Effect Of The Stopping Stripping Production Line To OEE (Overall Equipment Effectiveness) Of The Stripping Machine On The Primary Packaging Processes In The Pharmaceutical Industry

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Abstract

Increased production output is the main priority in the pharmaceutical industry. Productivity of primary packaging process which plays an important role in producing output can be improved and maintained by conducting regular OEE (Overall Equipment Effectiveness) analysis of the machinery and processes. OEE is a calculation method that is carried out thoroughly to identify the level of productivity and performance of machines or equipment. The OEE consists of three main measurements, namely availability, performance, and quality. In this study, line stop activities were observed during the primary packaging process that affected the OEE value of stripping machines in one of the pharmaceutical industries in the city of Jakarta. Research is carried out by observing, recording, and processing data related to primary packaging processes such as line stops and the number of products produced. Based on our study, we found that most of the line stops in the primary packaging process are caused by the changing of the polycellonium of the primary packaging material. Thus, we conclude that reducing changing of the polycellonium time from 10 minutes to 5 minutes will be beneficial to increase the operating time by 8% and increase the OEE value by 5%.

Keywords: *Primary Packaging Process, Overall Equipment Effectiveness* (OEE), *Stripping Machine, Net Operating Time*

1.   Introduction

The pharmaceutical industry has an important role in the effort of health services to the community by producing drugs that must meet the requirements of efficacy, safety and quality [1]. The pharmaceutical industry has benefited from margins and low competition for decades. Along with the development of the pharmaceutical field and increasing regulations to meet the aspects of efficacy, safety and quality, regulations and guidelines are always evolving, and pharmaceutical companies are always trying to meet these requirements [2]. In addition to fulfill the current guidelines, internally pharmaceutical companies are also making performance improvements.

Improving performance to achieve operational efficiency and effectiveness in terms of increasing the output of products as a production department achievement target to provide benefits for the company.

Previously, to increase the efficiency of the production process, workers' working time or adding new equipment and machinery was carried out. Meanwhile, currently it is known that improving efficiency and operational effectiveness should be done through optimizing engine performance optimally to improve equipment and engine reliability, improve operator performance, minimize turnaround times and reduce overall downtime.

Machinery and equipment are one of the supporting facilities for the production process in the pharmaceutical industry to carry out and perform its production activities. In an effort to increase productivity and machine output, it is necessary to evaluate machine performance regularly [4]. Evaluation that can be done is to do an OEE (Overall Equipment Effectiveness) analysis. OEE is a comprehensive calculation method to identify the level of productivity and performance of machines or equipment thereby efforts can be made to increase effectiveness [5]. In determining OEE there are three main measurement factors, namely the value of availability, performance, and quality [6].

The stripping machine plays the most role in producing the finished drug product. A stripping machine is a machine for carrying out the primary packaging process of tablets/caplets with packaging materials from polycellonium. Stripping machine performance was evaluated by calculating the OEE value [7]. In optimizing the OEE value of the stripping machine, one of the most possible way is to reduce its line stops in the production process. Line stop is a factor that causes the stripping machine to stop and not operate due to external factors without producing a product [8]. With the presence of a line stop in the process primary packaging, it can reduce the value of availability, performance and quality on the stripping machine which in turn affects the performance and OEE value. Therefore, it is important to analyze and evaluate what line stops occur and its affect the OEE value of the stripping machine in the primary packaging process. This study discusses and identifies the total number of times the line stop occurred and its effect the OEE value of stripping machines in the primary packaging process in one of the pharmaceutical industries in Jakarta.

2. Methods

The research was carried out through several stages of work, (1) Initial observation, by observing the facilities of the primary packaging area and following the entire series of primary packaging processes on the stripping machine for 1 month (2) Collecting the necessary data such as the total operating time and time loss on the stripping machine every day, the number of products obtained in one day, and the number of rejected products. Then the identification and classification of line stops found during the primary packaging process takes place. (3) Data processing to determine availability, performance, quality and OEE values. Furthermore, an analysis of the influence of the line stop on the value of OEE on the stripping machine was performed during the packaging process so that improvement can be carried out and optimized to be more efficient.

