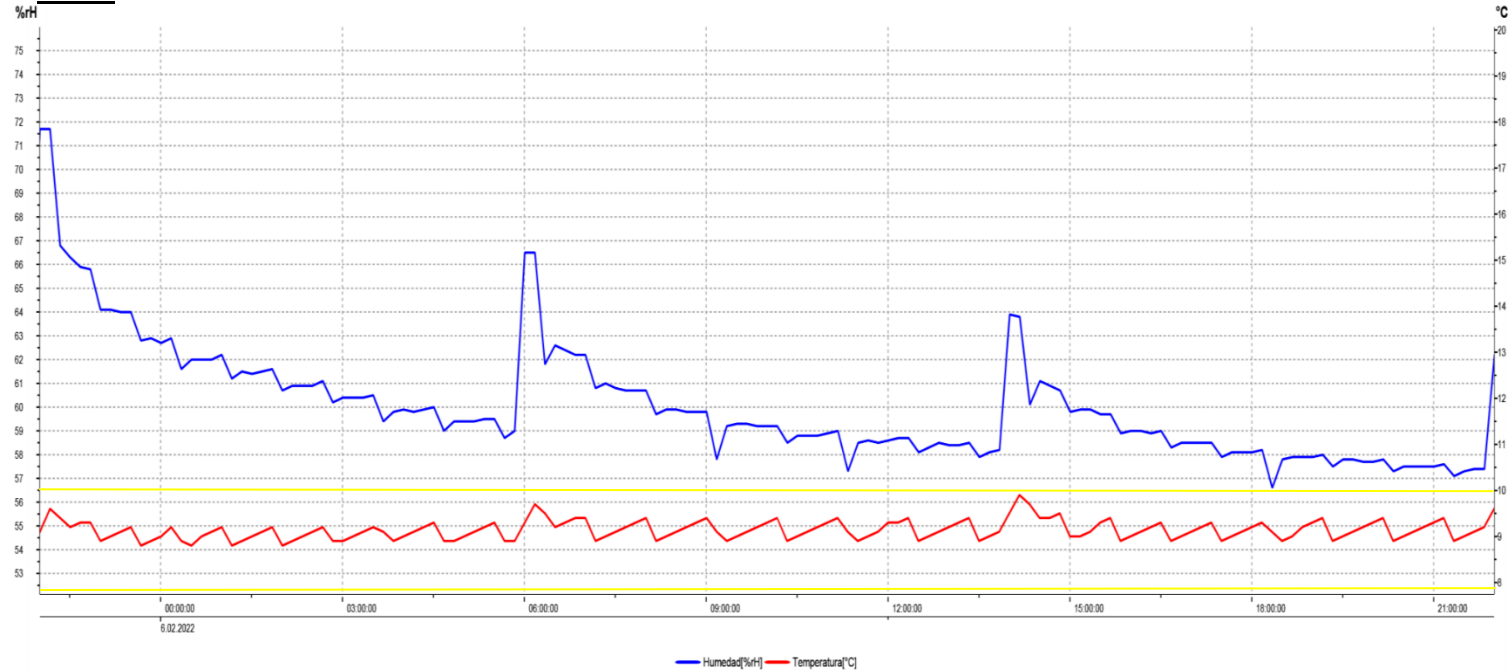
## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22. As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

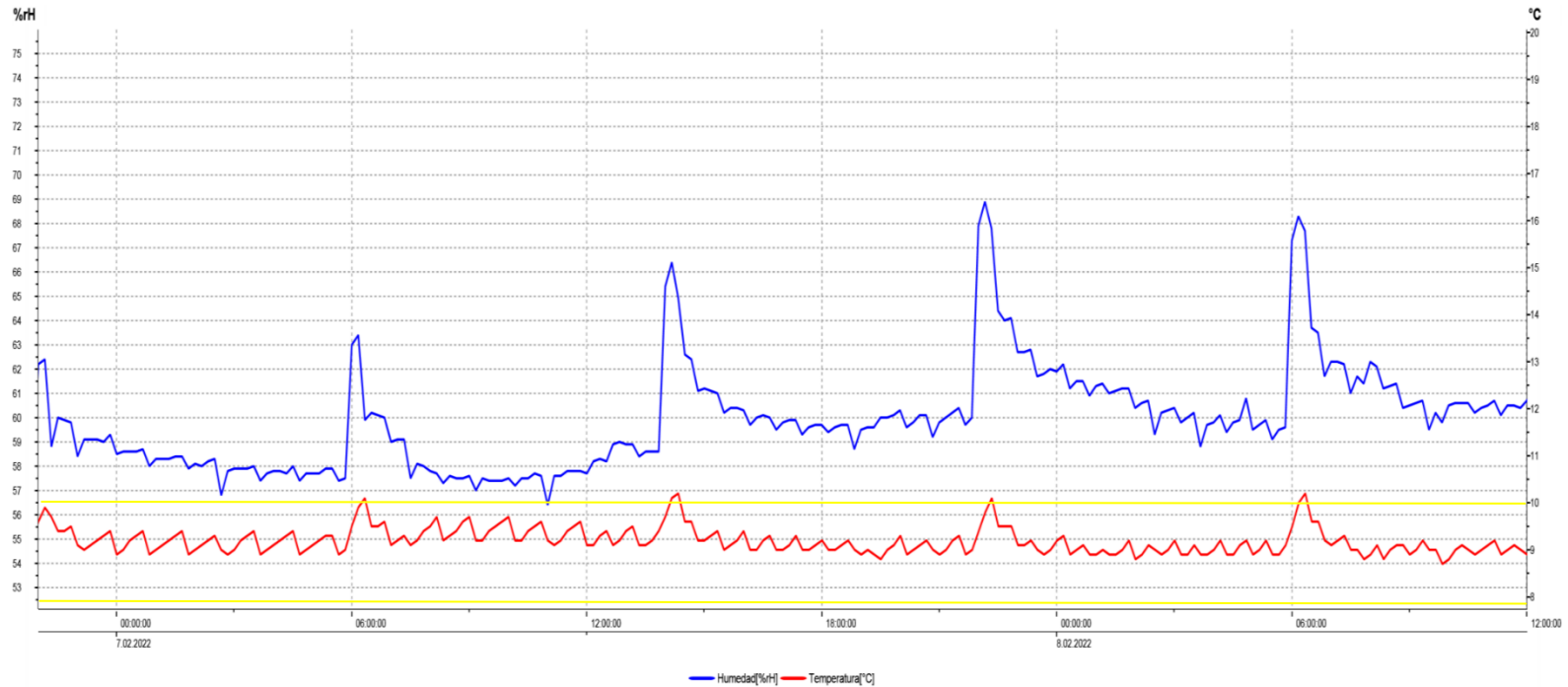
- P2047**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

