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Improvement of Preventive Maintenance Effectivity of Tablet Blistering Machine at PT XYZ Farma

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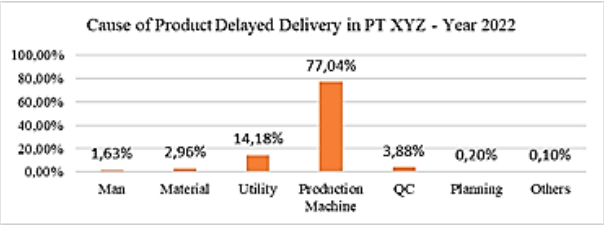
***Abstract*—** Machine damage can cause downtime which will disrupt production activities and cause delays in product supply to the market. In addition, downtime will also increase production costs so that products become less competitive. To prevent machine damage, it is necessary to perform effective preventive maintenance activities. This study aims to determine the cause of machine damage at PT XYZ Farma and determine actions for improvement. The research methods used are quantitative descriptive and qualitative. Data on Preventive Maintenance, Corrective, and Breakdown Maintenance were collected from January 2020 to May 2023. Root Cause Analysis (RCA) using fishbone diagrams is used to determine the cause of machine damage. For the sample of the study, the Tablet Blistering Machine, one of the critical machines, was selected. Based on the results of RCA, it is known that 3 main problems cause machine damage, which are incomplete Preventive Maintenance procedures, human error of technician or operator, and age of spare parts. Furthermore, corrective actions are formulated through Focus Group Discussion which aims to address the root of the problem so that subsequently the effectiveness of Preventive Maintenance can be increased, and downtime reduced.

***Keywords*—** Breakdown Maintenance, Corrective Maintenance, Downtime, Preventive Maintenance.

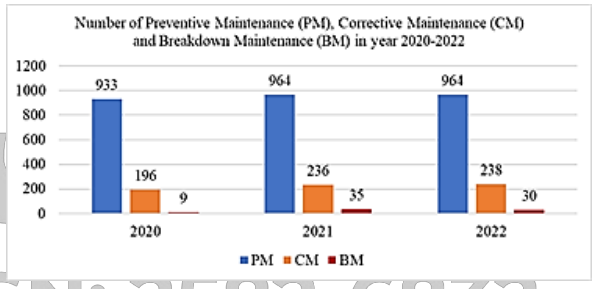
I. INTRODUCTION

Preventive Maintenance of machinery, equipment, and supporting facilities in a factory are very important. The activity aims to ensure that all machines, equipment, and supporting facilities are in good condition to support production activities. Any machine, equipment, and utility breakdown will disrupt production activities and as a result, the supply of products to the market will be delayed. The delay in supply will have an impact on business, the company will experience sales loss, or even worse if customers switch to other similar products, then the company will lose its customers permanently.

The above observation is also observed in the PT XYZ Farma plant, a pharmaceutical plant producing solid preparations and sterile injections. Downtime problems can cause delays in the supply of products to the market. Based on the data in the table below, damage to production machines and utilities is the biggest cause of delays in product supply to the market.



PT XYZ has implemented a routine PM of machines and utilities with implementation above 90%, however corrective maintenance (CM) and breakdown maintenance (BM) cause downtime still occur, as shown in the table below:



Based on the above table, 30 breakdown cases occurred in the year 2022 that caused the cost incurred for repairs to be around Rp. 300,000,000,- (USD 20,000.-). In addition, machine damage that occurs in the middle of the production process can affect the quality of the products produced, even as a result the product can be rejected, which will cause a significant loss to the company. The amount of company losses due to rejected products ranges from Rp. 150.000.000,- (USD 10,000.) to Rp. 1,200.000.000,- (USD 80,000.-) per batch, depending on the type of product.

Ravande (2022) stated that downtime wastes many manufacturing operational costs. Frequent downtime will increase manufacturing costs and ultimately increase the cost of goods produced. The increase in the cost of goods will make the products less competitive (De Felice et al., 2014). In addition to the increase in costs, machine breakdown might affect the product quality, especially in pharmaceutical products. The

manufacture of pharmaceutical products involves many production machines and equipment as well as utilities such as air, water, and compressed air which need to be in good condition so that product quality can be guaranteed (Annex 3 Good Manufacturing Practices: Guidelines on Validation Background, 2014).

