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Lean Manufacturing Implementation for Yield Optimization and Cost Efficiency Improvement in Semisolid Pharmaceutical Production: A Case Study on Miconazole Cream

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Abstract: Yield loss due to overfill during the filling process remains a major source of material waste and increased production costs in semisolid pharmaceutical manufacturing. This study aimed to implement a lean manufacturing approach to optimize production yield and improve cost efficiency in miconazole cream production. A quantitative descriptive case study was conducted on the semisolid production line of an Indonesian pharmaceutical company. Data were collected through direct observation, production records, in-process control (IPC) records, and historical operational data. Value Stream Mapping (VSM) and fishbone diagram analysis were used to identify waste and determine the root causes of process inefficiencies, while a before–after analysis evaluated the effectiveness of the implemented improvements. The filling process was identified as the primary source of process variability and overfill. Improvement actions, including holder position adjustment, tightening of fill weight specifications, and increased IPC frequency, reduced the average fill weight from 10.315 g to 10.115 g and increased production yield from 97.18% to 98.20%. These improvements generated an average cost saving of IDR 113,924 per batch, equivalent to a potential annual cost efficiency of IDR 134,771,855. The findings demonstrate that lean manufacturing effectively reduces process variability, improves production yield, and enhances cost efficiency in semisolid pharmaceutical manufacturing.

Keywords: Cost efficiency; Lean manufacturing; Pharmaceutical manufacturing; Production yield; Value Stream Mapping

Introduction

The pharmaceutical industry is one of the most highly regulated manufacturing sectors because its products are directly related to patient health and safety (Tabersky et al., 2018). Therefore, every stage of the manufacturing process must comply with quality, safety, and consistency requirements in accordance with the principles of Good Manufacturing Practices (GMP), which emphasize process control, validation, documentation, quality risk management, and the implementation of a comprehensive pharmaceutical quality system (International Conference on Harmonisation, 2008; WHO, 2021). At the same time, increasing global competition, rising raw material costs, and growing demands for productivity and sustainability require pharmaceutical manufacturers not only to produce products that comply with regulatory standards but also to optimize resource utilization, improve process efficiency, and control production costs to maintain their competitive advantage (Byrne et al., 2021; Moosivand et al., 2019). These challenges create a complex manufacturing environment in which productivity improvement initiatives must be carefully balanced with regulatory compliance, product quality consistency, and manufacturing process reliability. Consequently, improving operational efficiency is no longer viewed solely as a cost-reduction strategy but

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also as an integral component of the pharmaceutical quality system that supports the long-term sustainability and competitiveness of pharmaceutical manufacturers.

In response to these challenges, lean manufacturing has been increasingly adopted in the pharmaceutical industry as a strategic approach to improve operational performance while maintaining regulatory compliance. Lean manufacturing is a continuous improvement philosophy that focuses on value creation through the elimination of non-value-added activities (waste) across the production process (Nwamekwe et al., 2025; Makwana & Patange, 2021). The concept originates from the Toyota Production System (TPS), which is founded on two fundamental principles: the continuous elimination of waste and continuous improvement (Kaizen) to maximize customer value. According to this theory, operational excellence is achieved by improving process flow, standardizing work practices, and minimizing activities that do not contribute value to the final product (Liker, 2004; Yamamoto et al., 2019). Unlike conventional productivity improvement approaches that primarily emphasize production capacity expansion, lean manufacturing promotes streamlined process flow, reduced process variability, optimized resource utilization, and enhanced operational flexibility, thereby creating a more efficient and responsive manufacturing system (Leksic et al., 2020; Vinodh et al., 2011). In pharmaceutical manufacturing, lean implementation has been shown not only to improve operational efficiency by reducing waiting time, material waste, and other non-value-added activities, but also to strengthen process control, thereby supporting product quality consistency and compliance with Good Manufacturing Practices (Alifiya et al., 2025; Sari, 2023). Consequently, lean manufacturing is increasingly recognized as a strategic approach for simultaneously enhancing productivity, product quality, and cost efficiency in modern pharmaceutical manufacturing.

