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Implementation of Effective Quality Control to Improve Product Quality (Case Study Pt Metiska Pharmaceutical, Jakarta)

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Abstract:- The purpose of this research is to describe the application of quality control at PT Metiska Pharmaceutical. PT Metiska Pharmaceutical research results that the role of Quality Control in improving the quality of products to the make the finished material by knowing how much the possibility of missing raw materials Contribute 99%. That is Significantly, the role of a Quality Control Contributed 99% to provide the raw material preparation to take into account how the stocks of raw materials were missing.

This research uses quantitative method. The type of data used is the primary data. The primary data collection using a data collection form of the number of raw materials every month period and how many were produced from raw materials so that it can get the information in accordance with the company.

Keywords:- *Product Quality, Operational, Quality Control.*

I. INTRODUCTION

Quality issues have corporate tactics and strategies thoroughly in order to have competitiveness and survive against global competition with other company's products. The quality of a product can be interpreted as level or product conformity measure with predefined standards. So, good quality will be generated from that process both and in accordance with the quality standards that have been determined based market needs. The reality on the ground shows that that company successful and able to survive must have a program about quality. Because through a good quality program will be able to effectively eliminate waste and improve the company's competitiveness.

With paying attention to the quality will have an impact which is positive to the business in two ways: the impact on production costs and impact on income (Alisjahban, 2005). However, even though the production process has been well implemented, in reality there is often still a discrepancy between the resulting product and the expected. This is due to the deviations of various factors, whether derived from raw materials, labor and performance of machine facilities used in the production process. In order for the products produced to have quality in accordance with the standards set by the company and in accordance with consumer expectations, the company must perform activities that impact on the quality produced and avoid the number of defective products sold to the market. Quality control of products with layered checking system useful also oversee the level of efficiency. So, it can be used as a tool to prevent damage by refusing and accept various products produced by supplier and production process refuse or accept the product, it can also be a tool for monitoring production process.

According National Agency of Drug and Food Control Republic of Indonesia 2012, Pharmaceutical Industry is an entity that has a license from the Minister of Health to the manufacture of drugs or therapeutic agents. Medication is a material or combination of materials, including biological products, which are used to modify or explore physiological systems or pathological states for determination of diagnosis, prevention, cure, rehabilitation, improvement of health and contraception for men. Ingredients are good ingredients nutritious or not nutritious used in drug processing and quality standards as pharmaceutical raw materials

In the manufacture of drugs in the pharmaceutical industry, known by the name of Good Manufacturing Practice (CPOB). CPOB is a drug-making method that aims to ensure that the quality of the drug produced meets the requirements and purposes of use. CPOB concerning all aspects of production, from the quality management; personnel; buildings and facilities; equipment; sanitation and hygiene; production; quality control; quality assurance; self-inspection, quality audits, and audit supplier approval; the handling of complaints against products and product recalls; documentation; manufacture and analysis based on contracts; qualification and validation.

PT. Metiska Pharmaceutical was established in 1970 on the initiative of Mr. Memet Tanuwijaya, Mr. Ismail, and Mr. Karim Johan. Metiska name is an abbreviation of the names of the three founders. The factory is located on the road Metiska RS Fatmawati No. 12, Kebayoran Baru, South Jakarta. Products produced at that time only amounts to 19 kinds. In 1975 PT. Metiska Farma in cooperation with PT. Waris who is a Pharmacy Wholesaler (PBF), then in 1975 PT. Metiska cooperates with Drs. Fariaji from Borobudur Pharmacy, Jakarta. In 1980 the company was taken over by Drs. Hadi Wibowo and managed by Mr. H. Halet, in 1986 PT. Metiska Farma was taken over by Mr. Teguh Santoso until now.