Preventive Maintenance (PM) is generally carried out periodically according to a predetermined schedule, refers to standard operating procedures, and is carried out by trained technicians. Effective PM will prevent problems related to the breakdown of machines, equipment, and utilities that will disrupt production activities. However, from several observations, although the PM has been carried out regularly, problems with damage to machines, tools, and utilities are still often encountered, which can be caused by several factors such as improper maintenance procedures, inadequate technician skills, or any other unpredictable causes.

This study is performed at PT XYZ Farma to improve the PM effectiveness so that CM and BM which cause machine downtime can be reduced. Critical machines that have the most downtime events will be identified and then selected as research samples. Root Cause Analysis of the CM and BM in each machine selected will be performed. Based on the RCA, improvement of PM effectiveness will be proposed in a Focus Group Discussion consisting of key personnel (O. Nyumba et al., 2018).

II. LITERATURE REVIEW

Bakri Mohd Al-Fatihhi Mohd Szali Januddi, n.d. (2020)explained that there are several methods of maintaining and repairing machines and equipment to ensure that machines and equipment are in good condition. Some of the maintenance approaches applied in the industry are Preventive Maintenance (PM), Corrective Maintenance (CM), Breakdown Maintenance (BM), and Predictive Maintenance (PdM). Maintenance Strategies are defined as management methods used to achieve maintenance objectives (Tran Anh et al., 2018). The strategy determines maintenance, the type of work to be done, the frequency of maintenance, and the maintenance procedure that should be performed. Neglecting maintenance activities can lead to costly failures.

Preventive Maintenance can be defined as maintenance actions carried out on a predetermined schedule to maintain or extend the service life of machines by controlling the performance of machines and equipment to an acceptable level. The main purpose of Preventive Maintenance (PM) is to prevent damage to machinery and equipment. In other words, PM aims to prevent sudden damage to machines and tools that require CM or BM. An effective PM program reflects good organizational management in planning, coordination, evaluation, and continuous improvement throughout the organization. Implementation of a systematic PM program will increase factory effectiveness (Bakri Mohd Al-Fatihhi Mohd Szali Januddi, n.d., 2020).

CM and BM focus on corrective actions taken on machinery and equipment after damage is detected or occurred. The purpose of CM and BM is to repair the equipment to a minimum acceptable condition so that the machine/ equipment can be operated. Some of the causes of CM and BM include the ineffectiveness of the Preventive Maintenance (PM) program, lack of machine inspection, lack of evaluation of the load cycle on the machine, and improper engine design (Bakri Mohd Al-Fatihhi Mohd Szali Januddi, n.d., 2020). A proper PM plan, correct documentation, recording, and execution of maintenance at appropriate intervals will help the Engineering Department eliminate most CMs and BMs.

To increase productivity and efficiency in operational costs, organizations/ companies began to use the Predictive Maintenance (PdM) strategy to manage machinery and equipment maintenance activities. PdM is a maintenance policy carried out through maintenance before machine failure occurs, by assessing the condition of the machine, including the operating environment, and predicting the risk of machine failure in real-time, based on machine data collected. Forecasting the decline of machines is based on the assumption that most of the decline in machine function does not occur instantly and there is usually a steady trend of change from normality to abnormality (Shin & Jun, 2015).

The pharmaceutical industry is constantly looking for the right strategies to improve its operations to gain a competitive advantage. Preventive maintenance (PM) tends to be a major management issue for many pharmaceutical companies.

Proper maintenance management requires information about the maintenance performance of the machines and utilities for maintenance process planning and control (He and Gao, 2023). PM is very important for the Pharmaceutical Industry to maintain its competitiveness, reduce costs, improve the availability

and reliability of machines and tools, and meet safety and environmental requirements.

Critical machines require comprehensive maintenance compared to non-critical machines, such as daily maintenance, spot checks, and periodic reconditioning of machines. Daily maintenance is mainly carried out by the operator, including cleaning and lubrication before or after equipment operation; Spot check is a triple-check mechanism formed by operators, administrators, and technicians from the engineering department (Yinghua, 2018).

Maintenance management is part of the management strategy which needs to be well communicated to employees to ensure that the management strategy can be implemented to achieve the organization's objectives (Hariyadi, 2018). Employees involved in PM activities, such as technicians and operators play an important role in maintenance management, including the implementation of effective PM.

