Optimizing distilled water management in pharmaceutical production through the DMAIC methodology: a Lean Six Sigma approach

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Otimização da gestão de água destilada na produção farmacêutica por meio da metodologia DMAIC: uma abordagem Lean Six Sigma

Abstract

This study applies the Lean Six Sigma (LSS) Define-Measure-Analyse-Improve-Control (DMAIC) methodology to optimize distilled water management in pharmaceutical production. Water is a critical resource in drug manufacturing processes, yet inefficiencies in purification and distillation often result in substantial waste and energy consumption. Through a structured application of Lean Six Sigma tools, including Suppliers, Inputs, Process, Outputs, Customers (SIPOC), Value Stream Mapping (VSM), Failure Mode and Effects Analysis (FMEA), and 5W2H, this research identified key inefficiencies and implemented targeted improvements. The primary intervention involved automating distiller control using timers and production scheduling tables, leading to a 70% reduction in distilled water waste. The study not only enhances operational efficiency and sustainability but also demonstrates the applicability of LSS to environmental resource management in highly regulated industries. Findings contribute to advancing best practices in pharmaceutical sustainability, offering a replicable model for continuous improvement.

Keywords: Lean Six Sigma; DMAIC; distilled water; pharmaceutical production; sustainability; process optimization.

Resumo

Este estudo aplica a metodologia Definir-Medir-Analisar-Melhorar-Controlar (DMAIC) do Lean Six Sigma (LSS) para otimizar a gestão de água destilada na produção farmacêutica. A água é um recurso crítico nos processos de fabricação de medicamentos, mas ineficiências na purificação e destilação frequentemente resultam em desperdício substancial e alto consumo de energia. Por meio da aplicação estruturada de ferramentas Lean Six Sigma, incluindo Fornecedores, Entradas, Processo, Saídas, Clientes (SIPOC), Mapeamento do Fluxo de Valor (VSM), Análise de Modos e Efeitos de Falha (FMEA) e 5W2H, esta pesquisa identificou ineficiências-chave e implementou melhorias direcionadas. A principal intervenção consistiu na automação do controle do destilador utilizando temporizadores e tabelas de programação da produção, resultando em uma redução de 70% no desperdício de água destilada. O estudo não

apenas melhora a eficiência operacional e a sustentabilidade, como também demonstra a aplicabilidade do LSS à gestão de recursos ambientais em indústrias altamente regulamentadas. Os resultados contribuem para o avanço de boas práticas em sustentabilidade farmacêutica, oferecendo um modelo replicável de melhoria contínua.

Palavras-Chave: Lean Six Sigma; DMAIC; água destilada; produção farmacêutica; sustentabilidade; otimização de processos.

1. Introduction

Water is an essential raw material in pharmaceutical manufacturing, playing a pivotal role in drug formulation, laboratory analyses, equipment cleaning, and sterilization procedures (Fraga et al., 2023; Mendes et al., 2011). The quality and purity of water used in pharmaceutical processes are of utmost importance, as any form of contamination can adversely affect drug efficacy, compromise patient safety, and result in noncompliance with regulatory requirements. Regulatory agencies, such as the Brazilian Pharmacopeia and the Brazilian Health Regulatory Agency (ANVISA), mandate stringent quality standards for water used in pharmaceutical production.

These standards necessitate the use of advanced purification technologies, including filtration, deionization, ultrafiltration, reverse osmosis, and distillation (Marques & Pedro, 2021). Despite the widespread implementation of these technologies, considerable inefficiencies persist, particularly in the form of excessive water waste generated during purification and distillation processes (Pimenta et al., 2009). This situation mirrors findings from other industrial contexts, such as the Brazilian footwear industry, where comprehensive literature reviews have supported the systematization of production engineering knowledge, facilitating both academic inquiry and managerial decision-making (Godinho Filho, Fernandes, & Lima, 2009).

Such inefficiencies entail significant environmental and economic repercussions. Excessive water disposal in pharmaceutical operations contributes to increased production costs, elevated energy consumption, and greater environmental degradation, ultimately contradicting global sustainability goals (Zimmermann et al., 2020). As global pressure mounts for industries to adopt sustainable practices, optimizing water usage has become a critical focus. Inefficient process design, lack of systematic monitoring, and the absence of standardised water reuse protocols are frequently cited as contributing factors to excessive waste (Mendes et al., 2011; Costa et al., 2020).

Similar challenges were reported in studies on industrial foundries in São Paulo, where the

lack of production control systems and automation limited efficiency gains, despite organizational interest in technological improvements (Fernandes & Leite, 2002). Recent research indicates that implementing structured water reuse strategies can considerably reduce waste while ensuring compliance with quality and safety standards (Fragnani, 2019). Thus, there is a pressing need for systematic approaches that simultaneously improve resource efficiency, meet regulatory requirements, and align with corporate sustainability objectives (Silva, 2022).

