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Quality Control of Infusion RL 500 ml Single Port Flip-Off Product Packaging Using the Six Sigma Approach

Riki Ridwan Margana[1], Yani Iriani[2], Arief Rahmana[3], Annisa Maharani Suyono[4], Faza Millatina[5]
Widyatama University. Bandung. Indonesia
Email: riki.ridwan@widyatama.ac.id

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Packaging, Quality Control, Six Sigma, Single Port Flip-Off.

ABSTRACT
The purpose of this study is to calculate the Defects Per Million Opportunities (DPMO) and sigma level values for defective tubing packaging, identify the root causes of defective tubing packaging, and provide suggestions for improving the quality of defective tubing packaging for the Infusion RL 500 ml Single Port Flip-off product at PT Sanbe Farma Unit III. Based on data processing using the Six Sigma method, the DPMO value obtained was 34,703.93 defects per million and the sigma level value was 3.33. The analysis using the 5 Why's Analysis identified factors causing defects, including machine factors such as dull blades and shifting gripper stoppers, human factors such as careless operators, and material factors such as clumps of silica particles inside the tubing. In the improvement phase using the 5W 1H analysis method, proposed improvements include: scheduling blade orders, periodic blade replacements on machines, routine machine inspections before use, resetting production schedules, supervisor oversight during each shift, creating detailed production standard operating procedures, and updating tubing packaging material inspection standards.

1. INTRODUCTION

PT Sanbe Farma Unit III (Sterile and Preparation Plant) is a pharmaceutical company divided into two production departments: Small Volume Parenteral (SVP) and Large Volume Parenteral (LVP). The SVP department produces injectables, eye drops, and ear drops. Meanwhile, the LVP department produces infusions. The infusions manufactured include several types of closures, namely Single Function Closure (SFC), Single Port Flip-Off (SPFO), and Double Port Flip-Off (DPFO).

This study focuses on the packaging of the Infusion RL 500 ml product with a Single Port Flip-off type closure. During the pre-packing process of the infusions, defective products are often found. The types of defects identified include leaks, fiber particles, and defects in the tubing. Tubing is the hose or pipe part of the infusion set that functions as a means for the fluid or blood to flow from the infusion bag to the vein. Defects in the tubing can cause disruptions in the flow of the infusion fluid. Of these three types of defects, tubing defects are the most commonly encountered.

Based on the company's historical data from January 2022 to December 2022 in Table 1, there are findings of rejections in the packaging of the Infusion RL 500 ml Single Port Flip-Off product with the following percentages:

Table 1. Types of Rejects for Infusion RL 500 ml Single Port Flip-off in 2022

Month	Production Total (pcs)	Reject Foreign Particles		Reject Leaks		Reject Tubing	
		Total	%	Total	%	Total	%
January	496,337	383	0.08	4,522	0.91	14,231	2.87
February	254,765	196	0.08	2,208	0.87	6,257	2.46
March	162,018	122	0.08	1,663	1.03	4,960	3.06
April	370,147	263	0.07	2,925	0.79	8,176	2.21
May	160,823	109	0.07	1,229	0.76	2,962	1.84
June	87,494	75	0.09	1,182	1.35	2,331	2.66
July	14,638	15	0.10	205	1.40	709	4.84
August	73,031	47	0.06	627	0.86	1,698	2.33
September	536,054	454	0.08	4,924	0.92	6,386	1.19
October	101,190	67	0.07	965	0.95	2,229	2.20
November	232,478	171	0.07	3,538	1.52	3,538	1.52
December	365,416	284	0.08	3,582	0.98	6,545	1.79
Total		0.08%		1.03%		2.41%	

According to company rules, the defect percentage must not exceed 0.8% for each defect category. Therefore, quality control improvements are needed to enhance the packaging quality of Infusion RL 500 ml Single Port Flip-Off products.

Many researchers have utilized the Six Sigma method in addressing quality control issues. Hanifah & Iftadi (2022) conducted a study involving the application of the Six Sigma method and Failure Mode Effect Analysis for improving the quality control of sugar production. Yeni Mulyani (2022) conducted research to propose minimizing defects in formula milk products using the Six Sigma method, Fault Tree Analysis, and Failure Mode and Effect Analysis at PT Kalbe Morinaga Indonesia. Nababan & Purwanggono (2023) conducted research on quality control for sarsaparilla drink packaging using the Six Sigma method.