III. METHOD

The methodology used in this study is quantitative descriptive and qualitative. Historical data of machine PM, CM, and BM from January 2020 to May 2023 is gathered and analyzed. Critical machines for the research sample are selected using a risk analysis approach. CM and PM data of the critical machines are analyzed using Root Cause Analysis (RCA) to find the root cause. Fishbone analysis is used for the RCA method. Improvement of PM is discussed in the Focus Group Discussion (FGD) to determine the PM improvement to reduce the CM and BM in the future.

IV. RESULT

Historical data of PM, CM, and BM of machines in PT XYZ Farma were collected from January 2020 to May 2023. Based on the data collected 17 machines had CM and BM cases of more than 2%. To further analyze the root cause of CM and BM, critical machines are selected from the 17 machines using a risk analysis approach which is part of Risk Based Maintenance (Hamasha et al., 2023). Risk-Based Maintenance (RBM) is the implementation of maintenance activities that use a risk analysis approach. RBM focuses on the maintenance of critical production systems and machines aimed at reducing machine breakdowns, thereby increasing machine reliability, and optimizing maintenance costs (Hamasha et.al., 2023).

Risk analysis is the determination of risk by quantitative or qualitative methods of a situation (Stamatis, n.d., 2019), in this case, it is the risk that occurs related to machine damage. Some of the risks that can occur due to machine damage or breakdown are products may be rejected, the operational cost of machine repair may be increased, and delays in the supply of products to the market will cause a loss of sales. The table below describes the risk analysis scoring and the result:

RISK ANALYSIS

Machine	Frequency of usage	Impact to Quality	Cost for repair	Potential Loss	Calculation
	A	B	C	D	=AxBxCxD
Blisterring Tablet ES - 300	3	3	3	3	81
Filling Ampoule	3	3	3	3	81
Tablet Compression ES	3	3	3	3	81
Autoclave	3	3	3	3	81
Labeling Ampoule	3	3	3	3	81
Washing Ampoule	3	3	3	2	54
Sterilization Tunnel	3	3	3	2	54
Tablet Compression NES-R	2	3	3	3	54
Mixing Tank	3	2	2	3	36
Tablet Compression NES	1	3	3	3	27
Dry Heat Oven	3	2	2	2	24
Vaccum of Tablet Compression ES	3	2	2	2	24
Coating Tablet ES	1	3	2	3	18
Stripping Tablet ES	2	2	2	2	16
Blisterring Tablet ES - 200	1	3	2	2	12
Super mixer	1	2	2	3	12
Mixer	1	1	1	1	1

Risk Score	Frequency of usage	Impact to Quality	Cost for repair	Potential Loss
1	rarely used	no impact	low	low
2	often used	moderate	moderate	moderate
3	frequently used	critical	high	high

Based on the above table there are five machines that have risk scores above 80, which are tablet blistering machine, ampoule filling machine, tablet compression machine, autoclave, and ampoule labeling machine. It was decided that the tablet blistering machine was selected as a sample for the study.

Fishbone analysis is used to find the root cause of CM and BM on the machines selected.

To get more accurate and useful results in Fish-Bone Analysis, several aspects need to be considered in the implementation of the analysis (Besterfield, 2014).

Each team member takes turns providing ideas. The quantity of ideas that emerge in the discussion session is more driven than the quality of the ideas. One person's idea will trigger another's idea, and a chain reaction can occur.

All ideas are written on the diagram. It is necessary to create a solution-oriented atmosphere. Focus on solving the problem rather than discussing how it started. Facilitators should ask questions using why, what, where, when, who, and how techniques.

Fishbone analysis for this study is performed through Focus Group Discussion (FGD) among key personnel from the Engineering, Production, and Quality Assurance Department.

After all root causes have been found, the root cause is then categorized based on the type of root causes as listed in the table below:

Type of Root Cause	Color code
Age of spare part	
Lack of Training	
PM task incomplete	
Lack of Procedure	
Machine improvement	
Spare part quality	
Human Error	
Spare part stock	

The above categorization aims to facilitate further analysis, including determining the priority of improvements that need to be made.

