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Increasing Time Efficiency of Change over Process on Solid Product using SMED (*Single Minute Exchange of Dies*) Method in Pharmaceutical Industry

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Abstract:- Over time change over is a major problem that is often encountered in manufacturing industries. Efforts that can be made to overcome the length of change-over time, an industry will increase batch size to meet consumer demand. Fast change over time is the key to reducing large batch production and improving distribution channels. This research uses the Single Minute Exchange Of Dies (SMED) method which is a systematic method to reduce change over time so that it can reduce batch size to be more flexible to market demand and reduce the increase in storage of medicinal products that are very closely related to expiration time (expired time) which can harm consumers and the pharmaceutical industry, especially in this study. The process of monitoring changeover time in the wet granulation room is done by making a logbook that lists the time of start and end of change over which must be filled by the operator. Based on the monitoring, the change-over time in the wet granulation room in each drug preparation is different, with SMED the maximum changeover time is 120 minutes, where only product B has a faster time of 88 minutes.

Keywords:- *Changeover Time, SMED, Pharmaceutical Industry.*

I. INTRODUCTION

The problem that often arises in the manufacturing industry is that the changeover time is too long. Industry needs to reduce change-over time and production costs so as to improve performance and flexibility (Dave & Sohani, 2012). In overcoming the change-over time, an industry will increase batch size to meet consumer demand. With increasing batch size, the production process will run longer and be less flexible to the needs in the market and will increase storage capacity (inventory) (Pellegrini, Shetty & Manzione, 2012). To overcome the long change-over time, Shigeo Shingo in 1985 introduced the Single Minute Exchange Of Dies (SMED) method which was a systematic method to reduce change-over time (Pellegrini, Shetty & Manzione, 2012). SMED is one of many lean manufacturing methods to reduce waste (waste) in the manufacturing process. SMED provides a fast and efficient way of transferring a manufacturing process from a product that is running to the next product that will run. Fast change over time is the key to reducing large batch production and improving distribution channels. SMED is used as a tool / way to improve flexibility and provide the biggest advantage in reducing change-over time so that products are produced with smaller batch sizes (Dave & Sohani, 2012).

The pharmaceutical industry is one of the industries that is engaged in manufacturing which certainly requires the application of SMED to shorten change over time so that it can reduce batch size to be more flexible to market demand and reduce the increase in storage of medicinal products which are closely related to expiration time which can harm consumers and the industry itself. One of the processes used in the production of drugs is the granulation process, the granulation process requires a very long change-over time so it is necessary to apply the SMED method to the machines in the wet granulation chamber.

Granulisation is the process of mixing all raw materials into one. Before being used, the machine must be clean tag by the operator and re-verified by IPC (In Process Control). Clean tag process includes washing activities, namely washing equipment, machine spare parts, and raw material containers. But the actual operators who work are still lacking in efficiency. Therefore, companies need solutions to reduce these problems, so that the production process can be faster.

II. LITERATURE REVIEW

Scientific sources provide various publications about changeover time, some of which are used as references in this study. Changeover time is the process of changing production activities on a production line, from one product to another. The amount of time spent cleaning and replacing engine parts and arrangements for the next product. Flexibility from one product to another is guaranteed by a Changeover process that must be as efficient as possible to be able to meet customer demand and productivity targets using the Single Minute Exchange of Dies (SMED). The involvement of operators with ideas and implementation, communication, machine layout, phase of control is a key factor for successful implementation. [11] Karam, A. A., Liviu, M., Cristina, V., & Radu, H. (2018). The contribution of lean manufacturing tools to changeover time decreases in the pharmaceutical industry. A SMED project. Procedia Manufacturing, 22, 886–892.

