Improvement of Clean-in-Place (CIP) in the Evaporation Process of a Dairy Company Using Six Sigma

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Abstract

The semi-automated cleaning-in-place (CIP) integrated cleaning technique is very common in food manufacturing companies. It consists of removing residues and cleaning equipment without the need to disassemble the production line. However, there have been problems with high pH levels after cleaning in the dairy company under study. This situation can represent the risk of contamination of the products with chemical agents used in cleaning and cause production delays. This research aims to improve the CIP process of the company. The Six Sigma methodology based on the DMAIC cycle was used. 70.1% of the problems related to CIP are non-compliance with the conductivity limits during the soda and acid stages. The data was collected directly from the software used in the company to monitor the activity, and the 33 cleanings carried out in the evaporator for 3 months were considered. The capacity analysis indicates problems of both variation and compliance with the objective, with values Cp=0.71 and Cpk=0.03 for the soda stage, and Cp=0.53 and Cpk=0.09 for the acid stage. Through multiple regression analysis and ANOVA, the root causes of the conductivity problem were found: the work shift, CIP cycle duration, temperature, outlet flow, and DSI pressure. The improvement proposals are mainly focused on establishing and monitoring standardized protocols for different tasks of the CIP, which include determining the concentration of chemical solutions, removing mud from caustic soda solution, and cleaning inside the tubes. It is estimated that these measures can reduce the problem by 33.5%.

Keywords

Continuous improvement, Six sigma, Dairy, Standardization, CIP.

1. Introduction

Generally, the emphasis on process improvement falls on the main operations of the process. However, the analysis and improvement of activities that do not add value, but are necessary, such as activities related to production changes or equipment cleaning, often represent a way to reduce costs, improve the effectiveness of management programs and contribute to production goals (Hansen et al 2022), (Senvar and Akburak 2019). The case studied refers precisely to the cleaning process of a dairy company, whose development not only impacts the process times but also the quality of the product itself.

This company produces large volumes of powdered milk with different formulas. Fat residues are generated during production, especially in the evaporator line, where solids are separated, and water is removed using a vacuum generated by air injection. During the process, a layer of soil is created when a product containing milk proteins, starches, and minerals accumulates on hot surfaces at high temperatures. In this way, the need arises to eliminate bacteria from the environment that can contaminate production lines.

For this reason, the semi-automated cleaning-in-place (CIP) integrated cleaning technique is used, which consists of the action of chemical products combined with mechanical efficiency to remove residues and clean equipment without having to dismantle the line and clean manually (Moerman et al 2014). The CIP is based on the passage of a cleaning solution or a series of solutions that can eliminate residues and clean production equipment. It is a system that is used to clean and disinfect equipment that has been used in production.

A four-step sequence is used at the factory. The first is an alkaline solution, to remove protein and fat residues. The second is the intermediate rinse to completely push out the alkaline solution. The third is the acid solution to remove mineral residue. Finally, the fourth stage is the final rinse to remove the chemicals from the CIP and prepare the production line. Each stage uses different chemical concentrations and parameters to ensure effective cleaning. The process is designed to ensure efficient cleaning and achieve the desired conductivity at the end of the cleaning sequence, using mechanisms such as chemical dosing valves, spray balls, and flow and pressure adjustment. At the end of the CIP, the program returns to the water circulation stage, and the parameters of this stage are loaded in all the controllers.

Cleaning is done automatically, so the operator must verify that the CIP parameters at the interface remain stable during the operation, adjusting what is necessary to comply with the concentration and the total time established. These parameters include inlet flow, preheater temperature, DSI temperature, thermocompression pressure, flash tank inlet pressure, and fifth effect temperature. If there are variations in the process of any of these parameters, changes are generated in some of the other parameters; For this reason, a correct design of the installation and the CIP procedures is important.

Conductivity measurement is used in CIP to determine the effectiveness of cleaning and flushing. Conductivity picks up the change in the electric conductivity of a sample stream to indicate when a flushing process began and ended. For example, low conductivity in a rinse cycle indicates that all chemicals have been removed and the equipment is ready for the next batch of the product (Edwards 2015).

