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PROPOSED PRODUCTION IMPROVEMENT BY MINIMIZING THE NUMBER OF REJECT PACKAGING OF DRUG TABLETS DUE TO DEFECTS IN PACKING (CARTONING) MACHINE USING THE SIX SIGMA METHOD APPROACH AT PT. XYZ

Fathin Nur Aeni
Program Studi Teknik Industri ITI,
Jl. Raya Puspiptek Serpong, Tangerang Selatan-Banten, Indonesia, 15320
Email : fathinnura@gmail.com , madesudri32@gmail.com

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BSTRACT

PT. XYZ engaged in the pharmaceutical industry. In the secondary packaging section, several products have used packing (cartoning) machines, but there are still many rejected packaging produced during the packing production process. The number of rejects that exceeds the company's standards will certainly suffer losses due to damaged packaging and cannot be sold to consumers. This research focuses on process improvement through analysis of quality control of the packing process using packing machines (cartoning) to reduce the number of rejected containers so as to reduce company losses with the Six Sigma method approach with the stages of Define, Measure, Analyze, Improve. (DMAI). The recommended solution is to create a training agenda and evaluate training for all production operators. After the solution was implemented there was a decrease in the average DPMO to 10,909.0909 and an increase in the sigma value to 3.794 sigma and a decrease in loss costs of Rp. 42,333, - (73.91%) for every 1 batch of packing process. With the results of data processing, it will result in improvements to the production process in order to improve product quality and provide an advantage for the company.

Keywords: ***Six Sigma, Reject,*** **Mesin** ***Packing (Cartoning),*** **DMAIC**

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Universitas Muslim Indonesia
Address :
Jl. Urip Sumoharjo Km. 5 (Kampus II UMI)
Makassar Sulawesi Selatan.
Email :
Jiem@umi.ac.id
Phone :
+6281341717729
+6281247526640

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1. INTRODUCTION

The challenge of very tight global competition can eliminate entrepreneurs and business people who are not ready to face competition. This competition makes consumers accustomed to choosing different services in the form of products and services. And the last people who can stay in business and win competitiveness and competition are those who always try to continuously improve customer satisfaction (Syukron & Kholil, 2013).

PT. XYZ is a company engaged in the pharmaceutical industry, especially generic drugs. This company produces and markets drugs with ethichal (doctor's prescription) and OTC (Over The Counter) types of drugs.

Packaging of tablet drugs at PT. XYZ has been using packing (cartoning) machines since 2015. The process of using packing (cartoning) machines is not optimal, causing defective products which result in product rejection. Therefore it is necessary to make efforts to improve quality to reduce product rejects to the lowest level. Thus, it is expected that the company can increase profits and defend itself amidst industrial competition.

One of the products that is well known and has a fairly high demand in the market, one of which is the drug Samconal Caplet 500 mg. Samconal is a drug that contains paracetamol as its active ingredient, used to treat mild to moderate pain such as fever, headaches and toothaches.

In the packaging production process, Samconal Caplet 500 mg has a high number of rejects. Based on observations, interviews with production operators and from production data from January to. In March 2022, there was 4.18% packaging reject with the company's target of 3% for reject packaging from the total of each production process. The not yet optimal packing production process causes defective products which result in rejected packaged products that cannot be sold.

2. LITERATURE REVIEW

According to Gasperz (1997) quality is the totality of the features and characteristics possessed by products that are able to satisfy consumer needs. Quality is an important thing in a company. There are seven reasons for the need for quality for a company put forward by Russell and Taylor in Ariani (2008), namely:

1. Company Reputation
2. Cost Reduction
3. Increase in Market Share
4. Product and Service Accountability
5. International Impact
6. Appearance of Products and Services
7. Recommended Quality

3. METHOD

Three main areas that are targeted in six sigma are increasing customer satisfaction, reducing cycle times, reducing defects. Six sigma is a method of solving problems from high costs due to product defects caused by low product and process quality. Six sigma can become a management philosophy that aims to achieve a better quality through continuous quality improvement. The stages of quality control with six sigma are: 1. Define 2. Measure 3. Analyze 4. Improve 5. Control .

The successful implementation of six sigma in research has been proven by increasing the capacity of the manufacturing process to a zero failure rate. Failure Mode and Effect Analysis (FMEA) is a systematic technique for analyzing errors. This technique was first developed in 1950 by reliability engineers who were studying the problems caused by malfunctioning military equipment (Syukron & Kholil, 2013). Dam main purpose of implementing FMEA is to find and solve the main problems that arise at the design stage and the production process.