Various lean manufacturing tools have been developed to support process analysis and the implementation of continuous improvement initiatives in manufacturing systems (Brito et al., 2020; Oliveira et al., 2017; Shah & Patel, 2018). One of the most widely applied tools is Value Stream Mapping (VSM), which provides a comprehensive visualization of material and information flows, enabling the systematic identification of both value-added and non-value-added activities (Batwara et al., 2023; Martínez-Cerón et al., 2022). Through this mapping approach, organizations can identify sources of waste, process bottlenecks, waiting time, and flow imbalances that adversely affect operational efficiency (Liu & Yang, 2020). However, while VSM effectively reveals where inefficiencies occur, it does not explain the underlying causes of these problems. Therefore, root cause analysis using the fishbone diagram (cause-and-effect diagram) is employed to systematically identify the factors contributing to process inefficiencies from the perspectives of man, machine, method, material, measurement, and environment (Antony et al., 2022; Neves et al., 2018).

From a lean manufacturing perspective, activities that do not add value are classified as waste, which generally includes overproduction, waiting, transportation, overprocessing, inventory, motion, and defect (Dewi et al., 2021; Zahrotun & Taufiq, 2018). These seven categories of waste increase lead time, resource consumption, and production costs while reducing productivity and overall operational performance (Sutrisno et al., 2018). Previous studies have demonstrated that integrating Value Stream Mapping with root cause analysis enhances process visibility, facilitates bottleneck identification, supports the prioritization of improvement initiatives, and enables data-driven decision-making in lean manufacturing implementation (Gomaa, 2025; Liu & Yang, 2020; Seth et al., 2017; Yanti et al., 2023). Therefore, the integration of these two approaches provides an effective framework for identifying the root causes of process inefficiencies, developing targeted corrective actions, and achieving sustainable improvements in productivity and operational efficiency.

Several studies have reported that the implementation of lean manufacturing and Lean Six Sigma can significantly improve operational efficiency, reduce waste, and enhance process stability in pharmaceutical manufacturing (AL-Tahat & Nsour, 2025; da Silva et al., 2023). The implementation of various lean tools, including Value Stream Mapping (VSM), Single-Minute Exchange of Dies (SMED), and Kaizen, has also been shown to reduce changeover time, improve productivity, and enhance manufacturing process quality in pharmaceutical production (Karam et al., 2018). Furthermore, VSM has been widely applied to identify process bottlenecks, non-value-added activities, and opportunities for process optimization through waste elimination (Dara et al., 2024; Kumar et al., 2022). The integration of lean principles with pharmaceutical quality systems has also been reported to strengthen the control of critical process parameters, enhance compliance with Good Manufacturing Practices (GMP), and improve the long-term reliability of manufacturing processes (Garza-Reyes et al., 2018; Tetteh-Caesar et al., 2024).

Despite these advances, most previous studies have primarily focused on improving productivity, reducing cycle time, or implementing Lean Six Sigma in pharmaceutical manufacturing processes in general.

Research specifically investigating the application of lean manufacturing in semisolid pharmaceutical production, particularly for yield optimization and cost efficiency improvement through optimization of the filling process, remains limited. Moreover, previous studies have generally emphasized operational performance indicators, such as process time and productivity, without quantitatively evaluating the economic benefits associated with improved production yield and cost savings. Therefore, further research is needed to integrate Value Stream Mapping with root cause analysis to develop targeted improvement strategies that not only enhance operational efficiency but also deliver measurable improvements in production yield and cost efficiency in semisolid pharmaceutical manufacturing.

Miconazole cream is classified as a Pareto A product at XYZ Pharmaceutical Company, with an annual production target of 10,650,622 tubes based on the 2026 Corporate Work Plan and Budget (Rencana Kerja dan Anggaran Perusahaan, RKAP). This high production volume indicates that the product makes a substantial contribution to the company's operational performance and manufacturing costs, making process efficiency a critical concern. The manufacturing process consists of raw material weighing, mixing until a homogeneous bulk is obtained, and filling into aluminum tubes as the primary packaging. Among these stages, the filling process is particularly critical because it directly affects product fill weight, production yield, and raw material utilization efficiency. Consequently, optimizing the filling process is essential for improving process stability while minimizing material waste.

Based on this background, the present study aims to implement a lean manufacturing approach in semisolid pharmaceutical production to optimize production yield and improve cost efficiency. The study focuses on identifying sources of waste, implementing lean-based improvement initiatives, and evaluating process performance following the implementation of corrective actions in the production of miconazole cream. The findings are expected to provide practical insights into improving manufacturing process efficiency and serve as a reference for the implementation of lean manufacturing in the pharmaceutical industry.