In recent years, a recurring problem has arisen about high levels of pH measurements after chemical cleaning, which is monitored through conductivity during the process. These indicators are not consistent and do not remain within the technical limits required for the process, which could mean a risk factor for contamination of the products with chemical agents (caustic soda and nitric acid) used in cleaning. The development of this chemical cleaning implies a problem in terms of quality since its cleaning is not effective. There have been failures that make it necessary to stop production and hinder compliance with the final quality and production times. For this reason, there is a need to develop improvements that guarantee quality, safety, and cost standards.

1.1 Objectives

This study aims to improve the clean-in-place (CIP) in the evaporation process of a Chilean dairy company, based on the conductivity measurement in the soda and acid stages, through the identification and analysis of its variables, and the generation of customized solutions. The objective is to reduce the variability in the conductivity measurement and increase the effectiveness of evaporator cleaning.

2. Literature Review

Six Sigma is a continuous improvement methodology that focuses on reducing errors and increasing efficiency in organizational processes. It uses proven quality principles and techniques to achieve a high level of business performance, with the goal of the error-free operation. This methodology integrates elements of the contributions of various leaders in the field of quality to achieve a high level of excellence in process execution (Pyzdek and Keller, 2010). Six Sigma principles include a management structure with committed top-down leadership, training, accreditation, customer, and process focus, as well as being supported by a robust data-driven methodology (Gutiérrez and de la Vara 2009).

Six Sigma can be understood as a metric in that it is used to measure the performance of an organization's processes relative to products or services that are out of specification. As a work philosophy, by focusing on continuously improving processes and products using statistical tools and other support tools. It can also be understood as a goal since the purpose of Six Sigma is to statistically achieve a zero-defect rate in products or services (Socconini 2015).

The Six Sigma methodology seeks to continuously improve the processes of an organization using the scientific method. It focuses on identifying and eliminating defects through observation, analysis, and constant improvement, using statistical tools to evaluate the results and adjust assumptions, if necessary, to achieve an extremely low defect rate. When Six Sigma is applied to improve the performance of an existing product, process, or service, the DMAIC approach provides a useful framework for creating a closed process and maintaining control of the project. In this way, the model establishes the criteria to complete a specific phase and actions to verify if all the criteria have been

met before starting the next phase. Therefore, the DMAIC methodology is an essential tool for the implementation of Six Sigma, which allows for the identification and elimination of the problems that cause variability in a specific process (Pyzdek and Keller 2010).

The Define stage is crucial to the success of the process improvement project. During this stage, the problem or opportunity to be addressed is identified and defined, the project objectives are established, and the specific goals and the critical quality characteristics (CTQ) are defined, which are key indicators to measure the success of the project. In addition, a work team is established, and roles and responsibilities are assigned. The Define stage is important as it sets the framework for the rest of the project and ensures that the team is focused on addressing the right problem or opportunity (Socconini 2015).

The Measure stage is the second stage and focuses on collecting and analyzing data about the current process. During this stage, statistical methods, and tools for measuring process performance are established, data is collected, and graphs and tables are created to illustrate the collected data. In addition, benchmarks and desired performance targets are established. This stage is essential to establish a solid database and establish a baseline for the current process. Therefore, it seeks to choose the appropriate quality characteristic to develop the Six Sigma improvement project and select the appropriate metrics to establish the level of performance of the process and determine the Sigma level with which the process works. This will help identify problem areas and set realistic goals for process improvement (Pérez 2013).

The Analyze stage is the third stage and focuses on using the data collected in the previous stage to identify the causes of the problem or opportunity through the analysis of the value chain and sources of variation. During this stage, statistical techniques and tools are used to analyze the data and determine the root causes of the problem. Process analysis tools are also used to understand how the different steps of the process are related and how they can be improved. It is important to involve all team members to get different perspectives and ensure that all possible causes have been considered. This stage is essential to ensure that the root causes of the problem are being addressed and not just the symptoms (Socconini 2015).

