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Reducing Inefficiency in the Pharmaceutical Industry: a Case Study of Lean Manufacturing Implementation in a Pharmaceutical Industry

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ABSTRACT

The pharmaceutical industry in Indonesia has grown significantly, accounting for 27.8% of the ASEAN market share. However, despite this growth, the sector faces challenges, including intense competition, complex supply chain dynamics, and inefficiencies in production processes. This research investigates the factors contributing to the production decline and identifies non-value-added activities in the Vitamin C production line using Value Stream Mapping. The study applies Lean Manufacturing principles, supported by Root Cause Analysis, to propose improvement strategies that enhance line utilization and reduce waste. Data were collected through observation and interviews, leading to the development of current and future state process models. The findings reveal that ineffective scheduling, prolonged changeover times, and labor-intensive documentation significantly reduce production efficiency. To address these issues, the study recommends the implementation of rapid testing technologies, electronic batch records, and a Laboratory Information Management System. These interventions are expected to result in a 62.7% reduction in lead time and a 176% increase in production capacity. Financial analysis indicates strong economic feasibility, with a positive net present value and a short payback period. This study concludes that Lean Manufacturing tools, when tailored to pharmaceutical operations, can drive substantial improvements in productivity, process flow, and operational resilience.

KEYWORDS *Lean manufacturing, Value Stream Mapping, Pharmaceutical Industry, Production Efficiency, Waste.*

INTRODUCTION

Indonesia represents the largest pharmaceutical market in the ASEAN region, accounting for 27.8% of the total ASEAN market share, equivalent to USD 5.93 billion as of 2014 (Kemenperin RI, 2021). The pharmaceutical industry in Indonesia has experienced significant growth, driven by the increased demand for supplements, vitamins, and herbal medicines during the COVID-19 pandemic in early 2020. This growth led the chemical, pharmaceutical, and traditional medicine industries to record the highest GDP growth among 15 *Non-Oil and Gas Manufacturing Industries* in 2020, reaching 9.39% *year-on-*

year (*year on year*), an improvement from 8.48% *year-on-year* in 2019 (Kemenperin RI, 2021).

Despite this growth, the pharmaceutical industry faces several challenges. According to BPS (2023), the chemical, pharmaceutical, and traditional medicine industries recorded a significant decline in production growth of -3.52% *year-on-year* in the first quarter of 2023. However, signs of recovery appeared in the first quarter of 2024, with growth reaching 8.1%. Intense competition and complex supply chain dynamics further strain the sector, requiring robust supply chain integration to adapt to market fluctuations and improve performance (Masa'deh et al., 2022; Utami et al., 2023).

In response to these challenges, *lean manufacturing* has gained traction to enhance operational efficiency and reduce waste in the pharmaceutical industry. This approach emphasizes streamlining processes, improving quality, and adhering to *Good Manufacturing Practices* (*GMP*). Tools such as *Value Stream Mapping* (*VSM*), the *5S* method, and *Pareto Analysis* have proven effective in identifying and eliminating non-value-added activities while improving production efficiency (Utami et al., 2023).

This study focuses on implementing *lean manufacturing* practices in a pharmaceutical company that produces over-the-counter (*OTC*) products, including solid and semi-solid formulations and secondary packaging for injectable oncology and gastroenterology products. Vitamin C is one of the company's flagship products, with an annual production volume of 180–230 million tablets. However, the production of Vitamin C in the company has significantly declined in recent years, with a decrease of up to 37% in 2024, despite rising market demand of 3–5% per year.

The *lean* concept has been widely applied across manufacturing and service industries, frequently combined with strategies like *Agile Operating System* and *Six Sigma* (Anvari, 2012). Its implementation utilizes various tools including *Value Stream Mapping* (*VSM*), *5S*, *SMED*, *Kanban*, and *Kaizen* philosophy (Rewers et al., 2016), often supported by integrated information systems (Gaol et al., 2020) and *SCM* practices (Cahyono et al., 2023). These methodologies focus on eliminating *Muda* (waste), *Muri* (overburden), and *Mura* (unevenness) through strategic initiatives, contributing to sustainability while enhancing productivity and cost-effectiveness (Hosen et al., 2025). In regulated sectors like pharmaceuticals, *lean* principles improve process consistency and regulatory compliance (Klimecka-Tatar & Obrecht, 2024), demonstrating the approach's versatility across industries.