(a) Availability $= \frac{\text{operating time}}{\text{loading time}} =$

$$\frac{\text{loading time}-\text{downtime}}{\text{loading time}} \times 100\% \quad [9]$$

(b) Performance rate =
$$\frac{\text{processed amount x theoritical cycle time}}{\text{operation time}} \times 100\%$$
[9]

(c) Quality rate =
$$\frac{\text{processed amount}-\text{defect amount}}{\text{processed amount}} \times 100\%$$
[9]

OEE (%) = Availability (%) x Performance Rate (%) x Quality Rate (%) [9]

3. Result and Discussion

3.1 *Line Stop*

The stripping machine in the primary packaging process at PT ABC pharmaceutical industry is designed and regulated at a speed of 2,160 caplets/minute which is expected to produce 2,278,800 caplets in 1,440 minutes, of 3 shifts of 8 hours working time in a day. The expected target for the stripping machine to continue operating and produce products in 1 day is 1,055 minutes after reducing the consideration of unplanned downtime. Line stops are a factor that can cause losses due to the low efficiency of the stripping machine in the primary packaging process. The poor productivity of the stripping machine causes losses for the company or production department because the number of products obtained is low and does not achieve the target.

During the research process and data collection for one month, it was found that the line stops due to several factors such as were caplets stuck due to breaking in the machine channel, brushing sealing, workers' break time, changing of polycellonium and many more. The total line stops that occur are graphed by showing the total time (minute) of occurrence for 1 month in a primary packaging process can be seen in **Figure 1.**
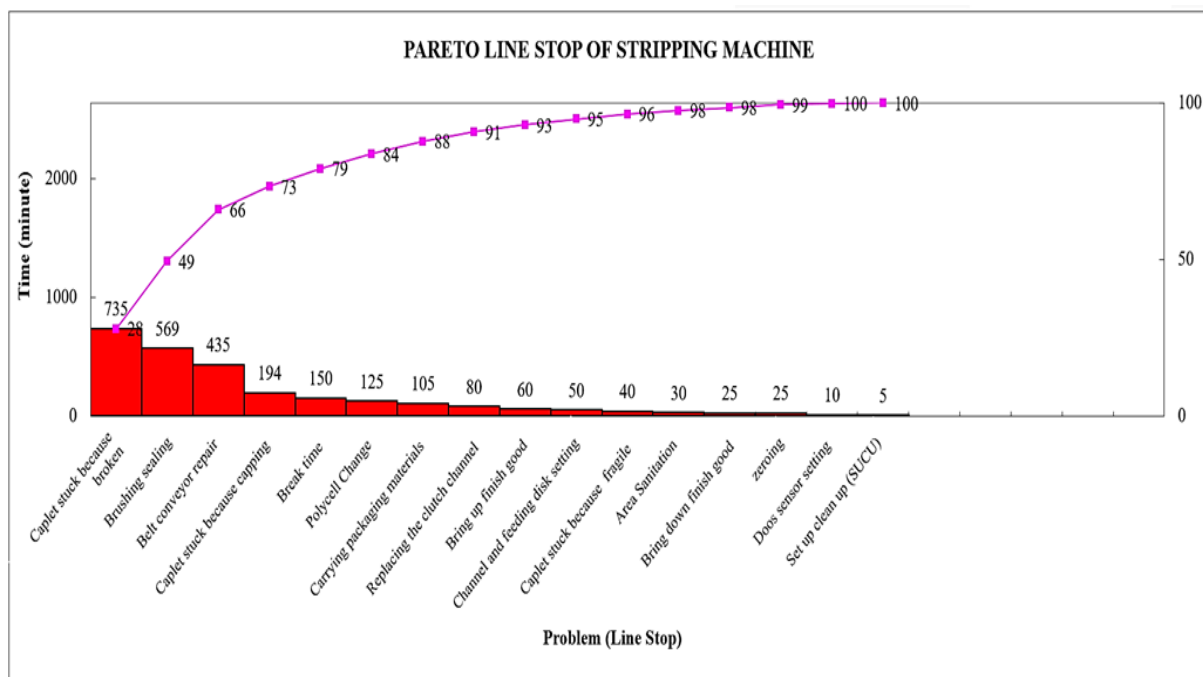