The Improve stage is the fourth stage and focuses on developing and implementing solutions to improve the process identified in the previous stage. The objective of this stage is to search and evaluate different solution options, selecting the best one to implement. It is important to involve all team members to ensure that all options have been considered and to ensure a successful implementation. These options may include redefining the process, applying new statistical techniques, seeking new approaches, and implementing new ways of doing things (Allen 2010). The Improve stage is essential to ensure that the process is more efficient and effective and that the established goals have been achieved.

The Control stage is the fifth and final stage and focuses on ensuring that the improvements implemented in the previous stage are maintained in the long term. During this stage, procedures, and mechanisms based on statistical tools are established to monitor and control the improvements implemented in the process to ensure that the expected results have been achieved (Pérez 2013).

3. Methods

The case study seeks to identify the causes of the variability of chemical agents during CIP, from the measurement of conductivity. As the concentration of a chemical increases, the conductivity of the solution also increases. Therefore, it can be used to provide an approximate value of the concentration in real-time. This six-sigma project is based on the DMAIC methodology; therefore, the five stages are developed sequentially. Table 1 mentions the techniques used in each phase. The collection of information and data includes historical information from the factory and the continuous recording of events relevant to the investigation (anecdotes, informal conversations, experiences, observations, reflections, interpretations, and explanations of what happens during the investigation process). Statistical analyzes of the collected data were performed using Minitab Software.

Define	Measure	Analyze	Improve	Control
 Semi-structured interviews Pareto chart Project charter Swimlane chart Parameter diagram 	 Data collection Boxplot Anderson Darling test Control charts Capability index 	 Semi-structured interviews Cause-effect diagram Five why technique Analysis of critical variables 	 Brainstorm Evaluation and selection of ideas 	 Response and control plan Project closure

Table 1. Techniques used in each DMAIC phase	Table 1. Techni	ques used in	each DMAIC	phase.
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4. Results and Discussion

4.1 Define Phase

The dairy company uses a 5-boiler falling film evaporator with vapor thermal recompression that is in a 7-level building. The liquid is evenly distributed at the top of the evaporator and descends as a thin film while the vapor flows in the opposite direction. During this process, proteins, starches, and minerals accumulate on the hot surfaces, which can create a layer of dirt that affects product quality and hygiene. The organization uses the CIP technique to ensure the removal of residues and the hygiene of the internal surfaces of the equipment. The CIP system is a semi-automated cleaning process comprised of a series of pumps, storage tanks, and piping that allow the circulation of cleaning and sanitizing solutions through production equipment without the need for disassembly.

The report studied the high pH level and inefficient removal of organic residues in the evaporator equipment and final process rinse water. To guide the solution to the problem, the option of analyzing and reducing some of the main problems associated with the evaporator CIP process was considered. To quantify them, the data recorded by the company in the year 2021 was used. The company records the frequency of problems associated with the cleaning cycle (Figure 1) such as non-compliance with conductivity limits during the soda and acid stages, unplanned stops, delays in starting the sequence due to hygiene and safety issues, and technical problems. Considering that in the first half of 2022, there was a 5.05% increase in the use of the CIP technique, solving the problems of conductivity instability in the alkaline and acid solution stages is established as a priority since it represents 70.1% of the problems associated with CIP process.

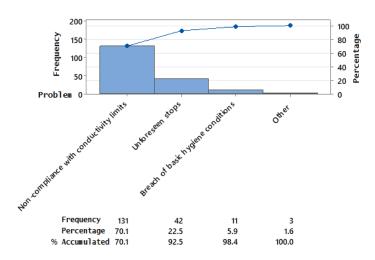


Figure 1. Pareto diagram of problems associated with CIP.

A Swimlane diagram was constructed to identify processes, responsibilities, and interactions with other departments. Areas for improvement and possible bottlenecks that could delay or affect the process were identified by identifying the theoretical sequence of how the CIP should be carried out and the measures to guarantee its effectiveness,

considering that the company does not include the time to verify conditions for the start of the sequence or the time dedicated to coordinating action plans for correcting noncompliance with basic conditions. A parameter diagram was used where the possible factors influencing its performance were specified (Figure 2). In this way it is proposed to identify the causes that generate the instability of the process and establish measures for continuous improvement, it is expected that the time and resources required to perform chemical cleaning will be reduced, considering that any improvement in the process should not negatively affect the critical quality factors.

