International Journal of Scientific and Academic Research (IJSAR) ISSN: 2583-0279
Volume 4, Issue 1, January– 2024
www.ijsar.net
CrossRef DOI: 10.54756/IJSAR.2024.1.3

Quality Control Analysis of Dry Syrup Products in the Filling and Cramping Process using the DMAIC Method in Pharmaceutical Companies

SaktiAjiLesmana[1], Novera Elisa Triana [2]

[1-2]Industrial Engineering Department, Faculty of Engineering, MercuBuana University

Jl. Raya Meruya Selatan, Kembangan, Jakarta 11650

Indonesia

ABSTRACT

The main factor that companies, especially pharmaceutical companies, must consider is producing quality products to compete. During the production process of Dry Syrup for pharmaceutical companies, several quality defects were found, such as Alcap loss, alcap torn, alcap scratched, alcap broken 1 ring, alcap broken 2 rings, bottles without alcap, alcap dented, and underweight with the acquisition of a defect percentage exceeding the maximum company tolerance limit of 5% in the last six months, from October 2022 to March 2023. This research is focused on the problem of Alcap Loss and Underweight defect types because they are the dominant defects among all defect types. The DMAIC method is used to solve and reduce product quality defect problems. The proposed improvements given are making a standardized range for setting screw knives with points on how to set screw knives and adding filling weight inspection intervals with filling weight monitoring sheets. The results of the application of improvements using the DMAIC method and the application of proposed improvements reduce product defects by 40% and increase the sigma value from 3.40 to a value of 3.84.

Keywords: Dry Syrup, DMAIC Method, Quality control, Defects.

1. INTRODUCTION

The pharmaceutical industry has a vital role in ensuring and improving public health, producing drugs to treat various diseases, minimizing the risk of health problems, and ensuring sustainable health services from generation to generation in the pharmaceutical industry. Therefore, all pharmaceutical industries must strive to produce medicinal products that meet the required quality standards (Food and Drug Administration, 2018).

Defective products result from the production process that do not meet standards but are economically more profitable when repaired than directly sold. In other words, the cost of repairing defective products is still lower than the proceeds from the sale of defective products after repair (Halim, 2000). According to Afnina & Hastuti (2018), one of the main factors companies must pay attention to is product quality. Customers will feel more satisfied if they show that the products used are of high quality.

In the production process of Dry Syrup product production in the filling and cramping process from October 2022 to March 2023 in the production department, there are problems related to product quality. This problem causes a large number of defects in dry syrup products. The following is data on the production and defects of dry syrup products for the last 6 months in Table 1.

Table 1. Dry Syrup Production and Defect Data (Oct 2022-Mar 2023)

Month	Defect Type (Bottle)								Total Defect (Bottle)	Total Production (Bottles)	Defect Percentage (%)
	Cramping							Filling			
	Alcap Tear	Alcap Loss	Alcap Break 2 Ring	Alcap Dent	Alcap Less Bottle	Alcap Disconnect 1 ring	Alcap Scratched	Under weight			
Oct-22	140	154	150	147	210	129	156	130	1216	16579	7
Nov-22	100	221	198	176	130	219	144	201	1389	23412	6
Dec-22	121	231	195	205	118	157	166	192	1385	15410	9
Jan-23	111	210	129	143	211	177	112	199	1292	14587	9
Feb-23	186	178	159	120	115	199	178	176	1311	22651	6
Mar-23	210	201	144	178	132	102	190	156	1313	19644	7
Total	868	1195	975	969	916	983	946	1054	7906	112283	44

Table 1. above it can be seen the types of defects that occurred during the production process of Dry Syrup products for the period Oct 2022-Mar 2023, namely, in the cramping process including, alcap torn, alcap loss, alcap broken 2 rings, alcap dented, bottle without alcap, alcap broken 1 ring, alcap scratched and in the filling process there is an underweight defect. The highest percentage of defects in Dry Syrup products occurred in Dec 2022 and Jan 2023 with a defect percentage of 9%. In the period Oct 2022 - Mar 2023, the pharmaceutical company produced 112283 bottles of medicinal products with a total defect of 44%.