One of the most effective strategies for achieving such objectives involves the modernization of industrial equipment. Retrofitting outdated systems with advanced controls and process optimization techniques can significantly enhance productivity, reduce resource consumption, and minimise inefficiencies (Siqueira et al., 2024). In the domain of additive manufacturing, heuristic optimization models have proven successful in improving batch layout and scheduling, thereby increasing throughput and profitability (De Antón et al., 2020). Furthermore, structured methodologies such as the Plan-Do-Check-Act (PDCA) cycle and Single Minute Exchange of Die (SMED) have been shown to reduce downtime, increase process reliability, and contribute to sustainable production outcomes.

LSS has gained widespread recognition as an effective methodology for reducing waste and enhancing efficiency in pharmaceutical processes. The DMAIC framework, a core component of LSS, has been extensively applied to streamline operations, reduce resource usage, and improve control over critical processes (Cabral et al., 2019; Paschoal, 2022). In the pharmaceutical and medical device sectors, DMAIC has shown notable success in minimizing water waste, energy consumption, and production costs (Moura et al., 2020; Santos, 2022). The integration of LSS with environmental sustainability principles under the Green Lean Six Sigma (GLS) model has further enabled organizations to achieve operational and ecological efficiencies in tandem (Nagadi, 2022). Additionally, data driven decision making tools, such as FMEA and VSM, offer robust mechanisms for identifying inefficiencies and optimizing resource utilization (Amaral, 2013).

Beyond operational benefits, optimiing distilled water management also supports pharmaceutical manufacturers in adhering to international sustainability mandates. The sector is increasingly expected to demonstrate environmental accountability, necessitating proactive measures to reduce natural resource consumption and minimise ecological footprints (Wanderley & Nascimento, 2017). Guidelines established by the World Health Organization (WHO) advocate the integration of sustainable water management practices into pharmaceutical operations (Dias, 2011). Lean methodologies therefore serve a dual function:

improving process efficiency while reinforcing corporate social responsibility by reducing environmental impact (Pimenta et al., 2009). A noteworthy example is the successful application of Green Lean principles in the food industry, where critical environmental inefficiencies, such as water and fruit loss in nectar production, were identified and mitigated using structured improvement tools (Bancovich Erquínigo et al., 2023).

This study applies the DMAIC methodology to analyse and reduce inefficiencies in the use of distilled water within a pharmaceutical production facility. By identifying root causes of waste, implementing targeted corrective actions, and establishing standardised procedures, the study aims to develop a sustainable and efficient distilled water management system. The findings are expected to provide valuable insights for the broader pharmaceutical industry, highlighting the effectiveness of LSS in promoting sustainable operations while ensuring regulatory compliance and cost effectiveness.

2. Theorical Background

2.1. Water management and sustainability in pharmaceutical manufacturing

Water is an indispensable resource in pharmaceutical operations, integral to formulation processes, equipment cleaning, and sterilization procedures. However, the excessive use and inefficient management of water pose significant economic and environmental challenges. While some pharmaceutical firms have adopted measures to reduce water consumption, many of these initiatives remain limited in scope and impact due to inconsistent organizational commitment and regulatory constraints (Giacchetti et al., 2017). Additionally, the absence of structured and standardised strategies for water reuse exacerbates inefficiencies. Rocha et al. (2019) highlighted the scarcity of research addressing effluent reuse in the pharmaceutical industry, indicating a gap in both academic literature and industrial practice.

Innovative treatment solutions, such as the combination of electron beam irradiation with conventional treatment methods, have demonstrated promising results in improving the efficiency of wastewater treatment (Kumar et al., 2023). Nevertheless, traditional techniques, including biological and advanced oxidation processes, present limitations, such as the generation of potentially hazardous by products and the proliferation of antibiotic-resistant microorganisms (Rocha et al., 2019). In response to these risks, the establishment of in-house laboratories for real time water quality monitoring has been proposed as a cost effective and quality driven strategy, enabling enhanced control over effluents while reducing reliance on external laboratories (Franco & Bilotta, 2014).

2.2. LSS as a process optimization strategy

LSS has emerged as a proven framework for enhancing resource efficiency and reducing waste across various manufacturing contexts, including the pharmaceutical sector. By applying the DMAIC methodology, organizations can systematically identify inefficiencies and implement evidence-based improvements (Amaral, 2013; Zimmermann et al., 2020). In pharmaceutical environments characterised by strict regulatory compliance and quality standards, LSS has demonstrated effectiveness in reducing costs, minimizing energy consumption, and improving operational agility (Silva et al., 2023).