Due to the relevance between the issues faced by previous researchers and the issues faced by the author currently, the author attempts to research the Quality Control Analysis of Infusion RL 500 ml Single Port Flip-off Product Packaging with the Six Sigma Approach (Case Study at PT Sanbe Farma Unit III).

Based on the conditions mentioned above, the objective of this research is to reduce the number of rejected products by calculating the Defects Per Million Opportunities (DPMO) and sigma level values for defective tubing packaging, identifying the root causes of the defective tubing packaging, and proposing improvements for the quality of defective tubing packaging of the Infusion RL 500 ml Single Port Flip-off product at PT Sanbe Farma Unit III.

The author will conduct a quality analysis of the product using the Six Sigma approach through the DMAIC (Define, Measure, Analyze, Improve, Control) stages in the production process of the Infusion RL 500 ml Single Port Flip-Off to understand the characteristics of the packaging defects that occur and the performance of the production process so that the products produced meet the specifications set by the company. The author will use the 5 Why's Analysis to identify potential failures or the root causes of product defects, enabling the author to propose improvements for the company. The hope is that the company can address the factors causing rejected products, thereby reducing the number of rejected products produced by the company and minimizing the losses experienced by the

company.

2. METHOD

In the context of quality control, particularly referring to the Six Sigma methodology, "Define" is the first step in the DMAIC (Define, Measure, Analyze, Improve, Control) approach. The "Define" phase in DMAIC is a crucial initial step in the quality improvement process, and it involves clearly determining and defining the problem to be solved and the objectives to be achieved. This phase sets the foundation for all subsequent activities by establishing a clear focus and direction for the improvement efforts.

This step is aimed at measuring and analyzing data related to the process or problem identified in the "Define" phase. The "Measure" phase plays a critical role in Six Sigma as it provides a deep understanding of the actual performance of the process being analyzed. The data gathered during this phase serves as the foundation for further analysis in subsequent steps of the DMAIC methodology, such as "Analyze" and "Improve." By using accurate and measurable data, companies can make better decisions and direct improvement efforts more effectively to achieve the desired quality objectives. In the "Measure" stage, the following calculation steps are undertaken:

Defects Per Unit (DPU)

Defects Per Unit (DPU) is a measure that reflects the average number of defects of all types per total units produced. The data required in this phase includes the number of defects that occurred and the total number of units produced. This metric helps identify the frequency of defects and is crucial for assessing the quality and reliability of the production process.

$$DPU = \frac{Jumlah\ produk\ cacat}{Jumlah\ produksi}$$

Defect Per Million Opportunities (DPMO)

Defects Per Million Opportunities (DPMO) is a key metric used in Six Sigma to quantify the rate of defects in a process per one million opportunities, providing a standardized way to measure quality on a large scale. DPMO is particularly useful because it allows organizations to compare performance across different processes or products, even if the complexity or volume differs significantly. Here's the formula for calculating DPMO:

$$\text{DPMO} = \frac{Defect}{Unit\ Inspected\ x\ Defect\ Opportunity}$$

Explanation of Terms:
Defect: This is the count of the number of defects found within the inspected units. A defect is any instance where the product or service fails to meet the predefined specifications or quality standards.
Unit Inspected: This refers to the total number of units that were examined during the quality control or inspection process. Each unit is checked for defects against the standards set by the organization.
Defect Opportunity: This is the total number of opportunities for a defect to occur per unit. An opportunity is defined as any event or point where a defect could occur. The definition of an opportunity depends on the specific characteristics of the process or product being analyzed.

Sigma Level

The Sigma Level, also known as the "Sigma Score," is a key metric in Six Sigma that measures the capability of a process to produce defect-free work. It indicates how often defects are likely to occur, giving a clear picture of the process quality. The higher the Sigma Level, the fewer the defects. To calculate the Sigma Level following the calculation of DPMO, you can use the following formula:

$$\sigma = normsinv\left(1 - \frac{DPMO}{1.000.0000}\right) + 1{,}5$$

Here's how the equation works:
1 - (DPMO / 1,000,000): This portion of the formula calculates the proportion of non-defective opportunities. DPMO is divided by 1,000,000 because DPMO stands for defects per

million opportunities, so this gives you the proportion of defects per opportunity. Subtracting this value from 1 gives the probability of a non-defective output.

