

Jurnal Sains dan Aplikasi Keilmuan Teknik Industri (SAKTI)

Journal of Industrial Engineering: Application and Research

Volume 05 No. 02 - December 2025 Journal homepage: www.sakti.machung.ac.id ISSN: 2829-8519 (print) – ISSN: 2829-8748 (online)

Application of Total Productive Maintenance and Overall Equipment Effectiveness in Improving Ampoule Filling Machine Performance

(A Case Study in a Pharmaceutical Manufacturing)

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Received 18 Aug 2025 / Revised 08 Oct 2025 / Accepted 22 Nov 2025 / Published 31 December 2025

Abstract. This study aims to improve the effectiveness of ampoule filling machines in a pharmaceutical manufacturing company through the implementation of Total Productive Maintenance (TPM) supported by Overall Equipment Effectiveness (OEE) evaluation. The study was motivated by a decline in machine performance during the period from January to August 2024, characterized by low production output, high downtime, and high defect rates. A quantitative research approach was employed using primary and secondary data collected from 30 production batches through field observations, interviews, and documentation review. Machine effectiveness was evaluated using OEE, which consists of availability, performance, and quality components, while efficiency losses were identified using the Six Big Lossesframework. Root causes were analyzed using a Fishbone diagram, and improvement actions were formulated based on relevant TPM pillars. The results show that the initial average OEE value was 56%, significantly below the world-class benchmark of 85%, with breakdown losses and quality defect losses identified as the dominant contributors to inefficiency. After implementing TPM-based improvements specifically the replacement and recalibration of malfunctioning swing conveyor sensors and the redesign of the ampoule outfeed system—the average OEE value increased to 71.9%. Improvements were also observed in the OEE components, with availability increasing to 86.5%, performance to 92.0%, and quality to 90.5%. These results indicate a substantial reduction in downtime and defect rates. The study confirms that the integration of TPM and OEE is effective in enhancing machine effectiveness and production efficiency in sterile pharmaceutical manufacturing.

Keywords: Machine effectiveness; Overall Equipment Effectiveness; Pharmaceutical industry; Six Big Losses; Total Productive Maintenance

1. Introduction

Production effectiveness is a critical factor in the pharmaceutical industry, particularly in the sterile drug segment, where stringent quality standards must be met to ensure patient safety. Sterile ampoule filling represents one of the most critical stages in pharmaceutical manufacturing, as it requires high precision, minimal downtime, and near-zero defects to comply with national and international regulations, including Good Manufacturing Practices (GMP) and the standards enforced by the Indonesian National Agency of Drug and Food Control (BPOM). Any equipment failure, process instability, or deviation in quality may result in substantial productivity losses, product rejection, and regulatory non-compliance (Muchiri & Pintelon, 2008).

PT X is a leading pharmaceutical company in Indonesia that produces sterile pharmaceutical products in ampoule form. One of the key processes in its production system is ampoule filling, which involves filling sterile liquid drugs into small glass containers under strictly controlled conditions (Taufik et al., 2023). This process is performed using automated ampoule filling machines operating continuously across three production shifts per day. Despite the use of automated equipment, operational performance data from 30 production batches observed between January and August 2024 indicate a decline in machine effectiveness. The average actual output achieved was only 79% of the planned target, with the lowest batch reaching just 73%, while the company's minimum performance standard is set at 90%. This performance gap signals inefficiencies in the production process that require systematic evaluation. The production output achievement per batch is illustrated in Figure 1.

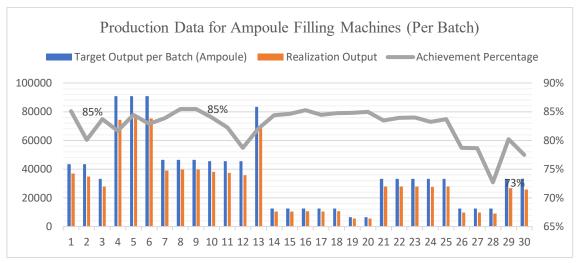


Figure 1 Data on Ampoule Filling Machine Production Volume (Per Batch)

In addition to reduced output, high machine downtime has emerged as a major obstacle in the ampoule filling process. Downtime analysis per batch shows that machine stoppages range from 0% to more than 30% of total processing time, significantly disrupting production continuity and capacity utilization. The downtime performance of the ampoule filling machine is presented in Figure 2.

