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Implementation of Total Productive Maintenance (TPM) Using Overall Equipment Effectiveness (OEE) Method on HPLC Instruments in Laboratory

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ABSTRACT

The study aimed to assess the efficacy of HPLC instruments in a pharmaceutical laboratory at PT. XYZ by evaluating three OEE matrices (availability, performance, and quality) and identifying the losses leading to low OEE scores affecting the chromatography process performance. The method used is quantitative to calculate the availability rate, performance rate, and quality ratio based on the breakdown data and quantity of product data, followed by calculating the OEE score and comparing the obtained OEE and the world-class standard OEE score. The results demonstrate that the average availability rate in 2022 is 90,73%, the performance rate is 90,45%, and the quality ratio is 95,55%, resulting in the OEE score of 78,42%, which does not meet the world-class OEE standards score. To identify the problems causing the low OEE score, a qualitative analysis is performed using Current Condition Analysis and Fish Bone Diagram. Research indicates that five factors contribute to low OEE scores for HPLC instruments in PT. XYZ, including Method, Man, Machine, Material, and Environment. For each factor, the proposed improvement is described to increase the OEE score, including establishing the maintenance procedure, a training program for laboratory personnel, inventory management for spare parts, and an operating procedure.

Keywords: *Total Productive Maintenance, Overall Equipment Effectiveness, HPLC, Fish Bone Diagram*

Introduction

The chromatography process plays a crucial role in the pharmaceutical industry. Analysts use chromatograms, which result from the chromatographic process, to identify the components in a sample, measure their concentrations, and calculate the relative amounts of each element. In other words, the chromatography process has a significant role in maintaining the quality of pharmaceutical products, which usually have high standards.

One instrument used in many industries for the chromatography process is High-Performance Liquid Chromatography (HPLC). HPLC works by separating the analyte components based on their polarity. A detector detects each mixture and records it as a chromatogram.

PT. XYZ is a pharmaceutical company that produces various pharmaceutical products used by domestic and international customers at PT. XYZ, HPLC instruments play an important role in ensuring that the products' components and chemical substances dosage comply with the established standards. The reliability of HPLC instruments determines whether the sample testing process can run efficiently.

Proper checks and maintenance are required to maintain the HPLC instruments in reliable condition and ready to use. The breakdown of HPLC instruments can hamper the sample testing process, thus disrupting the overall production process. The Total Productive Maintenance (TPM) program is one of the lean manufacturing methods that manufacturers can implement to maintain the reliability of equipment and machines. It is a systematic approach to maintaining and improving the integrity of production and quality systems through the equipment, processes, and employees that add business value to an organization. The main goal of TPM is to maximize equipment effectiveness, reduce breakdowns, and ensure reliable production processes. One of the TPM concepts that is widely known is overall equipment effectiveness (OEE)[1], [1]–[3]. It is a key metric in TPM which measures the effectiveness of equipment by combining its availability, performance efficiency, and quality rate. This provides insights into areas of potential improvement.

According to HPLC instruments breakdown data from the Maintenance Department at PT. XYZ shows that the breakdown intensity is relatively high, causing the chromatography process to be disrupted and the chromatogram process to be invalid as the output. Also, the sample as the input for the chromatogram process becomes waste if the HPLC instrument is troubled, causing more samples to be provided to replace the damaged sample. For this reason, it is necessary to analyze the performance of HPLC instruments and calculate the OEE score to identify which area needs improvement.

Research Methods

This research used a quantitative method to calculate the OEE score and a qualitative method to analyze the root cause of problems. Further steps are explained as follows:

Data Collecting Methods

The research starts with a literature study related to the topic, which includes Total Productive Maintenance, Overall Equipment Effectiveness, and Fish Bone Diagram. After that, the data required is collected to identify the problems in the real system. The secondary data is obtained from the Maintenance Department at PT. XYZ, including the operating time data, instrument breakdown time data, and instrument maintenance data. Other secondary data are the chromatogram quantities as the output of the instruments, damaged samples caused by the breakdown of instruments, and chromatograms that analysts cannot use due to the breakdown of the instruments. The data collected is from January to December 2022.

Data Analysis Methods

This research uses the Overall Equipment Effectiveness (OEE) approach as one of the measurement matrices for Total Productive Maintenance. OEE is a method used as a measurement tool to implement a TPM program to maintain equipment or machines[4]–[6]Thus, they can be in ideal conditions and ready to be used. OEE calculates the effectiveness of equipment or machines by considering the availability rate, the process's performance efficiency, and the output quality ratio [4].

The data required to compute the OEE score are downtime data, planned and unplanned downtime, product quantity produced by machines or equipment, and whether the products conform to the established standards.