One illustrative case study documents the implementation of LSS to optimise pharmaceutical import logistics, resulting in a 96% reduction in storage costs through the streamlining of customs clearance procedures (Paschoal, 2022). Further benefits have been observed in production planning and resource allocation, where the integration of LSS tools enabled improved forecasting, leaner workflows, and enhanced adaptability (Paschoal, 2022; Silva, 2024). In addition to manufacturing applications, LSS has been employed to improve access to biologic medicines, reducing process delays in drug dispensation and expanding patient access to essential treatments (Costa et al., 2020). The relevance of resource-based strategies in implementing lean practices has also been validated in traditional manufacturing sectors, where organizational resources, such as skilled labor and operational culture, proved decisive in supporting sustainable implementation of Lean Production models (Silva, Gohr, & Santos, 2019).

2.3. Process control and waste reduction in pharmaceutical water systems

Effective process control is fundamental to minimizing water waste in pharmaceutical facilities, particularly in the production of high purity water. Six Sigma methodologies applied to water management have demonstrated improvements in process capability and reductions in out of specification water output (Rimantho et al., 2017). Similar benefits have been reported in related industries. For instance, optimization of Cleaning-in-Place (CIP) operations in food processing plants, through mathematical modelling of chemical and water flow ratios, resulted in substantial reductions in resource consumption (Niamsuwan et al., 2011).

In the pharmaceutical industry, regulatory compliance serves as a catalyst for improvements in effluent treatment, with legal frameworks encouraging the adoption of environmentally responsible practices (Saviano et al., 2022). Beyond compliance, corporate social responsibility

initiatives have also gained traction, promoting a proactive approach to water conservation and sustainable production (Silva, 2017).

The integration of LSS principles with sustain ability focused water management practices offers a promising pathway to enhanced operational performance and environmental stewardship. The continuous evolution of water efficiency strategies, supported by advanced process control and data driven improvement methodologies, underscores the necessity for pharmaceutical manufacturers to adopt structured and proactive approaches to resource optimization.

3. Methodology

This research employed a mixed methods approach, combining qualitative and quantitative techniques to assess and improve distilled water utilization within a pharmaceutical manufacturing facility. The study was structured using the LSS DMAIC framework, which facilitated a systematic investigation of process inefficiencies, the implementation of corrective measures, and the monitoring of long-term outcomes (Amaral, 2013). The overarching objective was to minimise water waste without compromising production performance or regulatory compliance.

3.1. Data collection and diagnostic tools

Data were gathered through document analysis, semi structured interviews with personnel across departments, and a comprehensive review of internal production records related to distilled water usage. A suite of LSS tools was used to analyse the workflow and identify sources of inefficiency. These included:

- SIPOC for mapping high level process components.
- VSM and Process Mapping (PMAP) to visualise workflows and detect nonvalue adding steps.
- FMEA to identify and prioritise process risks (Moura et al., 2020).
- Ishikawa (Fishbone) Diagram to categorise root causes by key factors, including equipment, methods, people, and environment.

3.2. Problem definition and goal setting

The Define phase involved characterizing customer needs using the Voice of the Customer (VoC) tool, which identified excessive distilled water disposal as a primary concern for both

internal and external stakeholders. Project boundaries were clarified, and a reduction target of 50% in distilled water waste was established, aligning with operational and sustainability objectives.

3.3. Measurement phase

During the Measure phase, the distilled water production and consumption process was characterised in detail using process mapping tools. Key performance indicators (KPIs) were defined to measure volumes of water produced, discarded, and consumed, along with associated energy usage. A structured data collection plan was developed to ensure consistency and accuracy in tracking process variables. Data were gathered over a 12-month period using verification sheets and control spreadsheets.

3.4. Root cause analysis

The Analyse phase focused on identifying root causes of inefficiency. The Fishbone diagram provided a qualitative overview, while the Cause-and-Effect Matrix quantified the influence of each factor on waste generation. This dual layered analysis was essential for determining prioritization. High impact causes were further investigated using FMEA, revealing that manual operation of distillers, particularly the lack of programmed shutdowns, was a critical failure mode contributing to unnecessary water production.

3.5. Implementation of improvements

In the Improve phase, a set of targeted actions was developed and implemented. These included:

- Installation of programmable timers in distiller control panels to automate equipment shutdown.
- Measurement of distilled water flow rate to establish daily production requirements.
- Development of a time-based reference table for scheduling water production.
- Implementation of a visual management system to communicate production plans to operators.
- Training programmes to standardise operating procedures across shifts.