Another critical issue affecting production effectiveness is the high defect rate. Analysis of defective products per batch reveals defect percentages ranging from 17% to 38%, indicating serious quality losses during the filling process. The distribution of defect rates per batch is shown in Figure 3. The simultaneous occurrence of low productivity, high downtime, and high defect levels suggests that the ampoule filling machine is operating below optimal conditions and that comprehensive improvement actions are required.

To systematically evaluate equipment performance, Overall Equipment Effectiveness (OEE) was introduced as a comprehensive metric that integrates three key dimensions: availability, performance, and quality (Nakajima, 1988). OEE enables organizations to quantify machine effectiveness and identify dominant sources of performance loss. Furthermore, inefficiencies can be analyzed in greater detail using the Six Big Losses framework, which categorizes losses into

breakdowns, setup and adjustment losses, minor stoppages, reduced speed, defects, and startup losses, thereby supporting effective prioritization of improvement efforts (Warizki, 2019).

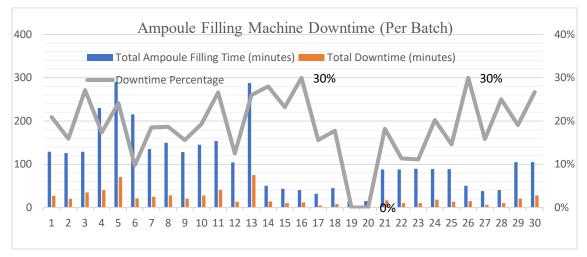


Figure 2 Downtime of Ampoule Filling Machine (Per Batch)

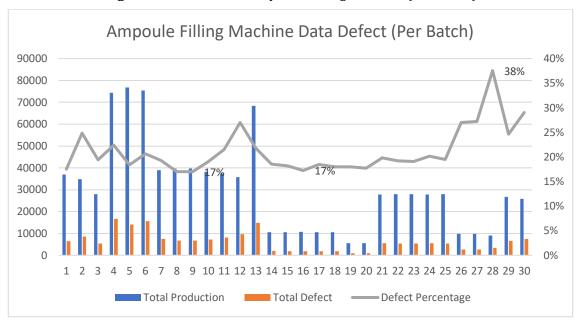


Figure 3 Defect Data of Ampoule Filling Machine (Per Batch)

As a strategic solution, Total Productive Maintenance (TPM) is considered a suitable approach for improving ampoule filling machine performance, as it emphasizes the involvement of all organizational elements to achieve zero breakdowns, zero defects, and zero accidents. TPM pillars such as Focused Improvement and Planned Maintenance are particularly relevant for addressing recurring failures, reducing downtime, and stabilizing process performance in sterile production environments. Therefore, this study aims to identify the root causes of low machine effectiveness and formulate improvement recommendations through the implementation of TPM supported by regular OEE measurements, with the ultimate goal of enhancing production efficiency and sustainability in sterile pharmaceutical manufacturing.

2. Methods

The methods employed to improve machine effectiveness in the ampoule filling process at PT X consist of the Overall Equipment Effectiveness (OEE) method and the Total Productive Maintenance (TPM) approach. OEE is used to quantitatively evaluate machine effectiveness based on three key components—Availability, Performance Rate, and Quality Rate—which collectively determine the overall OEE value (Pramewari, 2024). The calculated OEE value is subsequently

analyzed using the Six Big Losses framework to identify the dominant sources of inefficiency that most significantly affect machine performance.

Based on the results of the OEE and Six Big Losses analyses, improvement strategies are formulated and implemented using the principles of Total Productive Maintenance (TPM). The application of TPM is expected to reduce machine downtime, minimize defect rates, and enhance overall equipment effectiveness in a sustainable manner.