NORMSINV(): This function, which stands for "Normal Distribution Inverse," is used to find the Z-value (Sigma Level) that corresponds to the given cumulative probability from the standard normal distribution. This part of the formula converts the probability of non-defects into a Z-score or standard deviation units.
+ 1.5: This is an adjustment factor used in Six Sigma calculations. It accounts for the long-term shift in the mean that can occur over time in a process, providing a more realistic estimate of long-term process capability. This is known as "1.5 Sigma Shift."

The Analyze stage in the Six Sigma (DMAIC) methodology is the third step following the Measure stage. In this phase, the Six Sigma team conducts an in-depth analysis of the data collected during the Measure stage to understand the root causes of the problems identified in the Define stage. The primary goal of the Analyze stage is to identify the factors contributing to the issue and to understand the cause-and-effect relationships within the process being analyzed.

The Control stage in the Six Sigma (DMAIC) methodology is the final step of the quality improvement process. At this stage, after solutions have been implemented and the process has been improved, the focus is on maintaining and ensuring that the changes made are sustained and that process performance remains consistent with the established quality standards. The main objective of the Control stage is to prevent the recurrence of the same issues and ensure that the improvements made have a positive long-term impact.

3. RESULT AND DISCUSSION

Data Collection Results

Table 2 shows the historical data containing the production numbers and the number of rejects for the RL 500 ml Single Port Flip-Off Infusion at PT Sanbe Farma Unit III for the period from January 2022 to December 2022.

Table 2. Historical Data for Production of RL 500 ml Single Port Flip-Off Infusions

Month	Production Total (pcs)	Reject Total (pcs)
January	496,337	19,136
February	254,765	8,661
March	162,018	6,745
April	370,147	11,364
May	160,823	4,300
June	87,494	3,588
July	14,638	929
August	73,031	2,372
September	536,054	11,764
October	101,190	3,261
November	232,478	5,861
December	365,416	10,411
Total	2,854,391	88,392

Data Processing Results

Define

The steps taken in this stage include identifying the problem, setting targets, determining the priority problems to be addressed, and then creating a flowchart of the production process for RL 500 ml Single Port Flip-off Infusions at PT Sanbe Farma.

1) Problem Identification

The following types of defects have been identified as causes of defects in RL 500 ml Single Port Flip-off Infusions at PT Sanbe Farma during the period from January 2022 to December 2022.

Table 3. Defects in RL 500 ml Single Port Flip-off Infusions

Month	Production Total (pcs)	Defect Type			Reject Total
		Foreign Particles	Leaking	Tube	
January	496,337	383	4,522	14,231	19,136
February	254,765	196	2,208	6,257	8,661
March	162,018	122	1,663	4,960	6,745
April	370,147	263	2,925	8,176	11,364
May	160,823	109	1,229	2,962	4,300
June	87,494	75	1,182	2,331	3,588
July	14,638	15	205	709	929
August	73,031	47	627	1,698	2,372
September	536,054	454	4,924	6,386	11,764
October	101,190	67	965	2,229	3,261
November	232,478	171	3,538	3,538	5,861
December	365,416	284	3,582	6,545	10,411
Total	2,854,391	2,186	27,570	60,022	88,392

Based on the observations conducted by the author as shown in Table 3, the total number of rejects is 88,392 pieces for the period from January to December 2022. This total includes rejects caused by foreign particles, totaling 2,186 pieces; rejects caused by leaks, totaling 27,570 pieces; and rejects caused by tubing defects, totaling 60,022 pieces.

2) Determining Priority Problems

Out of the 88,392 pieces of RL 500 ml Single Port Flip-off Infusions produced at PT Sanbe Farma Unit III, the quality of rejected products is characterized by three types of defects: leaks, foreign particles, and tubing defects. The percentages of these three types of defects are illustrated in a pie chart in Figure 1.

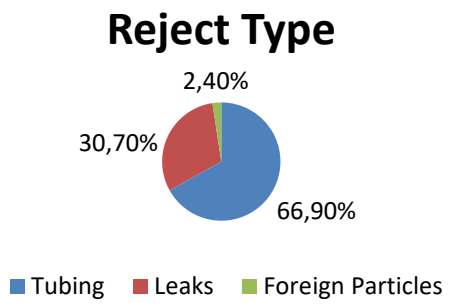

Figure 1. Circle Diagram of Reject Types of RL 500 ml SPFO Infusion

Based on the pie chart in Figure 1, it's found that the largest cause of defects, comprising 66.9% of the total number of rejects, is tubing defects. This type of defect is chosen as the priority problem that has the most significant impact on the quantity of rejected RL 500 ml Single Port Flip-off Infusions. Therefore, tubing defects are the focus of attention in this study. Figure 2 provides an illustration of packaging with tubing defects.