The pharmaceutical industry with generic products produces various types of products on its production lines with the shortest possible time causing frequent changeover processes. To reduce setting time and engine cleaning activities, the SMED analysis method is used to reduce unnecessary movement of the waste. The longest flow of time in turn is in the drying room to be a factor in the Time and Movement Study to find out the details of activity settings in the drying chamber. Produce increased production line productivity by converting activities and working activities so as to reduce the time of installation and cleaning of the machine. [12] Jababeka, K., & Indonesia, B. (2018). Improving Work System by Reducing Time Activity in Drying Room in Pharmaceutical Industry with Single Minutes Exchange Die (SMED) Setup. 3 (1), 50–58.

Changeover is a complex process for plastic injection molding and is carried out every day in the production area. Every minute is lost due to engine changes that are focused on the frequency of setting and the average setting time, evaluated through (eliminating, combining, rearranging and simplifying) the high level of production output with tolerability that can be achieved. Machine costomization is an alternative to reducing the inefficiency of turnover into focus. [13] Kemal Karasu, M., Cakmakci, M., Cakiroglu, M. B., Ayva, E., & Demirel-Ortabas, N. (2014). The improvement of changeover times via Taguchi empowered SMED / case study on injection molding production. Measurement: Journal of the International Measurement Confederation, 47 (1), 741–748. According to Suhaemi (2011) theoretically. the experiment was interpreted as a planned test or investigation to get new facts

III. METHODOLOGY

A. Granulation Method

Granulation is a process of powder particles made to have a sticky power to form large particles called granules. The purpose of granulation is to protect from segregation of additives, improve the nature of the mixture, improve the characteristics of mixed compression, reduce toxic dust material, avoid hygroscopic materials to form caking, and the density properties of powder. An ideal granulation will fill all the mixture additives in each granule and the active segregation will not occur. Granulations are of two types, dry granulation and wet granulation.

Wet granulation method uses liquid in the processing and dry granulation method no liquid is used.

B. SMED (Single Minute Exchange of Dies)

SMED (Single Minute Exchange of Dies) or also called change-over or rapid change-over reduction is part of the tools in Lean Manufacturing to analyze and reduce the resources needed to set equipment, including equipment replacement (Mulyana dan Sawarni, 2007). Change-over is a series of activities that begin when stopping to produce certain products until the engine returns to operate to produce other products. The change-over process consists of cleaning, dismantling, machine installation, and machine settings. The SMED method is a form of approach to increase output and reduce quality losses due to the change-over process. The target of SMED is a change-over process that takes less than 10 minutes (1 digit number in minutes). This method was first developed by Shigeo Shingo (1909 - 1990), principal engineer and consultant in the Toyota Production System (Liker, 2004). If the change-over time is faster, the industry can meet consumer demand without having to bear high inventory costs. Through SMED the industry no longer bases its production volume on forecasting, but on customer demands, so the industry becomes more responsive in meeting consumer needs. Six Big Losses (Six Big Losses) which are heavy obstacles.

There are 4 main phases in the application of SMED:

- *Phase A*

In this phase the industry has not yet grouped external and internal activities. External activity is defined as operational setup that is carried out while the engine is operating. While internal activity is an activity carried out when the engine is off (not operating). In this phase the industry is still in idle condition because the SMED method has not been implemented. Phase A starts with observing the change-over process (recording the whole process) along with an interview with the operator.

- *Phase B*

After making observations, the industry groups activities that have been recorded into internal or external activities. Phase B is the key to success in implementing the SMED.

- *Phase C*

To be able to reduce change-over time, activities that were previously carried out when the engine stopped operating must be carried out when the engine is operating. In phase C, the industry changes internal activities into conversion. Before making this change, it must be ensured that each activity has been grouped into the appropriate group of activities.

- *Phase D*

In this phase optimization of the sequence of processes that have been obtained. This optimization consists of Elimination, Combination, Redistribution, and Simplification (ECRS analysis) processes. Elimination is related to the process of removing certain internal activities which are considered not needed during the change-over process. The next internal change-over process will not be carried out again. Combination is done by parallelizing certain activities that are expected to be done at the same time. Redistribution, some activities can be changed in order to optimize the change-over process. Simplification is done by providing new equipment, personnel or technology to streamline the process. From this series of activities that have been optimized and defined, standard SMED procedures are prepared.