Method

This study was conducted on the semisolid production line of PT. XYZ pharmaceutical industry in Indonesia, focusing on the manufacturing process of miconazole cream products. The scope of the study covered the main production stages, including raw material weighing, mixing, and primary packaging (filling), with particular emphasis on the filling process as a critical stage directly affecting production yield and cost efficiency. Observations were carried out during a specific production period to obtain representative operational data.

This study employed a quantitative descriptive design using a case study approach to evaluate production process performance through the implementation of lean manufacturing. The approach was intended to identify waste, analyze the root causes of inefficiencies, and formulate improvement actions to enhance yield and cost efficiency. The study population included all production activities within the semisolid production line during the observation period, while the sample consisted of continuously collected operational production data. A total sampling technique was applied, in which all available data were used as research objects.

The dependent variables in this study were production yield and cost efficiency, while the independent variables included operational parameters such as cycle time, downtime, changeover time, production output, reject quantity, and product fill weight. In addition, process control parameters, including fill weight specification limits and in-process control (IPC) results, were used as indicators for process performance evaluation.

Data collection was conducted through direct observation in the production area, documentation review of production reports and IPC records, and analysis of historical company data. The collected data included machine operating time, production output, product fill weight variation, and waste-related data generated during the production process. All data were subsequently validated and processed to ensure analytical accuracy.

The study was carried out through systematic stages in accordance with lean manufacturing principles, beginning with problem identification and preliminary observation to understand the production flow and identify potential waste. Process mapping using Value Stream Mapping (VSM) was then performed to distinguish value-added and non-value-added activities, followed by the identification of major waste sources, particularly those related to overfill, waiting time, and process variability. Root cause analysis was conducted using a fishbone diagram covering human, machine, method, and material aspects. Based on the analysis results, lean-based improvement actions were designed and implemented, including process parameter adjustment, fill weight optimization, and strengthening of process control through in-process control (IPC). The final stage involved evaluating process performance by comparing

conditions before and after improvement implementation (before–after analysis), including post-improvement data collection and analysis to formulate conclusions and recommendations for continuous improvement. The overall research procedure is illustrated in Figure 1.

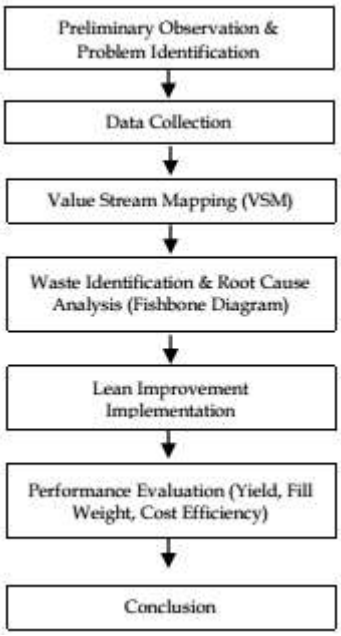

Figure 1. Research methodology flowchart

Quantitative analysis was performed to evaluate production process performance. Production yield was calculated as the ratio between the actual product output and the theoretical output or input material used in the production process. Yield was calculated using the following equation:

$$\text{Yield}(\%) = \frac{\text{Actual Product Output}}{Theoretical\ output} x\ 100\% \quad (1)$$

The average product fill weight was calculated to determine the tendency of filling variation during the production process using the following equation:

$$\bar{x} = \frac{\sum x}{n} \quad (2)$$

Cost efficiency was evaluated based on the potential cost savings obtained from yield improvement after the implementation of corrective actions, using the following equation:

$$Cost\ saving = (Yield_{after} - Yield_{before}) x\ Cost\ per\ unit \quad (3)$$

The calculated results were then analyzed descriptively to evaluate the effectiveness of lean manufacturing implementation in improving production yield and cost efficiency. A before–after analysis approach was applied to assess the impact of the implemented improvements on overall process performance.

Result and Discussion

The semisolid production process begins with the raw material weighing stage, followed by the mixing process, which includes base preparation and active ingredient blending. During the base preparation stage, tank heating is required to produce the oil phase and water phase before both phases are combined. The result of the mixing process is a bulk mass, which is subsequently stored in the quarantine area during the testing process conducted by the quality control department. After the bulk product is approved by the quality control department, the next stage is the filling process, in which the product is filled into aluminum tubes. The overall production process can be illustrated using Value Stream Mapping (VSM), as shown in Figure 2.