The formula to calculate OEE is:

$$OEE\ [\%] = Availability\ [\%] \times Performance\ Rate\ [\%] \times Quality\ Rate\ [\%] \quad (1)$$

According to Seichi Nakajima (1988), an ideal score for OEE is described in table 1:

Table 1. OEE Score Standards

Parameter	Standard
Availability	90%
Performance Rate	95%
Quality Ratio	99%
Overall OEE Score	**85%**

Nakajima (1988) stated that the availability rate is a ratio between operation time by eliminating equipment downtime and total time.

$$Availability\ Rate = \frac{Total\ Time - Downtime}{Total\ Time} \times 100\% \quad (2)$$

Performance rate is the ratio between the output produced by equipment or a machine and its operating time. The data required for performance rate calculation are the output produced by the machine, cycle time, and operating time.

The performance rate is calculated with the following formula:

$$Performance\ Rate = \frac{Output \times Cycle\ Time}{Production\ Time} \times 100\% \quad (3)$$

According to [1], [7], [8], the quality rate is a ratio that describes the ability of equipment or machines to produce products that conform to established standards. The rate is influenced by two main factors: products with defects or rejected products and the total product produced by the equipment or machine. It is calculated with the following formula:

$$Quality\ Rate = \frac{Output - Defect}{Output} \times 100\% \quad (4)$$

Result Analysis and Discussion

After the three factors are calculated and the OEE score is computed, the analysis will be conducted by comparing the actual OEE score with the OEE standard score according to world-class standards. If the actual OEE is below the standard, it is necessary to identify the root cause of the problems and propose several improvements to increase the actual OEE.

The root cause analysis will be performed using a Cause-Effect Diagram or Fishbone Diagram. The fishbone diagram, or the Ishikawa diagram or cause-and-effect diagram, is a visual tool used primarily in quality management and problem-solving [9]–[11]. It helps identify, explore, and graphically display the potential causes of a specific problem or issue. The diagram's layout resembles a fish's skeleton, hence its name.

Result and Discussion

Downtime Data

The following are downtime, planned maintenance, and operation time data obtained from the Maintenance Department for HPLC instruments in the pharmaceutical laboratory of PT XYZ from January to December 2022:

Table 2. Breakdown Data of HPLC instruments in 2022

Month	Total Downtime [minutes]	Planned Maintenance [minutes]	Operation Time [minutes]	Production Time [minutes]
January	627	3120	44640	40893
February	595	3120	40320	36605
March	560	3480	44640	40600
April	855	3240	43200	39105
May	600	3480	44640	40560
June	430	3330	43200	39440
July	165	3720	44640	40755
August	675	3480	43200	39045
September	1062	3480	44640	40098
October	450	3600	43200	39150
November	270	3480	44640	40890
December	1035	3720	43200	38445

Data Calculation

a. Availability Rate Calculation[12], [13]

Here is an example of the Availability Rate calculation for breakdown time in January:

$$Availability\ Rate = \frac{Total\ Time - (Downtime + Planned\ Maintenance)}{Total\ Time} \times 100\% \quad (1)$$

$$Availability\ Rate = \frac{44640 - (627 + 3120)}{44640} \times 100\%$$

$$Availability\ Rate = 91{,}61\%$$

The result of the overall Availability Rate calculation is described in Table 3 below:

Tabel 3. Result of Availability Rate Calculation

Month	Total Downtime [minutes]	Planned Maintenance [minutes]	Operation Time [minutes]	Production Time [minutes]	Availability Rate
January	627	3120	44640	40893	91,61%
February	595	3120	40320	36605	90,79%
March	560	3480	44640	40600	90,95%
April	855	3240	43200	39105	90,52%
May	600	3480	44640	40560	90,86%
June	430	3330	43200	39440	91,30%
July	165	3720	44640	40755	91,30%
August	675	3480	43200	39045	90,38%

September	1062	3480	44640	40098	89,83%
October	450	3600	43200	39150	90,63%
November	270	3480	44640	40890	91,60%
December	1035	3720	43200	38445	88,99%

b. Performance Rate Calculation [14], [15]
Here is an example of the Performance Rate calculation for data in January:

$$Performance\ Rate = \frac{Output \times Cycle\ Time}{Production\ Time} \times 100\% \quad (2)$$

$$Performance\ Rate = \frac{327 \times 120}{40893} \times 100\%$$
$$Performance\ Rate = 96{,}07\%$$

The result of the overall Performance Rate calculation is described in Table 4 below:

Table 4. Result of Performance Rate Calculation

Month	Production Time [minutes]	Cycle Time [minutes]	Output	Performance Rate
January	40893	120	327	96,07%
February	36605	120	322	95,83%
March	40600	120	305	82,00%
April	39105	120	328	91,09%
May	40560	120	334	89,83%
June	39440	120	328	91,24%
July	40755	120	327	87,95%
August	39045	120	341	94,66%
September	40098	120	324	87,13%
October	39150	120	326	90,63%
November	40890	120	326	87,65%
December	38445	120	329	91,30%

c. Quality Ratio Calculation [16], [17]
Example for Quality Ratio calculation using data from January:

$$Quality\ Rate = \frac{Output - Defect}{Output} \times 100\% \quad (3)$$

$$Quality\ Rate = \frac{327 - 12}{327} \times 100\%$$
$$Quality\ Rate = 96{,}33\ \%$$

The result of the overall Quality Ratio calculation is described in Table 5 below:

Table 5. Result of Quality Ratio

Month	*Output*	*Defect*	*Quality Ratio*
January	327	12	96,33%
February	322	20	93,79%
March	305	16	94,75%
April	328	11	96,65%
May	334	13	96,11%
June	328	10	96,96%
July	327	13	96,03%
August	341	18	94,72%
September	324	24	92,60%
October	326	14	95,71%
November	326	13	96,01%
December	329	10	96,96%

d. OEE Calculation [18], [19]
   Example for Quality Ratio calculation using data from January:

$$OEE\ [\%] = Availability\ [\%] \times Performance\ Rate\ [\%] \times Quality\ Rate\ [\%] \quad (4)$$

$$OEE\ [\%] = 91{,}61\% \times 96{,}07\% \times 96{,}33\%$$
$$OEE = 84{,}78\ \%$$

The result of the OEE calculation is described in Table 6 below:

Table 6. *Result of OEE Calculation*

Month	Availability Rate	Performance Rate	Quality Ratio	OEE
January	91,61%	96,07%	96,33%	84,78%
February	90,79%	95,83%	93,79%	81,60%
March	90,95%	82,00%	94,75%	70,67%
April	90,52%	91,09%	96,65%	79,69%
May	90,86%	89,83%	96,11%	78,44%
June	91,30%	91,24%	96,96%	80,76%
July	91,30%	87,95%	96,03%	77,10%
August	90,38%	94,66%	94,72%	81,04%
September	89,83%	87,13%	92,60%	72,47%
October	90,63%	90,63%	95,71%	78,60%
November	91,60%	87,65%	96,01%	77,08%
December	88,99%	91,30%	96,96%	78,78%
Average	90,73%	90,45%	95,55%	78,42%

Analysis and Discussion

Based on the calculation in the previous paragraph, the actual OEE score of the HPLC instruments in a pharmaceutical laboratory at PT. XYZ from January to December 2022 is below the OEE world-class standard. The comparison is expressed in the Table 7 below:

Table 7. Comparison of Actual OEE and Standard

Parameter	Standard	Actual Score
Availability	90%	90,73%
Performance Rate	95%	90,45%
Quality Ratio	99%	95,55%
Overall OEE Score	**85%**	**78,42%**

The average availability rate in 2022 was 90.73%, above the standard. The average Performance Rate in 2022 was 90.45%, below the standard. Meanwhile, the average Quality Ratio for 2022 was 78.42%, also below the standard. Although the average Availability Rate exceeded the standard, the Performance Rate and Quality Ratio's average values were below the standard, leading to an overall reduced OEE (Overall Equipment Effectiveness) value.

Based on these issues, an Analysis of the Current Condition (referred to as "ANAKONDA" or Analisis Kondisi yang Ada in Indonesian) was conducted to identify the root causes, and the results of this analysis are illustrated in a Fishbone Diagram[20][21][22].

