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Research Article

Quality Control to Reduce Defects in Amlodipine and Salbutamol Pharmaceutical Products: A Geography Case Study on Indonesia Pharmaceutical Industry

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Abstract

In the current era of globalization, where the pharmaceutical industry is required to be able to compete with the pharmaceutical industry both at home and abroad to fight for market share and be able to meet the drug needs for consumers, namely by increasing the fulfillment of the need for quality drugs. The quality of the products produced by a company is determined based on certain sizes and characteristics. Even though the production process has been carried out well, in reality, errors are still found and there are errors where the quality of the products produced does not comply with standards, or in other words, the resulting product is damaged or the product is defective. This study aims to determine the factors that cause defective products and know how to control quality so as to reduce the number of defective products in each stage of the production process. The analytical method used is descriptive analysis through Pareto diagrams, causal diagrams, and control charts u. The results showed that the production in October exceeded the control limit and several factors that caused defective products included humans, materials, machines, and methods.

Keywords

Quality Management, Quality Control, U-Chart.

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Introduction

The pharmaceutical industry is one of the elements that plays an important role in realizing national health through its activities in drug manufacturing. The high demand for drugs in the world of health requires the pharmaceutical industry to be able to produce good quality drugs. Therefore, all pharmaceutical industries must strive to be able to produce a medicinal product that can meet the required quality standards. Based on this, an industrial regulation is needed that is used to keep this industry on the right track, namely with CPOB (Good Manufacturing Practices), this CPOB involves all aspects of production and quality control which aims to ensure that the products made always meet quality requirements that have been determined in accordance with the intended use. CPOB covers all aspects of production and quality control, this is very beneficial for a company to be able to improve product quality and anticipate discrepancies in the production process so that the resulting product remains in accordance with predetermined standards and specifications.

Product quality is a comparison between customer expectations and product performance. Quality is very important in meeting customer needs. This is due to the increasing demands of consumers on quality for the products they buy. Product quality has an important role because the functions and benefits can be felt maximally if the product is of good quality. Good quality can be produced by carrying out quality control activities. Quality control that is implemented properly will have an impact on the quality of the products produced by the company. Quality standard activities include raw materials, production processes, and finished products. Therefore, quality control activities can be carried out starting from raw materials, during the production process, to finished products that have been adjusted to predetermined standards.

Quality products will provide business benefits for the company, and of course can also provide satisfaction for consumers by paying attention to product quality will have a positive impact on the business in two ways, namely the impact of production costs and the impact on income. The impact on production costs will occur in production cost savings with a focus on high quality, which will increase the performance of production resources so that it can reduce the level of production failure so there is no need for re-work. Meanwhile, the impact on increased income occurs through increased sales of quality products at competitive prices.

Table 1. Data on Amlodipine and Salbutamol Production and Defective Products (October 2015 - May 2016)

Month	Number of Production	Number of Batch	Number of Defective Products	Percentage
October	33.613	2	2.905	8,64%
November	57.876	3	1.277	2,21%
December	215.256	14	3.871	1,79%
January	100.903	6	2.048	2,03%
February	196.800	17	3.779	1,92%
May	177.265	16	3.856	2,17%
Average	130.285		2.956	3,12%

Source: Company Data

From Table 1, it can be seen that the amount of production is not the same every month, in March and April there are no production activities for Amplodipin and Salbutamol tablets. This is based on the planning and production scheduling that has been determined by the company. Based on these data, it can be seen that the average production per month during that period was 130,285 units, with an average product defect of 2,956 or about 3, 12% of the total production each month. This figure certainly exceeds the tolerance limits of the company that have been set, the limit for defective products that is produced does not exceed 3%. This can create a burden for the company, and the size of the number of defective products will affect how much the company costs for production goods that cannot be offered to consumers and shows that the quality control carried out by the company is not optimal. The resulting defective product is separated from a product that has good criteria and then the employee will re-work or rework it. The re-work activity requires additional time and costs, especially if there are a number of defective products that are outside the tolerance limits set by the company.