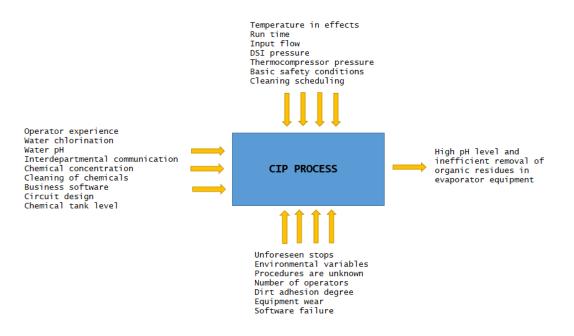


Figure 2. Parameter diagram for CIP process.

4.2 Measure Phase

To measure conductivity levels in the CIP cleaning process, the soda and acid stages are critical, since in their respective stages the chemicals are recirculated through the evaporator circuit. The data collection was to measure the conductivity levels during the CIP, the soda and acid stages are established as critical since in their respective stages the chemicals are recirculated through the evaporator circuit. The data collection was carried out through enterprise software that allows the extraction of accurate data on all variables and equipment activity during the cleaning process. The values of the conductivity meter of the fifth effect of the evaporator were recorded, this was done for 3 months, a period in which 33 complete cleanings were performed in the evaporator, for each cleaning data of the conductivity is exported every 7 minutes to ensure that the two critical stages defined are considered, with this it is sought to quantify the initial state of the problem.

A process capability report was used to determine the current behavior of each stage of the process concerning the desired behavior. Previously, an Anderson-Darling (AD) normality test was performed for both stages. The AD value for acid was 0.756 with a p-value < 0.05, however, after testing with other distributions, the most appropriate is the normal distribution, so normality was assumed. In the case of the soda stage, an AD value of 0.659 was obtained with a p-value < 0.084, so it is assumed that the data are normally distributed. For the capacity analysis, the specification limits were used to allow the removal of organic and microbiological matter in the evaporator circuit. The organization establishes a value of 75±15 (mS) for the acid circulation, while the caustic soda circulation has a conductivity of 110 ± 20 (mS).

In the capacity analysis of the CIP stages (Figure 3), a Cp value of 0.71 (Cp<1.67) was obtained for the soda stage, while the Cpk index is 0.03. In the case of the acid stage, the Cp value is 0.53(Cp<1.67) and the Cpk index is 0.09. This implies that the process is not capable of producing within the preset specification limits. These metrics show variation and averaging problems., so intervention is required to improve the process and achieve optimum performance.

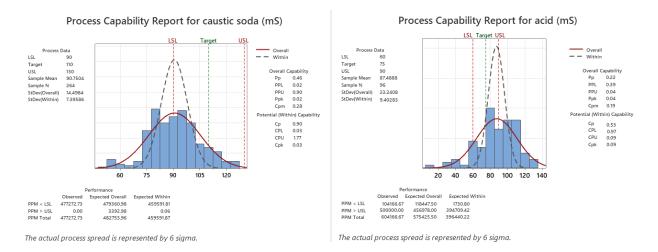
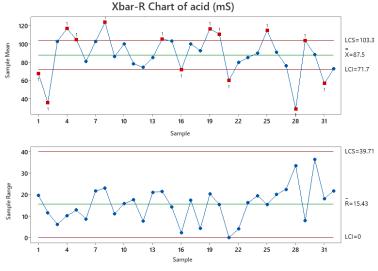


Figure 3. Process capability report for caustic soda conductivity (left) and acid conductivity (right)

To know the stability of the process based on both sets of data, control charts were made (Figure 4 and Figure 5). In the acid stage, 14 CIP processes are out of control limits of which, 5 coincide with quality events that were recorded by the operators in the shift reports, while the lower chart does not indicate common causes of the process during this stage. In the soda caustic stage, 14 values are above control limits, which is considered a special event, and of these values, 5 coincide with quality events that were recorded in shift reports and scheduling meetings. In addition, the lower chart identifies 2 common causes specific to the process during the soda stage. Although some of these points have records of quality problems related to the process, many of them do not have records that explain the variation in the graphs. Therefore, it is concluded that the process is not controlled over time and it is suggested that an analysis is needed to determine the root causes of these problems, identify procedures that are not being executed correctly, or processes that are not adding value to the process.