Corrective actions were documented using the 5W2H planning tool to ensure clarity regarding responsibility, location, timeline, resources, and justification.

3.6. Control and standardization

To guarantee long term sustainability of improvements, process standardization was introduced. This involved revising internal operating procedures, integrating automated monitoring tools, and institutionalizing training modules for relevant personnel. Continuous monitoring of KPIs was performed to assess the effectiveness of the interventions and ensure alignment with predefined targets.

This methodological approach enabled the systematic identification, quantification, and elimination of inefficiencies in distilled water management. By applying LSS principles, the project contributed to broader efforts in sustainable pharmaceutical manufacturing and demonstrated the applicability of data driven process optimization frameworks.

4. Results

The application of the DMAIC methodology enabled the identification and quantification of inefficiencies in the distilled water production process. Analysis of historical data revealed significant volumes of water discarded due to expiration of its 24-hour validity period, which was linked to overproduction and the absence of process scheduling.

4.1. Water waste quantification

The initial assessment, supported by VSM and employee interviews, showed that, on average, 106 litres of distilled water were discarded daily in 2023, representing approximately 70% of the total water produced. Figure 1 illustrates this average daily disposal rate.

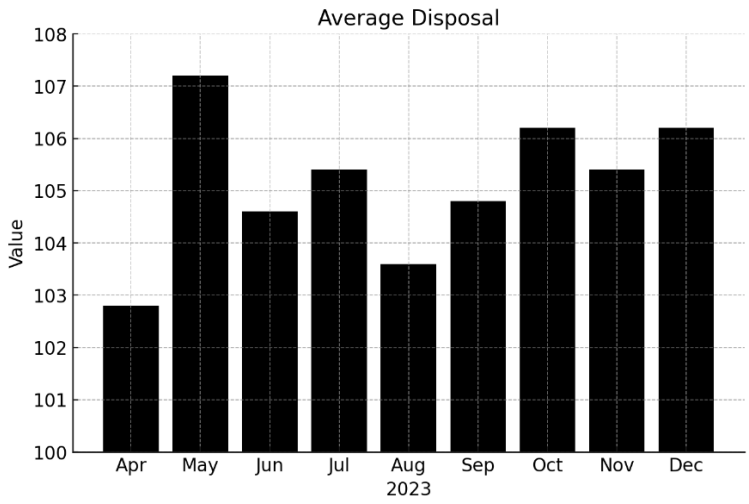

Figure 1. Daily average of discarded distilled water

Source: elaborated by the authors (2025)

Table 1 confirms the consistency of this waste pattern, with monthly averages remaining above 100 litres throughout the year.

Table 1

Average daily disposal of distilled water in 2023

Month	Average Disposal (L)
Apr/2023	102.75
May/2023	107.21
Jun/2023	104.50
Jul/2023	105.45
Aug/2023	103.58
Sep/2023	104.87
Oct/2023	106.26
Nov/2023	105.50
Dec/2023	106.30
Average	105.32

Source: elaborated by the authors (2025)

4.2. Process mapping and root cause identification

The VoC analysis, summarized in Table 2, revealed sustainability and cost reduction as critical needs.

Table 2

VoC – Stakeholder Needs

Stakeholders	Needs	Drivers	CTQs/CTPs
External Customer	Water disposal reduction	Sustainability	Reduced water waste
Internal Facilities	Energy and water cost savings	Utility consumption	Efficient water usage

Source: elaborated by the authors (2025)

SIPOC analysis, as shown in Table 3, highlighted the procedural flow, particularly the lack of feedback mechanisms linking production output to actual demand.

Table 3

SIPOC Diagram Summary

S	I	P	O	C
Distillation Room	Distillers and control systems	Water distillation and quality tests	Approved distilled water	Production
Production/ Quality	Handling, sampling, and cleaning	Expired water disposal	Discarded water	Production

Source: elaborated by the authors (2025)

The scope of the improvement project was defined in Table 4, aiming for a 50% reduction in waste through process modifications.

Table 4

Project scope summary

Out of Scope	In Scope
Pipeline leak inspections; maintenance activities	Modify distillation process to reduce water waste

Source: elaborated by the authors (2025)

4.3. Measurement tools and data collection

A detailed process map, as shown in Table 5, captured the sequence of activities, inputs, and outputs.

Table 5

Process map summary

X (Inputs)	Steps	Y (Outputs)
Equipment, alcohol, energy	Setup and operation of distillers	Validated distilled water
Sampling and analysis	Water quality approval	Distilled water for use
Expiration management	Disposal process	Water waste
X (Inputs)	Steps	Y (Outputs)

Source: elaborated by the authors (2025)

A corresponding data collection plan, as shown in Table 6, ensured traceability and accountability.