Literature Review

Quality

Quality is the overall features and characteristics of a product or service that can satisfy visible or disguised needs (Aggarwal et al., 2013; A et al., 2010; Chipeta et al., 2020; De, 2020; Dlalisa & Govender, 2020). Quality is everything that can meet customers (meeting needs). The definition of the quality of a product is a relative term that is highly dependent on the situation from a consumer's point of view, subjectively people say quality is something that fitness for use (Dvorak et al., 2011; Eser et al., 2020; Gulur et al., 2011; Hasibuan et al., 2018; Jabarullah, 2019; Kayaalp et al., 2020). The equation of the three experts above can be concluded again that quality is a good product or service that is expected to meet consumer needs and can provide satisfaction for consumers. The quality dimension is a measurement factor used to assess quality (KAyacilar & Karaca, 2020; Luber et al., 2020; Musazzi et al., 2020; Uslu & Ozkan, 2011), states that there are 8 (eight) dimensions of quality. These quality dimensions are:

1. Performance is the basic characteristics of a product.
2. Durability is the length of time a product lasts before it has to be replaced. The greater the frequency of consumer use of the product, the greater the durability of the product.
3. Conformance (suitability). Suitability of product performance and quality with standards, minimizing product defects.
4. Perceived Quality. Quality or quality received and felt by consumers.
5. Features. Product characteristics designed to enhance product functionality or increase consumer interest in the product.
6. Aesthetic. Product appearance that can be seen from the look, taste, smell, and shape of the product.
7. Reliability. The probability that the product will perform satisfactorily or not within a certain period of time. The less likely it is to malfunction, the reliable the product is.
8. Serviceability (Ease of repair). Ease of service or repair when needed.

Three reasons are important for quality for a company to continue to survive in a market namely

1. Company reputation. Good product quality will make the company's reputation increase and vice versa, poor quality will make the company's reputation become bad.
2. Product Reliability. Good and reliable product quality will be favored and liked by consumers so that consumers will return to buy the product.
3. Global Engagement. Products must meet global quality, design and price expectations.

Quality Control

Quality control is a technique and operational activities that are used to meet quality requirements. Quality control is quality control is an effort to maintain the quality or quality of the goods produced, so that they are in accordance with the product specifications that have been determined based on company management policies. Quality control is an activity that is oriented towards preventing damage, rather than focusing on detecting defects alone. Based on quality control proposed by experts, it can be concluded that quality control is a technique and a series of activities carried out in an effort to prevent damage and also maintain the quality of a product so that it is in accordance with predetermined standards and can meet consumer satisfaction.

There are several quality standards that can be determined by companies in an effort to maintain the output of manufactured goods including:

1. The quality standard of the raw materials used.
2. Quality standards of the production process (machines and workers who carry it out).
3. Standard quality of semi-finished goods.
4. Quality standard of finished goods.
5. Standard administration, packaging and delivery of the final product reaches the consumer.

Quality control or supervision in a manufacturing company is carried out in stages, including the following:

1. Inspection and control of the quality of raw materials (raw materials, auxiliary raw materials, etc.), the quality of raw materials in the process and the quality of finished products, as well as the standard for the amount of composition.
2. Inspection of products as a result of the manufacturing process. This applies to semi-finished goods as well as finished goods. The inspection that is carried out gives an idea of whether the production process is running as determined or not.
3. Examination of ways of packing and shipping goods to consumers. Perform fact analysis to find out any irregularities that may occur.
4. Machinery, labor and other facilities used in the production process must also be supervised according to standard requirements. If a deviation occurs, corrections must be made immediately so that the resulting product meets the planned standards.

There are several types of quality control, which can be described as follows:

Inspection

Inspection is a way of ensuring a production produces the expected quality level. The purpose of inspection is to detect bad processes as quickly as possible. Inspection does not correct deficiencies in the system or defects in a product, nor does it change a product or increase the value of the product. Inspection only finds product deficiencies and defects . Inspection can be divided into 3 (three) stages, namely:

a. Quality inspection and control before the production process

This activity is carried out on the raw materials to be used. Raw materials play an important role in producing a product with good quality.

b. Product inspection and quality control during the production process

This activity is carried out if any irregularities are found that have occurred during the production process. This is to keep the production process going well and minimize the error rate that occurs during the production process.

c. Inspection and testing of product performance

This activity is carried out to see whether the products produced have or have not met the quality standards set by the company and maintain or maintain the quality of the products produced.

Statistical Quality Control

Statistical quality control is quality control using quantitative and qualitative data. Quality Control is statistically divided into 2 (two) tools, namely:

a. Acceptances Sampling

Acceptance sampling, defined as the inspection of sample of units selected at random from a larger batch or lot and the ultimate decision about disposition of a lot, ussualy accurs at two points: incoming raw materials or components, or final production.