Tests are performed with unequal sample sizes.

Figure 4. Control chart for acid phase

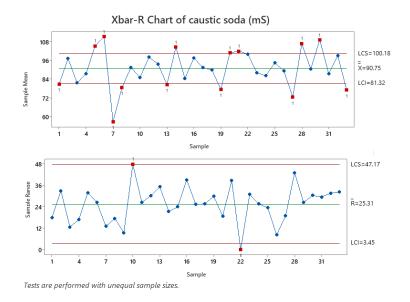


Figure 5. Control chart for caustic soda phase

4.3 Analyze Phase

To investigate the reasons why the process does not maintain chemical conductivity stability, interviews and meetings were held with company personnel directly or indirectly related to the process (operators, administrative personnel, maintenance personnel, and management). Based on the answers provided and direct observation, the different causes were organized using an Ishikawa diagram. The most critical causes that contribute to the variability of conductivity in the acid and soda stages are related to operational errors, deficiencies in the response system of the operators during evaporator cleaning, instability of evaporator conditions, and chemical cleaning.

A recurring cause of instability is the obstruction of the fifth effect calandria tubes after CIP. Although operators and logistics management are aware of this problem, there is no defined method to control the frequency of inspection of the equipment after cleaning. Failure to inspect does not allow identifying the presence of organic matter and chemical residues that negatively affect the production cycle. Also, the variability of chemical concentrations due to the lack of precision in the measurement system used by the operators implies a problem to determine the degree of concentration of the chemicals before performing the CIP. The operators measure the concentration hours or even minutes before, which increases the risk of not complying with the production plan. Similarly, the lack of precision in the system used by the operators to determine the level of sodium carbonate in the solution in the tank implies the lack of a standardized methodology for controlling the decantation of the recovered soda, so that even when the degree of cleanliness is met, there may be organic matter adhering to the evaporator after performing the process of cleanness. The causes identified correspond to problems in the design of activities and control values, which are managed according to the operator's experience. This has been indicated by the engineering staff of the organization. In addition, the run time, chemical cleaning rate, and machine operating variables are critical operating parameters and are established according to the conductivity indexes since instability generates alterations during the cleaning sequence. These problems are related to the skills of the operators to keep the equipment stable and the lack of understanding of the effects of not performing the process correctly. To find the root causes, specific analyses were carried out according to the sub-causes mentioned in Table 2.

Table 2. Sub-ca	uses identified.
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Cause	Sub-cause
Concentration instability during the cleaning process	1 Work shift 2 Run time 3 Caustic soda cleaning grade 4 Critical variables of the CIP process

1. Work shift.

To demonstrate that the work shift is indeed a factor influencing the variability of conductivity, an analysis of means (ANOM) of three samples corresponding to the shifts and the respective conductivity for each stage of the process was performed, the data corresponds to the monitoring of the conductivity values of 33 CIP sequences (Figure 6). From both analyses it is concluded that the shift is a critical root cause of the variability of the conductivity in the cleaning cycle, in addition, it is clear from the mean analysis that shifts B does not present problems in both stages of the cycle, while shift A for the soda stage and shift C for the acid stage do not comply with the standards for conductivity during the CIP. This is because the administrative, management, and technical department specialists have a fixed shift from 08:30 AM to 5:30 PM, so they have greater control over the process during those hours and the operators have a greater capacity to respond to deviations or failures during the cleaning cycle. In addition, when there is a shift change, there are adjustments of variables or instruments that the next shift does not know about or even does not perform, such as the inspection of the foam level during the cleaning operation or the adjustment of the valves to control the chemical levels in the feed tank.