The following data on the percentage of Dry Syrup product defects for the Oct 2022- Mar 2023 period is presented in diagram form in Figure 1. .

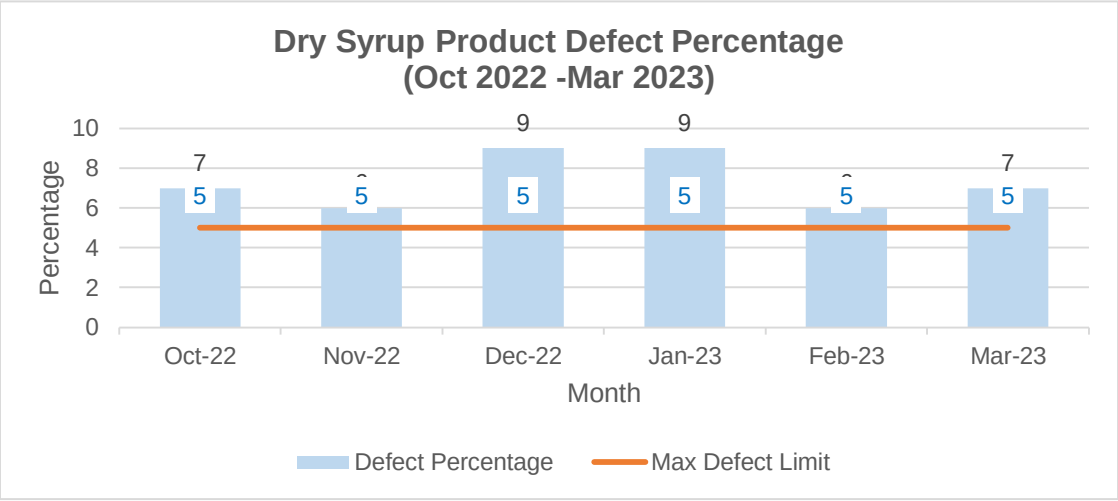


Figure 1. Percentage of Dry Syrup Product Defects

Based on the diagram above, every month the percentage of defective products produced has exceeded the maximum defect limit set by the company. The maximum defect limit allowed by pharmaceutical companies is 5%. This will certainly result in a lot of work time to repair the product. However, suppose this problem is not fixed immediately. In that case, it will i n c r e a s e a lot of work time to re-process and increase the amount of material usage and the potential for passing defects to customers. Therefore, defect problems that arise need to be improved with the aim of reducing product defects to create quality Dry Syrup products.

DOI:10.54756/IJSAR.2024.1.3

Several studies have been conducted regarding quality improvement and can be used as references in this study, namely.

Research Izzah N. & Rozi M. (2019), This research presents Six Sigma applications using DMAIC, namely. Define, Measure, Analyze, Improve and Control for defect reduction in Rebana Gresik UKM. This research focuses on improving the quality of tambourines to reduce the number of defects that occur in tambourine products to find the cause and make improvements to machine, human, and material factors.

Researcher Firmansyah & Yuliarty (2020), in the face of increasingly fierce competition in the home appliance industry. The company strives to continuously improve its competitive advantage by making continuous improvements. However, on its way it experienced problems encountered on the base plate of the electric iron. There are 3 types of sole plate defects found, namely: paint scratches, heating element stand out, and porous. The method used for product quality improvement using DMAIC. The results showed that: (1) the largest contributor to defects is porous with a percentage of 83.56% of the total defects (2) the average DPMO in 2017 is 3672.43 with a sigma value of 4.22. Proposed improvements include: separating slag from the fused material, installing chill blocks on the molding, changing the gating model to a spoon fed gate, installing a blower on the building ceiling, setting the melting furnace temperature range of 700-750o C and validating.