Value Stream Mapping serves as a particularly effective tool for identifying waste and streamlining production processes (Gunaki et al., 2022). When combined with *Root Cause Analysis* methods like *Fishbone Diagram* and *5Whys*, *VSM* has proven effective in reducing lead times and production waste (Tripathi et al., 2021; Suhardi et al., 2019), while also helping identify causes of deviations to implement preventive measures (Moorkoth et al., 2024). The digital transformation era has seen *lean* tools integrated with *Industry 4.0* technologies, creating a hybrid *Lean 4.0* framework that enhances real-time analytics and error-proofing capabilities (Rosin et al., 2019; Guo & Mantravadi, 2024), particularly valuable in quality-sensitive pharmaceutical operations requiring strict batch traceability and compliance.

Recent developments have expanded *lean* applications to supply chain management through *Lean SCM* (*LSCM*), which improves operational flow while enhancing supplier collaboration and customer visibility (Garcia-Buendia et al., 2023). This approach increasingly combines with green practices to meet both efficiency and sustainability objectives (Ricardianto et al., 2022), aligning with international standards like *ISO 14001* and *GMP*. The evolution of *lean* methodologies demonstrates their continued relevance and adaptability to contemporary business challenges, offering integrated

solutions that balance operational performance with environmental responsibility and quality assurance requirements across various industrial contexts.[a1]

The pharmaceutical industry in Indonesia, accounting for 27.8% of the ASEAN market share, has shown significant growth, particularly during the COVID-19 pandemic. However, this growth is juxtaposed with challenges such as declining production efficiency, complex supply chains, and operational inefficiencies, as evidenced by a -3.52% *year-on-year* production decline in early 2023. Despite partial recovery in 2024, the sector struggles with bottlenecks like prolonged changeover times and labor-intensive processes, which hinder productivity. Existing studies have explored *Lean Manufacturing* in pharmaceuticals, yet there remains a gap in tailored applications addressing specific inefficiencies in high-volume production lines, such as Vitamin C tablets, where demand consistently outpaces output. This research seeks to bridge this gap by identifying and mitigating non-value-added activities unique to such contexts.

The urgency of this study is underscored by the pharmaceutical industry's critical role in public health and economic stability, particularly in Indonesia, where market demand for essential products like Vitamin C grows at 3–5% annually. Despite this demand, production capacity has declined by 37% in 2024, risking supply shortages and lost revenue. Current inefficiencies, such as manual documentation and outdated testing methods, exacerbate these challenges, making operational improvements imperative. The COVID-19 pandemic further highlighted the need for resilient and agile manufacturing systems, emphasizing the timeliness of this research. Addressing these inefficiencies through *Lean Manufacturing* is not only a strategic priority but also a necessity to ensure industry sustainability and competitiveness.

This study introduces novelty by integrating *Value Stream Mapping* (*VSM*) with *Root Cause Analysis* (*RCA*) to diagnose inefficiencies in a high-volume pharmaceutical production line, a combination rarely explored in existing literature. While *Lean* tools like *VSM* are well-documented in manufacturing, their application in regulated pharmaceutical environments, where compliance and quality constraints limit flexibility, remains underexplored. The research further innovates by proposing digital solutions, such as electronic batch records and *PCR*-based testing, to replace traditional methods, aligning *Lean* principles with *Industry 4.0* technologies. This hybrid approach offers a replicable framework for similar regulated industries, enhancing both efficiency and compliance.

The research contributes to academia and industry by providing empirical evidence on the effectiveness of *Lean Manufacturing* in pharmaceutical production, specifically in reducing lead time and increasing capacity. It advances theoretical understanding by demonstrating how *Lean* tools can be adapted to highly regulated environments without compromising quality standards. Practically, the study offers an actionable roadmap for pharmaceutical firms to implement *Lean*-driven digital transformations, supported by financial feasibility analysis. Additionally, the findings highlight the synergistic potential of combining *Lean* methodologies with advanced technologies, setting a precedent for future research in operational excellence.

The primary objective of this study is to identify and eliminate non-value-added activities in the Vitamin C production line using *Lean Manufacturing* tools, thereby improving efficiency and capacity. Specifically, it aims to quantify inefficiencies through *VSM*, diagnose root causes using *RCA*, and propose targeted interventions such as automation and process redesign. The research also evaluates the financial viability of these improvements, ensuring they deliver measurable economic benefits. By aligning operational enhancements with customer demand and regulatory requirements, the study seeks to create a balanced approach to productivity gains.