V. DISCUSSION

A Tablet Blistering Machine is a machine used to pack tablets in the form of blister packaging. The machine consists of a mold that will form a tablet pocket of PVC foil using a heating plate and compressed air. The tablets are then filled into the pockets using an auto-feeding system followed by a heat-sealing process between the PVC pocket and the aluminum foil sheet. The following are the number of CM and BM cases and total downtime from January 2020 to May 2023:

Type of Machine Damage	Number of cases	%	DT hours	%
Mechanic and control system	21	42,0%	739,8	89,8%
Heating Plate	12	24,0%	42,3	5,1%
Supporting utilities	5	10,0%	18,0	2,2%
Printing equipment	5	10,0%	10,5	1,3%
Eye mark system	4	8,0%	7,7	0,9%
Sensor PT 100	3	6,0%	6,0	0,7%
Total	50		824,3	

Based on the data above, there are 6 types of problems that occur in the tablet blistering machine with 2 main types of damage that cause the longest downtime hours, which are problems related to the mechanic and control system and heating plate. To identify the root cause of each problem, Fishbone Analysis was carried out with the following results:

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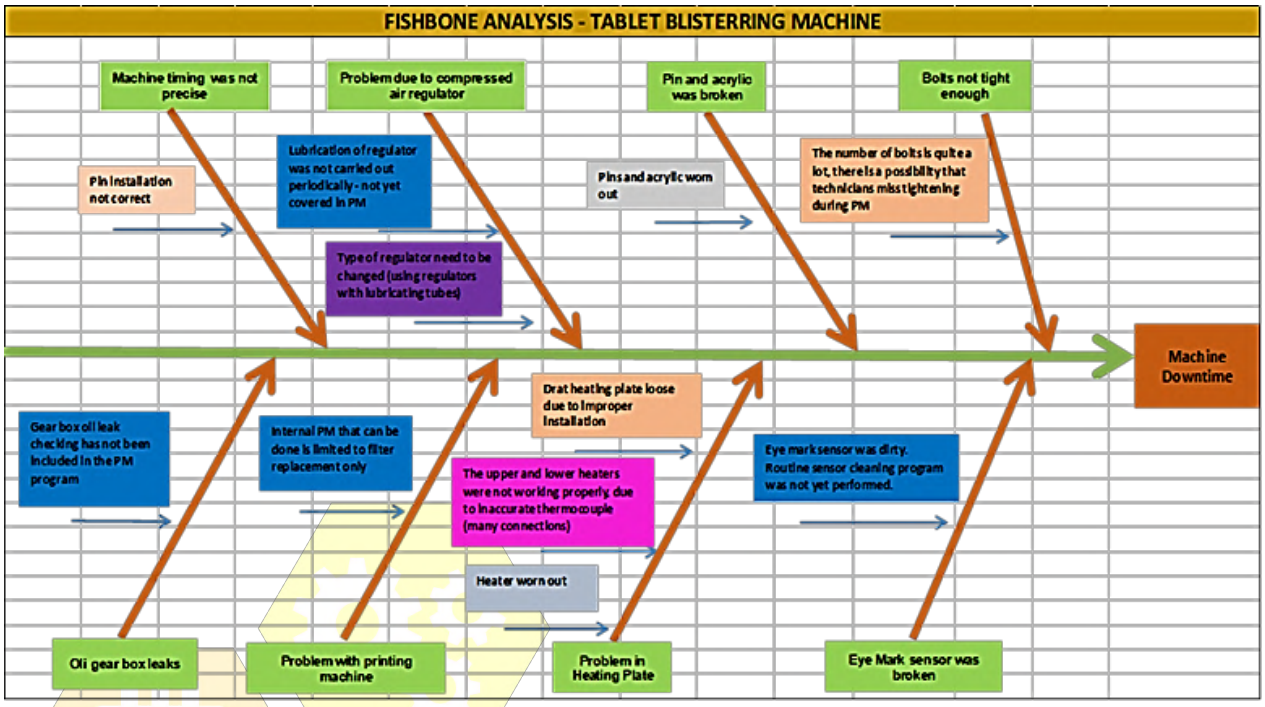

Each root cause identified from Fishbone Analysis is then categorized as follows:

Type of Root Cause	Color code	Total case	%
PM task incomplete		4	36,4%
Human Error		3	27,3%
Age of spare part		2	18,2%
Machine improvement		1	9,1%
Spare part quality		1	9,1%
Lack of Training		0	0,0%
Lack of Procedure		0	0,0%
Spare part stock		0	0,0%
	Total	11	

Based on the table above, it is known that there are 3 biggest root causes in the tblet blistering machine, which are: PM task incomplete (36.4%), human error (27.3%), and age of machine part (18.2%). Based on the results of the discussion in the FGD, several improvements were proposed to reduce the CM and BM cases in the future. The priority of implementing improvements is focused on the root cause of the most common problems found according to the results of the fishbone analysis.