In 1994 PT. Metiska Pharmaceutical receives 16 CPOB certificates, including non-antibiotic drug preparations, oral antibiotics, oral antibiotics, hard antibiotic penicillin capsules, hard cephalosporin antibiotic capsules, hard antibiotic capsules, non-antibiotic hard capsules, non-

antibiotic cream creams, oral non antibiotics, oral dry suspension of antibiotic penicillin, oral antibiotic oral dry suspension, ordinary non-antibiotic tablets, ordinary antibiotic tablets, antibiotics tablets, non-antibiotic coated tablets and ordinary antibiotic penicillin tablets. October of 2013 PT. Metiska Pharmaceutical received 4 CPOB certificates for ordinary tablet preparations and non betalactam coated tablets, nonalalactam oral fluid, non-betallic external drug fluid, and semi-solid non betalactam. In 2014 there are 4 certificates of CPOB received by PT. Metiska Pharmaceutical is a non-betalactam capsule, an ordinary antibiotic tablet of cephalosporin and its derivatives, a hard capsule of cephalosporin antibiotics and its derivatives, and oral powders of cephalosporin antibiotics and their derivatives. Based on the above, the researcher is interested in conducting research on the Effective Implementation of Quality Control to Improve Product Quality (Case Study PT Metiska Pharmaceutical Jakarta).

II. LITERATURE

A. Quality

The definition of quality has a very wide scope, relative, varied and variable, so the definition of quality has many criteria and very dependent on the context especially when viewed from the consumer's final assessment side and the definitions given by various experts as well from the point of view of the producer as the one who created the quality. Consumers and producers are different and will feel the quality differently according to the quality standards of each. Similarly, experts in providing the definition of quality will also be different from each other because they form it in different dimensions. Therefore the definition of quality can be interpreted from two perspectives, namely from the consumer and the producer side. But basically the concept of quality is often regarded as conformity, the overall characteristics or characteristics of a product expected by the consumer.

Josep Juran has an opinion that "Quality is fitness for use" which, when freely translated means quality (product) relates to the goodness of the goods used (Prawirosentono, 2007). Good quality according to the manufacturer is if the product produced by the company has been in accordance with the specifications that have been determined by the company. While the quality is bad is if the resulting product does not comply with the specified standard specifications and produce damaged products.

However the company in determining the product specifications should also pay attention to the wishes of the consumer, for without regard to the product generated by the company will not be able to compete with the company others who pay more attention to the needs of consumers. Good quality according to the consumer's point of view is if the purchased product complies with desire, menmiliki properties that suit the needs and equivalent to sacrifices incurred by consumers. When the quality of the product can not meet the wants and needs of consumers, then they will think of it as a poor quality product.

B. Quality Control

Quality control is a system of verification and custody or maintenance of a level or degree of quality of the product or process desired by means of careful planning, the use of appropriate equipment, continuous inspection and corrective action when necessary. Thus the results obtained from these quality control activities can actually meet the standards that have been planned or set.

Quality control activities will essentially constitute a whole set of activities in which seeks to achieve a state of "fitness for use" does not matter where these activities will be implemented starting at the time the products are designed, processed, until completed and distributed to consumers. By controlling the quality of the expected deviations that occur can be reduced as low as possible and the production process can be directed to the objectives to be achieved (Muhaimin, Sodikin, & Sidarto, 2013).

C. Drug's Good Manufacturing Practice (CPOB)

CPOB is a guideline in the pharmaceutical industry which involves all aspects of production and quality control and aims to assure that the drug products made to meet the quality control that have been determined in accordance with the intended use. Procedures carried out an industry by implementing all aspects of CPOB. The rapid expansion in pharmaceutical technology lead to changes very quickly as well in the conception of CPOB requirements. CPOB is dynamic concept that requires an adjustment from time to time following the technological developments in the field of pharmacy. CPOB guidelines in accordance with BPOM covers 6 aspects are :

- *Quality Management*

To achieve quality objectives in a consistent and reliable, Quality assurance system required thorough designed and implemented correctly and incorporate a good way of making drugs including Quality Control and Quality Risk Management. It let documented and its effectiveness monitored.