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IV. RESULT

The wet granulation room was chosen for the application of the SMED method because it is one of the rooms for making a tablet that requires a long change-over time. The application of the SMED method is one way to make time efficiency so as to produce products that are more flexible to market demand. The process of applying the SMED Method (Single Minute Exchange Of Dies) has 4 stages, namely observation of the process of change-over time, separation of internal and external time, internal to external time transfer, internal and external time optimization. In the process of implementing the SMED in the wet granulation room it starts with observing the change-over time. Preliminary observations were made on fexofenadine 180 mg preparations which had passed the granulation process. Equipment that has completed the granulation process of fexofenadine preparations takes longer than other preparations in the cleaning process because the product is more sticky in the granulation machine. In this observation the change-over time needed is 164 minutes.

The following stages of the production process require change over:

Fig 1:- Production Process of Solid Preparations

Table 1 is the time to change over for A product granulation:

No	Operator 1	Time (')	Operator 2	Time (')	Cleaner 1	Time (')
1	Soak the diosna with warm water	2	Wash bowl 1 + drying	48	Release of powrex filters	9
2	washing diosna (filling and rinsing with warm water)	23	Transfer bowl 2 to washing	1	Darkening of the lift	4
3	washing the inside of the diosna	23	Bowl 2 washing and drying	34	Cleansing the walls of the wet granulation chamber 1	5
4	Powrex washing	22	Release of hopper glatt from the elevator	1	Cleansing the wall of the wet granulation chamber from standing water	8
5	Flushing diosna and stairs	5	Bring the glatt hopper to the washing	1	Cleaning of the wall of wet granulation room 2	11
6	Drying the inside of the diosna	19	Washing hopper glatt and drying	11	Packing the wet granulation floor	15
7	Powrex drying	16	Bringing frewit to washing	1		
8	Darkening of the outside of the diosna	2	Washing and drying frewit	17		
9	Drying diosna stairs	3	Bringing frewit parts to washing	1		
10	Drying the outside of the diosna	20	Washing powrex parts and drying	30		
11	Drying / cleaning of Watson Marlow	4	Cleaning the washing room sink	1		
12	Flushing diosna with purified water	1				
13	Washing barrel extensions and drying	4				
14	Powrex and diosna 20 settings					
	Total	164		146		52

Table 1:- Change Over Time Granulation A Product

The following day, an observation of the change-over time in the wet granulation room was observed after carrying out a placebo granulation process. From the observation results, the time needed for the change-over is 88 minutes. Table 2 is changeover time of B Product Granulation:

No	Operator 1	Waktu (')	Operator 2	Waktu (')	Cleaner 1	Waktu (')
1	Soak the diosna with warm water	16	Bowl 1 washing, powrex filter hanger and drying	23	Release of powrex filters	6
2	Washing the diosna inside (Hand Washing)	12	Cleaning of the washing room and floor sink	8	Plastic mounting for powrex washing	3
3	Decrease the powrex filter	1			Washing stainless steel containers	2
4	Transfer bowl 1 to washing	1			Cleaning of wet granulation floor from standing water and remaining granules	7
5	Powrex washing	10			Cleaning of the elevator glatt	2
6	Flushing the inside of the diosna after brushing	11			Cleaning the diosna ladder from puddles	1
7	Owrex drying	9			Wet granulation and servolift wall cleaning	2
8	Drying diosna stairs	2			Packing the wet granulation floor	11
9	Drying the inside of the diosna	5				
10	Drying the outside of the diosna	7				
11	Drying the stairs diosna with tissue	1				
12	Drying diosna hopper	3				
13	Fill in the PPI	10				
	Total	88		31		34

Table 2:- Changeover time B Product Granulation

Where, the time needed for the change-over process is faster than the first observation on the fexofenadine 180 mg preparation. To make the standard changeover process time in the wet granulation room, a proposal / design time for change-over is based on the SMED (Single Minute Exchange Of Dies) method. The method prepared is of course taking into account the results of previous observations of the change-over process in the wet granulation chamber with different types of preparations. In this method, the change-over time in the wet granulation chamber is not more than 120 minutes. This change-over time applies to all types of products produced. This method is prepared after discussion with operators and production supervisors.