The benefits of this research extend across multiple stakeholders. For pharmaceutical companies, it offers a proven strategy to recover lost production capacity, reduce costs, and enhance competitiveness. Policymakers and regulators may leverage the findings to advocate for *Lean* adoption in the industry, fostering national self-sufficiency in drug manufacturing. Academically, the study enriches the body of knowledge on *Lean* applications in regulated sectors, while practitioners gain access to a structured methodology for continuous improvement. Ultimately, the research supports broader societal goals by ensuring reliable access to essential medicines, aligning operational efficiency with public health outcomes.

RESEARCH METHOD

This study employs a mixed-methods case study approach, combining qualitative and quantitative techniques to investigate inefficiencies in a pharmaceutical Vitamin C production line. The research focuses on a single production facility in Indonesia, with data collected from January to December 2024. The population includes all production processes, operators, and documentation related to the Vitamin C tablet manufacturing line. *Purposive sampling* is used to select experienced operators and supervisors with over one year of tenure, ensuring depth and relevance in data collection. Key metrics such as cycle time, lead time, and downtime are analyzed, with sample sizes determined using statistical formulas to ensure a 95% confidence level and 5% margin of error. This approach allows for a comprehensive examination of both operational workflows and human factors influencing productivity.

Data collection utilizes multiple instruments, including real-time digital production logs, structured interviews, and direct observations, ensuring triangulation for enhanced validity. The research instruments are validated through expert review and pilot testing to confirm their alignment with *Lean Manufacturing* principles and pharmaceutical industry standards. Reliability is assessed using *Cronbach's alpha* for survey components and inter-rater consistency for observational data. The procedure follows a five-phase framework: problem identification, literature review, data collection, *Value Stream Mapping* (*VSM*) and *Root Cause Analysis* (*RCA*), and financial justification. Software tools such as Microsoft Excel for statistical calculations and specialized *Lean* tools like *VSM* software are employed to map processes and analyze bottlenecks. Additionally, financial feasibility is evaluated using *Net Present Value* (*NPV*) calculations with a 10% discount rate.

The data analysis technique integrates descriptive and inferential methods to quantify inefficiencies and test proposed improvements. Current and future state *VSMs* are developed to visualize process flows and identify waste, while *RCA* tools like *Fishbone diagrams* and *5Whys* isolate underlying causes of delays. Quantitative data, such as cycle times and inventory levels, are analyzed using mean, standard deviation, and *takt time* comparisons. Thematic analysis is applied to qualitative data from interviews to uncover operational challenges. The hybrid methodology ensures robust findings, combining empirical metrics with contextual insights to validate *Lean* interventions. This systematic approach not only diagnoses inefficiencies but also provides a replicable model for *Lean* implementation in regulated manufacturing environments.

RESULT AND DISCUSSION

Production Process Overview

The manufacturing process of Vitamin C (ascorbic acid) tablets in the pharmaceutical industry is a meticulously regulated sequence designed to ensure

product quality, efficacy, and compliance with Good Manufacturing Practices (GMP). This process integrates advanced technologies and stringent quality control measures at each stage.

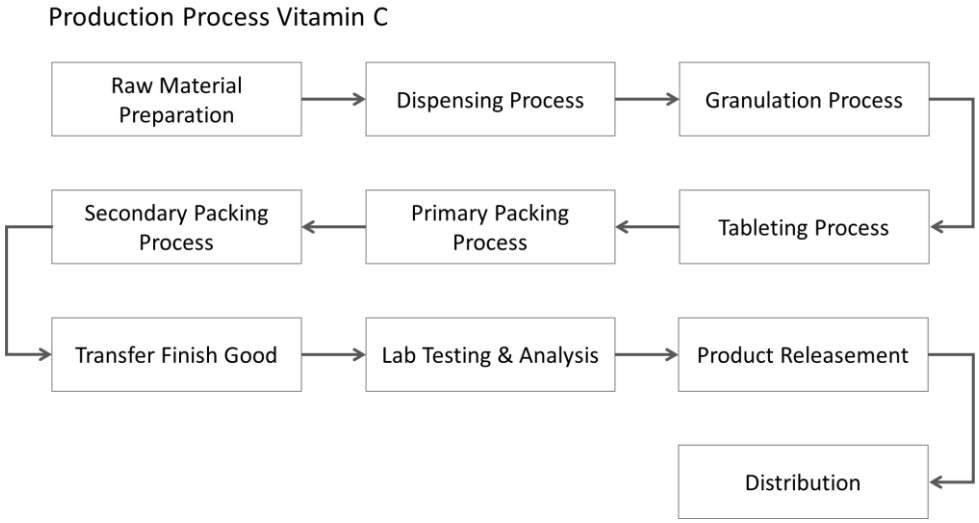

Figure 1. Vitamin C Production Process Flow
Source: The production process flow diagram developed by the authors.