Table 6

Data collection plan

What to Measure	Measurement Type	Unit	Source
Distilled water volume (produced/discarded)	Volume	Litres	Water control spreadsheet (2023–2024)
Energy consumption	Energy	kWh	Verification forms

Source: elaborated by the authors (2025)

The Ishikawa Diagram, as illustrated in Figure 2, categorized contributing factors under key dimensions such as equipment, method, and workforce.

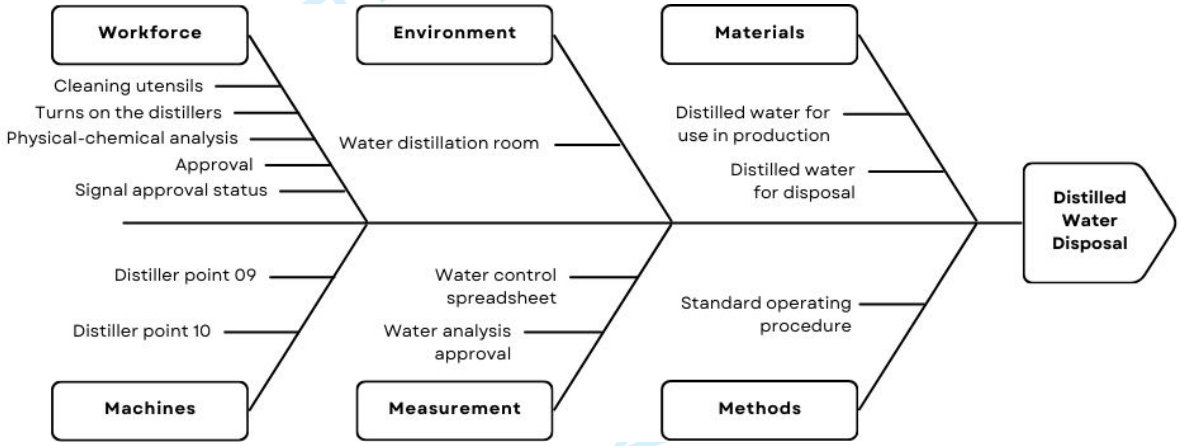

Figure 2. Fishbone diagram

Source: elaborated by the authors (2025)

Subsequently, the Cause-and-Effect Matrix, as shown in Table 7, prioritized critical contributors, particularly operators and distillers, based on weighted impact.

Table 7

Cause-and-Effect Matrix (Top Items)

Causes	Impact Weight	Total Score
Production Operators	5 × 5 × 5	125
Distillers 9 & 10	5 × 5 × 5	125
Discarded Water	5 × 5 × 5	125

Source: elaborated by the authors (2025)

An Effort–Impact Matrix, as illustrated in Figure 3, supported decision making for improvement prioritization.

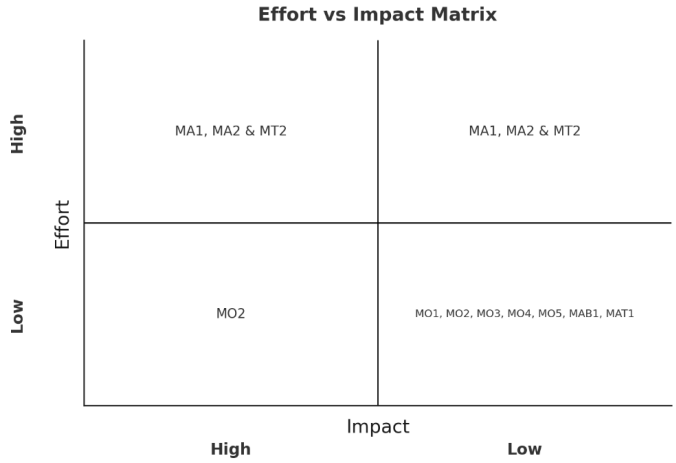

Figure 3. Effort–Impact Matrix

Source: elaborated by the authors (2025)

Meanwhile, Figure 4 highlighted the persistent high discard rate.