2. LITERATURE REVIEW

2.1 Definition of Dry Syrup Products

Dry Syrup products are mucolytic drugs that work to thin phlegm by breaking disulfide bonds in phlegm. This drug is used to treat acute and chronic respiratory tract in adult or pediatric patients (aged 5 years and over). In general, Dry Syrup preparations are made using medicinal ingredients that are unstable and not dispersed in water carriers.

2.2 Definition of Quality

According to Gasperz (2001), quality is conformance to requirements, which is in accordance with what is required or standardized. A product has quality if it complies with predetermined quality standards.

2.3 DMAIC

According to Breyfogle in Muntaha (2016), DMAIC (Define, Measure, Analyze, Improve, Control) is a basic component of the Six Sigma methodology, which is used to improve the performance of a process by eliminating defects.

Define is a step to determine the target of quality improvement activities with six sigma. The define stage aims to define and explain the products that will be improved. The initial stage in defining is to determine the dominant defects in dry syrup products using Pareto diagrams, which are categorized as CTQ.

The following are the tools used in the define process, namely:

a. Critical to Quality (CTQ), product criteria that have been standardized as a benchmark for the quality of products produced by the company in order to meet customer needs.

b. Pareto Diagram: According to Yemima (2014), the Pareto Diagram is a bar graph that shows problems based on the order of the number of occurrences.

Measure has the aim of collecting data that is appropriate and relevant to the scope of the problem that has been previously determined. The tools used measure the performance of the process which is expressed in Defects per Billion Opportunities (DPMO) or converted to sigma size (Fitriyaningsih, 2018).

Analysis: at this stage, identification of the root of the problem is carried out based on data analysis. Tools that can be used at this stage are cause and effect diagrams (fishbone).

Improve: this stage is the stage of determining the solution chosen to improve process performance, what

DOI:10.54756/IJSAR.2024.1.3

action plans will be taken, when and by whom the action will be carried out, and what parameters will be measured from each plan. At this stage, it will be described using the 5W+1H chart.

Control, the last stage is Control, aims to control every activity, to get good results and can reduce unnecessary time, problems, and costs. At this stage, the results of improvements can be in the form of SOPs and inspection processes.

3. RESEARCH METHODS

3.1 Type of Research

The type of research used in this study is quantitative research with a descriptive approach.

3.2 Data Collection Methods

The method or steps in conducting data collection can be seen as follows.

1. Observation, direct observation of the production process in the field to obtain valid data in supporting the making of this research.
2. Interviews, collecting information related to the causes of product defects through interviews by asking several questions directly to operators, supervisors and engineering.
3. Literature Study, studying reading sources that can provide information from various sources that have to do with the problem being studied.
4. Documentation and collection of data needed from the company's historical data in accordance with the research needs and problems studied, such as Dry Syrup product defect checking data and product defect types in the form of product defect photos.