The sequence of production process described in below explanation:

a. Initiation via Enterprise Resource Planning (ERP) System
   The production cycle commences with the generation of a Manufacturing Order (MO) through an integrated Enterprise Resource Planning (ERP) system, such as SAP.
   This digital initiation ensures synchronization across various departments, aligning production schedules with inventory management and procurement processes
b. Raw Material Preparation and Dispensing Process
   Upon MO activation, raw materials and excipients are retrieved from controlled storage environments. Each component is precisely weighed according to the master batch record, adhering to predefined tolerances to maintain dosage accuracy and uniformity. This step is critical, as deviations can impact the final product's quality and therapeutic efficacy.
c. Granulation Process
   The weighed materials undergo granulation, typically via wet granulation techniques. This involves blending the active pharmaceutical ingredient (API) with excipients, adding a granulating fluid to form a wet mass, followed by drying to achieve desired moisture content. The granules are then sieved to obtain uniform particle sizes, enhancing flow properties and compressibility.
d. Tableting Process (Tablet Compression)
   The dried granules are directed to the compression stage, where they are compacted into tablets using rotary tablet presses. Compression parameters,

such as force and speed, are meticulously controlled to ensure tablets meet specifications for weight, hardness, thickness, and disintegration time.

e. Packaging Operations (Primary and Secondary Pack)
Post-compression, tablets are subjected to primary packaging, often involving blister packs or strip packaging using heat-sealing techniques to protect against environmental factors. Secondary packaging includes labeling and boxing, ensuring compliance with regulatory requirements for traceability and information dissemination.

f. Quality Control and Assurance
Finished products undergo rigorous quality control testing, including physicochemical assessments (e.g., assay, dissolution) and microbiological evaluations, in accordance with pharmacopeial standards such as the Indonesian Pharmacopoeia (FI), United States Pharmacopeia (USP), and British Pharmacopoeia (BP). Only batches that meet all quality criteria proceed to the next stage.

g. Storage and Distribution
Approved batches are stored in temperature-controlled warehouses, typically maintained between 23–27°C, to preserve product stability. Distribution is conducted following Good Distribution Practice (GDP) guidelines, ensuring that products reach end-users without compromising quality.

Analysis and Result

To evaluate process performance, 50 samples were collected at each production stage. Data analysis included calculating sample means, required sample sizes, and standard deviations. The current state Value Stream Mapping (VSM) revealed a total production lead time of 628.15 hours (26 days), with value-added time constituting just 0.05%, highlighting significant opportunities for process improvement. Key metrics analyzed included Process Time, Delay Time, Cycle Time, Inventory, and Waiting Time.

Table 1. Key metrics Current State Value Stream Mapping

Production Process	Yield (%)	P/T (h)	D/T (h)	C/T (h)	Inventory (batch)	W/T (h)
Dispensing	100%	0.0043	0.0003	0.0046	3,498	15.9403
Granulation	95%	0.0087	0.0003	0.0091	2,272	20.6397
Tableting	93.5%	0.0092	0.0015	0.0107	2,080	22.3168
Packing	98.5%	0.0114	0.0016	0.0129	1,950	25.2190
Lab Testing & Analysis	100%	0.1952	0.0005	0.1957	1,980	387.5047
Product Release	100%	0.0701	0.0090	0.0791	1,980	156.5300
Summary	**98%**	**0.2990**	**0.0131**	**0.3121**		**628.1505**

Source: All data in this table were obtained and processed by the authors.

To enable a valid comparison between current state Value Stream Mapping (VSM) metrics and takt time, all process times were standardized to a uniform unit of kilograms. Analysis revealed that the cycle times for lab testing (0.1957 hours/kg) and product release (0.0791 hours/kg) exceeded the takt time of 0.0133

hours/kg. These discrepancies identify both stages as critical bottlenecks within the production system. Their inefficiencies threaten production flow, reduce throughput, and risk failure to meet customer demand. This misalignment highlights the need for targeted improvements to enhance synchronization, reduce delays, and align operations with lean manufacturing objectives.