- *Human Resources*

The Pharmaceutical Industry should have qualified and experienced personnel in sufficient quantities. Each personnel let unencumbered excessive responsibility to avoid risks to the quality of medicines. A Pharmaceutical Industry must have an organizational structure that outlines the duties and authority of each personnel in accordance with its position

- *Training*

All personnel involved in the manufacture of drugs, should be trained about the activities in accordance with its duties as well as the principles of CPOB. Special attention is given to those who work in sterile areas and clean areas or who work with materials that have a high risk, or which cause sensitization to do on an ongoing basis with sufficient frequency to ensure that personnel are familiar with the CPOB requirements.

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- *Building and Facility*

Buildings and facilities for the manufacture of drugs be of design, construction, layout adequate, as well as customized condition and being treated well to facilitate the implementation of correct operation, cleaning and maintenance of good so that any risk of error, cross contamination and various other errors that can degrade drug quality can be avoided and controlled.

- *Production*

Let production carried out by following the procedures established and comply with CPOB to ensure the products meet the requirements of a manufacturing authorization and a marketing authorization (registration). Handling of materials and finished products, such as receipt and quarantine, sampling, storage, labeling, weighing, processing, packaging and distribution let conducted in accordance with written procedures or instructions and, if need be noted. Each stage of processing, products and materials let protected against microbial contamination or other pollution. During the processing of all materials bulk-product containers or equipment and production machines if necessary for this designation let also mentioned stages of production process. Any deviations from the instructions or procedures avoided wherever possible. If there are deviations then let no written consent of the head of the quality assurance and if necessary involve quality control section.

- *Quality Control*

Quality control is an important part of the CPOB to ensure that the product consistently has quality appropriate to its intended use. The involvement and commitment of all interested parties at all stages is a must to achieve quality objectives from the start of manufacture to the distribution of finished products. Quality control is not limited to laboratory activities, but also includes all decisions relating to the quality of the plant. Quality control should cover all laboratory analysis activities, including sampling as well as inspection and testing of starting materials, intermediate products, bulk products and finished products. These activities include stability tests, environmental monitoring programs, testing conducted in the framework of validation, handling of lagging samples, preparation and updating of material and product specifications, and testing methods.

The smoothing documentation and procedures applied by the quality control department shall ensure that the necessary tests have been carried out before the material is used in production and the product is approved prior to distribution. Quality control personnel should have access to the production area for sampling and necessary investigations. Some of the key tasks of Quality Supervision are:

- Make and revise the monitoring procedures and specifications.
- Prepare detailed written procedures for conducting all checks, tests and analyzes.
- Prepare written sampling programs and procedures.
- Ensure proper labeling of material and product containers.
- Smooth or refuse any batch of starting materials, intermediate products, bulk products or finished products.
- Conduct a continuous evaluation of the stability of all finished products and starting materials if necessary, and establish conditions for the storage of materials and products on the basis of their stability data.
- Act or assist the implementation of the validation program
- Prepare a secondary reference standard in accordance with applicable testing procedures and keep such a reference standard in proper condition.
- Keeps an analytical record of the test results of all samples taken.
- Evaluate the finished product and determine whether the product can be graduated or re-processed or must be destroyed.
- Participate in a self-inspection program together with other parts of the company

III. METHODOLOGY

In this study, the population is the result of data quality checks Xepazym type of drug which has been run from January to April 2018 at PT Metiska Pharmaceutical Jakarta. We took months of January to April 2018 as an object of observation for the year show the latest year of production and the number of defective products is relatively high. In the method of data collection is performed the sampling of data checks the quality produced in a certain period. Within one month taken five pieces of data so that total there are 16 pieces of sample data.

This study uses a simple linear regression analysis taking into account the amount of supply of raw materials used in making a tablet Xepazym. Researchers will look at how the raw materials incurred in the manufacture of drugs and how the results so produced from the drug.