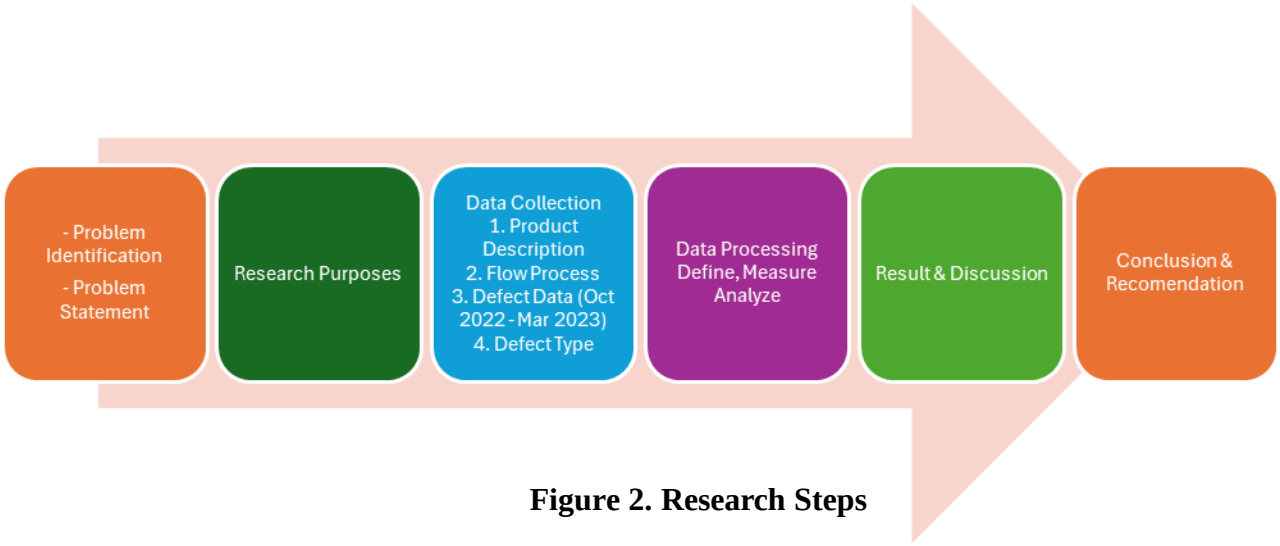


Figure 2. Research Steps

3.3 Data Processing and Analysis Methods

The method used is DMAIC, the DMAIC concept known as the define, measure, analyze, improve and control cycle, which is expected to reduce the number of Dry Syrup product defects and improve the performance of the production process. After data processing, data analysis is then carried out on each data processing process. The purpose of data analysis is to compare the shortcomings and advantages of the results of data processing. The processing results are continued in the Improve and Control stages.

5. RESULTS AND DISCUSSION

This result and discussion will explain the problems from the results of field observations about the high defect factors of Dry Syrup products in the filling and cramping processes; the focus of quality improvement is on

DOI:10.54756/IJSAR.2024.1.3

alcap loss defects and underweight defects, which are the dominant defects in the cramping and filling processes. At the measuring stage, the highest sigma level was obtained at 3.40, which shows that the process performance is still not good and there will be a potential increase in the value of defects if quality improvement is not carried out. An improvement plan was created and analyzed using 5W+1H.

4.1 Stages of Improvement

Proposed improvements were made using 5W+1H to the factors causing the defect alcap loss and underweight, referring to the fishbone diagram.

a. 5W+1H Improvement Plan Defect Alcap Loss

Table 2. 5W+1H Improvement Plan Defect Alcap Loss

Factors causing the problem	Proposed Improvements
Production target	Checking product production targets
There is no competency training on machine operation and settings	Provide regular training (additional training/refreshment) to operators regarding competency in setting machine parameters
Screw knife setting problem	Propose to create a standardized range for setting threaded knives
There is no procedure regarding threaded knives	Propose to add a point on how to set up the screw knife before the production process.

b. 5W+1H Improvement Plan Defect Weight Underweight

Table 3. 5W+1H Improvement Plan Defect Weight Underweight

Factors causing the problem	Proposed Improvements
Unstable weight	Propose to create a standardized range of impeller speed setting for granule filling distribution
There is no competency training on machine operation and settings	Provide regular training (additional training/refreshment) to operators regarding competency in setting machine parameters
Absence of weight check intervals	Propose to create and add a check sheet with weight inspection intervals during filling to prevent the occurrence of unqualified weights

4.2 Control Stages

The controls that are accepted and applied to the filling and cramping process dry syrup products for improvement in improving product quality.

a) Control against Design improvement that impacts critical goals to minimize defect Alcap loss. The repair design for the alcap loss defect is to make a standardized screw knife setting using an OPL (One Point Lesson) sheet containing how to set the screw knife.