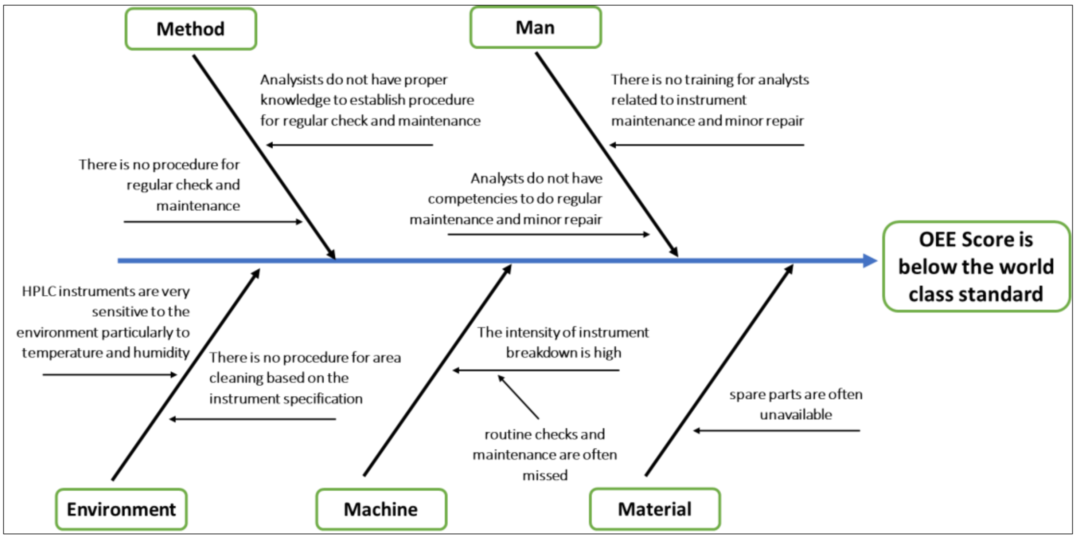

Figure 1. Fish Bone Diagram

Based on the Analysis of the Current Condition (ANAKONDA) and mapping with the Fishbone Diagram[12], [23]–[25], there are five main factors influencing the low OEE value of the HPLC instrument in PT XYZ's laboratory:

1. Method

The current condition indicates that laboratory personnel cannot implement a method or procedure for regular checks and maintenance to prevent breakdowns. Therefore, the company must hand it over to the vendor, which requires more time and cost.

2. Man

The laboratory personnel do not have the proper competency to conduct maintenance and minor repairs on the HPLC instrument. As a result, maintenance and minor repairs still need to be carried out by the vendor. This means that when minor repairs are required, the company needs to call the vendor, extending the breakdown duration.

3. Machine

The high frequency of breakdowns results from routine checks and maintenance often not being performed as scheduled. This is because the company must call a competent vendor to perform the maintenance for routine checks and maintenance.

4. Material

From the material perspective, the prolonged breakdown duration is also due to the unavailability of replacement parts needed for repairs. Part damage occurs due to missed routine checks and maintenance, sometimes leading to breakdowns. Waiting times are extended for replacements since the required parts are occasionally not in stock, necessitating the company to purchase them from the vendor.

5. Environment

Given that the HPLC instrument is sensitive, its reliability is also affected by the environmental conditions in which it operates. Temperature and humidity levels must be maintained according to the instrument's specifications, and dust and dirt must also be prevented.

Suggested Improvements to Increase the OEE Score

Based on the factors described above, several improvement works can be proposed to increase the OEE Score, as follows:

Table 8. Proposed Improvements

Factors	Issue Description	Proposed Improvement
Method	There is no procedure established for laboratory personnel to do regular checks and maintenance	Development and establishment of procedures that can be implemented by laboratory personnel to do regular checks and maintenance
Man	Laboratory personnel do not have the competencies and knowledge to do regular maintenance and minor repair	Conduct certified training to ensure laboratory personnel have competencies in regular maintenance and minor repairs; hence the regular maintenance and minor repairs do not need to wait for vendor services
Machine	Instruments often experience breakdowns due to routine checks and maintenance that are sometimes not carried out on schedule	Perform regular check and maintenance checks according to the schedule after ensuring that the laboratory personnel have the proper competencies to do the maintenance
Material	The materials or spare parts to replace the broken part are often not available due to the unplanned breakdown	Identification of parts that often troubled and conducted inventory management for the spare part of HPLC instruments
Environment	An environment where the HPLC instruments are operated must comply with the conditions stated in the instrument specification and instrument manuals.	Establish an operating procedure according to the instruments' manuals and specifications and place the procedure near the instruments so that the operator can clearly read it

Conclusion

Based on the calculations and analysis of the OEE score for the HPLC instruments at PT XYZ, it can be concluded that The Overall Equipment Effectiveness (OEE) score for HPLC instruments at PT. XYZ Laboratory for 2022 is 78,42%, which does not meet the world-class OEE standard of 85%. The breakdown's high intensity and long duration results in a low-performance rate. Also, it causes a low-quality ratio due to the high number of defects in the chromatograms as output of the process resulting from frequent disruptions in the instrument's reliability. The mapping result using Current Condition Analysis and Fish Bone Diagram shows that the low OEE score is attributed to five factors: Method, Man, Machine, Material, and Environment. Several improvements can be proposed to increase the OEE score based on each factor, including establishing maintenance procedures, training for laboratory personnel, inventory management for spare parts, and establishing operating procedures.

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