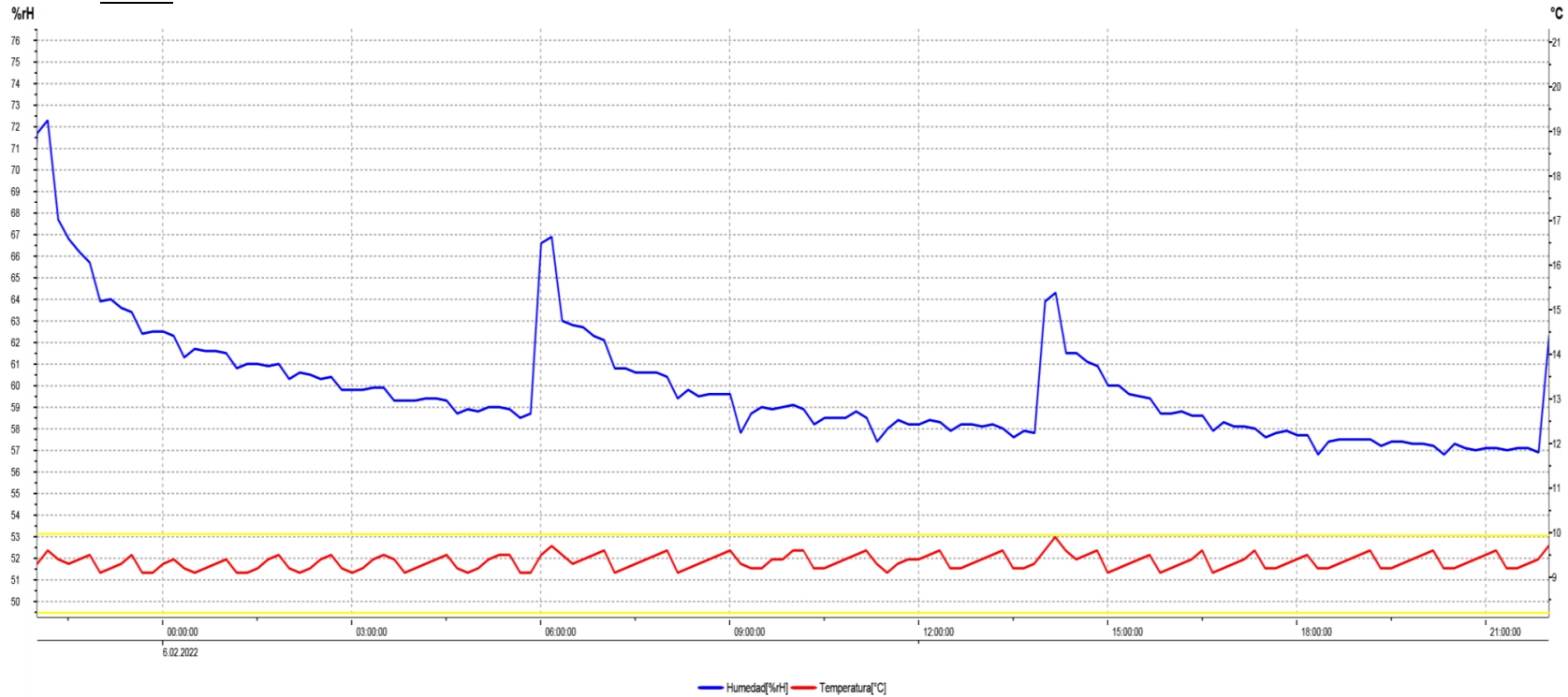


This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22.

As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains constant.

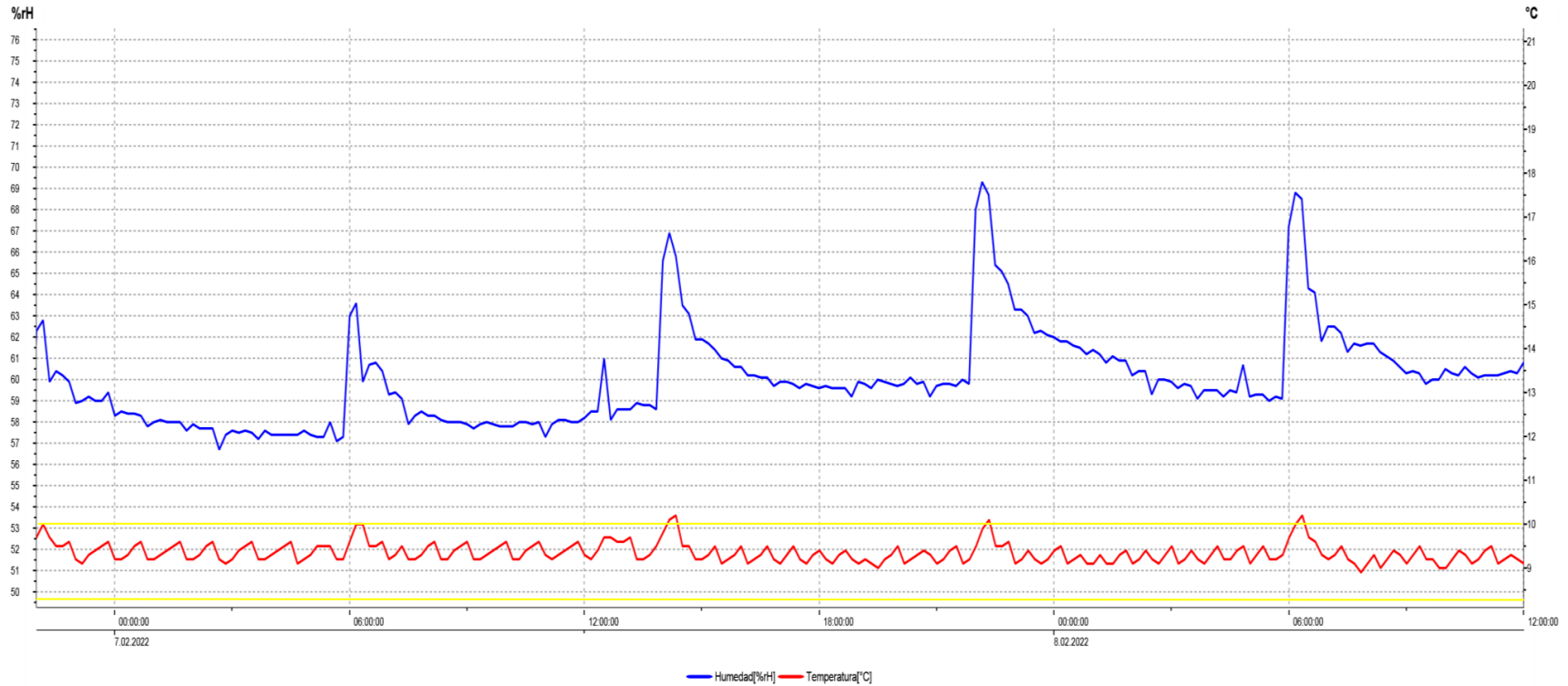
## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

- **P2049**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22. As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

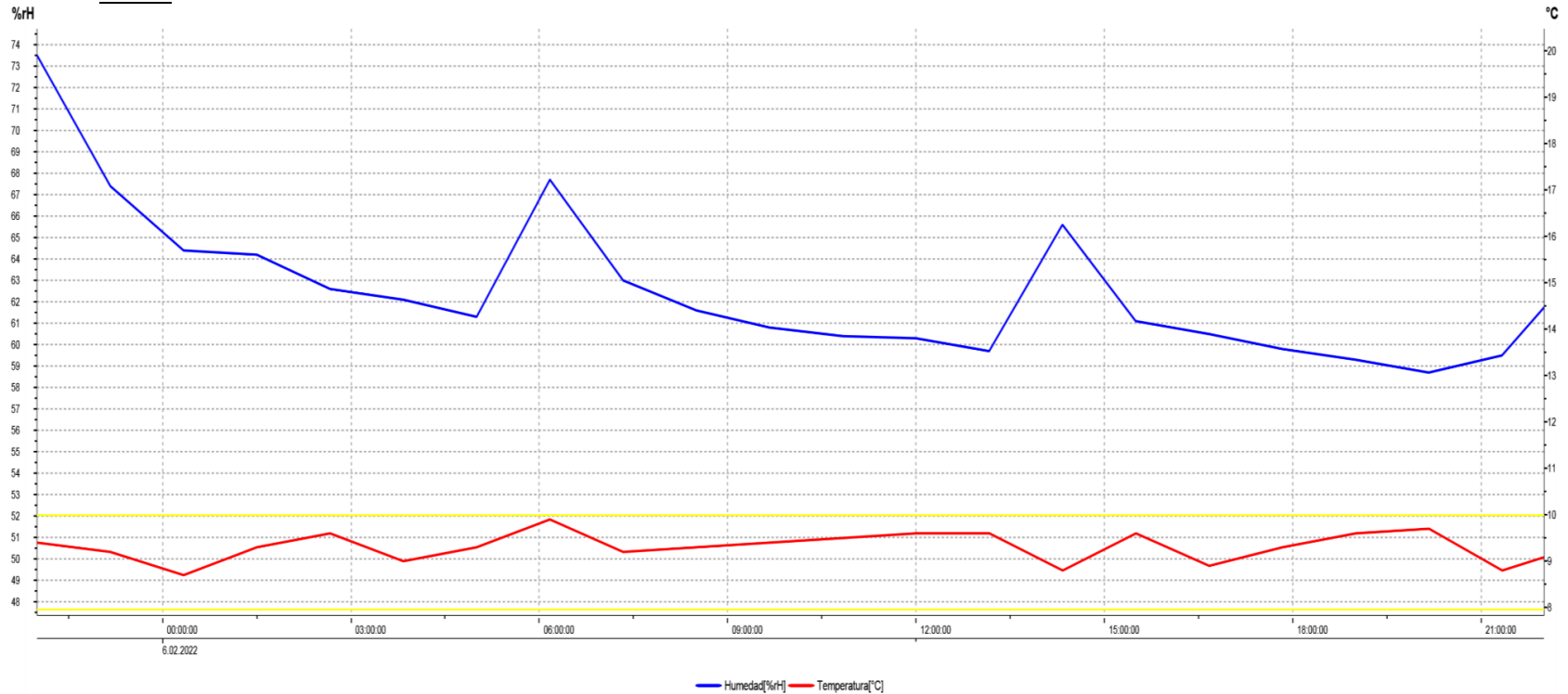


This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22.