Figure 1. Pareto Line Stop of Stripping Machine Graphic

With the longer halt of the production process due to stopped in stripping process, it will affect the number of products produced. Line stops that appear on

stripping machines make the machine not operate and do not produce products thereby the value of operating time of stripping machines becomes reduced. Reduced operating time of stripping machines will degrade the availability, performance and quality of the stripping machine so that the OEE value will decrease. The number of products (in batches) produced by the presence of a line stop in the primary packaging process can be seen in **Figure 2.**
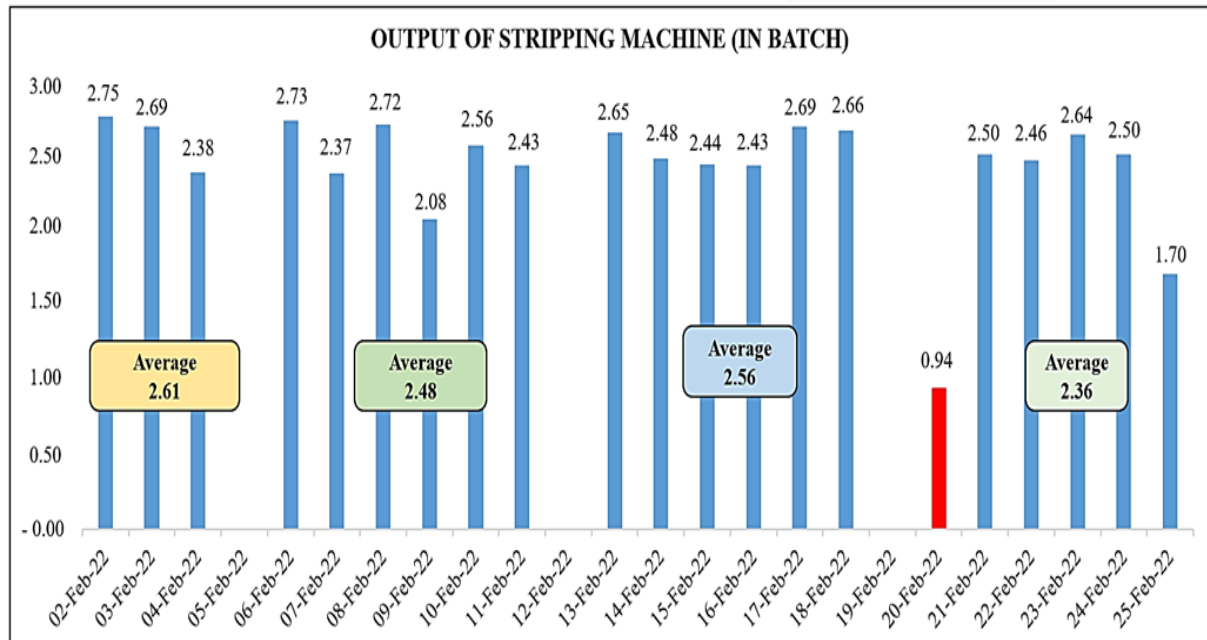

Figure 2. Output Of Stripping Machine (In Batch)

In the pharmaceutical industry loss of machinery and equipment should be avoided. These losses are known as the Six Big Losses. Six Big Losses are 6 loss factors that contribute greatly to the high value of lost machine productivity thereby reducing the work effectiveness of the stripping machine [10]. The basis for determining Six Big Losses determines the results of OEE measurements [5]. Based on the type of loss, Six Big Losses are divided into 3 main categories, namely Downtime losses, Speed losses, and Quality losses which can be seen in **Table 1.**

Table 1. Type of Six Big Losses

Category	Type	Description
Downtime	Equipment failure/breakdown	Loss due to damage to the machine/equipment or inoperation of the machine
	Set up and adjustment	Loss due to installation, tuning or replacing of products on machine/equipment
Speed Losses	Idling and minor stoppages	Loss due to machine/equipment stopping on a short period of time