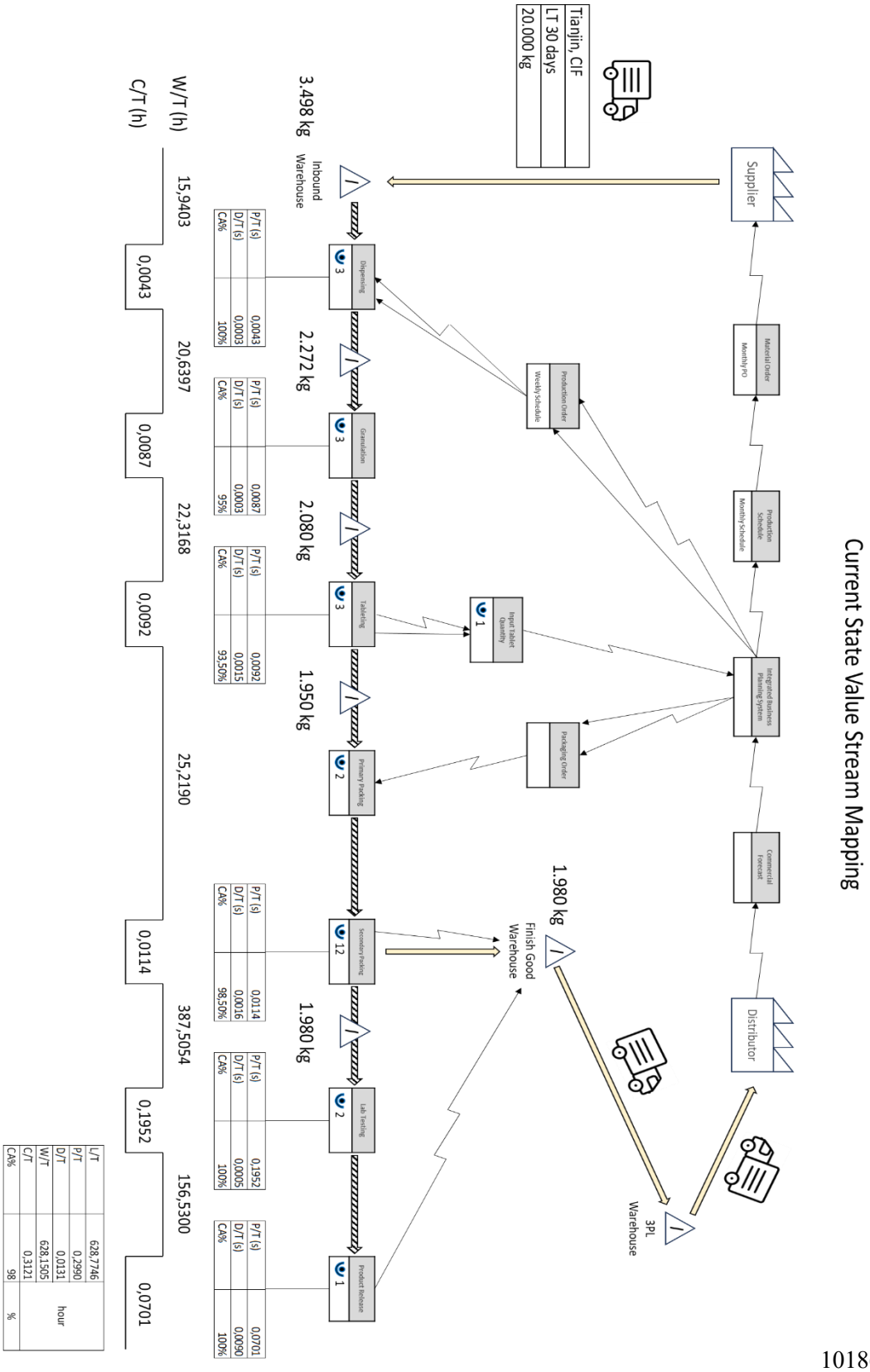

Figure 2. Current State VSM
Source: The current state VSM developed by the authors.

Key performance indicators identified two significant bottlenecks: lab testing and product release. Lab testing had a cycle time of 117.43 hours, and product release required 47.7 hours, both far exceeding the takt time of 0.0133 hours/kg. These delays, primarily due to capacity limitations, manual documentation, and inadequate scheduling, contributed to more than 80% of total production waiting time.

Root cause analysis was carried out using Fishbone Diagrams and the 5Whys methodology. For lab testing, primary causes included reliance on traditional microbial testing methods, limited use of automation, and underutilized laboratory instruments. Product release delays were largely attributed to the manual handling of batch records and sequential review workflows.