DOI:10.54756/IJSAR.2024.1.3

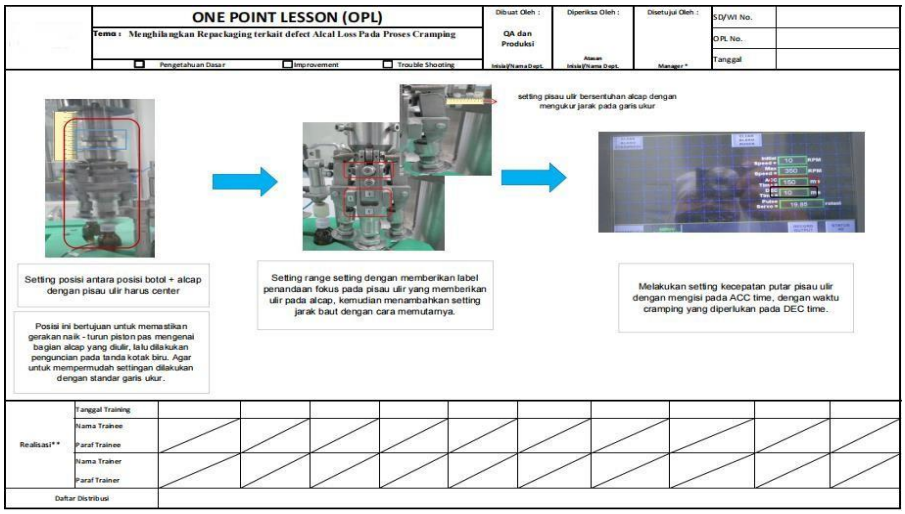
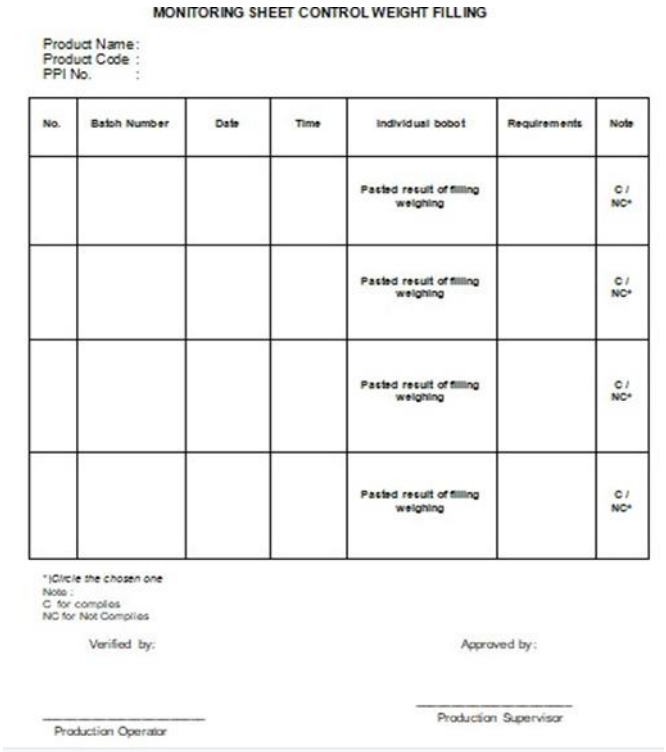


Figure 3. OPL Standardization of Thread Knife Setting

b) Control against Design improvements that impact critical goals to minimize underweight defects. The design of this improvement is to create a weight check interval sheet filling is made to ensure the filling weight is always within the range of requirements.



MONITORING SHEET CONTROL WEIGHT FILLING

Product Name :
Product Code :
PPI No. :

No.	Batch Number	Date	Time	Individual bobot	Requirements	Note
				Pasted result of filling weighing		C / NC*
				Pasted result of filling weighing		C / NC*
				Pasted result of filling weighing		C / NC*
				Pasted result of filling weighing		C / NC*

*)Circle the chosen one
Note :
C for complies
NC for Not Complies

Verified by:

Production Operator

Approved by:

Production Supervisor

Figure 4. Filling Weight Control Sheet

4.3 Comparison of Dry Syrup Product Defects Before and After Improvement

The implementation of these improvements resulted in a decrease in defects in the production of dry syrup products, as shown in table 4. below.