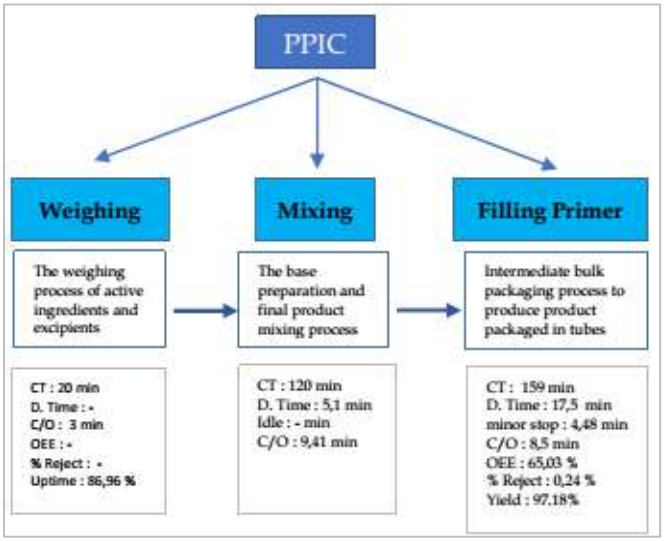

Figure 2. Value stream mapping (VSM) of the miconazole cream production process

Based on the analysis using Value Stream Mapping (VSM), waste was identified within the production process, particularly related to inefficiencies and process variability at the filling stage. Initial data showed that the production yield of miconazole products was approximately 97.18%, indicating that material loss still occurred during the production process. Although this value is generally considered high, even a small deviation in yield can have a significant impact on cost efficiency in large-scale production. In addition, the average product fill weight before improvement ranged from 10.20–10.40 grams (Table 1), which consistently

exceeded the established target limit (10.20 g). This condition indicated the presence of systematic overfill practices as a form of compensation for process variability. These findings are consistent with previous studies reporting that Value Stream Mapping effectively identifies process bottlenecks, non-value-added activities, and process variability that negatively affect manufacturing performance (Abdulmalek & Rajgopal, 2007; Khan et al., 2020; Seth et al., 2017). Similar applications of VSM in pharmaceutical and manufacturing industries have demonstrated its effectiveness in supporting waste identification and prioritizing improvement opportunities (Sucipta & Kusumastuti, 2025).

Further analysis indicated that a deviation of approximately ±0.1 g per unit in large-scale production could accumulate into substantial product mass losses, thereby reducing overall process efficiency. In high-volume pharmaceutical manufacturing, even minor deviations in fill weight may result in considerable raw material losses and increased production costs. This finding indicates that the observed overfill was not merely a quality issue but also represented a source of process inefficiency caused by excessive material consumption. From a lean manufacturing perspective, such conditions can be classified as overprocessing waste, as they arise from unnecessary processing beyond product requirements and inadequate control of process variability. Similar observations have been reported in pharmaceutical manufacturing, where uncontrolled process variation increases material consumption and reduces process capability, highlighting the importance of systematic process control to improve manufacturing efficiency (Aucasime-Gonzales et al., 2020; Duarte et al., 2025).

Table 1. Product Weight before Improvement (Weeks 1–10, 2026).

Week	Average product weight (gram)	Yield (%)
1	10.315	96.31
2	10.257	97.12
3	10.316	97.09
4	10.263	97.18
5	10.323	97.39
6	10.273	97.34
7	10.334	97.27
8	10.252	97.37
9	10.269	97.40
10	10.276	97.32
Average	10.315	97.18

To identify the root causes of the observed waste, a root cause analysis was conducted using a fishbone diagram (cause-and-effect diagram). This approach enabled the classification of contributing factors into several major aspects, namely human (man), machine, method, and material factors (Figure 3).