This type of inspection can be used by the customer to ensure that quality standards are met prior to shipment. This examination is less efficient because of the large amount of time and energy that is required to carry out the inspection.

b. Statistical Process Control

Statistical Process Control is a process used to monitor standards, measure, and take corrective action when goods or services are produced . Statistical Process Control, which is a tool to monitor the quality standards of a product. Statistical quality control using SPC (Statistical Processing Control) has 7 tools that are very useful in measuring and controlling quality, including:

1. Flow Chart
2. Pareto Diagram (Pareto Analysis)
3. Check Sheet
4. Cause-and-Effect Diagram
5. Bar Chart (Histogram)
6. Scatter Diagram
7. Control chart or control chart

CPOB (Good Manufacturing Practices)

The regulations regarding the mandatory application of CPOB for the pharmaceutical industry are based on the Decree of the Minister of Health of the Republic of Indonesia No.43 / Menkes / SK / VII / 1989 regarding the proper manufacturing methods of drugs. CPOB is a guideline that concerns all aspects of production and quality control, aims to ensure that medicinal products are made and always meet the quality requirements that have been determined according to the purpose of the user.

The latest CPOB or c-GMP (current Good Manufacturing Practice) is one of the government's efforts (Badan POM) to ensure the efficacy, safety and quality of drugs produced by the Indonesian pharmaceutical industry to comply with international standards, so that domestic medicinal products are capable of compete both the domestic market and the export market. In addition, the application of c-GMP also encourages the pharmaceutical industry to be more efficient and focus on the implementation of drug production, including the selection of production facilities that are most likely to be developed.

Research Methods

The analysis method used is qualitative analysis and quantitative analysis. The research variables used in this study are defective products from the production results. The population in this study was the total defect production of tablet drugs, namely Amlodipin and Salbutamol during October 2015 - May 2016. Sampling in this study used purposive sampling because the sampling taken was based on the specific objectives the researcher wanted to achieve. The samples used in this study were Amlodipine and Salbutamol which were found to have defects and were recorded in Production Section I.

The analysis begins by identifying problems that arise and preparing quality control tools and collecting data by making preliminary observations to companies that have problems regarding quality control, conducting a literature review of any tools that can help in increasing the quality level of the company, processing the data has been collected or that has been given by the company and analyzes the results of the calculation of the data, then concludes all the results of the calculations and provides advice to the company to maintain company standards in the future. The following are the stages in this research, namely:

Qualitative Data Analysis

Qualitative data analysis is an approach that uses existing data to analyze existing problems. The data is used as input and compared with existing theories to assist research and is presented descriptively in tables, graphs and descriptions. This qualitative data analysis can be done using flow charts or flow charts and fishbone or fishbone diagrams.

Quantitative Analysis

1. \Quantitative data analysis, an analysis that uses production data and uses numerical calculations. The measuring instrument used in research on quality control is by using the U-chart control chart. U in U-chart means defect "unit" in the sample group. U-chart calculates defect points per unit inspection report in a period that may have varied sample sizes. U-chart is used in cases where the samples taken vary or indeed the entire product produced will be tested. This means that the U-chart is used if the sample size is more than one unit or it may vary over time. In the U-chart, we need to first calculate the μ defect for every n sample, namely: $\mu\, i = \frac{xi}{ni}$. The value of μi will be plotted on the control chart,

Where: xi = number of defects in the i-th subgroup

ni = the number of inspection report units in the i-th subgroup.

There are two models for solving the U-chart and its control limits, namely using:

1. The daily / individual model: ū ± 3 = $\sqrt{\frac{\bar{u}}{ni}}$
2. The average model: ū ± 3 = $\sqrt{\frac{\bar{u}}{\acute{n}}}$

Results And Discussion

Results

Every company in carrying out its production activities always tries to produce a product in accordance with the specifications set by the company. The types of damage and factors causing disability / failure in the production of non-coated tablets in production section I are as follows:

Incorrect product mass / weight

Variation in mass or product weight is a type of product failure that can be determined based on the weight of the drug and the diameter of the drug, which can be seen whether the drug chips are perfect or not after going through the printing process.

Human Factor

- In the initial weighing and mixing process, the amount of the drug mixture is not suitable so that it can cause an excess or insufficient amount of dough in the drug.
- The workforce is less skilled and meticulous, which causes the rejection of the drug in the supervision of the print results and when setting up the machine is less skilled and precise, because each drug product is different, both in size and shape where the machine must be set up in order to produce the appropriate product.