2.1. Overall Equipment Effectiveness (OEE)

Overall Equipment Effectiveness (OEE) is a performance measurement method used to evaluate how effectively manufacturing equipment is utilized. According to Jono (2019), overall equipment performance is influenced by three fundamental factors: availability, performance rate, and quality rate, each expressed as a percentage. OEE serves as a comprehensive metric for assessing productivity and identifying improvement opportunities in machine utilization (Nakajima, 1988).

Furthermore, Satwika (2016) states that OEE evaluates machine effectiveness based on:

Availability, which reflects the proportion of planned production time during which the machine is operational;

Performance Rate, which compares actual operating speed with the standard speed;

Quality Rate, which represents the proportion of good products relative to total production output.

The OEE value is calculated using the following equation:

In practice, achieving 100% efficiency for all three components is unrealistic. Therefore, world-class manufacturing standards define a minimum OEE benchmark of 85%. The reference standards are presented in Table 1.

Table 1. Overall Equipment Effectiveness (OEE) World Standards

OEE Factor	World Class		
Availability	90,0%		
Performance	95,0%		
Quality	99,9%		
OEE	85,4%		
Source: Gasperz, (2002)			

2.2. Six Big Losses

According to Nakajima (1988), maintenance activities should not only focus on preventing equipment failure and reducing downtime, but also on minimizing losses caused by inefficient machine operation. To systematically identify the sources of inefficiency, the **Six Big Losses** concept is applied. These losses are classified into three main categories: **downtime losses**, **speed losses**, and **defect losses**.

2.2.1. Downtime Losses

Downtime losses consist of losses caused by machine stoppages, including breakdowns and setup adjustments.

Breakdown Losses refer to time losses due to unexpected machine failures and are calculated as:

$$Breakdown Losses = \frac{Breakdown Time}{Loading Time} \times 100\%$$
 (2)

Setup adjusment losses are lost time during setup

Setup and Adjustment Losses represent time losses incurred during machine setup or parameter adjustment:

$$Setup Adjusment Losses = \frac{\text{Total Setup and adjusment Time}}{\text{Loading Time}} \times 100\%$$
 (3)

2.2.2. Speed Losses

Speed losses occur when machines operate below their standard operating speed or experience frequent minor stoppages.

Reduced Speed Losses are calculated as:

Reduced Speed losses =
$$\frac{Less\ speed\ Time}{Loading\ Time}\ x\ 100\%$$
 (4)

Idling and Minor Stoppage Losses refer to short, repetitive interruptions during machine operation:

Idling Minor Stoppage Losses =
$$\frac{Nonproductive\ Time}{Loading\ Time} \times 100\%$$
 (5)

2.2.3. Losses Due to Defects

Defect losses arise from the production of non-conforming products and are divided into reduced yield losses and process defect losses.

Reduced Yield Losses occur during the initial stage of production:

Reduced Yield Losses =
$$\frac{Cycle\ Time\ x\ Defect\ Setting}{Loading\ Time}\ x\ 100\% \tag{6}$$

Process Defect Losses occur after the production process has started:

Process Defect Losses =
$$\frac{Cycle\ Time\ x\ Reject}{Loading\ Time}\ x\ 100\%$$
 (7)

2.3. Fishbone Diagram

The Fishbone Diagram, also known as the Ishikawa Diagram, is a quality management tool used to identify and analyze the root causes of problems within a process. Introduced by Dr. Kaoru Ishikawa, this method supports systematic brainstorming to identify underlying causes rather than merely addressing symptoms (Hisprastin & Musfiroh, 2020).

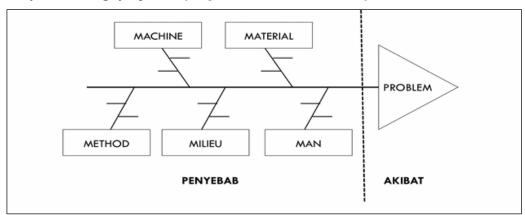


Figure 4 illustrates the general structure of the Fishbone Diagram.

Source: Hisprastin & Musfiroh (2020)

2.3.1. Steps for Creating a Fishbone Diagram

The first step in developing a Fishbone Diagram is to clearly define the main problem. Subsequently, potential causes are categorized into the **5M** factors: **Man** (human factors), **Method** (work procedures), **Machine** (equipment), **Material** (raw materials), **Milieu/Environment** (work environment).