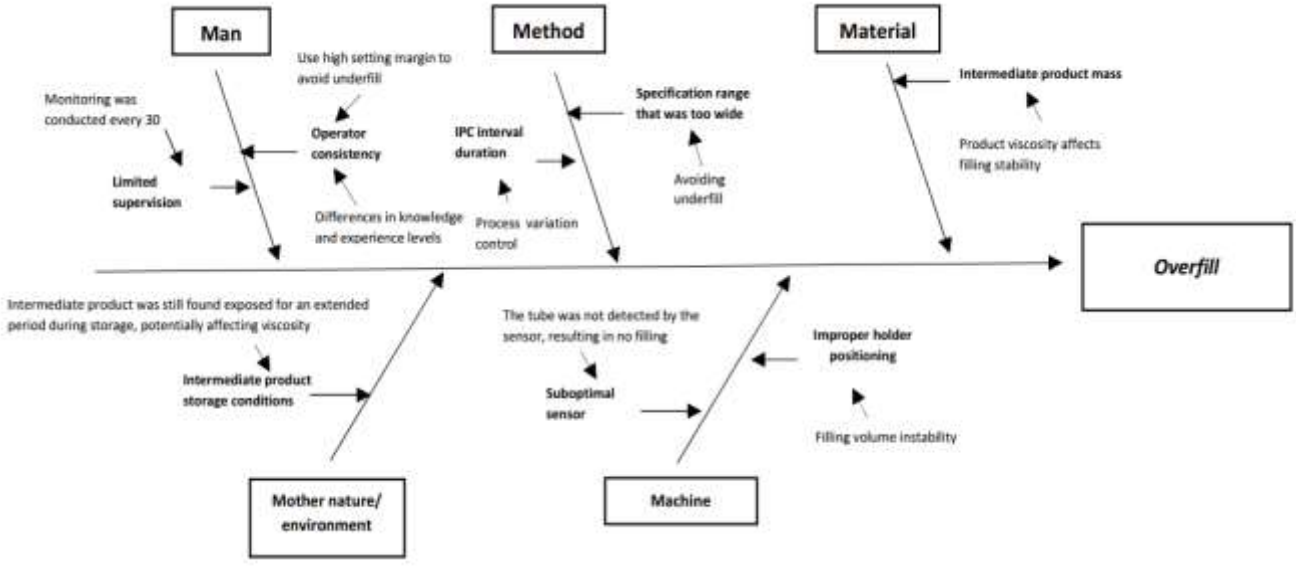

Figure 3. Fishbone diagram illustrating the root cause analysis of overfill

The analysis results showed that, from the machine aspect, improper holder positioning and inappropriate sensor settings contributed to instability in the filling process, thereby triggering variations in product fill weight. From the method aspect, excessively wide fill weight specification ranges and suboptimal process control through in-process control (IPC) led operators to tend toward excessive filling as a preventive measure against the risk of underfilled products. From the human aspect, inconsistencies in process parameter settings and limited supervision during production further increased operational variability. Meanwhile, from the material

aspect, although no significant deviations were identified, variations in material characteristics still had the potential to affect filling process stability.

Based on the root cause analysis using the fishbone diagram, improvement actions were systematically designed in accordance with lean manufacturing principles, particularly waste elimination and process variation control. The improvements focused on dominant factors affecting filling process instability, especially machine and method aspects, which were identified as having the greatest contribution to the occurrence of overfill.

From the machine aspect, holder positioning was adjusted to ensure that the tube was aligned more precisely with the filling sensor. This improvement aimed to enhance the accuracy and consistency of filling volume, thereby minimizing fill weight variation. In addition, sensor settings were adjusted to ensure more stable tube position detection and to prevent filling fluctuations (Figure 4).

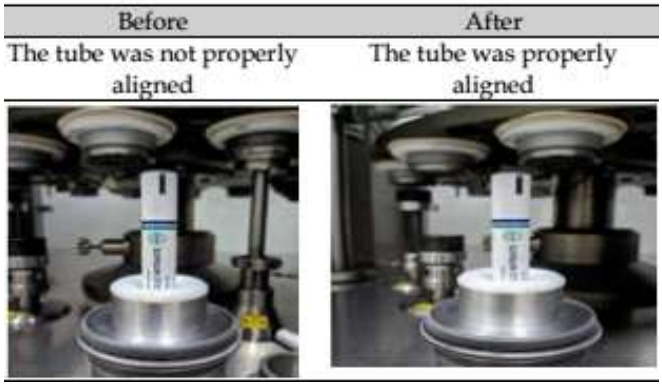

Figure 4. Tube holder alignment before and after improvement

From the method aspect, the fill weight specification range was tightened from 10.000–10.400 g to 10.000–10.200 g. This adjustment was intended to reduce the tendency for overfill that had previously been used as a "buffer" against process variability. In addition, the frequency of in-process control (IPC) was increased to ensure that the filling process remained within the established control limits. Through more frequent monitoring, process deviations could be detected earlier and corrected immediately.

From the human aspect, efforts were made to strengthen operator discipline in following standardized process parameters and to increase awareness regarding the importance of fill weight control. This approach aimed to reduce variability caused by human factors and improve operational consistency.