Method Factors

Standardization of diameter for different types of drugs will be an inhibiting factor and make it difficult for workers to know the type and size of the diameter, size and mass of the chips of each type of drug.

Raw Material Factor

The results of the extract or mixing do not meet the predetermined specifications, where the raw material has been contaminated or there are certain contents that are not or have not been obtained from the mixing process so that the dough will not combine completely.

Engine Factor

Lack of preventive maintenance of production machines, so that there are some parts of the machine that are worn down which causes the printing on the drug to slow down and the dough to stick and to add weight to the next dough.

There Was A Spot On The Tablet

The occurrence of spots on the tablet is a type of defect that can be seen on the tablet, such as stains from engine oil during the printing process.

Machine

Machines or tools used during this process can be a factor causing failure, because the machine used is not maintained and the cleaning of the printer used is irregular, causing oil to hit the tablets and problems when the machine is used.

Human

Labor in this process is a factor that causes the product to experience defects because the

workforce is less skilled at caring for and using a printing machine so that oil comes out on the machine and sticks so that the tablet medicine becomes spot and dirty.

Incomplete Tablet On The Strip (Pecong)

Type of pecong failure or the absence of 1 or more tablets on the strip. This obstruction occurs during the primary packaging process, namely tablet stripping.

Human

Labor in the process is one of the factors causing failure due to operators who are not careful and focused on work, and for operators who are not careful before they forget to do an initial check on the machine to be used.

Material

The presence of a fragile tablet material or the mass and thickness that is not suitable makes it crushed or broken during the stripping process, the broken drug will inhibit it and remain in the machine so that the pecong drug strips or there are no tablets in the package.

Method

There was a procedural error in operating the machine during the stripping process due to the incorrect setting of the stripping machine resulting in congestion on the machine being used.

Machine

The machine used in this process is hampered by the tablet material so that it gets stuck during the tablet stripping process, so that there are or more empty tablets in the strip.

Packaging Strip Leaks

Type of failure or leaky strip packaging defects, where the cause is due to the material itself such as PVC that is too thin or perforated alufoil due to human factors, machines, methods and human factors. This obstruction occurs during the primary packaging process, namely tablet stripping.

Human

Workers or operators in the process are one of the factors causing failure due to a lack of understanding of defects and sometimes operators will continue to insist on carrying out processes to pursue their production targets and lack of monitoring during the production process.

Machine

The machine used causes a leak in the packaging caused by the mold or freeder temperature setting that is not suitable which causes the desired temperature not to be reached and the heater wattage is insufficient as well as an error control theme.

Material

Because the examination of the foil material samples used for packaging is not 100% perfect, the raw materials used are difficult to control the quality as a whole, the examination of the strip packaging material, especially the foil is only carried out at the beginning of the foil roll, if at the beginning the roll passes the test then one roll passes the test . In addition there is a small hole in the alufoil. In PVC material there are also irregularities if the material is too thin and often causes leaks.

Method

There are procedural errors and machine operation during the process, which is caused by operators or workers who do not understand the working procedures of the products being packaged, for example, feeder setups that are too fast and continuous use of feeders, causing engine temperatures to change.
The defect production data in Table 1 is analyzed using the u-chart to determine whether or not the data is out of control limits that have been determined.

Table 2. Calculation of Amlodipine Drug Control Limit

Month	Number of Production	Number of Defective Products	U $u = \frac{c}{n}$	$\bar{u}$ $\bar{u} = \frac{\Sigma c}{\Sigma n}$	UCL $UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	LCL $UCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$
October	9.760	1.053	**0,108**	0,022	0,036	0,008
November	9.842	387	0,040	0,022	0,045	0
December	121.056	1.982	0,016	0,022	0,032	0,012
January	71.548	1.315	0,018	0,022	0,034	0,009
February	196.806	3.779	0,019	0,022	0,029	0,015
May	158.310	3.706	0,023	0,022	0,029	0,015
Total	567.322	12.222				

Source: Data Processing (2021)

Table 3. Calculation of Salbutamol Drug Control Limit

Month	Number of Production	Number of Defective Products	U $u = \frac{c}{n}$	$\bar{u}$ $\bar{u} = \frac{\Sigma c}{\Sigma n}$	UCL $UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	LCL $UCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$
October	23.853	1.852	**0,078**	0,024	0,035	0,013
November	48.034	570	0,012	0,024	0,043	0,004
December	94.200	1.889	0,020	0,024	0,035	0,013
January	29.355	733	0,025	0,024	0,041	0,006
February	-	-	-	-	-	-
May	18.955	150	0,008	0,024	0,062	0
Total	214.397	5.194				

Source: Data Processing (2021)

From Table 2 and Table 3 above, it can be seen that in October the defective products of the Amlodipine and Salbutamol drugs exceeded the limits of reasonableness and tolerance of the existing defective products. These deviations indicate that the quality control carried out by the company still needs to make improvements. Therefore, it is necessary to create new control limits for the product or data under study in order to obtain a uniform data. This can be done by eliminating or removing data that has defective values beyond control limits. To calculate the new control limit, it is necessary to recalculate after the data that is outside the limit is removed.