2.4. Total Productive Maintenance (TPM)

Total Productive Maintenance (TPM) is a comprehensive maintenance strategy that involves all organizational levels, from top management to operators, with the objective of preventing breakdowns, reducing downtime, and improving operational effectiveness (Nakajima, 1988). TPM is founded on three core principles: total effectiveness, total participation, and a total maintenance system.

TPM has evolved from traditional preventive maintenance into a proactive and integrated maintenance system that has been widely implemented across industries (Warizki, 2019). The success of TPM implementation is commonly measured using TPM performance indicators, including availability \geq 90%, performance \geq 95%, quality \geq 99%, and OEE \geq 85%, as defined by the Japan Institute of Plant Maintenance (JIPM).

2.4.1. Eight Pillars of TPM

TPM is supported by eight interrelated pillars designed to enhance equipment effectiveness and organizational productivity. These include:

Autonomous Maintenance, empowering operators to perform routine maintenance;

Focused Improvement, emphasizing continuous improvement based on performance evaluation;

Planned Maintenance, involving scheduled preventive and corrective maintenance;

Quality Maintenance, aiming to achieve zero defects;

Education and Training, enhancing operator competence;

Office TPM, applying TPM principles to administrative functions;

Safety, Health, and Environment (SHE), promoting safe and healthy working conditions.

All TPM pillars are underpinned by the 5S principles (Seiri, Seiton, Seiso, Seiketsu, and Shitsuke), which establish a clean, organized, and disciplined work culture (Priyanta et al., 2008).

2.4.2. Benefits of TPM

The implementation of TPM provides numerous benefits, including improved productivity and product quality, reduced machine downtime and production costs, enhanced delivery reliability, and improved workplace safety. In addition, TPM fosters employee involvement and motivation, contributing to the long-term sustainability of production processes (Warizki, 2019).

3. Results and Discussion

3.1. Stages of the Ampoule Filling Process

As illustrated in Figure 5, the ampoule filling process at PT X is conducted aseptically in compliance with Good Manufacturing Practices (GMP) and regulations issued by the Indonesian National Agency of Drug and Food Control (BPOM). The process begins with the preparation of materials and equipment, in which the pharmaceutical solution is filtered using a 0.2-micron filter, and all equipment is sterilized according to established procedures. The sterile solution is subsequently transferred through a closed system to the filling machine located in a Class B cleanroom.

Ampoules are washed using an automatic washing machine with Water for Injection (WFI) and compressed air, followed by sterilization in a tunnel sterilizer at temperatures exceeding 300 °C. The filling process is carried out automatically and precisely in a Class A environment, where environmental parameters such as particle count, temperature, and pressure are strictly controlled. After filling, the ampoules are sealed using a gas-fired burner to create an airtight glass seal. The sealed ampoules then undergo visual inspection to detect defects, are labeled automatically in accordance with regulatory requirements, and packaged. Finished products are

stored in a temperature- and humidity-controlled warehouse using the First In First Out (FIFO) principle to maintain product quality during storage and distribution.

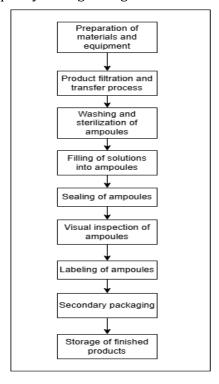


Figure 5. Stages of the Ampoule Filling Process

3.2. Overall Equipment Effectiveness Before Improvement

To evaluate the performance of the ampoule filling machine prior to improvement, Overall Equipment Effectiveness (OEE) was calculated using production data from January to August 2024. OEE measurement was conducted per batch and comprised three components: availability, performance, and quality. The OEE calculation results before improvement are presented in Table 2.