The value of the Risk Priority Number (RPN) is an indicator used to assess risk. Risk Priority Number (RPN), risk assessment is carried out to help identify damage that is quite severe related to the process. And the stages of data processing carried out are implementing the DMAI cycle (Define, Measure, Analyze, Improve).

GMP (Good Drug Manufacturing Practice) is part of the manufacturing cycle that is carried out on products to produce finished drugs. With the requirements for packaging materials, namely: 1. Can protect the product. 2. No interaction between drugs and packaging. 3. Safe, not easy for children to open. 4. Interesting, especially for over-the-counter drugs, but must comply with the provisions of the BPOM marking. Pharmaceutical packaging materials can be divided into three, namely primary, secondary and tertiary packaging materials.

The data used at this stage is packaging production data in January – March 2022 and data on the number of packing and types of defect.

(Table 1. Data on the number of packages and types of rejects for January - March 2022).

No.	Amount *Packing*	Defect Type			Amount *Defect*	Percentage (%)
		Torn Carton	Untidy Carton	Closing Carton Open		
1	1100	15	16	12	43	3,92%
2	1100	17	19	14	50	4,55%
3	1100	14	18	23	55	5%
4	1100	12	21	22	55	5%
5	1100	18	16	11	45	4,09%
6	1100	22	12	13	47	4,27%
7	1100	14	17	10	41	3,73%
8	1100	16	12	17	45	4,09%
9	1100	12	19	13	44	4%
10	1100	10	15	15	40	3,64%
11	1100	15	18	19	52	4,73%
12	1100	11	13	11	35	3,18%
Total	13200	176	196	180	552	4,18%

In the product Samconal Caplet 500 mg which is the object of research at PT. XYZ there are still variations in defects. There are three types of defects in the Samconal Caplet 500mg product packaging, namely untidy carton, torn carton, and open closing box. The company has a target of 3% reject packaging from the total of each packing process, but from the results obtained there are still some that exceed 3%.

3.1. Identification Critical to Quality (CTQ)

Critical to Quality (CTQ) is defined as the main attribute that directly influences the achievement of quality. Based on the results of a field study with the head of the packing department (secondary solids) as well as interviews and discussions with the company, it was found that the Critical to Quality (CTQ) of the 500mg packaging of the Samconal Caplet product.

(Table 2. Critical To Quality (CTQ) Product Packaging Samconal Caplets 500mg)

No.	CTQ	Defect Type	Spesification
1	The closing dus is perfectly closed	Closing carton is open	Well closed
			There are no dents
2	Carton closed neatly	Untidy	Boxes can be formed according to the design
3	Carton not torn	Torn	Not exist torn

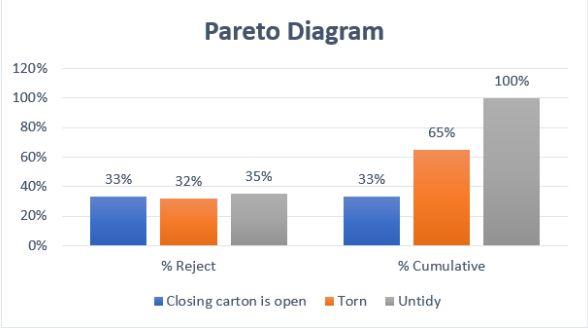
From the CTQ above, it can be concluded that the reject on the 500 mg Samconal Caplet box packaging was caused by factors that caused problems with the packaging resulting in a discrepancy in the CTQ set by the company.

3.2. Identify Reject Types with Pareto Charts

Pareto diagrams are used to find out and determine the most influential types of rejects to be discussed further. The following is the result of calculating the Pareto chart.

(Table 3. Calculation of Reject Percentage with Pareto Chart)

No	Type of Reject Packaging	Number of Rejects	% Reject	%Cumulative
1	Closing carton is open	180	33%	33%
2	Torn	176	32%	65%
3	Untidy	196	35%	100%
Amount		552	100%	



(Figure 1. Packaged Reject Pareto Diagram)

In Pareto diagram above, it can be seen that the cumulative percentage is caused by three types of rejects, namely closing open boxes, torn boxes, and untidy boxes. Untidy reject boxes as many as 196 with a percentage of 35% is the dominant cause.