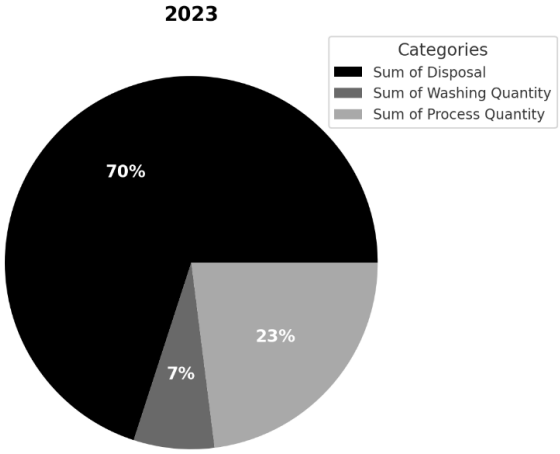

Figure 4. Percentage of water discarded

Source: elaborated by the authors (2025)

Monthly analysis revealed that 32,988 liters of distilled water were discarded over a 12-month period, as shown in Table 8. The associated energy costs were estimated at R$ 40,423.68, and equipment operation time totaled 1,320 hours.

Table 8

Monthly and annual discard summary

Period	Disposal Volume (L)
2023 Total	24,330
2024 Total*	8,658
Grand Total	32,988

*Data until April 2024

Source: elaborated by the authors (2025)

4.4. Risk Analysis and key failures

FMEA results, as shown in Table 9, revealed that the most critical failure mode was excess water production due to the lack of automatic distiller shutdown. The highest Risk Priority Number (RPN) was 800, later reduced to 280 after automation.

Table 9

FMEA – Critical Failure Mode

Process Step	Failure Mode	RPN (Before)	RPN (After)	Action
Water Production	Excess water production	800	280	Install timer and schedule output

Source: elaborated by the authors (2025)

4.5. Implemented improvements

Timers were installed in distillers to automate shutdowns, as illustrated in Figure 5.

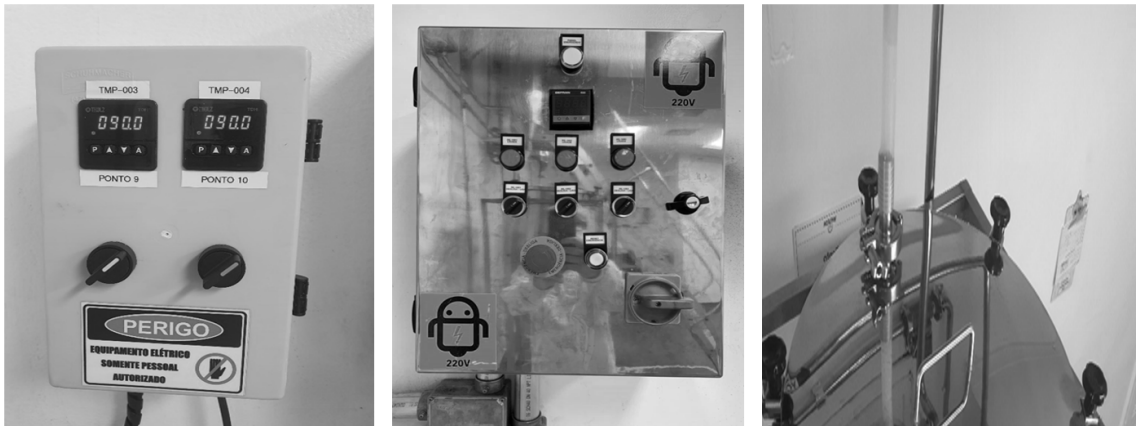

Figure 5. Timer installed in distillation panel

Source: elaborated by the authors (2025)

A time–volume production table was developed and made available through visual management boards. Operators were trained and a standard operating procedure (SOP) was formalized.

The 5W2H plan, as shown in Table 10, outlined key actions, responsibilities, costs, and timelines. The timer acquisition cost was R$ 540.00.

Table 10

5W2H action plan

What	Why	Who	How	Cost	Where	When
Install timers	Reduce water waste	Employee A	Automation	R$ 540.00	Distillation room	25/03/2024
Create reference table	Optimise production volumes	Employee B	Measure takt time	No cost	Distillation room	05/03/2024
Standardise procedure	Ensure consistent practices	Employee A	SOP development	No cost	Internal documentation	05/03/2024

Source: elaborated by the authors (2025)

4.6. Performance outcomes

The Prioritization Matrix, as shown in Table 11, confirmed that timer installation offered the highest impact with low cost and effort. Trend analyses revealed a clear decline in both water waste and operational costs following implementation.

Table 11

Prioritization Matrix

Action	Impact	Effort	Cost	Total Score
Timer Installation	High	Low	Low	109
Equipment Setup	High	High	High	65
Operator Training	Low	Low	Low	15

Source: elaborated by the authors (2025)

The effectiveness of the implemented improvements is further illustrated in the trend analyses. Figure 6 presents a downward trend in the volume of discarded distilled water over

time, confirming the consistent reduction achieved following the introduction of automated timers and scheduled production practices.