As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains fairly constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

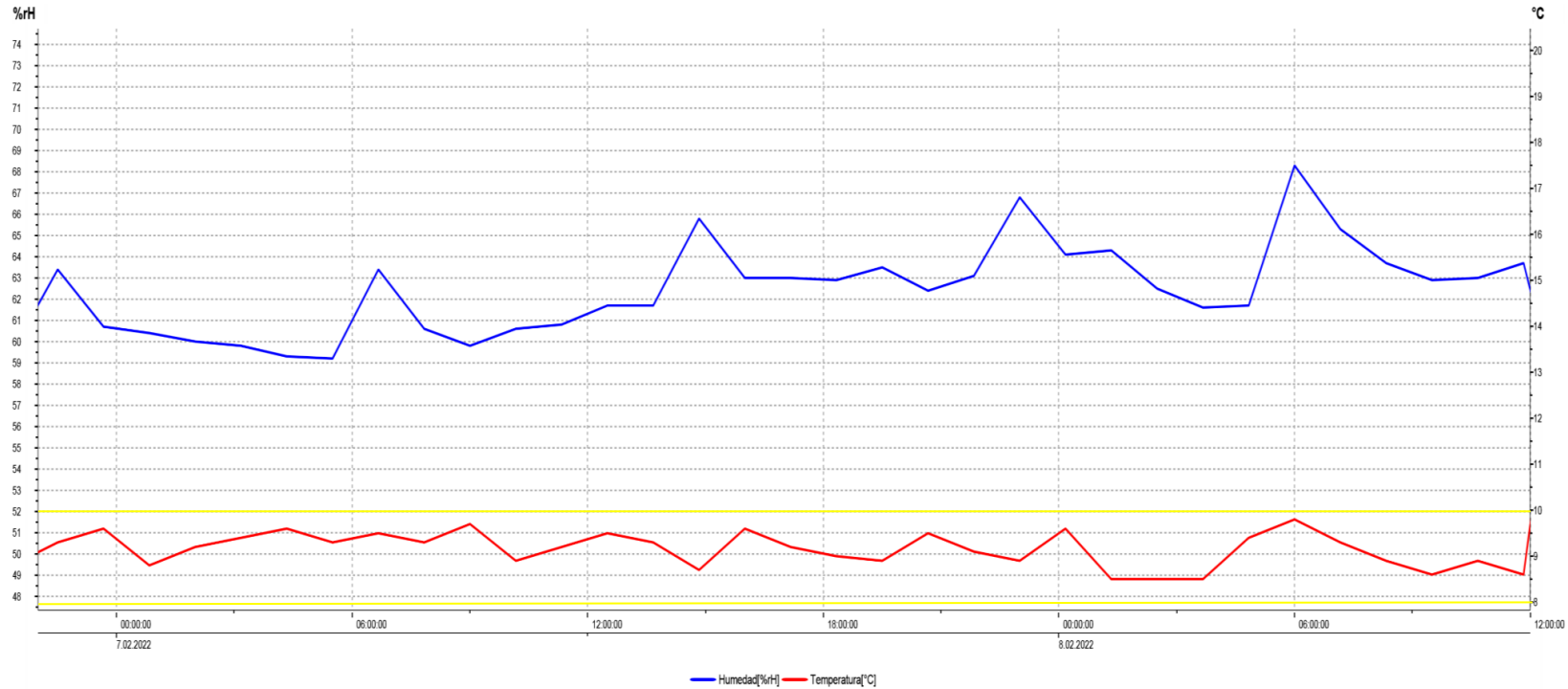
- **P2055**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

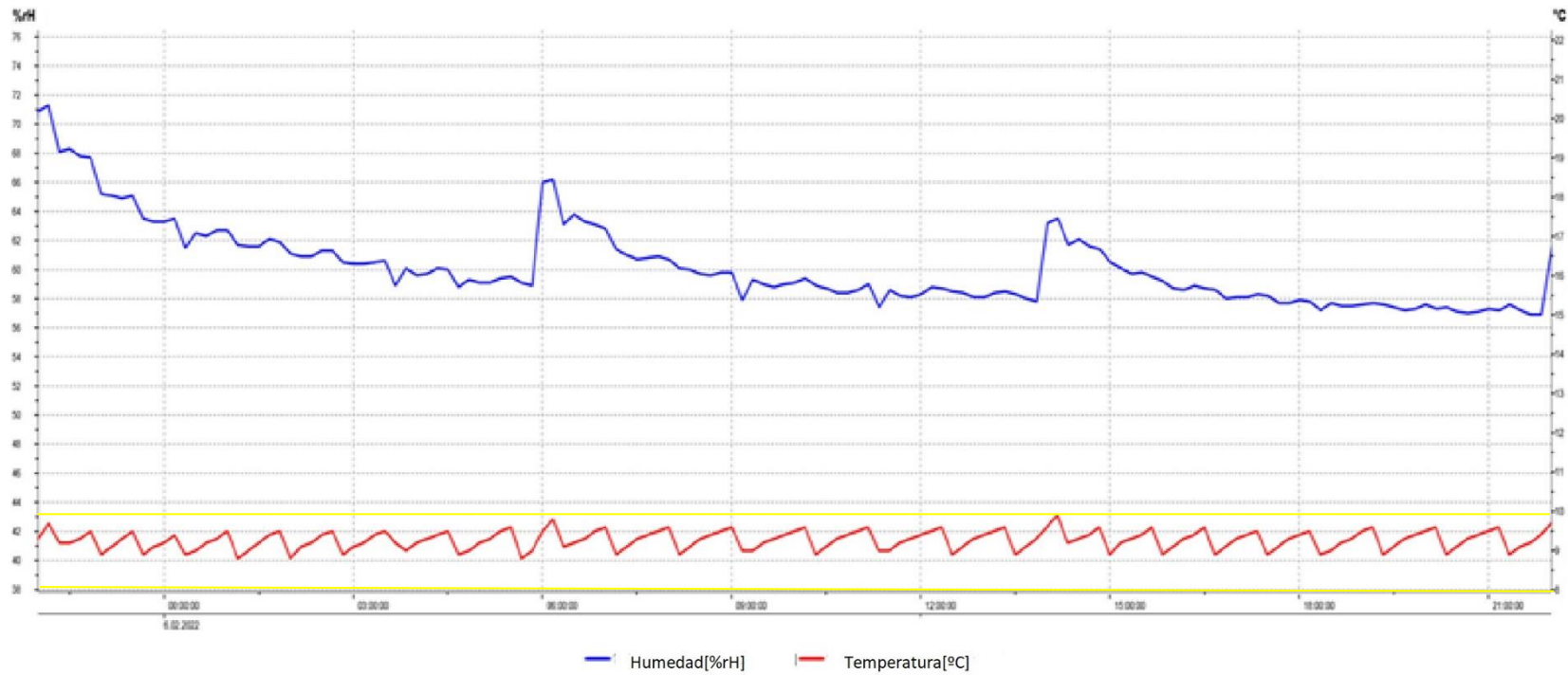


This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22.

As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains fairly constant.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM

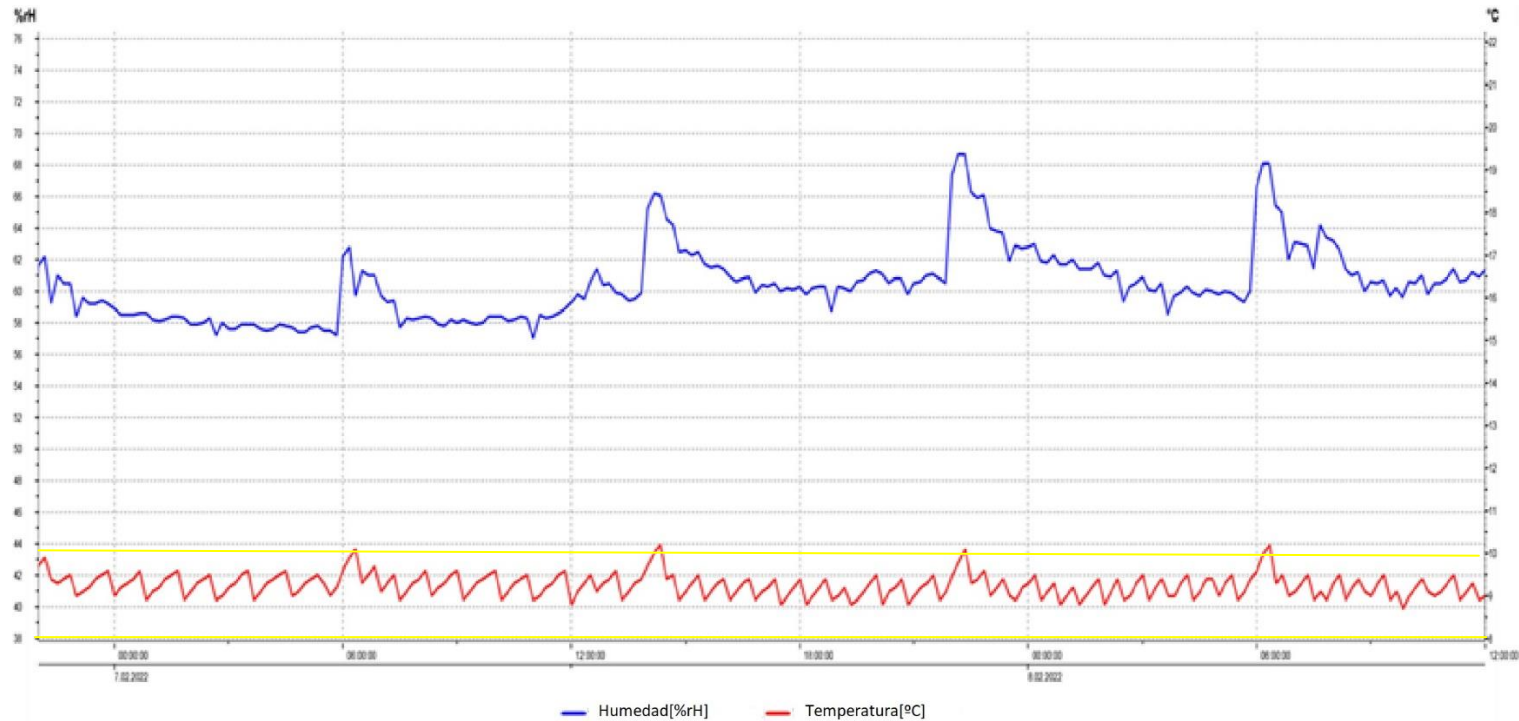
- **P2061**



This graph shows the non-opening of the cold storage doors. This non-opening of doors occurred from 22:30 hours on 5/02/22 until 21:00 hours on 6/02/22.

As can be seen, the temperature of the room remains constant, around 9 °C, and with few temperature spikes, even though the cold room is closed.

## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – COOL ROOM



This chart shows one week of cold room work. This working day took place from 00:00 on 7/02/22 until 12:00 on 8/02/22.

As can be seen, the room temperature remains constant, around 9,5 °C, and with some more temperature peaks than the previous graph but that is because this graph is from a normal working week, for this reason the peaks are more frequent and yet the temperature remains constant.

**ATTACHMENT 5: CONCLUSION STATEMENT**

The Operational Qualification of the noted equipment stands complete. Any Deviations to the OQ are identified as a Deviation and attached with resolution requirements defined and timing if applicable.

Comments:

**Final decision:** Complies

Does not comply

Performed by: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_

Date: \_\_\_\_\_



## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – ASTRAMATIC REVERSE OSMOSIS

# Operational Qualification Protocol (OQ)- ASTRAMATIC REVERSE OSMOSIS – DATA ACQUISITION

REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [OQ -10270304\_ASTRAMATIC]



## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		13/04/2022 (11:50) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8000 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca 4	
			Anti-incrustante: Marca 1	
			Bisulfito: Marca 1	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.	Sosa: 1100 ml/h		
			Anti-Incrustante: 500 ml/h		
			Bisulfito: 1250 ml/h		
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar		
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar		
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,16 bar		
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar		
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar		
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	7 bar		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	52,8 µS/cm
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,5
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,11 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,1 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,2 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	4,6 µS/cm

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	5068 l/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	1 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	17,54 µΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4963 l/h
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		19/04/2022 (9:02) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8000 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca 1	
			Anti-incrustante: Marca 1	
			Bisulfito: Marca - A	

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación Osmosis</i> los cabales de las 3 bombas y anotar su valor.	Sosa: 1100 ml/h	
			Anti-Incrustante: 560 ml/h	
			Bisulfito: 950 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,11 bar	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	7 bar	

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 $\mu\text{S/cm}$ - 200 $\mu\text{S/cm}$	Observar y anotar el valor de conductividad que da el indicador AT-77002	108,7 $\mu\text{S}$	
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	11,5	
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,175 bar	
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,2 bar	
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,8 bar	
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 $\mu\text{S/cm}$ - 200 $\mu\text{S/cm}$	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	19 $\mu\text{S}$	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4951 l/h	
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,8 bar	
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar	
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	21,8 MΩ	
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4837 l/h	
Revisado por:	Hora y Día:			

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Día y hora - Turno de Mañana/Tarde		19/04/2022 (16:14) - Tarde		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	9000 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca 1	
			Anti-Incrustrante: Marca 1	
			Bisulfito: Marca P	

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cables de las 3 bombas y anotar su valor.	Sosa: 1100 ml/h	
			Anti-Incrustante: 560 ml/h	
			Bisulfito: 950 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,11	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	7 bar.	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	102,2 µS
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	11,5
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,21 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,2 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,8 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	19,2 µS

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla <i>Salida Osmosis</i> el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4914 L/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,8 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla <i>ED</i> el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	25,8 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla <i>ED</i> el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4816 e/h.
Revisado por:	Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Día y hora - Turno de Mañana/Tarde		20/04/2022 (13:16) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8500 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca A	
			Anti-Incrustante: Marca P	
			Bisulfito: Marca P	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.	Sosa: 600 ml/h	
			Anti-Incrustante: 560 ml/h	
			Bisulfito: 960 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,16 bar	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	7 bar	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	64,8 $\mu$ S
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,9
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,305 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,5 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,8 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	2,3 $\mu$ S

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4911 e/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	3 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	1 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	24,73 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4579 e/h
Revisado por:	Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Dia y hora - Turno de Mañana/Tarde		20/04/2022 (17:34) - Tarde.		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	9000 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca A	
			Anti-Incrustrante: Marca P	
			Bisulfito: Marca V	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.	Sosa: 600 ml/h Anti-incrustante: 560 ml/h Bisulfito: 950 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,16 bar.	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	7 bar	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	57,6 µS
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,9
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	2,285 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,5 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,8 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla ED/ el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	2,3 µS

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FI-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4909 L/h	
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	3 bar	
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	1 bar	
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	21,73 MΩ	
Caudal de agua a la salida de los EDI (FI-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4713 L/h	
Revisado por:	Hora y Día:			

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		29/04/2022 ( 9:29 ) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8500 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca "4"	
			Anti-Incrustante: Marca "D"	
			Bisulfito: Marca "P"	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

				Sosa: 850 ml/h Anti-Incrustante: 560 ml/h Bisulfito: 950 ml/h	
			Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.		
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar		Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar		Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar		Observar y anotar el valor de presión que da el indicador PI-77001	4,0 bar	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar		Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar		Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar		Observar y anotar el valor de presión que da el indicador PI-77017	7 bar	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	34,7 $\mu$ S
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	9,9
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	2,955 bar.
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10 bar.
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar en la pantalla ED/ el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	6,1 $\mu$ S

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	5093 l/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,4 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar.
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	0,53 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4908 l/h
Revisado por:	Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Dia y hora - Turno de Mañana/Tarde		24/04/2022 (16:10) - Tarde		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8500 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,6 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca "G"	
			Anti-incrustante: Marca "D"	
			Bisulfito: Marca "P"	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación Osmosis</i> los cabales de las 3 bombas y anotar su valor.	Sosa: 1000 ml/h Anti-Incrustante: 560 ml/h Bisulfito: 950 ml/h
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,12 bar
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7 bar
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	6,5 bar

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	43,5 $\mu$ S
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	2,935 bar.
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 $\mu$ S/cm - 200 $\mu$ S/cm	Observar en la pantalla ED/ el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	5,6 $\mu$ S

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla <i>Salida Osmosis</i> el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	5107 e/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,5 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla <i>EDI</i> el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	0,96 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla <i>EDI</i> el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4992 e/h
Revisado por:	Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Día y hora - Turno de Mañana/Tarde		28/04/2022 (17:53) - Tardp		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8500 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,6 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca "I"	
			Anti-incrustante: Marca "I"	
			Bisulfito: Marca "V"	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