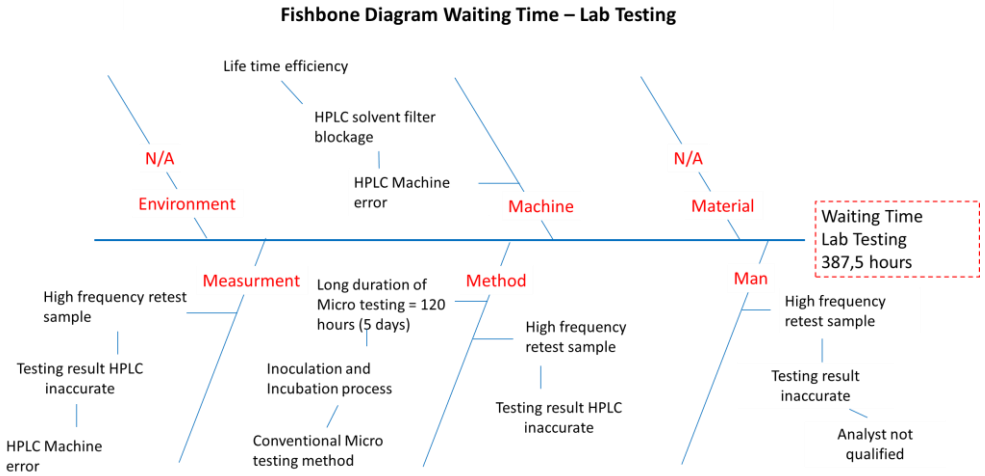

Figure 3. Fishbone Analysis Lab Testing
Source: Fishbone Analysis Lab Testing developed by the authors.

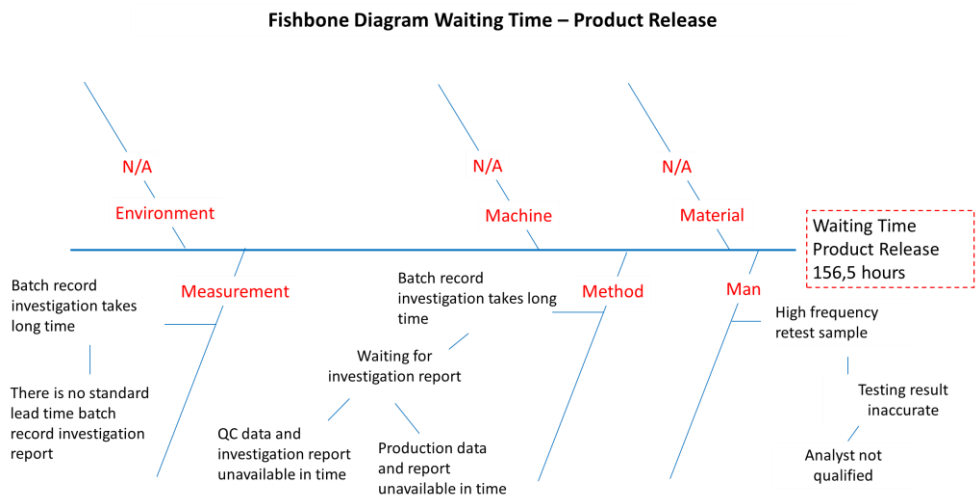

Figure 4. Fishbone Analysis Product Release
Source: Fishbone Analysis Product Release developed by the authors.

The comparative analysis between the current and future state VSMs demonstrates a substantial improvement in key metrics that reflect the overall performance of the value stream. The total lead time (L/T) decreased significantly from 628.15 hours to 234.02 hours, representing a 62.7% increase in time efficiency. This result underscores the success of targeted improvement efforts focused on the two major bottlenecks lab testing and product release which alone contributed more than 80% of the total waiting time in the current state (544 out of 674 hours).

Table 2. Key metrics Future State Value Stream Mapping

Production Process	Yield (%)	P/T (h)	D/T (h)	C/T (h)	Inventory (batch)	W/T (h)
Dispensing	100%	0.0043	0.0003	0.0046	3,498	15.9403
Granulation	95%	0.0087	0.0003	0.0091	2,272	20.6397
Tableting	93.5%	0.0092	0.0015	0.0107	2,080	22.3168
Packing	98.5%	0.0114	0.0016	0.0129	1,950	25.2190
Lab Testing & Analysis	100%	0.0488	0.0005	0.0493	1,980	97.5601
Product Release	100%	0.0175	0.0090	0.0264	1,980	52.3464
Summary	**98%**	**0.0999**	**0.0131**	**0.1130**		**234.0223**

Source: All data in this table were obtained and processed by the authors.