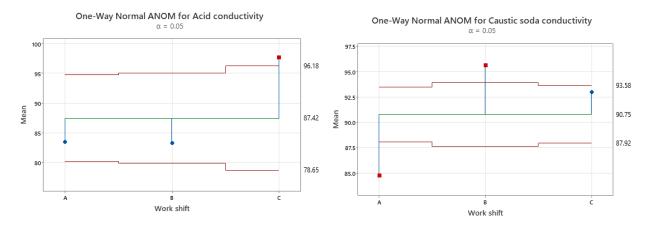


Figure 6. Analysis of means for acid (left) and caustic soda (right)

2. Run time.

During the cleaning cycle, the operator, through the software, must guarantee compliance with the operation sequences and the duration of each CIP step to comply with the total time of the process. Considering that the CIP cleaning action requires sufficient time to act and remove organic and chemical matter the factory established that the optimum cleaning time should be 210 minutes, thus the variable under observation is the CIP cycle duration time measured in minutes of 60 CIP processes in the evaporator during the months of March and November 2022. Figure 7 shows the result of a bilateral hypothesis analysis for a sample of the CIP cycle time at the factory. The null hypothesis is rejected since the p-value is 0.027, also the box plot provides relevant information for the cleaning time sample since the data is concentrated in the right part of the distribution, so the mean is higher than the median and indicates that the data present high variability. The CIP cycle time is a critical root cause of the process, which implies that it must be continuously monitored and validated. If the cleaning time is too short, it can be inefficient, and if it is too long, it can cause delays in the production process and damage to the equipment.

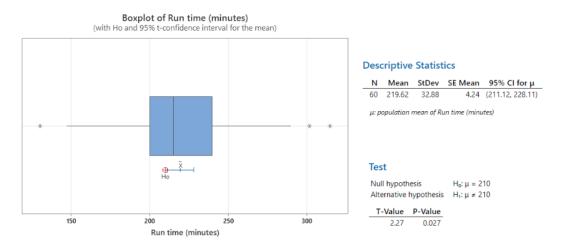


Figure 7. Bilateral hypothesis analysis of CIP run time.

3. Caustic soda cleaning grade.

Before starting the CIP sequence, operators must verify the cleanliness of the soda in the CIP station through an analysis in the factory laboratory. This analysis seeks to determine that the amount of sodium carbonate in the caustic soda meets the cleanliness standard. The variable under observation is the cleanliness level of the soda, which should not exceed 3 grams of dissolved sodium carbonate per liter in the caustic soda solution pool of the evaporator CIP station. Figure 8 shows the result of a one-sided hypothesis analysis for a sample of 42 measurements of dissolved sodium carbonate concentration in the soda tank during the first half of 2022. The analysis indicates a failure to meet the cleanliness standard, as the p-value of 0.033 rejects the null hypothesis. The boxplot shows that the data are scattered and concentrated above the target. It is concluded that the soda cleaning rate in the evaporator CIP station is a critical root cause of the variation in conductivity during the process. Therefore, attention should be given to correcting the cleaning rate procedure to maximize chemical recovery from the station, reduce effluent volumes, generate operating cost savings, and decrease the environmental impact of the process.

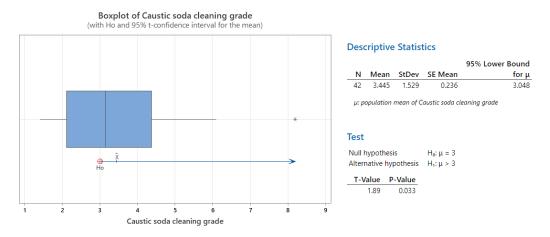


Figure 8. One-sided hypothesis analysis for soda cleaning grade

4. Critical variables of the CIP process.

The effectiveness of the CIP depends on the correct design and installation of the cleaning circuit and the control of critical variables such as time, temperature, pressure, concentration, and flow rates in the evaporation software. A multiple linear regression analysis was performed in Minitab software for each stage of the CIP to identify the relationship between critical process variables that explain the variation in conductivity. In the first stage, the significance of the model and p-value of each variable was evaluated considering an acceptance value of 0.15, to

guarantee that the other critical variables do not influence them. Finally, a model acceptance value of 0.05 was considered. From the analysis, it was concluded that the variables of evaporator inlet temperature, concentrate outlet flow, DSI vapor pressure, DSI temperature, homogenizer temperature, and fifth effect temperature explain the behavior of conductivity in the soda stage. These 6 variables explain the variance difference of 43.72% and improvements should therefore be focused on the identified variables. In the case of the acid stage, the predictor variables of the conductivity model are the concentrate outlet flow and the preheater temperature, which explain 50.95% of the variance.