The following is a list of proposed improvements for the tablet blistering machine:

No.	Root Cause	Improvement Proposal
1.	PM Task incomplete	To review and complete PM task list with the following item:
		1. Regular lubrication of compressed air regulator
		2. Regular cleaning of eye mark sensor
		3. Checking of oil in the gear box for any leackage
		4. Contract Service arrangement with Printing Machine supplier
2.	Human Error	To perform re-training and assessment:
		1. Systematics of periodic tightening of machine bolts (for technician)
		2. Correct instalation of heating plate (for machine operator)
		3. Installation of pin machine timing
3.	Age of Spare Part	Stock availability of pin, heater, thermocouple PT100
4.	Machine improvement	To replace the compressed air regulators with tube types
5.	Spare parts quality	The thermocouple used must be intact (not joint)

According to the results of the FGD, several improvements were proposed according to the table above, including improvements to PM procedures, retraining of machine technicians and operators, availability of spare parts stock, machine improvement, and attention to the quality of thermocouples. The current PM procedure needs to be completed and improved. PM procedures may be completed concerning

preventive actions related to historical CM and PM. PM procedure may also be improved based on inputs from the machine suppliers. Some machines are not completed with manuals that contain detailed machine maintenance procedures, so it is important to discuss with the suppliers about PM procedures to prevent CM and BM cases.

Training of operators and technicians is also important. Personnel capabilities have a significant influence on the company's performance, including maintenance performance (Rizal et al., 2022). Training modules need to be improved to include all aspects of the correct operation of the machine and its maintenance according to the PM procedure. Through appropriate training, it is expected that the skills of the operators and technicians will improve(Roberto et al., n.d., 2019). The effectiveness of training needs to be measured to ensure training objectives have been achieved.

Determining the age of spare parts is very important to reduce CM and BM cases. Spare part stock management is very important to prevent downtime or emergency ordering of spare parts that need high costs (He & Gao, 2023). The company needs to re-evaluate the availability of spare parts stock so that when required the spare part can be replaced before damage occurs resulting in CM and BM. The success of Preventive Maintenance activities is greatly supported by the optimal management of spare part stock to support Preventive Maintenance activities (Dellagi et al., 2020).

Another root cause is the material quality of spare parts. Some cases of CM and BM are caused by poor spare parts quality. It is necessary to find new suppliers who can supply spare parts of good quality. Machine operating procedures also need to be improved according to RCA results to prevent the recurrence of similar CM and BM cases.

Based on the history of downtime collected from January 2020 to May 2023, it is known that the number of downtimes that occur in tablet blistering machines is quite high (18,4% of the available days per year). This can be caused due to the age of the machine, which has been more than 25 years since the machine was made. For this machine, the maintenance period should be shortened (Al-Duais et al., 2022).

The company needs to set priorities and timelines for the improvement proposed in FGD. By implementation of the proposal, it is expected that the downtime cases will be reduced, and the operational effectiveness will be increased. PM effectiveness will impact the overall maintenance performance, where good maintenance management will allow optimal use of company resources and generate significant savings (Viveros et al., 2023).

VII. CONCLUSION AND RECOMMENDATION

Critical machines for the study were selected using a risk analysis approach. The tablet blistering machine was one of the critical machines that need to be further investigated for improving PM effectiveness. Based on the study it was concluded that the main root cause of CM and BM cases in the tablet blistering machine was due to incomplete PM task list, human error due to lack of technicians/ operators training, and the age of spare parts. An improvement proposal has been formulated to resolve the root causes and improve the PM effectiveness.

To further improve the PM effectiveness in PT XYZ, several recommendations are suggested. The company needs to extend the study to other machines based on the scoring results in the risk analysis table. It is also important to start the implementation of predictive maintenance, e.g. by using a simple technique such as an infrared thermal sensor for detecting heat caused by worn-out bearings. Implementation of autonomous maintenance, by training the machine operators to perform daily maintenance of machines is also suggested for preventing CM and BM.

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