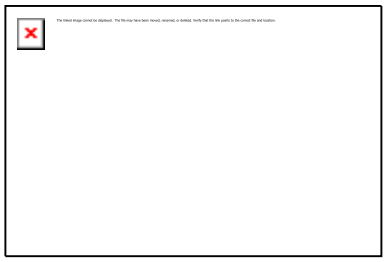

Figure 2. SPFO Tubing Defects

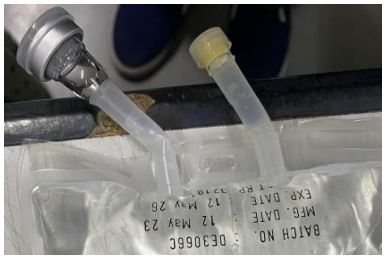

Figure 3. DPFO Tubing Defects

3) Setting Targets

Based on Table 1, it's known that the number of rejects due to tubing defects in 2022 is 60,022 pieces or 2.41%, exceeding the company's target of less than 0.8% per defect category. The company expects improvements to reduce the number of rejected products. It is hoped that if the number of rejects due to tubing defects is addressed, the number of rejects can be reduced to near-zero defects or achieve 3.4 defects per million (6 sigma).

Measure

The Measure stage aims to measure the number of product defects by determining Critical to Quality (CTQ) to understand the quality characteristics needed to calculate Defects Per Million Opportunities (DPMO) and Sigma Level. Based on the prioritization of issues, one type of defect that is Critical to Quality (CTQ) is determined in Table 4.

Table 4. Critical to Quality

Characteristics	Information
Tubing Defects	The product packaging in the port/tubing section is not printed perfectly, the tubing is folded, the tubing is tilted, and the tubing is crossed.

Based on Table 4, the data from monitoring and observing the production process, Critical to Quality (CTQ) for RL 500 ml Single Port Flip-Off Infusion product packaging is determined to have one dominant type of defect, which is tubing defects. The next step is to calculate the Defects per Million Opportunities (DPMO) and sigma level. The calculation results for DPMO and sigma level are provided in Table 5.

Table 5. DPMO and SQL Calculation Results

Month	Production Total (pcs)	Reject Total (pcs)	CTQ	DPU	DPMO	Sigma
January	496,337	19,136	1	0,04	38,554.45	3,27
February	254,765	8,661	1	0,03	33,996.04	3,33
March	162,018	6,745	1	0,04	41,631.18	3,23
April	370,147	11,364	1	0,03	30,701.32	3,37
May	160,823	4,300	1	0,03	26,737.47	3,43
June	87,494	3,588	1	0,04	41,008.53	3,24
July	14,638	929	1	0,06	63,464.95	3,03
August	73,031	2,372	1	0,03	32,479.36	3,35
September	536,054	11,764	1	0,02	21,945.55	3,52
October	101,190	3,261	1	0,03	32,226.50	3,35
November	232,478	5,861	1	0,03	25,210.99	3,46
December	365,416	10,411	1	0,03	28,490.82	3,40
Total	2,854,391	88,392		0,03	30,967.03	3,37
Average	237,866	7,366			34,703.93	3,33

Defect per Unit (DPU) calculation is a value obtained by comparing the number of defective products with the total production in January 2022. Defect per Million Opportunities (DPMO) calculation is a value derived from comparing Defect per Unit (DPU) with the number of Critical to Quality (CTQ) multiplied by one million (1,000,000). Sigma Level calculation is done by converting the Defects per Million Opportunities (DPMO) value to a Sigma Level based on a sigma table. The addition of the SHIFT value assesses the variance shift that will ultimately affect the Sigma Level. The Sigma Shift value for Quality Level Five Sigma is 0.5, then for Quality Level 5.5, it is one, and for Quality Level 6-Sigma, it is 1.5. By using the same formula for January 2022, the Sigma Level can be determined.