4.4 Improve Phase

Once the main causes of the variation in conductivity were identified, solutions were proposed to meet the objective defined by the team. Through work sessions and brainstorming among team members, operators, and technical specialists, along with field trips to identify and analyze possible solutions, improvement opportunities are identified for a series of problems in the cleaning process, oriented to the execution and control of the critical variables of the processes during the cleaning sequence through the standardization of processes given the low complexity of implementing administrative resources to carry out the improvements. According to the information gathered from workers and logistics management, the need to update and create Standard Operating Procedures (SOPs) to streamline the management of the CIP process, maintain the cleaning process in balance and reduce quality incidents was established as a priority.

The documents elaborated aim to reduce the variability in conductivity and guarantee efficiency and effectiveness in the cleaning activities in the plant. The procedures indicate step by step the key activities to be performed according to the quality management standards expected by the logistics management and Champion CIP of the plant, defining the tools, operating conditions, frequencies, and people responsible for starting and finishing an activity. The procedures seek that these activities become routines that through standardization and optimization of resources reduce the variability of the conductivity that affects the degree of adhesion of chemicals and organic matter after the cleaning process, in addition to defining quality controls and precise measurements in each step of the process. The proposal seeks to guarantee the removal of organic and microbiological matter, eliminating any unnecessary steps in the process, increasing the speed of the operation, and ensuring that the final product meets the quality standards established by the company. These correspond to the activities related to the manual cleaning process of the evaporator tubes, concentration measurement, and chemical cleaning. The procedures are described below.

-Determination of sodium carbonate in caustic soda solution: Defines the identification procedure of a compound through a sample analysis, which allows determining the grams per liter of sodium carbonate in caustic soda used in the evaporator CIP technique.

-Removal of mud from caustic soda solution: Defines the times and procedures required to decant the dirt retained in the soda solution and remove it through controlled evacuation.

-Determination of concentration of chemical solutions in CIP station: Defines the procedure to identify a compound through a sample analysis to determine the concentration of the tanks with nitric acid and caustic soda solution used in the CIP process.

-Manual cleaning of the evaporator tubes: Establishes the cleaning verification frequency of the equipment and the action procedure to unclog and remove most of the residues adhered inside the tubes, leaving them in conditions for a new production cycle using a pressure washer.

Most of the root causes identified are related to non-compliance with critical variables during the cleaning sequence, although the procedure is an automatic sequence during the process, attention must be paid to the activities to prevent the accumulation of chemicals in the equipment, so operators must adjust the flow, temperature, and pressure parameters if necessary. Despite having a standard procedure for the CIP process, it was not updated with the operating parameters and activities of the cleaning sequence, which led to non-compliance with the required standards. The SOP was updated to include the recording of soda solution concentration percentage and nominal cleaning values, as well as defining the use of business software to record the operation. The development of standardized procedures for the key activities of the evaporator cleaning sequence ensures that the activities are executed in a structured manner, creating a specific performance evaluation system and a continuous training program for the evaporator operators. The improvement proposals were known and validated by the evaporation area personnel through an induction guided by the Champion CIP.

4.5 Control Phase

After generating improvement proposals, it is necessary to design action protocols for the use of these alternatives, and thus avoid failures during the of solutions, ensuring that process modifications are kept under control and the expected results are achieved. The response and control plan for implementing improvements (Table 3) shows who is responsible for evaluating the results of the implementation and includes the identification and resolution of problems or challenges that arise during the process.