DOI:10.54756/IJSAR.2024.1.3

Table 4. Dry Syrup Product Defect Data After Improvement

Month	Total Defects	Total Production	Defect Percentage (%)
Apr-23	447	21450	2.1
May-23	361	18820	1.9
Total	808	40270	4

Based on the defect data in the table above, after the improvement, there is a decrease in defects. In table 4.there is a decrease in the total percentage of defects up to 40%. This means it can overcome critical causal factors.

Based on DPMO data and Sigma values from data processing table 4., there is a decrease in DPMO and an increase in sigma after improvement. The sigma value is obtained.

3.84. this shows the performance of the Dry Syrup product production process is better.

6. CONCLUSION

6.1 Summary

After conducting research and discussing the results of research on improving the quality of dry syrup products in the filling and cramping process, the researcher concludes, including:

(1) three factors cause defects in Dry syrup products during the filling process and cramping, namely human factors (lack of knowledge and skills in operating the machine), machine factors (improper screw knife settings, absence of standardized screw knife settings and unstable filling weight settings, absence of standardized granule impeller speed settings), and method factors (no points on how to set the screw knife in the procedure and no interval for checking the filling weight). (2) The implementation of improvement proposals to reduce the occurrence of Alcap loss defects and underweight defects in Dry syrup products includes creating a standardized range for setting screw knives by including screw knife setting steps and adding filling weight inspection intervals using a filling weight monitoring sheet. (3) The results of implementing improvements with the DMAIC method obtained an increase in process performance with a sigma value from 3.40 to 3.84.

6.2 Suggestion

Some suggestions that researchers can give from the research results are research using several other improvement methods, such as FMEA as a tool for quality control, so that the failure model that occurs by causing defects is known in depth so that it can reduce defects to zero defects, so that the company does not experience losses.

LITERATURE

Abdul Halim, d. (2000). Management Control System. Yogyakarta: Publishing and Printing Unit of the YKPN Academy of Company Management.

Afnina, A. & Y. Hastuti. (2018). The Effect of Product Quality on Customer Satisfaction. Journal of Samudra Economics and Business 9 (1): 21-30.

Badan POM RI (2018). Regulation of the Food and Drug Supervisory Agency Number 4 of 2018 Concerning the Supervision of the Management of Medicines, Medicinal Materials, Narcotics, Psychotropic Substances, and Pharmaceutical Precursors in Pharmaceutical Service Facilities. Jakarta.

Firmansyah R. &Yuliarty P. (2020).Implementation of the DMAIC Method on Sole Plate Quality Control at PT KencanaGemilang.Journal of Research and Application of Industrial Systems & Engineering (PASTI).

Fitriyaningsih. (2018). Analysis of the Use of the Six Sigma-DMAIC (Define, Measure, Analyze, Improve, Control) Method in the Cutting Material Process at PT NSSI Industry Indonesia in an Effort to Reduce Defective

DOI:10.54756/IJSAR.2024.1.3

Products. [Final Project] MercuBuana University

Gasperz, Vincent. (2001). Analytical Methods for Quality Improvement. Jakarta: PT Gramedia Pustaka Utama.

Izzah N. & Rozi M. F. (2019).Analysis of Quality Control with the Six Sigma- DMAIC Method in an Effort to Reduce Defects in Rebana Products at UKM AlfiyaRebana Gresik. Scientific Journal: SOULMATH, Vol 7 (1).

Mahmud, A. (2012). Planning and Controlling Textile Yarn Quality at PT Indo Prima Sentosa Textile Factory.(Thesis). S1. Faculty of Engineering, MercuBuana University.

Yemima. 2014. Application of Demerit Control Map and Pareto Diagram on Production Quality Control. (Thesis) S1. Mulawarman University.

DOI:10.54756/IJSAR.2024.1.3