				Sosa: 1050 ml/h Anti-Incrustante: 560 ml/h Bisulfito: 950 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> <i>Osmosis</i> los cabales de las 3 bombas y anotar su valor.			
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013		4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014		4,2 bar	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77001		4,15 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015		10 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016		7,5 bar	
		Observar y anotar el valor de presión que da el indicador PI-77017		7 bar	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	70,5 µS	
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,9	
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,229 bar	
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12,5 bar	
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,5 bar	
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	2,3 µS	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4955 l/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	3 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	1 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	21,27 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4753 l/h
Revisado por.	Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Dia y hora - Turno de Mañana/Tarde		29/04/2022 (d: 17) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	1000 L	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,8 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: Marca "A"	
			Anti-Incrustrante: Marca "A"	
			Bisulfito: Marca "A"	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.	Sosa: 1050 ml/h Anti-Incrustante: 560 ml/h Bisulfito: 990 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar	
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar	
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,13 bar	
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar	
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar	
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77017	6,5 bar	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	62,7 µS
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,9
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,125 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,5 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla ED/ el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	2,3 µS

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4973 e/h
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,9 bar
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	21,27 MΩ
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4953 e/h
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		02/05/2022 (11:22) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Aire comprimido del manómetro inicial	0 bar – 12 bar	Observar y anotar la presión que da el manómetro de inicio del proceso de osmosis	4 bar	
Nivel de agua en D-77131	0 L – 10000 L	Observar y anotar el nivel del tanque que alimenta los equipos de osmosis. Tanque D-77131	8500 l	
Presión de entrada del filtro doble (PI-77011)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77011	4,7 bar	
Presión de salida del filtro doble (PI-77012)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77012	4 bar	
Agentes químicos (bisulfito, antiincrustante y sosa cáustica)	0 % - 100 %	Observar y anotar en qué nivel se encuentran los depósitos de los agentes químicos. Anotar la letra del depósito en que esta el nivel.	Sosa: <i>Nunca 3"</i>	
			Anti-incrustante: <i>Nunca 3L"</i>	
			Bisulfito: <i>Nunca 7,5L"</i>	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

				Sosa: 1050 ml/h Anti-Incrustante: 560 ml/h Bisulfito: 990 ml/h	
Presión de entrada de los filtros de seguridad (PI-77013)	Cabal máximo de 4 L/h	Observar en la pantalla <i>Dosificación</i> Osmosis los cabales de las 3 bombas y anotar su valor.			
Presión de salida de los filtros de seguridad (PI-77014)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77013	4,2 bar		
Presión en PI-77001	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77014	4,2 bar		
Presión a la entrada de la primera etapa de la primera fase osmótica (PI-77015)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77001	4,13 bar		
Presión a la entrada de la primera etapa del segundo paso osmótico (PI-77016)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77015	10 bar		
Presión de salida del agua de la primera etapa osmótica (PI-77017)	0 bar – 25 bar	Observar y anotar el valor de presión que da el indicador PI-77016	7,5 bar		
		Observar y anotar el valor de presión que da el indicador PI-77017	6,5 bar		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Conductividad del agua a la entrada del segundo paso osmótico (AT-77002)	0,05 µS/cm - 200 µS/cm	Observar y anotar el valor de conductividad que da el indicador AT-77002	63,6 µS
pH del agua a la entrada del segundo paso osmótico (pH-77001)	0 - 14 pH	Observar en la pantalla Osmosis Paso 2 el valor del pH que marca el indicador pHIT-2 y anotar su valor.	10,9
Pressure at PI-77002	0 bar - 10 bar	Observar y anotar el valor de presión que da el indicador PI-77002	3,10 bar
Presión en la entrada de la segunda etapa del primer paso osmótico (PI-77022)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77022	12 bar
Presión en la entrada de la segunda etapa del segundo paso osmótico (PI-77023)	0 bar - 25 bar	Observar y anotar el valor de presión que da el indicador PI-77023	10,5 bar
Conductividad del agua a la salida del segundo paso osmótico (AT-77003)	0,05 µS/cm - 200 µS/cm	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-1 y anotar su valor.	29 µS

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Caudal de agua a la salida del segundo paso osmótico (FT-77002)	2000 L/h – 80000 L/h	Observar en la pantalla Salida Osmosis el valor del cabal de permeado que marca el indicador FI-1 y anotar su valor.	4997 l/h	
Presión de entrada de EDIs (PI-77019)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77019	2,8 bar	
Presión de salida de EDIs (PI-77020)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77020	0,8 bar	
Conductividad del agua a la salida de los EDI (AT-77004)	0,05 µS/cm - 200 µS/cm O 20 MΩ - 0,005 MΩ	Observar en la pantalla EDI el valor de la conductividad que marca el indicador CI-2 y anotar su valor.	23,27 MΩ	
Caudal de agua a la salida de los EDI (FT-77003)	2000 L/h – 80000 L/h	Observar en la pantalla EDI el valor del cabal de permeado que marca el indicador FI-4 y anotar su valor.	4933 l/h	
Revisado por:	Hora y Día:			



## OPERATIONAL QUALIFICATION PROTOCOL (OQ) – DISTRIBUTION LOOPS

# Operational Qualification Protocol (OQ)- DISTRIBUTION LOOPS – DATA ACQUISITION

REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [OQ -10272015\_ *DISTRIBUTIONLOOPS*]



## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		13/04/2022 (11:50) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 88% D-77202: 87%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,2 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,2 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,5 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	330 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	338 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	398 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	154,1 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	146,1 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espeque a travague	
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 32,1	
			Conductividad (µS): 0,128	
Revisado por:		Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		19/04/2022 (9:33) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 77% D-77202: 76%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,5 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,2 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,4 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	358 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	360 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	324 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	153,4 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	152,1 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espera a rifangul	
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 32,4	
			Conductividad (µS): 0,729	
Revisado por.		Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		19/04/2022 (16:23) - Tarde		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 74% D-77202: 72%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,2 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,5 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	349 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	353 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	207 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	153,1 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	151,7 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Exagera a 180 w/m <sup>2</sup>	
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 34,8	
			Conductividad (µS): 0,651	
Revisado por:		Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		20/04/2022 (9:07) - Mañana		Valido/Nulo
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 93% D-77202: 89%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	5 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	377 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	346 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	351 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	153,4 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	147,0 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	65,0 W/m <sup>2</sup>
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 26,9
			Conductividad (µS): 0,55
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		20/04/2022 (15:20) - Tarde		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 96% D-77202: 95%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,2 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,2 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	1 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	339 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	344 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	289 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	153,4 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	146,9 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	80,1 W/m <sup>2</sup>
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 27,3
			Conductividad (µS): 9527
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		24/04/2022 (9:24) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L -- 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 90 % D-77202: 89 %	
Presión de salida del bucle 1 (PI-77211)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,2 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,6 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	335 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	327 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	357 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	155,6 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	147,4 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espera arranque	
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 27,9	
			Conductividad (µS): 0,505	
Revisado por:		Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Dia y hora - Turno de Mañana/Tarde		23/04/2022 ( 15:40 ) ~ Tarde		
Parámetro de control	Rango de aceptación	Aciaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 82 % D-77202: 83 %	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,2 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,4 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	350 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	336 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	365 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	155,4 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	147,3 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espera arranque
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 26,6
			Conductividad (µS): 9486
Revisado por:		Hora y Día:	

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		22/04/2022 ( 9:40 ) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L -- 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 90 % D-77202: 89 %	
Presión de salida del bucle 1 (PI-77211)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,2 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar -- 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,5 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	363 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	344 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	375 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	154,7 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	146,9 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Fuera de rango
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 28,9
			Conductividad (µS): 0,520
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		25/04/2022 (9:37) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 78% D-77202: 77%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3,29 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,29 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,9 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	371 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	350 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	336 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	156,3 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	147,0 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espectro airaunque
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 16,0
			Conductividad (µS): 359
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Dia y hora - Turno de Mañana/Tarde		26/04/2022 ( 4:31 ) - Mañana		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/Nulo
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 87% D-77202: 86%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	2,8 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,5 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	385 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	344 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	382 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	154,13 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	146,15 W/m <sup>2</sup>	
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Enseña oxígeno	
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 37,7	
			Conductividad (µS): 4,31	
Revisado por:		Hora y Día:		

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Día y hora - Turno de Mañana/Tarde		26/04/2022 (16:17) - Tarde		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 85% D-77202: 84%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	3 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,4 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	362 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	340 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	355 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	153,1 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	146,0 W/m <sup>2</sup>
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Empaca arriague.
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 54,4
			Conductividad (µS): 3,130
Revisado por:	Hora y Día:		

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		54/05/2022 (13:23) - Tarde (Fin de semana)		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla <i>Depósitos de Stock</i> el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 84% D-77202: 83%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	2,6 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,1 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,2 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	1048 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	1008 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	413 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**


Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	Espera arranque
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	Espera arranque
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espera arranque
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 77,8
			Conductividad (µS): 0,819
Revisado por:		Hora y Día:	

## OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST

Día y hora - Turno de Mañana/Tarde		14/05/2022 (9:09) - Mañana (Fin de semana)		
Parámetro de control	Rango de aceptación	Aclaración de la toma de valores	Resultado obtenido	Valido/No
<b>Parámetros de funcionamiento críticos con la demanda de agua de la planta</b>				
Niveles de los depósitos de acumulación de agua (D-77201 y D-77202)	0 L – 50000 L	Observar en la pantalla Depósitos de Stock el valor del que marca el indicador de los depósitos en porcentaje y anotar su valor.	D-77201: 84% D-77202: 83%	
Presión de salida del bucle 1 (PI-77211)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77211	2,6 bar	
Presión de salida del bucle 2 (PI-77212)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77212	4,1 bar	
Presión de salida del bucle 3 (PI-77203)	0 bar – 10 bar	Observar y anotar el valor de presión que da el indicador PI-77203	2,2 bar	
Control del ozono en el bucle 1 (AT-77201)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77201	1036 mV	
Control del ozono en el bucle 2 (AT-77202)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77202	992 mV	
Control del ozono en el bucle 3 (AT-77203)	-1575 mV - +1575 mV	Observar y anotar el valor de ozono que da el indicador AT-77203	396 mV	

**OPERATIONAL VERIFICATION OF EQUIPMENT CHECK LIST**

Control de funcionamiento de la lámpara UVA 1 (UVA-77201)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77201	Espera arranque
Control de funcionamiento de la lámpara UVA 2 (UVA-77202)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77202	Espera arranque
Control de funcionamiento de la lámpara UVA 3 (UVA-77203)	0 W/m <sup>2</sup> - 180 W/m <sup>2</sup>	Observar y anotar el valor de la lámpara UVA-77203	Espera arranque
Lecturas del TOC	No hay establecidos valores máximos de lectura	Observar y anotar los valores del TOC	TOC (ppb): 77.7
			Conductividad (µS): 0,764
Revisado por:	Hora y Día:		

	<b>USER REQUIREMENTS SPECIFICATIONS (URS)</b>
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## User Requirements Specifications (URS) – BÁSCULA Y DETECTOR DE METALES

**REVLON LOCATION: EL PLA DE SANTA MARIA**  
 Document#: [URS\_BASCULA\_DETECTORDEMETALES]



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanroma	Project Engineer Intern		
Oscar Sancho	Project Engineer		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Javier Guarnido	Production Manager		

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### 1. DESCRIPCIÓN DE LA INSTALACIÓN

#### Descripción de la instalación

Se requiere una báscula y un detector de metales para el control de tubos de producto cosmético en distintos tamaños y pesos y para poder detectar algún metal sobrante o piezas sueltas. Se requiere un sistema de rechazo para eliminar los tubos de crema no adecuados para la venta final.

### 2. REFERENCIAS

#### Referencias

- GAMP (buenas prácticas de fabricación automatizada)
- Directiva de máquinas 2006/42/CE

### 3. ESPECIFICACIONES DE LA INSTALACIÓN

En las secciones siguientes se registran las especificaciones de la instalación, el valor de la especificación necesaria y sus unidades correspondientes.

Especificación de la instalación	Valor	Unidades
Báscula aceptable para tubos de crema con unas dimensiones de:	L30 x A15 x A15	mm
	L200 x A50 x A50	mm
Báscula aceptable para tubos de crema de un peso de entre:	5 - 500	g
Báscula aceptable para tubos de crema con un rendimiento de entre:	70 – 80	Unidades/minuto
Detector de metales capaz de detectar metales encapsulados y piezas sueltas para tubos de crema con unas dimensiones:	L30 x A15 x A15	mm
	L200 x A50 x A50	mm
Detector de metales y báscula con capacidad de rechazo de los tubos de crema no validos	-	-

Altura de trabajo entre:	800 - 900	mm
Extensión total del equipo aproximada	2000	mm

#### **4. DOCUMENTOS ENTREGADOS POR EL PROVEEDOR**

Los documentos que se le piden al proveedor para obtener más información sobre el equipo son los siguientes

<b>Documentos</b>
<ul style="list-style-type: none"> <li>- Certificado de garantía (mínimo 2 años) conforme cumple con los parámetros detallados en la especificación - URS</li> <li>- Especificaciones técnicas de las máquinas de bascula y detector de metales</li> <li>- Manual de la máquina e instrucciones de las máquinas de bascula y detector de metales</li> </ul>

## Design Qualification (DQ) – BÁSCULA Y DETECTOR DE METALES

LOCALIZACIÓN REVLON: EL PLA DE SANTA MARIA

Documento#: [DQ\_BASCULA\_DETECTORDEMETALES]

### AUTORES REVLON:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanromà	Project Engineer Intern		
Oscar Sancho	Project Engineer		

### APROVADORES REVLON:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Javier Guarnido	Production Manager		

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## 1. OBJETIVO

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El objetivo de este documento es verificar que los Requerimientos de Usuario (URS) definidos para la báscula y un detector de metales para el control de tubos de producto son cubiertos por la solución propuesta.

La revisión de diseño es una actividad incluida en la etapa de análisis y diseño del sistema del Plan de Validación (VMP\_02).

La aprobación del presente documento supone la aceptación formal del diseño propuesto.

## 2. RESPONSABILIDADES

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Las responsabilidades específicas para este documento de cada uno de los grupos que conforman el equipo del proyecto son las siguientes:

Departamento	Revisión de Diseño		
	Elaboración	Revisión	Aprobación
Ingeniería	X	X	X
Producción		X	X
Quality Assurance		X	X

## 3. REVISIÓN DE DISEÑO

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Previamente a la emisión de la DQ, se ha emitido el documento de Requerimientos de Usuario (URS), en el que se recogen los diferentes requisitos para la implantación de Xxx.

Los resultados de dicha revisión se presentan a continuación en este documento.

URS Ref.	Especificación del URS	URS Cubierto?	Comentarios
1	Báscula aceptable para tubos de crema con unas dimensiones de: L30 x A15 x A15 mm y L200 x A50 x A50 mm	Si	-
2	Báscula aceptable para tubos de crema de un peso de entre 5 – 500 gr	Si	-
3	Báscula aceptable para tubos de crema con un rendimiento de entre 70 – 80 Unidades/minuto	Si	-
4	Detector de metales capaz de detectar metales encapsulados y piezas sueltas para tubos de crema con unas dimensiones: L30 x A15 x A15 mm y L200 x A50 x A50 mm	Si	-
5	Disponer de alarma (aviso) nivel de detergente bajo	Si	-
6	Detector de metales y báscula con capacidad de rechazo de los tubos de crema no validos	Si	-
7	Altura de trabajo entre 800 – 900 mm	Si	-
8	Extensión total del equipo aproximada de 2000 mm	Si	-

#### **4. OBSERVACIONES**


Tras la evaluación del cumplimiento de los requerimientos de usuario, se han identificado las siguientes observaciones.

<b>Referencia Observación</b>	<b>URS relacionado</b>	<b>Descripción</b>	<b>Evaluación y Acción Correctora</b>
N/A	N/A	N/A	N/A

#### **5. CONCLUSIONES**

Tras finalizar la revisión de la documentación aportada para la implantación de las de la báscula y el detector de metales se concluye que:

1. Todos requisitos evaluados en las ofertas pedidas a los diferentes proveedores cumplen con los requisitos comentados en la URS.

	<h2>USER REQUIREMENTS SPECIFICATIONS (URS)</h2>
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## User Requirements Specifications (URS) - TERMODESINFECTADORA

REVLON LOCATION: EL PLA DE SANTA MARIA

Document#: [URS\_TERMODESINFECTADORA]



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanroma	Project Engineer Intern		
Oscar Sancho	Project Engineer		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Javier Guarnido	Production Manager		

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## 1. DESCRIPCIÓN DE LA INSTALACIÓN

### Descripción de la instalación

Se instalará una máquina termodesinfectadora para limpiar y desinfectar todos los utensilios usados en la zona de limpieza del área de pesadas y del área de envasado.

## 2. REFERENCIAS

### Referencias

- 21 CFR Parte 11 para registros electrónicos
- Equipos de bioprocesamiento (ASME BPE 2012) [16]
- GAMP (buenas prácticas de fabricación automatizada)
- Directiva de máquinas 2006/42/CE

## 3. ESPECIFICACIONES DE LA INSTALACIÓN

En las secciones siguientes se registran las especificaciones de la instalación, el valor de la especificación necesaria y sus unidades correspondientes.