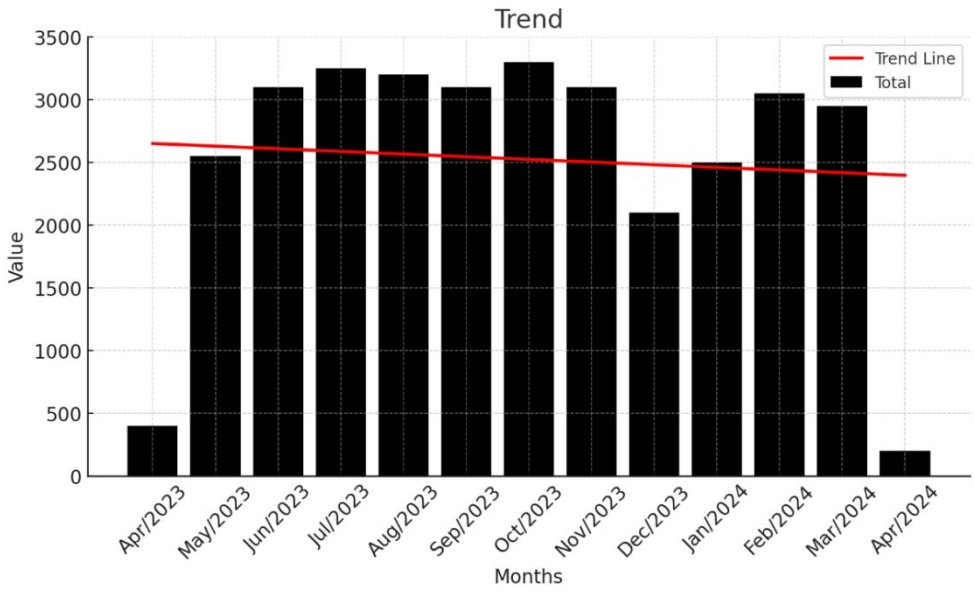

Figure 6. Trend in water disposal

Source: elaborated by the authors (2025)

Similarly, Figure 7 highlights a substantial decline in monthly energy costs, particularly evident in the months of March and April 2024, after process automation was fully implemented. These figures demonstrate the project's success not only in minimizing water waste but also in enhancing energy efficiency, two key indicators of operational sustainability.

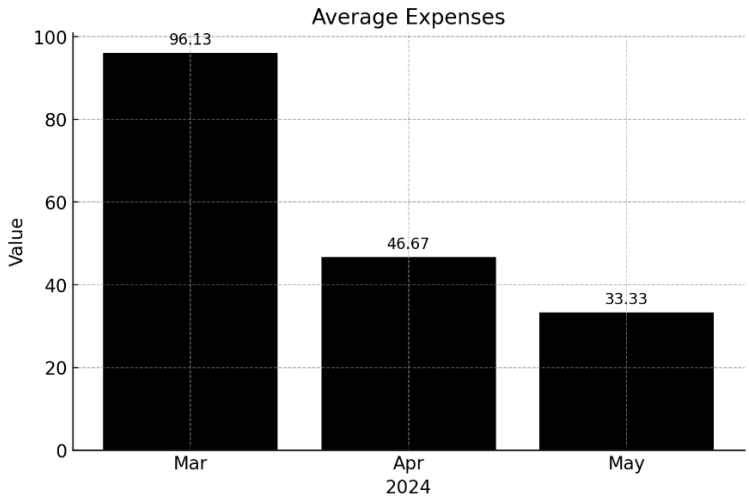

Figure 7. Monthly energy cost trends

Source: elaborated by the authors (2025)

After implementation, the daily average disposal dropped from 106 litres to 33.3 litres, equating to a 70% reduction, well above the initial 50% target. This demonstrated both the effectiveness of the interventions and the engagement of operational teams in sustainability efforts.

5. Discussion

The results of this study demonstrate the effectiveness of the LSS DMAIC methodology in addressing inefficiencies related to distilled water management in pharmaceutical production. The structured application of data driven tools enabled the identification of critical waste points, formulation of targeted improvements, and implementation of sustainable operational practices.

5.1. Operational and economic implications

One of the most significant findings was the identification of excessive distilled water production due to the absence of production scheduling and manual control of distillers. By installing programmable timers and establishing standard operating procedures, the process was successfully automated, reducing variability and aligning production with actual demand. This aligns with broader findings in the industry 4.0 domain, where structured decision-making regarding technological adoption remains underexplored, despite growing interest in digital transformation frameworks (Silva et al., 2022). These improvements led to a 70% reduction in water waste, surpassing the project's initial 50% target.