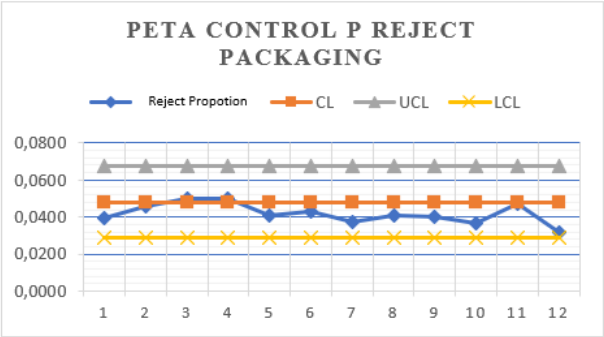
3.3. Statistical Process Quality Control with Control Chart P

The p map is used because the package reject data is a type of attribute data and the amount of packing each month is different.

(Table 4. Calculation Results of P Reject Control Map)

Subgroup	Size of Subgroups	Number of *Reject*	*Reject* Propotion	CL	UCL	LCL
1	1100	43	0,0391	0,0481	0,0675	0,0287
2	1100	50	0,0455	0,0481	0,0675	0,0287
3	1100	55	0,05	0,0481	0,0675	0,0287
4	1100	55	0,05	0,0481	0,0675	0,0287
5	1100	45	0,0409	0,0481	0,0675	0,0287
6	1100	47	0,0427	0,0481	0,0675	0,0287
7	1100	41	0,0373	0,0481	0,0675	0,0287
8	1100	45	0,0409	0,0481	0,0675	0,0287
9	1100	44	0,04	0,0481	0,0675	0,0287
10	1100	40	0,0364	0,0481	0,0675	0,0287
11	1100	52	0,0473	0,0481	0,0675	0,0287
12	1100	35	0,0318	0,0481	0,0675	0,0287
Total	13200	552				

Control chart p can be obtained from the calculation of proportions, center line, upper control limits and lower control limits. The following is a graph of the p control chart for the type of untidy packaging reject:



(Figure 2. P Reject Control Map Packed)

From these data it is known that the packing process using a cartoning machine looks stable, but it still needs to be improved because there are still rejects during the packing proces.

3.4. Performance Level Measurement

Performance level can be calculated or measured by determining DPMO (Defect per Million Opportunity) and sigma level. The following is the DPMO calculation and the sigma level for the company.

1. DPMO calculation

$$DPMO = \frac{\text{Many reject packages}}{\text{Number of packages packed}} \times 1.000.000$$

$$DPMO = \frac{552}{13200} \times 1.000.000 = 41818{,}1818$$

2. Calculating the sigma level based on six sigma using Microsoft Excel.

$$Level\ sigma = \text{normsinv}\left[\frac{1.000.000 - DPMO}{1.000.000}\right] + 1{,}5$$

$$Level\ sigma = \text{normsinv}\left[\frac{1.000.000 - 41818{,}1818}{1.000.000}\right] + 1{,}5$$

$$Level\ sigma = 3{,}230$$

(Table 5. DPMO Value and Sigma Level)

Amount Packages (Pcs)	Amount *Reject* (Pcs)	DPMO	*Level Sigma*
13200	552	41818,1818	3,230

From the results of calculating the DPMO value and sigma level in the packing process, the DPMO value is 41,818.1818, which means that out of one million opportunities there are 41,818.1818 times the possibility of the packing process using a cartoning machine which produces rejected products.

3.5. Process Capability

The process capability calculation serves to measure the current capability of each process in producing products according to specifications. The following is an example of calculating the capability of processing attribute data on the type of untidy packaging reject.

$$CP = \frac{level\ sigma}{3}$$

$$CP = \frac{3{,}230}{3}$$

$$CP = 1{,}066$$

(Table 6. Reject Packaging Process Capability Value)

Amount Packages (Pcs)	Amount *Reject* (Pcs)	DPMO	*Level Sigma*	Process Capability
13200	552	41818,1818	3,230	1,076

In calculating the process capability that the company is in the value range of 1.076 where the process is considered capable enough.

4. ANALYSIS

The analysis was carried out using an approach that is suitable for the purpose. The approach taken in an effort to achieve this goal is six sigma using the DMAIC (Define, Measure, Analyze, Improve, Control) phase.

4.1. Improvement Recommendation

Simulation of the zero value of data removal for the untidy packaging reject type can be seen in the following table.