Especificación de la instalación	Valor	Unidades
Equipo preparado para agua desmineralizada	-	-
Programa para temperatura de servicio a 80 °C	-	-
Equipo con capacidad de secado	-	-
Material	Acero Inoxidable (preferiblemente 316 y/o 304)	-
Garantizar que la dosificación de los detergentes es correcta	-	-
Disponer de alarma (aviso) nivel de detergente bajo	-	-

Garantizar que no haya fugas	-	-
Medida exterior de la máquina de lavar, alto	940	mm
Medida exterior de la máquina de lavar, ancho	675	mm
Medida exterior de la máquina de lavar, fondo	685	mm
Medida de carga de la cesta superior, ancho	489	mm
Medida de carga de la cesta superior, fondo	440	mm
La/s bomba/s y/o válvulas deben ser de diseño sanitario para evitar la contaminación del agua	-	-
Diseño drenable – garantizar evacuación del agua – correcto drenaje	-	-

#### **4. DOCUMENTOS ENTREGADOS POR EL PROVEEDOR**

Los documentos que se le piden al proveedor para obtener más información sobre el equipo son los siguientes

Documentos
<ul style="list-style-type: none"> <li>- Certificado de garantía (mínimo 2 años) conforme cumple con los parámetros detallados en la especificación - URS</li> <li>- Especificaciones técnicas de la máquina termodesinfectadora</li> <li>- Manual de la máquina e instrucciones de mantenimiento y limpieza</li> </ul>

## Design Qualification (DQ) – TERMODESINFECTADORA

LOCALIZACIÓN REVLON: EL PLA DE SANTA MARIA

Documento#: [DQ\_TERMODESINFECTADORA]

### AUTORES REVLON:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanromà	Project Engineer Intern		
Oscar Sancho	Project Engineer		

### APROVADORES REVLON:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Javier Guarnido	Production Manager		

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## 1. OBJETIVO

El objetivo de este documento es verificar que los Requerimientos de Usuario (URS) definidos para la termodesinfectadoras del área de pesadas y el área de envasado son cubiertos por la solución propuesta.

La revisión de diseño es una actividad incluida en la etapa de análisis y diseño del sistema del Plan de Validación (VMP\_02).

La aprobación del presente documento supone la aceptación formal del diseño propuesto.

## 2. RESPONSABILIDADES

Las responsabilidades específicas para este documento de cada uno de los grupos que conforman el equipo del proyecto son las siguientes:

Departamento	Revisión de Diseño		
	Elaboración	Revisión	Aprobación
Ingeniería	X	X	X
Producción		X	X
Quality Assurance		X	X

## 3. REVISIÓN DE DISEÑO

Previamente a la emisión de la DQ, se ha emitido el documento de Requerimientos de Usuario (URS), en el que se recogen los diferentes requisitos para la implantación de Xxx.

Los resultados de dicha revisión se presentan a continuación en este documento.

URS Ref.	Especificación del URS	URS Cubierto?	Comentarios
1	Equipo preparado para agua desmineralizada	Si	-
2	Programa para temperatura de servicio a 80 °C	Si	-
3	Equipo con capacidad de secado	Si	-
4	Material de acero Inoxidable (preferiblemente 316 y/o 304)	Si	-
5	Garantizar que la dosificación de los detergentes es correcta	Si	-
6	Disponer de alarma (aviso) nivel de detergente bajo	Si	-
7	Garantizar que no haya fugas	Si	-
8	Medida exterior de la máquina de lavar, alto de 940 mm	Si	-
9	Medida exterior de la máquina de lavar, ancho de 675 mm	Si	-
10	Medida exterior de la máquina de lavar, fondo de 685 mm	Si	-

11	Medida de carga de la cesta superior, ancho de 489 mm	Si	-
12	Medida de carga de la cesta superior, fondo de 440 mm	Si	-
13	La/s bomba/s y/o válvulas deben ser de diseño sanitario para evitar la contaminación del agua	Si	-
14	Diseño drenable – garantizar evacuación del agua – correcto drenaje	Si	-

#### **4. OBSERVACIONES**

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Tras la evaluación del cumplimiento de los requerimientos de usuario, se han identificado las siguientes observaciones.


Referencia Observación	URS relacionado	Descripción	Evaluación y Acción Correctora
N/A	N/A	N/A	N/A

#### **5. CONCLUSIONES**

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Tras finalizar la revisión de la documentación aportada para la implantación de las termodesinfectadoras se concluye que:

1. Todos requisitos evaluados en las ofertas pedidas a los diferentes proveedores cumplen con los requisitos comentados en la URS.

	<b>USER REQUIREMENTS SPECIFICATIONS (URS)</b>
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## User Requirements Specifications (URS) – OSMOSIS INVERSA

**REVLON LOCATION: EL PLA DE SANTA MARIA**

Document#: [URS\_ *OSMOSISINVERSA*]



### REVLON AUTHORS:

Name	Title	Signed	Date
Abdó Barceló	Project Engineer		
Christian Sanroma	Project Engineer Intern		
Oscar Sancho	Project Engineer		

### REVLON APPROVERS:

Name	Title	Signed	Date
Rosa Gimeno	Quality Assurance Specialist		
Eduard Ibañez	Project Engineering Manager		
Javier Guarnido	Production Manager		

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## 1. DESCRIPCIÓN DE LA INSTALACIÓN

### Descripción de la instalación

Se instalará una planta de osmosis inversa parecida a la actual (Astramatic). Las características de la planta serian que la planta de osmosis para mas de un equipo EDI de producción de entre 7 y 8 m<sup>3</sup>/h con una calidad del agua inferior a 1,3 µS/cm.

## 2. REFERENCIAS

### Referencias

- GAMP (buenas prácticas de fabricación automatizada)
- Directiva de máquinas 2006/42/CEvel

## 3. ESPECIFICACIONES DE LA INSTALACIÓN

En las secciones siguientes se registran las especificaciones de la instalación, el valor de la especificación necesaria y sus unidades correspondientes.

Especificación de la instalación	Valor	Unidades
Tanque pulmon con nivel transparente y numeración, con boca de hombre para su inspección y limpieza y con capacidad de	5	m <sup>3</sup>
Material del tanque pulmón	Poliéster blanco	-
Dos bombas de alimentación con su cuadro eléctrico para la maniobra acopladas al tanque pulmón con un colector distribuidor de cuatro tomas. Cada bomba con un variador de frecuencia	-	-
El colector para la salida del tanque tiene que ser de	4	pulgadas
Un <i>bypass</i> para el tanque pulmón	-	-

Contador de entrada de la osmosis de	40	mm
Realización de la sanitización de la planta en la misma planta, tanto n las membranas como en el EDI.	-	-
Tanque cónico y de color blanco para las limpiezas	-	-
Trabajo paralelo de las dos osmosis cada 24 h. En caso de demanda elevada, que las dos se pongan en marcha.	-	-
Fuente de alimentación del EDI con potencia sobrada	-	-
Posibilidad de ampliar la instalación con colocación de nuevas membranas	-	-
Calidad de salida del agua en el segundo paso de osmosis entre	2-3	µS/cm
Producción entre	7-8	m <sup>3</sup> /h
Pantalla en frente de la otra instalación	-	-

#### **4. DOCUMENTOS ENTREGADOS POR EL PROVEEDOR**

Los documentos que se le piden al proveedor para obtener más información sobre el equipo son los siguientes

<b>Documentos</b>
<ul style="list-style-type: none"> <li>- Certificado de garantía (mínimo 2 años) conforme cumple con los parámetros detallados en la especificación - URS</li> <li>- Especificaciones técnicas de la osmosis inversa</li> <li>- Manual de la máquina e instrucciones de la planta de osmosis</li> </ul>


**CUALIFICACIÓN DEL DISEÑO (DQ)**


**REVLON**



**HISTORIAL DEL DOCUMENTO**

Versión	Fecha	Motivo de la edición
0	13/11/17	Presentación VMP

**FIRMAS Y APROBACIONES**

PREPARADO POR			
Nombre	Responsabilidad	Fecha	Firma
J. Páramo	Ingeniería. Veolia Water	05/12/2017	

REVISADO POR			
Nombre	Responsabilidad	Fecha	Firma
J. Lamuedra	Ingeniería. Veolia Water	05/12/2017	

APROBADO POR			
Nombre	Responsabilidad	Fecha	Firma
Oscar Sancho	Ingeniería	13/12/2017	
Milagros Ruiz	QA	13/12/2017	



PLANTA DE GENERACION DE AGUA PURIFICADA

Proyecto: 1750233125  
REVLON

DQ

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## 1. INTRODUCCIÓN

Este protocolo se redacta en función de lo establecido en el punto 6.2.1. del Plan Maestro de Validación que afecta al sistema para producir agua purificada de la planta de producción de REVLON, en Pla de Santa María (Tarragona).