If the result of the change-over time exceeds the target time that has been proposed in the SMED method. The failure to achieve this change-over target can be caused by several things: first, the change-over process is carried out by different operators; second, optimization of internal and external time is less than optimal. Different operators also influence the change-over time because the speed at which the cleaning process from each operator is different. To achieve the change-over target time to match the method that has been prepared, it is necessary to monitor the changeover time in the wet granulation chamber. The monitoring process is carried out by making a logbook that lists the time of start and end of change over which must be filled by the operator. By filling out this logbook, the length of time spent on the change-over process can be known,

whether it is below the target or above the target set according to the SMED method. So that the change-over process in the wet granulation room can always be evaluated until it reaches the set target and can be maintained consistently.

V. CONCLUSION

A. *Conclusion*

- Changeover time in the wet granulation chamber on each drug preparation is different.
- The change-over time target in the wet granulation chamber is less than 120 minutes so that only B products produce faster changeover time.
- Monitoring of changeover time in the wet granulation chamber is needed to achieve the target and can be maintained consistently.

B. *Recommendation*

Attached to the changeover time monitoring form as a suggestion for improvement to increase the time efficiency.

REFERENCES

[1]. Dave, Y. & Sohani, N. 2012. Single Minute Exchange of Dies : Literature Review. International *Juournal of Lean Thinking*, 3:27-37.
[2]. Liker, J.K. 2004. The Toyota Way: 14 Management Principle from the
[3]. World's Greatest Manufacturer. McGraw-Hill, New York.
[4]. Pellegrini, S., Shetty, D. & Manzione, L. 2012. Study and Implementation of Single Minute Exchange of Die (SMED) Methodology in a Setup Reduction Kaizen. *International Conference on Industrial Engineering and Operations Management Istanbul, Turkey*, July 3 – 6, 2012.
[5]. Putra, Nugraha Udiana, & Witantyo. Analisis Kerusakan WobblerBar pada Proses Pengumpanan Batu Kapur PT Semen Gresik Unit 1 Tuban. 2013.
[6]. Shingo, S. 1985. A Revolution in Manufacturing: the SMED System. Productivity Press, Cambridge, MA.
[7]. Yunarto, Nanang. 2014. Optimasi Formula Tablet Salut Enterik Natrium Diclofenak dengan Bahan Penalut Kollicoat 30D. *Jurnal Kefarmasian Indonesia*, 4, 65-74.
[8]. Wahjudi, Didik., Soejono Tjitro., Rhismawati Soeyono. (2009). Case Study Of Improving Overall Equipment Effectiveness (OEE) Throught Total Productive Maintenance (TPM) Implementation. *Nasional Mechanical Engineering Seminar IV.*
[9]. Mulyana, Ahmad & Sawarni Hasibuan. Implementasi Single Minute Exchange of Dies (SMED) untuk Optimasi Waktu Changeover Model pada Produksi Panel Telekomunikasi. Jurnal Sinergi. 2017; 21 (2). 107-114.
[10]. Suwanda. (2011). *Desain Eksperimen untuk Penelitian Ilmiah*. Bandung: Alfabeta.
[11]. Suhaemi, Z. (2011). Metode Penelitian dan Rancangan Percobaan. Diktat. Padang: Fakultas Petanian Universitas Taman Siswa.

LOGBOOK MONITORING of CHANGE OVER TIME in GRANULATION ROOM

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