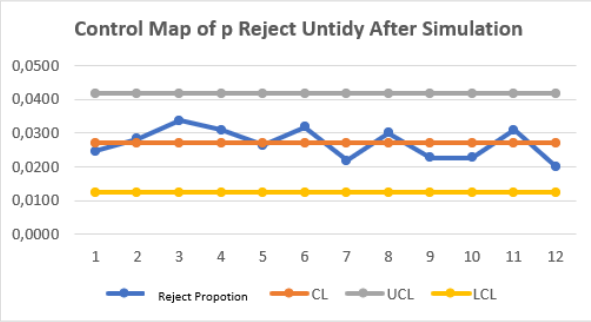
(Table 7. Data on the Number of Untidy Pack Rejects with Zero Value Simulation)

No.	Ammount Packages	Defect Type			Ammount *Defect*	Percentage (%)
		Torn Carton	Untidy Carton	Closing Carton Open		
1	1100	15	0	12	27	2,45%
2	1100	17	0	14	31	2,81%
3	1100	14	0	23	37	3,36%
4	1100	12	0	22	34	3,09%
5	1100	18	0	11	29	2,63%
6	1100	22	0	13	35	3,18%
7	1100	14	0	10	24	2,18%
8	1100	16	0	17	33	3%
9	1100	12	0	13	25	2,27%
10	1100	10	0	15	25	2,27%
11	1100	15	0	19	34	3,09%
12	1100	11	0	11	22	2%
Total	13200	176	0	180	356	2,70%

The following is the calculation of the control map p from the data of the type of untidy packaging that is removed, which can be seen in the following table.

(Table 8. Results of Control Map Calculations on Untidy Pack Reject Data After Simulation of Zero Value on Untidy Pack Reject)

Sub Gruop	Size of SubGroup	Ammount Reject	Reject Propotion	CL	UCL	LCL
1	1100	27	0,0245	0,0270	0,0417	0,0123
2	1100	31	0,0282	0,0270	0,0417	0,0123
3	1100	37	0,0336	0,0270	0,0417	0,0123
4	1100	34	0,0309	0,0270	0,0417	0,0123
5	1100	29	0,0264	0,0270	0,0417	0,0123
6	1100	35	0,0318	0,0270	0,0417	0,0123
7	1100	24	0,0218	0,0270	0,0417	0,0123
8	1100	33	0,0300	0,0270	0,0417	0,0123
9	1100	25	0,0227	0,0270	0,0417	0,0123
10	1100	25	0,0227	0,0270	0,0417	0,0123
11	1100	34	0,0309	0,0270	0,0417	0,0123
12	1100	22	0,0200	0,0270	0,0417	0,0123
Total	13200	356				



(Figure 3. Untidy Pack P Reject Control Map After Simulation)

The graph of the control chart p on the type of untidy reject after the simulation can be obtained from the calculation of the proportion, center line, upper control li mit and lower control limit.

(Table 9. Calculation of the DPMO Value, Sigma Level and Process Capability After the Untidy Packaging Reject Data Simulation Is Removed)

Amount Packages (Pcs)	Amount Reject (Pcs)	DPMO	*Level Sigma*	Proses Capability
13200	356	26969,6970	3,427	1,142

From the results of the calculation of the DPMO value and the sigma level of packaging after simulating a zero value on the data on the type of reject untidy packaging, the DPMO value is 41,818.1818, which means that out of one million existing pins, there are 26,969.6070 times the possibility of the packing process using a packing machine (cartoning) which produces reject products.

To reduce the number of rejected containers, it is necessary to improve by honing the skills possessed by each operator, one of which is to make changes to the model training activities that have been carried out, which aims to enable operators to understand and understand how to set up or operate a cartoning machine. correctly and precisely.

The company, to be precise the secondary Solid department, has implemented training activities to address the lack of operator skills, but the training is less effective. Where the model of training activities carried out is only limited to providing insight into machine material, and during the implementation of training activities there has been no direct evaluation of operators from the results of the training carried out. Where the implementation of training is carried out outside the working hours of the operators, and is carried out one month per shift.

5. Analysis and Results

This study has implemented the use of the six sigma method as an effort to reduce the number of rejects that occur, or towards zero defects. In the analysis of the number of rejected products using the Pareto diagram, the cumulative percentage of rejected types was obtained using the Pareto diagram, the cumulative percentage of rejected types in the box packaging was ± 80% caused by three types of rejects, namely untidy boxes, torn boxes, and closing open boxes. Untidy reject boxes as many as 196 with a percentage of 35% are the dominant causes so that in this study the focus was on these rejects..

5.1. Improvement Implementation

Improvement recommendations implemented at PT. XYZ on July 4 2022. The packaging material used for the implementation of repairs is a plain dummy with the same size from the supplier as the existing.