## 2. OBJETIVO

La Cualificación del Diseño proporciona evidencia documental de que el diseño de la instalación cumple con los requerimientos de los documentos:

- Oferta Técnico – Económica REVLON 2017-128 rev7-A.

## 3. DESCRIPCIÓN

Se verificará la documentación de diseño y que la instalación cumple con los requerimientos del documento antes mencionados.

Todas las desviaciones serán registradas y se someterán a la revisión y comentarios de REVLON y del personal técnico de VEOLIA para evaluar su criticidad y su resolución.

Se podrá continuar con la siguiente fase, FAT, siempre y cuando las desviaciones encontradas en la ejecución de la DQ no afecten o impidan la ejecución de las pruebas de FAT.

## 4. VERIFICACIONES

La Cualificación del Diseño se desarrollará en la siguiente etapa de verificación:

- DQDOC Revisión de la documentación de diseño






PLANTA DE GENERACION DE AGUA PURIFICADA

Proyecto: 1750233125  
REVLON

DQ

**5. LISTA DE FIRMAS AUTORIZADAS**

Nombre	Cargo	Iniciales	Firma autorizada
JONATHAN PARAMO	JEFE PROYECTO	JP	
JORGE LANUEDRA	JEFE PROYECTO	JL	
Oscar Suedo	Ingenieria	OS	



PLANTA DE GENERACION DE AGUA PURIFICADA

Proyecto: 1750233125  
REVLON

DQ

6. INFORME DE DQ

Informe de cualificacion			
Descripcion Test		C/NC	Iniciales/ Fecha
1. DQDOC	Verificar la existencia e idoneidad de la documentación de diseño.	C	JF 13-11-17
En base a los resultados obtenidos en los TEST, el resultado de las pruebas es: Marcar con una cruz donde corresponda.			
Resultado	CONFORME <input checked="" type="checkbox"/>	NO CONFORME <input type="checkbox"/>	
Comentarios: SE VERIFICA LA PRESENCIA DE LA DOCUMENTACION DE DISEÑO			
<del>J. Parano 13/11/17</del>			
<b>PREPARADO POR</b>			
Nombre	Responsabilidad	Fecha	Firma
JONATAN PARANO	JEFE PROYECTO	13-11-17	
<b>REVISADO POR</b>			
Nombre	Responsabilidad	Fecha	Firma
JORGE LAMIEDRA	JEFE PROYECTO	13-11-17	
<b>APROBADO POR</b>			
Nombre	Responsabilidad	Fecha	Firma
MILAGROS RUIZ	QA	13-11-2017	
Osco Saicho	Ingenieria	13-11-17	

## 9.5. Self-evaluation Questionnaire

a) Evaluate the acquired competences according to the tasks you have carried out.

Degree Competences		Task in which you have observed the competence	Self evaluation [Rank 1 to 10]	Aspects to be improved
<b>SPECIFIC COMPETENCES</b>				
A1.1	Effectively apply knowledge of basic, scientific and technological materials pertaining to engineering.	No correspondence	-	-
A1.2	Design, execute and analyze experiments related to engineering	No correspondence	-	-
A1.3	Be able to analyze and synthesize the continuous progress of products, processes, systems and services, whilst applying criteria of safety, economic viability, quality and environmental management. (G6)	Reactor cleaning Study	8	-
A1.4	Know how to establish and develop mathematical models by using the appropriate software in order to provide the scientific and technological basis for the design of new products, processes, systems and services and for the optimization of existing ones. (G5)	No correspondence	-	-
A2.1	Be able to apply the scientific method and the principles of engineering and economics to formulate and solve complex problems that arise in processes, equipment, installations and services, in which the material undergoes changes to its composition, state or energy content, these changes being characteristic of industrial chemistry and other related sectors such as pharmacology, biotechnology, materials sciences, energy, food and the environment. (G1)	Reactor cleaning Study	7	-
A2.2	Conceive, project, calculate and design processes, equipment, industrial installations and services in the field of chemical engineering and related industrial sectors in terms of quality, safety, economics, the rational and efficient use of natural resources and the conservation of the environment. (G2)	Reactor cleaning Study	8	-
A2.3	Lead and technically and economically manage projects, installations, plants, companies and technological centres in the ambit of chemical engineering and related industrial sectors. (G3)	Reactor cleaning Study	7	-

A3.1	Apply knowledge of mathematics, physics, chemistry, biology and other natural sciences by means of study, experience, practice and critical reasoning in order to establish economically viable solutions for technical problems (I1).	Reactor cleaning Study	7	-
A3.2	Design and optimize products, processes, systems and services for the chemical industry on the basis of various areas of chemical engineering, including processes, transport, separation operations, and chemical, nuclear, electrochemical and biochemical reactions engineering (I2).	No correspondence	-	-
A3.3	Conceptualize engineering models and apply innovative problems solving methods and appropriate IT applications to the design, simulation, optimization and control of processes and systems (I3).	No correspondence	-	-
A3.4	Be able to solve unfamiliar and ill-defined problems by taking into account all possible solutions and selecting the most innovative. (I4)	Reactor cleaning Study	6	-
A3.5	Lead and supervise all types of installation, process, system and service in the different industrial areas related to chemical engineering (I5).	In the internship	7	-
A3.6	Design, construct and implement methods, processes and installations for the integrated management of waste, solids, liquids and gases, whilst also taking into account the impacts and risks of these products (I6).	Reactor cleaning Study	7	-
A4.1	Lead and organize companies and production and service systems by applying knowledge and abilities regarding industrial organization, commercial strategy, planning and logistics, mercantile and labour legislation, and financial and costs accounting (P1).	No correspondence	-	-
A4.2	Lead and manage the organization of work and human resources by applying criteria regarding industrial safety, quality management, occupation risk prevention, sustainability and environmental management (P2).	No correspondence	-	-
A4.3	Manage research, development and technological innovation whilst ensuring the transfer of technology and taking into account property and patent rights (P3).	No correspondence	-	-
A4.4	Adapt to structural changes in society caused by economic, energy or natural factors so as to be able to	Reactor cleaning Study	7	-

	solve any resulting problems and to contribute technological solutions with a high commitment to sustainability (P4).			
A4.5	Lead and monitor the control of installations, processes, products, certification, auditing, verification, testing and reports (P5).	No correspondence	-	-
A5.1	Carry out, present and defend (once all the curriculum credits have been obtained) an original individually produced piece of work before a university panel. The work will consist of a professional integrated Chemical Engineering project that synthesizes (TFM1)	Final project	9	-
<b>TRANSVERSAL COMPETENCES</b>				
B1.1	Communicate and discuss proposals and conclusions in a clear and unambiguous manner in specialized and non-specialized multilingual forums (G9).	Equipment qualification	8	-
B1.2	Adapt to changes and be able to apply new and advanced technologies and other important developments with initiative and entrepreneurial spirit. (G10)	Reactor cleaning Study	7	-
B2.1	Lead and define multidisciplinary teams that are able to make technical changes and address management needs in national and international contexts. (G8)	No correspondence	-	-
B3.1	Work in a team with responsibilities shared among multidisciplinary, multilingual and multicultural teams	In all the project	9	-
B4.1	Be able to learn autonomously in order to maintain and improve the competences pertaining to chemical engineering that enable continuous professional development. (G11)	Equipment qualification	9	-
B5.1	Carry out and lead the appropriate research, design and development of engineering solutions in new or little understood areas, whilst applying criteria of creativity, originality, innovation and technology transfer. (G4)	No correspondence	-	-
B5.2	Bring together knowledge, make judgements and take decisions on the basis of incomplete or limited knowledge whilst taking into account the social and ethical responsibilities of professional practice. (G7)	Equipment qualification	8	-
<b>NUCLEAR COMPETENCES</b>				
C1.1	Have an intermediate mastery of a foreign language, preferably English	Yes	10	-
C1.2	Be advanced users of the information and communication technologies	Yes	10	-
C1.3	Be able to manage information and knowledge	Yes	10	-

C1.4	Be able to express themselves correctly both orally and in writing in one of the two official languages of the URV	Yes	10	-
C2.1	Be committed to ethics and social responsibility as citizens and professionals	Yes	10	-
C2.2	Be able to define and develop their academic and professional project	Yes	10	-

b) Evaluate the final master project and suggest improvements.

<b>Key steps</b>	<b>Evaluation [Mark 1 to 10]</b>	<b>Improvement proposed</b>
Selection/assignment of the project (dissemination, communication, assignment requirements...)	7	It could be more technical project to apply the diferents things studied in the master
Stay (welcome, length, relationship, follow-up made by the company...)	10	-
Follow-up made by URV tutor	10	-
Other aspects to be considered (which ones...)	-	-