Table 4. Production Data of Amlodipine and Salbutamol Drugs After Adjustment

Month	Amlodipin		Salbutamol	
	Production	Defective Products	Production	Defective Products
November	9.842	387	48.034	570
December	121.056	1.982	94.200	1.889
January	71.548	1.315	29.355	733
February	196.806	3.779	-	-
May	158.310	3.706	18.955	150
Total	557.562	9.169	190.544	3.342

Source: Company Data

Table 5. Calculation of Amlodipine Drug Control Limit After Adjustment

Month	Number of Production	Number of Defective Products	U $u = \frac{c}{n}$	$\bar{u}$ $\bar{u} = \frac{\Sigma c}{\Sigma n}$	UCL $UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	LCL $UCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$
November	9.842	387	0,040	0,016	0,035	0
December	121.056	1.982	0,016	0,016	0,025	0,007
January	71.548	1.315	0,018	0,016	0,026	0,005
February	196.806	3.779	0,019	0,016	0,022	0,009
May	158.310	3.706	0,023	0,016	0,022	0,009
Total	557.562	9.169				

Source: Data Processing (2021)

Table 6. Calculation of Salbutamol Drug Control Limit After Adjustment

Month	Number of Production	Number of Defective Products	U $u = \frac{c}{n}$	$\bar{u}$ $\bar{u} = \frac{\Sigma c}{\Sigma n}$	UCL $UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	LCL $UCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$
November	48.034	570	0,012	0,018	0,034	0,001
December	94.200	1.889	0,020	0,018	0,027	0,008
January	29.355	733	0,025	0,018	0,033	0,003
May	18.955	150	0,008	0,018	0,051	0
Total	190.544	3.342				

Source: Data Processing (2021)

Discussion

The following is the classification of the factors that must be considered and those which influence and cause product damage.

Man (Human)

Humans are workers who are directly involved in the production process. Labor is an important element in a company, especially in production activities. Even though currently the company has used advanced technologies, the company still needs manpower to operate it. Thus, production activities in a company cannot be separated from the role and interference of

workers. The workers in the production section I consist of men and women with different ages and levels of education. In addition, work experience also affects work performance and performance. So this has a relationship with the quality of the product produced.

Material (Raw Material)

Is something that is used by the company as components in the manufacture of products to be produced. The raw materials used in the production process greatly affect the quality of the products produced and the smoothness of production. The company itself produces the main raw material for making medicine, namely the raw material for drugs that produce quinine sulfate and quinine HCl. In addition, the company is currently producing a very important raw material in the pharmaceutical world, namely pharmaceutical salt, where most of the pharmaceutical industry in Indonesia is still importing raw materials for this pharmaceutical salt.

Machine

The machines and equipment used in the production process are supporting factors in modern production activities. As a company that has a high amount of production, it will be greatly helped by the technology of the machine because it can produce products quickly. However, machines can also be the cause of product defects. The following machines or production equipment are used:

a. Fluid Bed
b. Dryer
c. Super Mixer
d. Diosna granulator
e. Ultra Turax,
f. laboratory tools such as HPLC, Spectrophotometer and Polarimeter.

Method

The work method is a series of work methods that are arranged in such a way with various considerations and are deemed most suitable for carrying out production activities and have a major effect on the smooth running of the production process. the functioning of the work methods applied in the company to regulate all the parts involved in the production process. Thus, if this work method is not implemented properly, there will likely be irregularities that cause defective products.
Based on the results of the analysis carried out, it is necessary to make efforts to improve the four factors that are thought to cause failure / defect in the production process of Amlopdipin and Salbutamol tablets. The following are efforts made to reduce the failure rate:

Human

The company conducts training and development for employees regarding product defects so that they can work according to the SOP and to minimize work errors, and motivate workers to carry out their work better by not making mistakes again.