From the identification of the participants' needs, there are 7 skills needed to be learned by the participants in this training evaluation training, namely:

1. Setting Conveyor
2. Setting Stopper Carton
3. Setting Carton Press
4. Setting Filler Mesin
5. Setting Closing Dus
6. Laying the packaging in Stopper Carton
7. Operation of the machine when there is a problem

5.2. Analysis of Statistical Conditions Before and After Repair

The data used is direct observation in July 2022 for 1 week after implementation.

Data on the number of packing and types of reject after the implementation of improvements can be seen in the table below:

(Table 10. Data on the number of packing and types of reject after repair)

No.	Packages Amount	Reject Type			Reject Amount	Percentage (%)
		Untidy	Torn	Closing Carton Open		
1	1100	2	5	3	10	0,91%
2	1100	3	8	2	13	1,18%
3	1100	2	8	2	12	1,09%
4	1100	3	10	1	14	1,27%
5	1100	4	7	0	9	0,82%
Amount	5500	14	38	8	60	1,09%

And the calculation of the DPMO value and sigma level after repair is obtained as follows:

(Table 11. Calculation of DPMO Values and Sigma Levels After Repair)

Packages Amount (Pcs)	Reject Amount (Pcs)	DPMO	*Level Sigma*
5500	60	10.909,0909	3,794

Comparison of DPMO values and Sigma Levels before and after implementation of improvements:

(Table 12. Comparison of DPMO and Sigma Values Before and After the Improvement Implementation)

Before Implementation		After Implementation	
DPMO Average	Sigma Value	DPMO Average	Sigma Value
41.818,1818	3,230	10.909,0909	3,794

It can be seen from the results of the average DPMO value and sigma value before and after the implementation of improvements. Prior to implementation, the average DPMO value was 41,818.1818 after the implementation was 10,909.0909. That way the average value of DPMO has decreased by 73.91%.

The sigma value before implementation was at 3.230 sigma, while after implementation it was 3.794 sigma, with an increase of 14.85%. Comparison of the resulting losses before and after repairs.

Comparison of conditions before and after the implementation of improvements also affects the reduced cost of reject containers. The following is a comparison of the losses generated before and after the repair:

(Table 13. Comparison of Loss Cost Before and After Repair)

Loss cost Per-batch	
Before Repair	Rp. 71.070
After Repair	Rp. 28.737
Difference before and after repair	Rp. 42. 333

In the comparison table above it can be seen that the cost of losses has decreased from before the implementation of the repair of Rp. 71,070 while after the implementation of repairs Rp. 28,737. reduction in loss costs per one batch of Rp. 42,333 (73.91%). The average total packing per month for Samconal Caplet 500 mg is 30 batches, so if you calculate it per month, the reduction in loss costs is Rp. 1,269,990, - and of course greatly affects the profits generated by PT. XYZ.

CONCLUSION

Based on the results of processing and analysis of data that has been done, the conclusion is obtained:

The cause of product rejection in the packaging process for the Samconal Caplet 500 mg product was due to defects in the untidy box, torn box and open closing of the box that occurred during the packing process. And of the three defects, the one that has the most influence on product rejection is the untidy box with a percentage of 35%.

In the causal diagram it is known that the type of reject can be influenced by four factors, namely humans, machines, materials and methods. With recommendations for improvement solutions, namely making simulation calculations of zero values for the most dominant type of reject, namely untidy packaged rejects. And to reduce the occurrence of untidy packaging rejects is the skill and skills possessed by operators, namely by carrying out additional inductive activities and training evaluations so that presenters can determine the material to be used in training and evaluation activities with the aim of knowing how much understanding operators have in attend the training held.

After the solution was implemented there was a decrease in the average DPMO to 10,909.0909 and an increase in the sigma value to 3.794 sigma and a decrease in loss costs of Rp. 42,333 (73.91%) for every 1 batch of packing process explained that the

improvement solutions carried out brought changes for the better and affected the profits generated by PT. XYZ.

SUGGESTION

Some suggestions that can be given to companies or further research are:

1. 1. It is hoped that the improvement solutions that have been provided can be considered for continuous application in companies as an effort to reduce or solve the problem of reject containers during the production process using cartoning machines.
2. It is expected that the company can form a special team to monitor the application of six sigma in every production and packing process, so that product quality can always be maintained properly.
3. The application of six sigma is expected not only to be applied to the packaging production process, but also to reduce the number of other defects.

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