	Reduced Speed	Loss due to decreased production speed in machinery/equipment
Defects	Process Defect	Loss due to defective products or reprocessed products
	Reduced Yield Losses	Loss at the beginning of production time until it reaches a stable production time

3.2 Overall Equipment Efectiveness (OEE)

OEE is a method used as a measuring tool in the implementation of the Total Productive Maintenance (TPM) system to optimize machines and equipment under ideal conditions resulting high product being produced as output. The TPM system ensures that all production equipment and machine can operate in

[9]

proper conditions in order to avoid damage and delays in the production process [2]. OEE is used as an analysis to monitor and improve the efficiency of machines in the production process. OEE value is the result of multiplication of three main measurement factors, namely availability, performance and quality rate [9]. The three measurement factors in OEE have their respective sections listed on **Table 2.**

Table 2. OEE Study Parameters

Availability	Performance	Quality
Planned downtime	Speed losses	Production rejects
Breakdowns	Small stops	Rejects on start up

[3]

1. Availability

Availability describes the utilization of available time for machine/equipment operations. Availability is the ratio of operation time by eliminating machine/equipment downtime to loading time [6]

2. Performance rate

Performance rate shows the ability of the machine/equipment in producing products. Performance rate is obtained by multiplying the quantity of products produced by the ideal cycle time against the available time in the production process (operation time). [3]

3. Quality rate

Quality rate represents the ability of the machine/equipment in producing products that are in accordance with the standard. Quality rate is the ratio of the number of products produced in good condition produced compared to the total number of units of products produced during the production process [3]

The research was conducted by measuring and calculating each of the OEE parameter measurement factors which can be seen in Table 3. The OEE value was obtained by multiplying the three main factors. The availability value of 85.05% is

influenced by several things, such as presence of line stops that cause the machine to stop operating and loading time is more than predict. The performance value of 107.11% is obtained from optimizing the machine stripping speed in producing the product. Furthermore, defective products produced are low so the quality value obtained is 99.55%.

Table 3. Stripping Machine OEE Value

Stripping Machine OEE Value			
Parameter	Classification	Output	Percentage
Availability (Minute)	Loading time	21,405	85.05%
	Operating time	18,205	
Performance (Pcs)	Target output	3,932,280	107.11%
	Actual output	4,211,905	
Quality (Pcs)	Actual output	4,211,905	99.55%
	Good ouput	4,192,860	

3.3 OEE Value Target Adjustment

The ideal production process is production that results in zero failures in terms of machine or equipment, zero defects and rework as well as zero industrial accidents [6]. OEE values range from 0 - 100%, where 0% is inefficient, 100% is very efficient and if the OEE value of 85% is considered a benchmark for the production capability is ideal. PT ABC pharmaceutical industry targets the OEE value for stripping machines on primary packaging process by 90%. This 90% OEE value is studied and evaluated with consideration that is adjusted to the machine conditions and targets to be achieved [11]

Initially, the net operating time (total machine operating time minus planned downtime) previously amounted to 1,045 minutes for a whole one day with an estimated line stop time of 395 minutes thereby the number of products (strips) based on the OEE value is shown in **Table 4.**

Table 4. OEE and Output of Stripping Machine Before Line Stop Adjustment

Shift	Net Operating Time (minute)	Strip/minute	OEE				
			95%	90%	85%	80%	75%
1	395	216	81,054	76,788	72,522	68,256	63,990
2	295	216	60,534	57,348	54,162	50,976	47,790
3	355	216	72,846	69,012	65,178	61,344	57,510
TOTAL STRIP			214,434	203,148	191,862	180,576	169,290