Machines

Periodic checks are carried out on machines and replacement spare parts for machine parts where problems often occur must be available. Perform regular checks to monitor the state of the machine which is still stable and the need for preventive maintenance and autonomous maintenance so as to increase machine productivity.

Material

- Carry out CPB procedures that have been established by the company.
- create written guidelines for the extraction steps and provide oral guidelines to employees / operators working on the extraction process.
- More stringent checks in the QC department for inspection of all raw materials with good quality standards or materials and checking for good and thick foil and PVC materials.

Method

Work must be in accordance with the work method that has been determined even though the target is being pursued so that it needs supervision by the superior in order to carry out work according to the SOP, provide training and development to the workforce.

Conclusion and Suggestion

Conclusion

Based on the results of the analysis of the research that has been carried out, it can be concluded that:

1. The company has set quality standards and has carried out product quality control in the production process to controlling the finished product with the quality standards set by the company. The implementation of quality control in the company is considered to be good as the company implements aspects of CPOB (Good Manufacturing Practices) in all aspects of its company activities including its production. In controlling the production process, the company supervises each processing and production process, which includes checking the correctness of raw materials and the quantity according to the CPB (Batch Processing Note), physical inspection of granules, moisture content, average weight, unit weight, material content. active, hardness, friability of disintegration and dissolution. The company controls its quality in every processing and production process to prevent the production of drugs that do not meet specifications and to monitor which production processes are experiencing problems. To control the finished product, the company conducts an inspection by identifying the finished product according to the specifications of each drug. If the results meet the specifications, they will be released to follow the next process / distributed to consumers, but if they do not pass the test, the error will be investigated to determine the corrective steps.
2. The production process for non-coated tablet drugs in the Production I section of the company starts from the central weighing of the raw materials; the weighed materials will be placed in the staging area. Furthermore, the implementation of the granulation process or the manufacture of wet granules to drying the granules, the tablet molding process, then the primary packaging process, namely stripping and the secondary packaging process as well as the final inspection. To solve problems or constraints that occur during the production process, the company places a supervisor in each production process.
3. Based on the results of the analysis using the Fishbone Diagram, it can be seen that several factors that cause damage in the production process come from human error (human error), machines, methods and materials. as for the types of disabilities are as follows:

- Incorrect product mass / weight
- A spot occurs on the tablet
- Incomplete tablet on the strip / pecong
- Leaking strip packaging
- Furthermore, the use of statistical tools with the control chart u in controlling the quality of non-coated tablet products in the Production I section, namely the Amlodipine and Salbutamol drugs in the October 2015 - May 2016 period identified that the process was controlled by conducting a data uniformity test, it could be seen that all samples were within the limit. which has been determined. Previously, there were still samples that were out of control (outliners), it was

seen that there were points that exceeded the specified limits, namely in October in both types of products.

4. Actions taken by the company in an effort to reduce the level of defect / default product caused by several factors can be done in the following ways:

Human

- The company conducts training and development for employees regarding product defects so that they can work according to the SOP and to minimize work errors.
- Motivate workers to do their job better by not making mistakes again.

Machine

- Periodic checks are carried out on machines and replacement spare parts for machine parts where problems often occur must be available.
- Perform periodic checks to monitor the state of the machine which is still stable and the need for preventive maintenance and autonomous maintenance so as to increase machine productivity so as not to hamper the production process.

Material

- Carry out the CPB (Batch Processing Notes) procedure that has been determined by the company.
- Create written guidelines for the extraction steps and provide oral guidelines to employees / operators working on the extraction process.
- More stringent checks in the QC department for inspection of all raw materials with good quality standards or materials and checking for good and thick foil and PVC materials.

Method

Work must be in accordance with the work method that has been determined even though the target is being pursued so that it needs supervision by the superior in order to carry out work according to the SOP, provide training and development to the workforce.

Suggestion

Some suggestions that can be put forward to overcome the level of defect / product failure are as follows:

a. The Statistical Process Control (SPC) method can be an additional method that companies use in order to find out the types of defects that often occur and what factors cause these disabilities to occur. Thus, it can assist companies in taking preventive measures to reduce the occurrence of defective products.

b. Based on the research results, quality control in the company must be further improved, because an increase in quality control will affect the quality of the products produced. By focusing on factors that cause defects such as machine, human error, material and method factors. Because these factors are the main cause of product defects.

c. Tighten supervision during the production process so that employees can carry out work procedures in accordance with the SOPs that have been determined by the company.

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