Table 2. OEE Calculation Results Before the Improvements

Batch	Availability Rate	Performance Rate	Quality Rate	OEE
1	79%	91%	83%	59,2%
2	84%	82%	75%	51,9%
3	73%	74%	81%	43,6%
4	83%	98%	78%	62,6%
5	76%	87%	82%	54,1%
6	90%	97%	79%	69,5%
7	82%	89%	81%	58,3%
8	81%	81%	83%	54,5%
9	84%	92%	83%	64,4%
10	81%	82%	81%	53,3%
11	73%	83%	79%	47,7%
12	88%	98%	73%	62,8%
13	74%	80%	78%	46,5%
14	72%	73%	82%	43,0%
15	77%	80%	82%	50,3%
16	70%	95%	83%	55,2%
17	84%	98%	82%	67,3%
18	82%	72%	82%	48,3%
19	100%	99%	82%	80,9%
20	100%	92%	82%	75,9%

21	82%	97%	80%	63,4%
22	89%	90%	81%	64,1%
23	89%	88%	81%	63,0%
24	80%	98%	80%	62,2%
25	85%	92%	81%	63,1%
26	70%	70%	73%	35,9%
27	84%	77%	73%	47,1%
28	75%	76%	63%	35,5%
29	81%	79%	75%	48,1%
30	73%	84%	71%	43,7%
Averages	81%	86%	79%	56%

The results indicate that the average OEE value during the observation period was 56%, which is significantly below the world-class benchmark of 85% set by JIPM. OEE values fluctuated across batches due to variations in availability, performance, and quality rates. Among these components, the **quality rate** contributed most to the low OEE value, with an average of only 79%, compared to availability at 81% and performance at 86%. This finding suggests that quality-related losses played a dominant role in reducing machine effectiveness.

3.2.1. Six Big Losses Analysis

The Six Big Losses analysis was conducted to identify the dominant sources of inefficiency affecting the ampoule filling machine. **Table 3** summarizes the percentage contribution of each loss category from January to August 2024.

Table 3. Summary of the Six Big Losses Percentage for January-August 2024

	Availabil	ity Rate	Performanc	e Rate	Rate Of Q	uality
Batch	Breakdown Losses (%)	Setup And Adjustmen t Losses	Idling And Minor Stoppage Losses	Speed Losses	Quality Defect And Required Losses	Yield Losses
1	21%	7,8%	0%	7,4%	12,6%	4,0%
2	16%	0%	0%	15,0%	17,2%	4,2%
3	27%	7,0%	0%	18,8%	10,5%	2,0%
4	17%	5,2%	0%	1,9%	18,1%	1,8%
5	24%	0%	0%	9,7%	12,2%	2,1%
6	10%	0%	0%	2,6%	18,1%	1,1%
7	19%	11,1%	0%	9,3%	13,9%	4,5%
8	19%	0%	0%	15,1%	11,3%	3,5%
9	16%	0%	0%	6,7%	13,2%	4,0%
10	19%	0%	0%	14,9%	12,5%	3,6%
11	27%	0%	0%	12,7%	13,1%	3,3%
12	13%	0%	0%	1,5%	23,2%	8,8%
13	26%	7%	0%	14,6%	12,9%	2,4%
14	28%	0%	0%	19,3%	9,8%	4,5%
15	23%	0%	0%	15,2%	11,2%	4,7%
16	30%	0%	0%	3,4%	11,5%	4,8%
17	16%	0%	0%	1,9%	15,2%	6,9%
18	18%	0%	0%	23,4%	10,6%	3,9%
19	0%	0%	0%	1,4%	17,7%	9,1%
20	0%	0%	0%	7,8%	16,3%	8,7%
21	18%	10,2%	0%	2,8%	15,7%	5,9%
22	11%	0%	0%	9,2%	15,2%	3,1%
23	11%	0%	0%	11,1%	14,8%	2,9%
24	20%	0%	0%	1,8%	15,7%	2,8%
25	15%	0%	0%	7,0%	15,3%	2,8%
26	30%	0%	0%	20,8%	13,3%	5,0%
27	16%	26,3%	0%	19,6%	17,6%	4,3%
28	25%	0%	0%	18,2%	21,3%	8,8%

29	19%	8,6%	0%	17,3%	15,7%	1,3%
30	27%	0%	0%	11,8%	17,9%	1,9%
Averages	19%	2,8%	0%	10,7%	14,8%	4,2%

To further quantify the impact of these losses, time loss values were calculated by multiplying each loss category by the loading time. The results are shown in **Table 4**.