TOTAL BATCH	2.68	2.54	2.40	2.26	2.12

The results show that the OEE of the Stripping machine in February reached 90.7% with the details listed in **Figure 3**. Based on the OEE value, it can be determined the number of products produced according to the calculations made in **Table 4**. However, the OEE value of stripping machines, especially availability factors, still be able to be improved and optimized by reducing the line stop time that appears in the primary packaging process. At the time of the research, it was found that the line stops which takes a long time and can be minimized is the time for changing the polycellonium. At the beginning, the OEE calculation of the stripping machine used a matrix calculation with a polycellonium change time of 10 minutes according to **Table 4**. However, the time that need to changes the polycellonium on the stripping machine must be standardized rationally. Standard time is the time required for a trained worker to complete a certain task, work at a sustainable rate, and operate the machine and equipment properly [12].
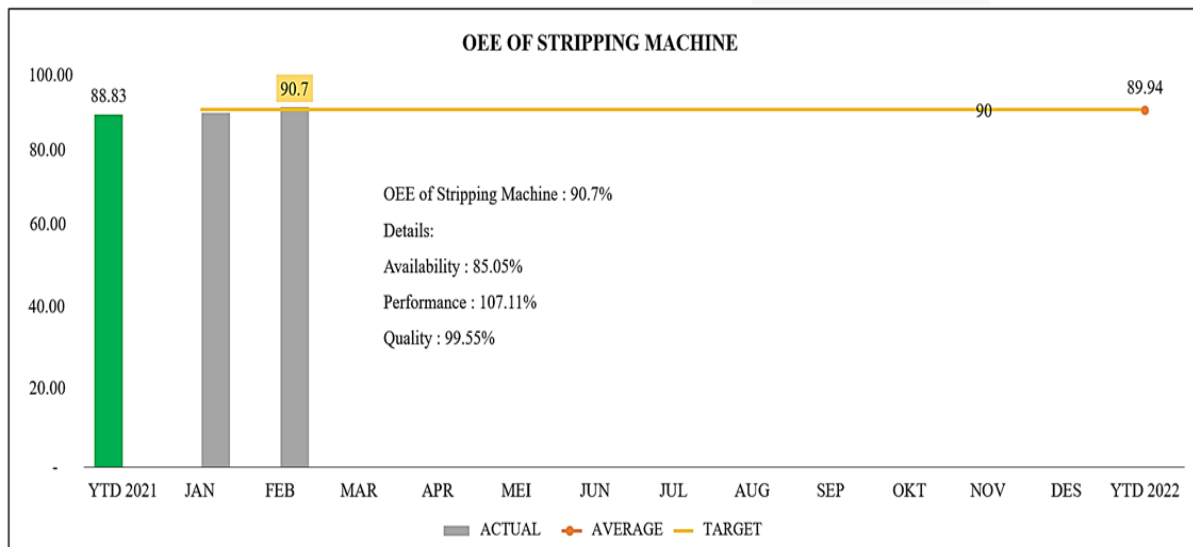

Figure 3. OEE Value of Stripping Machine

The results showed that the effective time for changing the polycellonium was 5 minutes. Therefore, the reduction in polycellonium changing time needs to be changed from 10 minutes to 5 minutes. By reducing the polycellonium change time to 5 minutes, the net operating time increases so that the number of outputs in the form of total strips and the number of batches also increases. By reducing the line stop time, the number of products produced can be determined based on the OEE value according to the new calculations made in **Table 5**.

Shift	Net Operating Time (minute)	Strip/minute	OEE				
			95%	90%	85%	80%	75%
1	425	216	87,210	82,620	78,030	73,440	68,850
2	325	216	66,690	63,180	59,670	56,160	52,650
3	385	216	79,002	74,844	70,686	66,528	62,370

TOTAL STRIP	232,902	220,644	208,386	196,128	183,870
TOTAL BATCH	2.91	2.76	2.60	2.45	2.30

Table 5. OEE and Output of Stripping Machine After Line Stop Adjustment

The line stop effect has a big impact on the OEE value and the number of products produced. Changes in line stop time in the form of changing polycellonium from 10 minutes to 5 minutes on the stripping machine increase the net operating time by 8% and this can increase the OEE value approximately by 5%. With the increasing net operating time, it is expected that the availability of stripping machines that can operate longer is present and produce more products so that can optimize stripping machine performance and OEE targets are also achieved.

4.   Conclusion

Based on the study, OEE is an effective method for optimizing the production process in the pharmaceutical industry by evaluating machine performance. The result showed that reducing the changing of polycellonium time from 10 minutes to 5 minutes as one of the line stops on the stripping machine during the primary packaging process increase the net operating time by 8% and increase the OEE value by 5%.

Acknowledgement

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