Based on the calculation results from the production and rejection numbers from January 2022 to December 2022, the average Defects per Million Opportunities (DPMO) value is 34,703.93 defects per million, and the average sigma level is 3.33 sigma. This indicates that the average sigma level is between 3-4 Sigma. According to Table 2.2, the company's sigma value exceeds the industry average in Indonesia, but it still incurs a cost of poor quality ranging from 25-40% of sales. With this research, it is hoped that the company's product quality will approach zero defects or achieve 3.4 defects per million (6 Sigma).

Analyze

The analyze stage aims to analyze problems or factors that cause defects in products using the 5 Why's Analysis. The results of the 5 Why's Analysis are summarized in table 6.

Table 6. Why's Analysis

Problem	Reason	Why 1	Why 2	Why 3	Why 4	Why 5	Solution
Tubing Defects	Machine	Blunt knife	The lifespan of the knife has been long	Not conducting regular knife replacements	There is no schedule for regular knife replacements.	Delayed knife ordering	Creating a schedule for knife replacements and orders.
			The knife are rubbing against coarse particles in the tubing	There is no checking of particle size in the tubing	Not included in the PMIS	New findings	Updating PMIS for checking the quality of the inner part of the tubing.
		Gripper Stopper Slipping	The usage life of the gripper has been long (worn out)	There are broken bolt components	There is no inspection schedule before the packaging process starts	Pursuing high production targets	Conducting regular inspections and adjusting production scheduling.
	Human	The operators are not careful enough	The storage of softbags in the trolley during the sterilization process is not tidy and they stack up	During the sterilization process, the packaging starts and changes shape	There are no rules regarding the maximum limit of soft bags in the trolley	There is no SOP	Update the SOP regarding the maximum limit of softbags on the trolley to avoid overloading.
			Storage of softbags on the conveyor is untidy	Softbags getting stuck in the conveyor	Operators chatting	No supervision	Conduct supervision during each shift and issue warnings.
	Material	There are clumps of silica particles inside the tubing	There is no quality check on the inside of the tubing	It's not in the PMIS	Observations regarding the impact of particle size haven't been conducted yet	New findings	Updating the PMIS for checking the quality of the inner part of the tubing.

Improve

The Improve stage involves planning improvements for the tubing defects, which are the priority issue affecting the quality of RL 500 ml Single Port Flip-Off Infusion packaging at PT Sanbe Farma. Below are the improvements that can be made using the 5W 1H method, outlined in Table 7.

Table 7. 5W 1H Improve

Problem	Reason	What	Why	Where	When	Who	How
Cacat Tubing	Machine	Scheduling knife orders	To ensure spare parts are always available	Purchasing department	Once a year	The purchasing staff	The purchasing staff schedules knife orders based on needs and annual replacement schedules.
		Regular knife replacement	To ensure the tubing cutting process remains perfect	Production department	5 months	Engineer	The engineer changes the machine knives every 5 months before they become dull.
		Routine machine inspection	Ensuring all machine components are in their correct positions and functioning properly	Production department	Before the machine is used	Engineer	Routine maintenance is carried out before the machine is used.
		Rescheduling production	To optimize the quality of the products produced	PPIC Department	One month before production	PPIC Manager	To reschedule production to match machine capacity.
	Human	Supervision every shift	Ensuring that the production and packaging	Production and packaging department	Every day	Production and packaging supervisors	The supervisor checks the performance of operators

		processes are carried out according to SOP				during each shift.
	Creating a detailed production SOP regarding the number of soft bags used in a trolley	Preventing soft bag stacking	Packaging department	Immediately	The Research and Development department and Validation	Creating an SOP for product transfer to sterilization, including the maximum capacity details of the trolley.
Material	Updating PMIS for checking the quality of the tubing material components	Ensuring that the tubing used is of good quality, free from clumps of silica particles	Department of Quality Control	Immediately	The Research and Development department and Validation	Updating the PMIS for tubing specification analysis, including measuring particles within the tubing to avoid coarse silica clumps.

Based on Table 7, it can be concluded that improvements can be made to reduce tubing defects in the packaging of RL 500 ml Single Port Flip-Off Infusions. Proposed improvements that can be made include:

1) Scheduling knife orders

The cause of not regularly changing knives is the limited availability of knife spare parts. One improvement effort that can be made is to schedule spare part orders so that the appropriate time and quantity needed can be determined. To minimize shipping costs, it is suggested to order spare parts to meet the knife spare part needs within a year. However, it would be better to calculate based on inventory methods such as Material Requirement Planning (MRP) before ordering. The advantage of the MRP method is to ensure that items are always available.