Table 4. Time Loss Calculation Results (seconds)

	Availability Rate		Performance Rate	Quality	, Rate
Batch	Breakdown	Setup Losses	Reduced Speed	Defect Losses	Yield Losses
DUICH	Losses	(seconds)	Losses (seconds)	(seconds)	(seconds)
	(seconds)				
1	1625	600	570	972	313
2	1210	0	1137	1298	318
3	2090	540	1454	814	156
4	2346	720	260	2496	246
5	4176	0	1680	2116	368
6	1290	0	333	2329	148
7	1539	900	750	1126	368
8	1710	0	1357	1014	315
9	1229	0	517	1014	311
10	1653	0	1293	1091	313
11	2495	0	1170	1208	309
12	811	0	92	1450	550
13	4493	1200	2517	2237	422
14	840	0	578	293	136
15	593	0	393	288	121
16	720	0	81	276	115
17	307	0	37	292	133
18	486	0	631	286	105
19	0	0	12	149	76
20	0	0	70	147	78
21	950	540	147	827	312
22	581	0	485	804	165
23	594	0	600	800	158
24	1068	0	99	839	152
25	801	0	376	816	147
26	900	0	624	399	150
27	365	600	446	401	99
28	600	0	437	512	210
29	1197	540	1089	989	84
30	1701	0	745	1125	118
Total	38370	5640	19976	28406	6496

Based on the cumulative time losses, **Table 5** presents the total contribution of each Six Big Losses category.

Table 5. Summary of Cumulative Percentage of Time Losses (January–August 2024)

Losses Group	No	Six Big Losses	Time Losses (seconds)	Percentage (%)	Cumulative Percentage (%)
Downtime	1	Breakdown Losses	38370	38,801	38,801
Losses	2	Setup And Adjustment Losses	5640	5,703	44,505
Speed Losses		Idling And Minor Stoppage			
	3	Losses	0	0,000	0,000
	4	Speed Losses	19976	20,201	64,706
Quality Losses	5	Quality Defect Losses	28406	28,725	93,431
	6	Yield Losses	6496	6,569	100,0
		Total	98888	100	-

The visualization of time losses is shown in **Figure 6**.

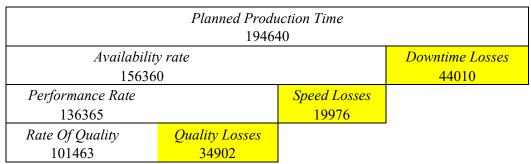


Figure 6. Time Losses in Ampoule Filling Machines

The analysis shows that from the total planned production time of **194,640 seconds**, only **101,463 seconds** (**52.1%**) were effectively used to produce products that met quality standards. Downtime losses amounted to **44,010 seconds**, reducing available operating time to **156,360 seconds**. Speed losses further reduced effective time by **19,976 seconds**, while quality-related losses accounted for **34,902 seconds**.

Breakdown losses were identified as the largest contributor to inefficiency, totaling **38,370 seconds (38.8%)**, indicating frequent machine failures and unplanned stoppages. Quality defect losses contributed **28.7%**, reflecting instability in process quality, while speed losses accounted for **20.2%**, indicating that the machine frequently operated below its ideal capacity.

3.1.2. Fishbone Diagram Analysis

To identify the root causes of these losses, a Fishbone Diagram was developed by categorizing potential causes into six dimensions: **man, machine, method, material, measurement, and environment**. The relationship between these factors and the low OEE value is illustrated in **Figure 7**.

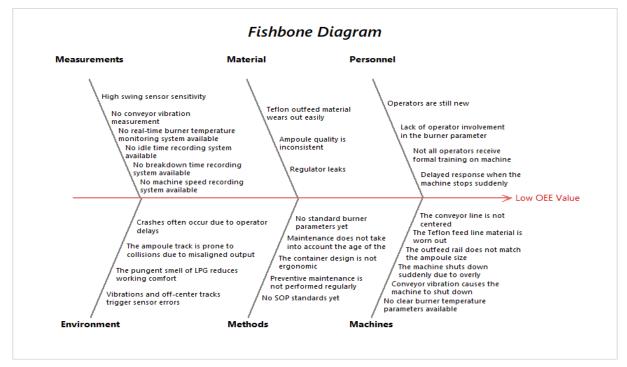


Figure 7. Fishbone Diagram of the Ampoule Filling Machine

The analysis revealed that machine-related factors, such as sensor malfunction and unstable output flow, were the dominant contributors to breakdown and quality losses.