IV. RESULT AND DISCUSSION

Pankreatin is a very fine powder which is the main raw material in the manufacture of tablets Xepazym. Pankreatin the granting of very fine powder, easy to fly, light, and have a scent. Shortages of raw materials that cause problems in the production are:

- In weighing pankreatin and carrier material obtained mixed results
- During the process of mixing the ingredients and then do the re-weighing the different results obtained with the time before the mixing process

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Period	Period			
	January 2018	February 2018	March 2018	April 2018
1	52.000	50.000	57.000	53.000
2	54.000	52.000	55.000	55.000
3	53.000	53.000	58.000	54.000
4	55.000	55.000	56.000	56.000

Table 1. Raw Material Used (mg)
Source : PT Metiska Pharmeutical, 2018

Period	Period			
	January 2018	February 2018	March 2018	April 2018
1	51.560	49.324	56.454	52.442
2	53.673	51.773	54.234	54.332
3	52.773	52.634	57.642	53.442
4	54.883	54.593	55.244	55.423

Table 2. Result Use of Materials (mg)
Source : PT Metiska Pharmeutical, 2018

From Table 1 and Table 2 then the next step is to figure out what percentage of the raw material is missing

Months	Period	Percentages
January	1	0,84%
	2	0,60%
	3	0,43 %
	4	0,22 %
February	1	1,35 %
	2	0,43 %
	3	0,70 %
	4	0,74 %
March	1	0,96 %
	2	1,40 %
	3	0,63 %
	4	1,35 %
April	1	1,05 %
	2	1,22 %
	3	1,03 %
	4	1,03 %

Table 3. Percentage Which Raw Materials are Missing
Source : Processed Data Results, 2018

From Table 3 it can be seen that the largest percentage of the raw materials that undergo lost due to easy to fly, light, and have a scent is in the period of 2 March 2018, amounting to 1.40%. while the percentage of raw materials terkeci who have lost as easy to fly, light, and have a scent is in the period to 4 January 2018. The more inventories of raw materials lost due to travel on the wind, it will affect the outcome so medication kind Xepazym. From the results of the inventory of raw materials provided in Table 1 and the results of the drug produced in Table 2, we made into a simple linear regression, as follows:

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	,995[a]	,991	,990	201,606

Table 4. R Square

a. Predictors: (Constant), RAW.MATERIAL
Source : Data SPSS, 2018

In table 4 it can be seen that the role of Quality Control in improving the quality of products to make the finished material by knowing how much the possibility of missing raw materials contribute 99%. That is significantly the role of a Quality Control contributed 99% to provide the raw material preparation to take into account how the stocks of raw materials were missing. The remaining 1% is influenced by variables outside the research.

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	53,194	1378,873		,039	,970
	RAW.MATERIAL	,990	,025	,995	38,988	,000

Table 5. T Test

a. Dependent Variable: USE.OF.MATERIALS
Source : Data SPSS, 2018

In table 5 it can be seen that the role of Quality Control in improving the quality of products to make the finished material by knowing how much the possibility of missing ingredients provide a positive and significant impact. With a beta value of 0.999 and a standard significance of 0.000.

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V. CONCLUSION

Based on the foregoing discussion, it can be a number of conclusions on the analysis of PT Metiska Pharmaceutical. Conclusion of Quality Control are as follows

- Prior to the production process of this company is always a check on raw materials to be used, checks on the machine so that when the production process do not occur defects or damage to the outcome and the machine to be used
- This company has always perform controls on production for the results produced in accordance with market demand
- Examination of the product so that goods produced by poor quality or defects not to be used and not to the hands of the customer and always maintain the quality of goods produced to maintain customer trust,

REFERENCES

[1] Anonim, 2009. Petunjuk Operasional Penerapan Cara Pembuatan Obat yang Baik 2006. Badan POM:Jakarta.

[2] Anonim, 2012. Cara Pembuatan Obat yang Baik, Jakarta: Departemen Kesehatan Republik Indonesia.

[3] Keputusan Menteri Kesehatan RI No. 245/MenKes/SK/X/1990 tentang Ketentuan danTata Cara Pelaksanaan Pemberian Izin Usaha Industri Farmasi.

[4] Peraturan Menteri Kesehatan Republik Indonesia No. 1799/Menkes/Per/XII/2010 Tentang Industri Farmasi.

[5] Priyambodo, Bambang. 2007. Manajemen Farmasi Industri. Global Pustaka Utama:Yogyakarta.