2) Regular Knife Replacement

Regular knife replacement is recommended every 5 months to prevent tubing defects. Based on interviews with engineers, knife replacement has been done only when the knives are dull, with an average replacement interval of about 6-8 months. With regular replacement, it is hoped that packaging defects in RL 500 ml Single Port Flip-Off Infusions, such as uneven tubing cuts, will be reduced.

3) Routine Machine Inspection

To reduce the likelihood of damage to machine components, such as broken bolts and worn-out parts, it is recommended that engineers conduct machine inspections before the infusion packaging process. Machine inspections have only been conducted on Sundays.

4) Adjusting Production Scheduling

High production targets can affect machine resilience and the focus level of production operators, which can in turn impact the quality of the products. Therefore, production scheduling should be aligned with machine capacity and the capabilities of production operators. Production scheduling can be done one month before the production process is carried out, aligning with consumer demand.

5) Supervision on Every Shift by Supervisor

Currently, supervision by the supervisor is only conducted during shifts 1 and 2. With supervision on every shift up to shift 3, it is expected that operator performance will be maintained, resulting in quality products.

6) Creation of Detailed Standard Operating Procedure (SOP) for Handling

One of the causes of infusion defects is the stacking of softbags during the sterilization process. An improvement that can be made to prevent this from happening again is the creation of an SOP regarding the maximum capacity of softbags that can be loaded into the trolley.

7) Updating the Packaging Material Inspection Standard (PMIS) for tubing

One way to control the quality of product packaging is to ensure that the packaging material used is of high quality according to the company's specifications. With the finding of silica particles inside the tubing that can cause knives to dull more quickly and increase the number of packaging defects in the form of foreign particles in the infusion, there is a need to update the Packaging Material Inspection Standard (PMIS). The added specification in the analysis is the testing of particle size that makes up the tubing.

Discussion

One of the proposed solutions found is to create an SOP for handling the assembly of infusions in the trolley. The dimensions of the trolley are 955 x 705 x 1500 mm, and it can accommodate 25 trays. Each tray has dimensions of 950 x 700 x 20 mm. A Single Port Flip-off RL 500 ml infusion requires approximately 250 x 100 mm of space to avoid overlapping. Based on surface area calculations, each tray can hold a maximum of 27 RL 500 ml Single Port Flip-off infusions. Therefore, one trolley can accommodate 665 pieces of RL 500 ml Single Port Flip-off infusions. The proposed SOP for the infusion handling process can be as follows:

1) Operators must wear Personal Protective Equipment (PPE), including a wearpack, head protection, mask, gloves, and foot protection.
2) Inspect the softbags on the conveyor to ensure there are no leaks.
3) Arrange the softbags in the tray starting from the top-left corner. Ensure that there is sufficient space between the softbags and the edges of the tray.
4) The maximum number of softbags in each tray is 27 pieces.
5) Store subsequent softbags with sufficient space (no overlapping).

Fully loaded trolleys are placed into the autoclave for the sterilization process.

4. CONCLUSION

In the 500 ml Single Port Flip-Off RL Infusion

product at PT Sanbe Farma Unit III in 2022 which experienced tubing defects, the Defect Per Million Opportunities (DPMO) value was 34,703.93 defects per million and the average sigma level value was 3 .33, which means that quality control is still not working well, so it is necessary to implement the six sigma program continuously so that the company's targets can be achieved.

There are three factors that cause tubing defects that affect the quality of the Infusion RL 500 ml Single Port Flip-Off packaging, namely machine factors caused by blunt knives and shifting stopper grippers, human factors consisting of operators who are not careful, material factors which is caused by the presence of lumps of silica gel granules on the inside of the tubing.

Proposed improvements that can be made from the results of quality control using the Six Sigma - DMAIC method to improve the packaging quality of the Infusion RL 500 ml Single Port Flip-Off product produced at PT Sanbe Farma Unit III is by making a knife order schedule, changing the knife at periodic machine checks, routine machine checks before use, rearranging production schedules, monitoring each shift by supervisors, creating detailed production Standard Operating Procedures (SOP) and updating tubing Packaging Material Inspection Standards (PMIS).

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