3.1.3. Total Productive Maintenance Implementation

Based on the analysis results, improvement actions were implemented in stages following TPM principles. Initial improvements focused on replacing the swing conveyor sensor and modifying the ampoule output line. These actions were prioritized due to their direct impact on machine effectiveness, low implementation cost, and short execution time.

The sensor replacement aimed to reduce detection errors that frequently caused unplanned downtime by installing a more stable and accurate sensor and recalibrating its sensitivity to actual operating conditions. The output line modification involved changing the configuration from two narrow lanes to a single wider lane to prevent ampoule accumulation and collisions. A specially designed scoop was also added to facilitate smoother transfer to trays. These improvements represent short-term corrective actions approved by management as a foundation for broader TPM implementation. The implemented changes are shown in **Figure 8**.

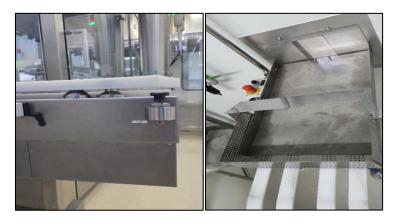


Figure 8. Sensor and Ampoule Outfeed Improvements

3.2. Overall Equipment Effectiveness After Improvement

Following the implementation of improvements, OEE was recalculated to evaluate their effectiveness. The results are presented in **Table 6**.

Batch	Availability Rate	Performance Rate	Quality Rate	OEE
1	91,3%	96,7%	92,9%	82,0%
2	89,8%	99,6%	97,0%	86,8%
3	76,4%	92,3%	88,5%	62,4%
4	84,4%	97,1%	92,1%	75,5%
5	85,9%	98,6%	95,3%	80,7%
6	87,9%	94,4%	93,5%	77,6%
7	75,9%	92,8%	86,1%	60,6%
8	88,6%	85,7%	90,6%	68,8%
9	84,4%	98,5%	90,7%	75,4%
10	79,1%	97,6%	90,2%	69,6%
11	71,9%	98,0%	89,6%	63,1%
12	89,5%	95,7%	93,0%	79,7%
13	74,0%	86,8%	87,3%	56,1%
14	100%	87,1%	87,8%	76,5%
15	100%	89,0%	82,9%	73,8%
16	73,3%	81,5%	83,8%	50,1%
17	84,4%	98,6%	82,6%	68,7%
18	82,2%	72,2%	83,1%	49,3%
19	100%	91,8%	95,7%	87,9%
20	100%	97,2%	95,3%	92,6%
21	84,7%	96,4%	95,9%	78,3%
22	89,5%	94,0%	95,7%	80,5%

Table 6. OEE Calculation Results After Improvement

23	88,9%	96,9%	92,5%	79,7%
24	81,8%	98,0%	95,0%	76,2%
25	86,7%	94,4%	96,1%	78,7%
26	77,3%	80,5%	85,9%	53,5%
27	100%	78,1%	85,7%	66,9%
28	100%	91,5%	86,2%	78,9%
29	81,0%	90,4%	91,6%	67,1%
30	87,0%	77,1%	91,9%	61,6%
Average	86,5%	91,6%	90,5%	71,9%

The results indicate that the average OEE value increased to **71.9%**, compared to **59.2%** before improvement. This improvement reflects a substantial enhancement in machine effectiveness, particularly in the **availability and quality** components. However, the OEE value remains below the world-class standard of **85%**, indicating that further continuous improvement is required.

These findings are consistent with previous studies, which emphasize that the effectiveness of TPM implementation depends on a mature maintenance system, operational discipline, and active participation across organizational levels (Muchiri & Pintelon, 2008; Ahuja & Khamba, 2008). Therefore, sustained technical improvements combined with a comprehensive TPM strategy have strong potential to further improve machine effectiveness and move performance closer to world-class standards.