Furthermore, processing time (P/T) was reduced by 66.6%, from 0.2990 to 0.0999 hours, which positively impacted overall process throughput. Importantly, this increase in operational efficiency was achieved without compromising product quality, as capability assurance (CA%) remained stable at 98%, confirming regulatory compliance and product integrity.

Correspondingly, the cycle time (C/T) and waiting time (W/T) also decreased by 63.7% and 62.7%, respectively, reflecting the effectiveness of continuous improvement measures and the integration of digital solutions such as electronic

batch records (eBR), real-time release dashboards, and Laboratory Information Management Systems (LIMS).

From a technical perspective, the adoption of PCR-based rapid microbiological testing significantly reduced lab testing times by up to 75% compared to traditional agar-based methods. Similarly, administrative delays in the product release phase were mitigated by real-time quality review workflows enabled by eBR and QA dashboards, also contributing to a 75% reduction in release cycle times. These outcomes confirm that lean-driven digital transformation can simultaneously enhance efficiency, product quality, and regulatory compliance in pharmaceutical operations.

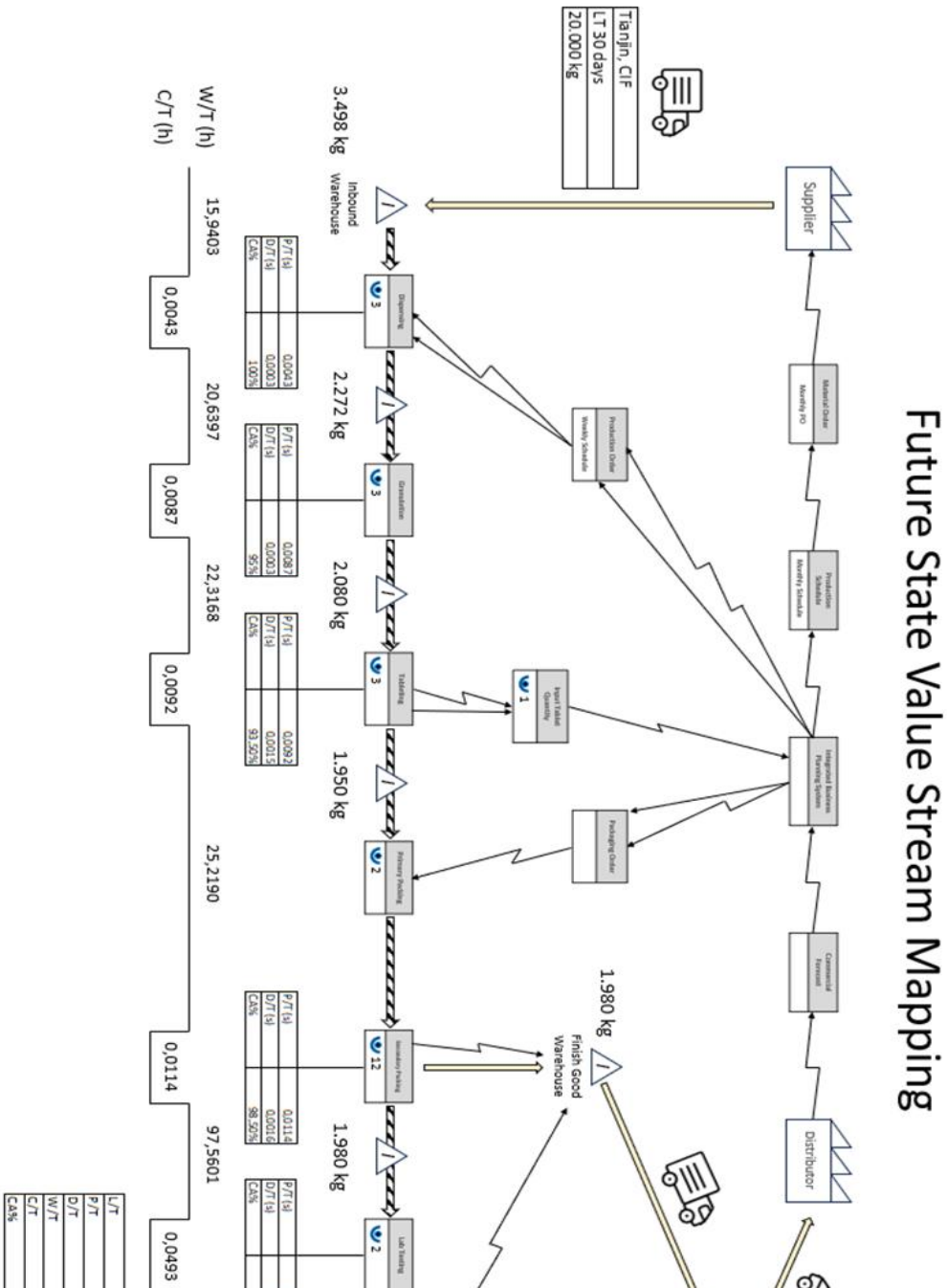

Figure 5. Future State VSM
Source: The future state VSM developed by the authors.