Meanwhile, from the material and environment aspects, process conditions were controlled to maintain stability, although these factors were not identified as dominant contributors. This included maintaining material consistency and ensuring that environmental conditions adequately supported smooth production operations.

The implementation of these improvements demonstrated that a lean approach focused on simple yet targeted improvements (focused improvement) could provide significant impacts on process performance. Parameter adjustments and enhanced operational control proved effective in reducing process variability without requiring major investment in equipment. This finding is consistent with the principle of continuous improvement, in which efficiency enhancement is achieved through gradual, data-driven improvements.

Overall, the fishbone diagram analysis demonstrated that the observed waste resulted from the interaction of multiple technical and operational factors rather than a single isolated cause. These findings indicate that effective waste reduction requires integrated improvement strategies involving process parameter optimization, equipment adjustment, and strengthened process control. This integrated approach is consistent with previous Lean Six Sigma studies, which emphasize that sustainable process improvement should simultaneously address technical, operational, and organizational factors (Medne & Lapina, 2019). Similar findings have been reported by Sakdiyah et al. (2022), who demonstrated that process inefficiencies generally arise from the interaction of human, machine, method, and material factors rather than from a single isolated cause. This similarity indicates that the root causes identified in the present study are consistent with broader evidence from lean manufacturing applications.

Table 2. Product weight after improvement (Weeks 11–15, 2026)

Week	Average product weight (gram)	Yield (%)
11	10.115	98.22
12	10.117	98.09
13	10.116	98.20
14	10.113	98.18
15	10.115	98.31
Average	10.115	98.20

The improvements implemented in the filling process, particularly through holder position adjustment, tightening of fill weight specification ranges, and increased in-process control (IPC) frequency, were proven effective in reducing the average product fill weight so that it approached the established target more closely. The reduction in average fill weight indicated a decrease in overfill practices and better control of filling process variability. As a consequence, process efficiency improved, directly

contributing to enhanced production yield. By reducing fill weight deviation per unit, material loss during production could be minimized, resulting in improved effective yield despite the relatively simple nature of the implemented changes (Table 2). These findings indicate that better process parameter control can significantly improve production performance from both technical and economic perspectives through enhanced process stability and more efficient raw material utilization, ultimately contributing to improved cost efficiency, as reflected by the cost savings achieved after the implementation of corrective actions (Table 3).

Table 3. Cost Saving After Improvement

Week (a)	Yield (%) (b)	Yield Difference ($Yield_{after} - Yield_{before}$) (c=b-97.18%)	Difference output (tube) (d=c/100*9000)	Cost per unit tube (e)	Cost Saving (f=d*e)
11	98.22	1.04	94	1241	116.158
12	98.09	0.91	82	1241	101.638
13	98.2	1.02	92	1241	113.924
14	98.18	1	90	1241	111.690
15	98.31	1.13	102	1241	126.210
Average	98.20	1.02	92	1241	113.924

If the cost efficiency achieved for each batch was IDR 113,924, then based on the 2026 RKAP target, in which miconazole production was projected to reach 10,650,622 tubes or 1,183 batches, the potential annual cost efficiency could reach IDR 134,771,855.

These results indicate that a lean manufacturing approach based on root cause analysis and operational data can significantly improve process performance without requiring major investment. In addition, process variation control was proven to be a key factor in maintaining the balance between product quality and production efficiency. Therefore, the implementation of lean manufacturing has strong potential as an effective strategy for improving operational performance and sustaining the competitiveness of the pharmaceutical industry.

Conclusion

This study demonstrated that lean manufacturing effectively optimized production yield and improved cost efficiency in semisolid pharmaceutical manufacturing. Value Stream Mapping identified the filling process as the primary source of waste, while fishbone analysis revealed that process inefficiencies were mainly associated with machine, method, human, and material factors. Lean-based improvement actions focusing on equipment adjustment, tighter process control, and optimized filling parameters, reduced the average fill weight from 10.315 g to 10.115 g and increased production yield from 97.18% to 98.20%, resulting in measurable cost savings. Overall, the findings confirm that a lean manufacturing approach supported by root cause analysis and operational data can effectively improve process stability, resource utilization, and both the technical and economic performance of pharmaceutical manufacturing processes.

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Author Contributions
P.W.I. contributed to data collection and manuscript writing. A.N.W. & E.W.F. provided critical review and final approval of the manuscript.

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Conflicts of Interest
Authors declare that no conflict of interest in this publication.

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