4. Conclusions

Based on the results of this study, the implementation of Total Productive Maintenance (TPM) supported by Overall Equipment Effectiveness (OEE) measurement on the ampoule filling machine at PT X indicates that the initial level of machine effectiveness was relatively low. The average OEE value prior to improvement was 56%, which is significantly below the world-class benchmark of 85%, indicating substantial inefficiencies in the production process.

Analysis using the Six Big Losses framework identified breakdown losses, setup and adjustment losses, and quality defect losses as the dominant contributors to low machine effectiveness. These losses were primarily caused by technical issues such as swing conveyor sensor failures, unstable LPG supply, and burner settings that did not meet operational standards.

Improvement actions were implemented through a TPM-based approach, emphasizing planned maintenance, focused improvement, and autonomous maintenance. Key actions included sensor replacement and calibration, modification of the ampoule outfeed path, and the application of appropriate scooping tools to prevent ampoule accumulation and collisions. As a result of these improvements, the average OEE value increased to 71.9%, with availability, performance, and quality rates reaching 86.5%, 92.0%, and 90.5%, respectively. This improvement demonstrates the positive impact of targeted technical interventions on machine performance.

In conclusion, the application of TPM has proven effective in improving the effectiveness of the ampoule filling machine at PT X. However, since the achieved OEE value remains below the world-class standard, continuous and comprehensive TPM implementation is recommended to further enhance machine reliability, product quality, and long-term production efficiency.

References

Ahuja, I. P. S., & Khamba, J. S. (2008). Total productive maintenance: Literature review and directions. *International Journal of Quality & Reliability Management*, *25*(7), 709–756. https://doi.org/10.1108/02656710810890890

Gaspersz, V. (2002). Total quality management. Jakarta: Gramedia Pustaka Utama.

- Hisprastin, Y., & Musfiroh, I. (2020). Ishikawa diagram dan failure mode and effect analysis (FMEA) sebagai metode yang sering digunakan dalam manajemen risiko mutu di industri. *Jurnal Farmasetika*, 6(1), 1–9. https://doi.org/10.24198/jf.v6i1.27105
- Jono. (2019). Evaluasi dan peningkatan produktivitas penggunaan mesin melalui overall equipment effectiveness (OEE). Surabaya: Penerbit Mesin Produktif.
- Muchiri, P., & Pintelon, L. (2008). Performance measurement using overall equipment effectiveness (OEE): Literature review and practical application discussion. *International Journal of Production Research*, 46(13), 3517–3535. https://doi.org/10.1080/00207540601142645
- Nakajima, S. (1988). *Introduction to total productive maintenance (TPM)*. Portland, OR: Productivity Press.
- Pramewari, M. I. (2024). Improving machine efficiency at PT PID Ongkowidjojo: OEE and FMEA analysis leading to significant gains in primary stage 3. *Journal of Industrial Engineering: Application and Research*, 4(2). https://doi.org/10.33479/sakti.v4i2.96
- Priyanta, D., Imani, T., & Gurning, S. (2008). Implementasi total productive maintenance dengan metode overall equipment effectiveness (OEE) untuk menentukan maintenance strategy pada mesin tube mill 303 (Studi kasus: PT Spindo Unit III). *Journal of Marine Engineering*, Institut Teknologi Sepuluh Nopember, Surabaya.
- Satwika, Y. B. (2016). Desain total productive maintenance (TPM) guna mengurangi losses menggunakan overall equipment effectiveness (OEE) pada lini X PT Pindad Turen [Undergraduate thesis]. Malang.
- Taufik, F. M., Puri, G. N., Meidina, M., & Zidan, R. M. (2023). Analisis pengukuran efektivitas mesin pada proses filling menggunakan metode overall equipment effectiveness (OEE) dan six big losses di PT Sanbe Farma. Bandung.
- Warizki, A. (2019). Studi penerapan total productive maintenance (TPM) untuk peningkatan efisiensi pada pabrik kelapa sawit Kebun Sei Intan PTPN V, Riau.