The financial analysis of the lean implementation project in the Vitamin C production line reveals strong economic feasibility and substantial return on investment. Following the proposed operational improvements, production capacity increased by 76%, raising annual output from 150 million to 264 million tablets. This expansion led to an annual revenue increase to €4,000,000, attributed to a 67% rise in production volume. The total investment required for implementation amounted to €298,000, with key financial assumptions including a 22% tax rate, 10% discount rate, 7-year depreciation period, and a 5% annual growth rate.

Table 3. NPV Calculation

(in Euro)	Years of Investment							
	0	1	2	3	4	5	6	7
Sales Revenue	2,272,727	4,000,000	4,200,000	4,410,000	4,630,500	4,862,025	5,105,126	5,360,383
Operating Cost	-	2,080,000	2,184,000	2,293,200	2,407,860	2,528,253	2,654,666	2,787,399
Depreciation	-	42,571	42,571	42,571	42,571	42,571	42,571	42,571
EBIT	-	1,877,429	1,973,429	2,074,229	2,180,069	2,291,201	2,407,889	2,530,412
Tax		413,034	434,154	456,330	479,615	504,064	529,736	556,691
Net Cash Flow		1,506,966	1,581,846	1,660,470	1,743,025	1,829,708	1,920,725	2,016,293
Discounted Cash Flow	(298,000)	1,369,969	1,307,311	1,247,535	1,190,509	1,136,105	1,084,199	1,034,677
Cumulative DCF	(298,000)	1,071,969	2,379,279	3,626,815	4,817,324	5,953,429	7,037,628	8,072,305
Investment	298,000							
Operating Cost	52% of sales revenue							
Tax	22%							
Discount Rate	10%							
NPV in years 7	**8,072,305 Euro**							
Payback Period	**1 Year**							

Source: All data in this table were obtained and processed by the authors.

Net Present Value (NPV) calculations based on these parameters yielded a cumulative NPV of €8,072,305 over seven years, signifying a highly profitable investment. The Earnings Before Interest and Taxes (EBIT) grew steadily from

€1,877,429 in year one to €2,530,412 in year seven. Net cash flow also increased annually, ranging from €1,506,966 to €2,016,293. Importantly, the payback period was achieved within just one year, indicating low investment risk and strong liquidity.

In conclusion, the lean transformation not only improved operational efficiency but also delivered robust financial outcomes, validating the project's viability and reinforcing its strategic value in enhancing production performance and competitiveness within the pharmaceutical industry.

CONCLUSION

This study demonstrates the significant potential of *Lean Manufacturing* tools, particularly *Value Stream Mapping* (*VSM*) and *Root Cause Analysis* (*RCA*), to enhance efficiency in pharmaceutical production. By analyzing the Vitamin C tablet manufacturing line, the research identified critical bottlenecks in lab testing and product release, which accounted for over 80% of production delays. The implementation of targeted interventions—such as electronic batch records, *PCR*-based microbiological testing, and a *Laboratory Information Management System* (*LIMS*)—resulted in a 62.7% reduction in lead time, a 176% increase in production capacity, and improved cycle time efficiency by 63.7%. Financial analysis further confirmed the viability of these improvements, with a *net present value* (*NPV*) of €8,072,305 and a payback period of just one year. These findings underscore the effectiveness of *Lean* methodologies in optimizing high-volume, regulated production environments while maintaining compliance and product quality.

For future research, expanding the scope to include multiple production lines or pharmaceutical products could provide broader insights into the scalability of *Lean* interventions. Investigating the long-term sustainability of these improvements, including their resilience to regulatory changes or market fluctuations, would also be valuable. Additionally, exploring the integration of advanced *Industry 4.0* technologies—such as AI-driven predictive analytics or IoT-enabled real-time monitoring—could further enhance *Lean* applications in pharmaceutical manufacturing. Studies examining the human factors influencing *Lean* adoption, such as employee resistance or training requirements, would complement the technical focus of this research. By addressing these areas, future work could refine and expand the framework developed in this study, offering more comprehensive strategies for operational excellence in the pharmaceutical industry.

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