From an economic perspective, the reduction of 32,988 litres of discarded water translated into substantial savings in energy consumption and operational hours, equivalent to over 1,300 hours of equipment operation and R$ 40,423.68 in energy costs. These figures underscore the financial benefits of process optimization, especially when implemented with low cost, high impact solutions such as automation and visual management.

5.2. Contribution to organizational learning and process improvement culture

Although the host organization lacked a formal continuous improvement programme, this project fostered interdisciplinary collaboration among the engineering, production, and maintenance teams. The openness to change and positive reception of proposed improvements reflected a readiness to embrace process innovation.

Importantly, the project also served as a practical learning opportunity, enabling participants to apply LSS tools in a real-world context. Employees, even those without prior theoretical

knowledge of improvement methodologies, gained valuable tacit knowledge through hands on involvement in data analysis, root cause identification, and solution development. This experiential learning is instrumental in cultivating a culture of continuous improvement within industrial environments.

5.3. Integration with Environmental Sustainability Objectives

The initiative aligns closely with global sustainability goals and pharmaceutical industry expectations for responsible resource management. Water scarcity, environmental degradation, and regulatory pressure require pharmaceutical manufacturers to adopt more sustainable practices (Wanderley & Nascimento, 2017; Dias, 2011). By significantly reducing water waste, this project directly contributes to environmental stewardship, reinforcing the notion that operational excellence and sustainability are not mutually exclusive, but rather complementary objectives.

The demonstrated success of LSS tools, especially FMEA, SIPOC, Fishbone Diagrams, and 5W2H, reinforces their value not only for productivity enhancement but also for resource conservation. Heuristic models for task allocation, such as those applied to mixed-model assembly lines, demonstrate how targeted operational restructuring, without complex sequencing, can yield efficiency gains and reduce resource constraints, reinforcing the broader applicability of such tools (Reginato et al., 2016). The ability to quantify and validate improvements using KPIs ensured that outcomes were not only achieved but also sustained through monitoring and standardization efforts.

5.4. Methodological considerations and limitations

One notable challenge encountered was isolating the individual impact of each improvement action. As is common in LSS implementations, several improvements were deployed concurrently, complicating the attribution of specific results to interventions. For instance, although there is strong evidence that the automation of distillers was a key factor in waste reduction, other changes, such as visual management and operator training, likely had compounding effects that are difficult to disentangle.

Despite these limitations, the study demonstrates how the DMAIC approach facilitates rapid and measurable performance improvements even in resource constrained environments. Moreover, the methodology's flexibility allows for iterative refinement, which is essential for adapting solutions to operational realities.

5.5. Opportunities for future work

This case study opens several avenues for further investigation. Future research could focus on developing predictive models using historical data to anticipate water demand and optimise distillation schedules dynamically. Additionally, expanding the scope to include water reuse strategies, such as pretreatment and recovery of expired distilled water, may further enhance sustainability outcomes. The replication of this methodology in other utility intensive processes (e.g., steam generation, clean in place systems) may also reveal broader applications across pharmaceutical manufacturing.

6. Conclusions

This study demonstrated the effectiveness of the LSS DMAIC methodology in addressing inefficiencies in distilled water usage within a pharmaceutical production environment. By systematically applying tools such as SIPOC, VSM, FMEA, Fishbone Diagrams, and 5W2H, the project achieved a 70% reduction in water waste, surpassing the original target of 50%. This outcome not only yielded considerable operational and financial benefits, including substantial reductions in energy costs and equipment operating time, but also contributed to environmental sustainability by minimizing resource consumption.

The successful implementation of low cost, high impact improvements, such as automating distiller shutdowns and standardizing production schedules, highlights the practical applicability of LSS in regulated and resource sensitive industries. These results affirm that structured methodologies can drive meaningful improvements even in the absence of a formal institutional culture of continuous improvement.

Moreover, the project fostered cross functional collaboration and empowered operational personnel through active engagement in problem solving activities. This inclusive approach facilitated the development of tacit knowledge, laying the groundwork for a stronger organizational commitment to process excellence.

However, one methodological limitation was the difficulty in isolating the impact of individual interventions due to their concurrent implementation. Despite this, the overall reduction in waste and energy consumption validates the effectiveness of the combined strategies.

Importantly, the findings underscore the untapped potential of operational data within pharmaceutical facilities. While such data are often used for reactive control, they remain underutilized for preventive or predictive process optimization. The study therefore advocates

for broader adoption of LSS principles and the integration of data analytics to enhance competitiveness and sustainability in the pharmaceutical sector.

In conclusion, this research contributes to the advancement of best practices in pharmaceutical water management and offers a replicable model for continuous improvement. By aligning operational efficiency with environmental responsibility, the proposed methodology supports long term sustainability and regulatory compliance in industrial contexts.

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