Description of the operation	Specification	Technical	Sample	Frequency	Control method	Reaction plan
Control of cleaning (soda)	[0-3] g/L of sodium carbonate	Sample analysis	80 ml	Before the start of the CIP process	Operator inspection	Change the soda tank solution and coordinate with the line manager.
Control of cleaning (soda)	Acid [1.2% - 1.8%] Soda [2% - 2.8%]	Sample analysis	80 ml	Before the start of the CIP process	Operator inspection	Do not start the cleaning sequence. Report to the First Line Manager
Cleaning of soda	Color change, loss turbidity	Solution decantation	Not applicable	8 ± 2 at the end of the CIP process	Operator inspection	Inform the line manager. Change soda solution
5to effect inspection	No solid and chemical waste	Visual	Not applicable	2 ± 1 at the end of the CIP process	Operator inspection	Inform the line manager. perform manual cleaning of the equipment
CIP sequence	Equilibrium of critical variables	Visual	Not applicable	Continuous	Operator inspection	Modify the critical variables. Abort CIP cleaning. Inform line manager

Table 3. Response and control plan.	
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In addition, in the case of mud removal in the soda solution, no record is kept of the activities, so a categorical control was implemented through the spreadsheet on the operator's console. As well as a specific form has been created for the inspection of the fifth effect of the evaporator, which establishes the inspection points and will make it possible to keep a record of the interventions on the evaporator to detect unjustified excess cleaning in time. Finally, an internal CIP behavior verification guide has been developed to standardize the causes of conductivity variability and ensure compliance with the nominal operating values. This guide seeks to reduce the variability of the process and guarantee that it is carried out with homogeneous quality between shifts, preserving the knowledge of the operators and eliminating activities that do not add value.

5. Conclusion

The improvement proposals presented manage to explain 51.96% and 43.72% of the causes that originate the instability of conductivity during the acid and soda stages, respectively; the remaining percentage can be explained by the qualitative analysis and, in addition, by variables for which there are no records. It is estimated that approximately 47.8% of the conductivity problem can be solved with the proposals presented, which represents about 33.5% (47.8% of the 70.1%) of the CIP cycle problems. These results are significant for the organization since they are related to the activities of the operators and the management of the critical variables during the CIP sequence and imply a contribution to the development of the company's strategic plan through a common knowledge base and a learning experience within the area.

The use of the DMAIC methodology and the Six Sigma approach was a success as it allowed to efficiently address the problems related to the standardization of production, allowed to focus from the beginning on the critical variables from the point of view of time loss and execution errors, which is a fundamental factor in the instability of the conductivity that impacts the removal of organic and chemical matter. The methodology proved to be effective in terms of achieving in a short time some of the most important root causes of the problem presented and seeking customized solutions in improving the quality and efficiency of the cleaning process.

The company has partially implemented the proposals. Some of the changes made are related to the removal of sludge from the caustic soda tank solution. Currently, the operators have been able to keep the soda evacuations under control. In addition, the adjustment of the evacuation valves was regulated, and the level sensors were maintained to prevent overflow. As for the proposed standard operating procedure for the CIP, the soda concentration percentage and cleanliness ratings were updated on the operator control panel. To verify that the proposals have met the objective established in the definition phase, it is sufficient to compare the data before and after the implementation of the proposed improvements. Before the implementation of the improvements, pH values of 9.7 on average are recorded after a CIP process. After the implementation of the improvements, considering the data from December 2022 to April 2023, an average pH of 8.7 was obtained, a decrease of 10.8%. Regarding the measurement of cleanliness by adenosine triphosphate (ATP) detection, before implementing the improvements, an average of 53.5 relative light units (URL) was obtained after CIP cleaning. After implementing the improvements, a decrease of 56.7% was obtained, reaching an average value of 23.2 URL. Before process improvements were introduced, the conductivity in the soda stage recorded a mean of 111.8 mS and a standard deviation of 16.1 mS. Similarly, in the acid stage, a mean of 66.2 mS and a standard deviation of 8.4 mS was recorded. After applying the improvements in the soda stage, a mean of 108.8 mS and a standard deviation of 2.3 mS was recorded, and in the acid stage, a mean of 75.2 mS and a standard deviation of 3.3 mS was recorded, indicating a significant reduction in the variability of the data. These values demonstrate that the gradual implementation of the proposals presented has contributed to improving the consistency and accuracy of the process, which reduces the risk of possible microbial contamination due to insufficient cleanliness.

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