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Enhancing Pharma Manufacturing Efficiency: Integrating Lean Six Sigma and Fuzzy FMEA for Waste Reduction

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ABSTRACT

In pharmaceutical manufacturing, inefficiencies such as waiting times, excessive material usage, and packaging defects can significantly impact productivity and quality. This study adopts a Lean Six Sigma approach, integrating lean manufacturing and six sigma methodologies, to systematically address these challenges. Through Process Activity Mapping (PAM), it was determined that value-added (VA) activities account for approximately 63% of total production activities, while non-value-added (NVA) and essential non-value-added (ENVA) activities contribute about 34% and 4%, respectively. Critical waste was identified using the genba shikumi method, followed by Failure Modes and Effects Analysis (FMEA) to determine Risk Priority Numbers (RPNs). Fuzzy logic was applied to prioritize the suggested improvements for more accurate risk assessments. Key recommendations based on Fuzzy RPN rank include, enhancing bulk product quality before printing, implementing rigorous inspections of the printing process, optimizing machine utilization, and adjusting production schedules using the Shortest Processing Time (SPT) method.

1. Introduction

During the COVID-19 pandemic, the Pharmaceutical Industry in Indonesia experienced a significant increase in GDP. There was a growth of 11.58%, reaching Rp30.8 trillion from 2019 to 2020. Subsequently, there was another increase of 14.29%, reaching Rp42.4 trillion from 2020 to 2021. The rise in GDP value in the pharmaceutical industry sector serves as an indicator of a substantial increase in demand for pharmaceutical products (Badan Pusat Statistik, 2021). Aligned with the Action Plan Document of the Ministry of Health of the Republic of Indonesia for the years 2020-2024, which emphasizes "Enhancing self-reliance and the use of domestic pharmaceutical and medical device products" (Ministry of Health RI, 2020), national companies operating in the pharmaceutical industry are required to meet the high demand for pharmaceutical products, especially in emergency situations such as the recent Covid-19 pandemic. This is aimed at maintaining national resilience in drug supply and improving the life expectancy of patients affected by diseases during the ongoing outbreak.

One pharmaceutical company in Indonesia has secured legal approval to manufacture drugs. During on-site observations, several wastes were identified in the drug packaging process, including motion waste, transportation waste, waiting waste, and product defects. Motion waste involves

unnecessary movements by workers, particularly in the primary and secondary packaging stages, that has impact to overall efficiency. Transportation waste arises from the inefficient layout of machinery, which is located in different rooms and not arranged sequentially, leading to increased distances for material handling, while waiting waste is evident in the significant delays between processes, such as the two to three hours lost during machine cleaning in the granulation stage. In the case of defect waste, it can be observed that the most common type of defect is crushed and dirty tablets, accounting for 25.9%. Other defect types, contributing to 80% of all defects, include broken tablets at 16.5%, leaking strips and entangled aluminum foil at 14.3%, and incomplete, duplicate, wrinkled, and empty tablets at 13.2%. For some strips with defects deemed still salvageable, a rework process will be implemented. This rework process incurs additional time and costs, causing financial and operational losses to the company. This indicates the presence of overprocessing waste, an excess process that ideally should be reduced or eliminated.

The Lean Six Sigma approach is employed to address existing problems in the company. This approach consists of two concepts: Lean Manufacturing, a method used to eliminate waste in a company or organization, and the Six Sigma concept, used to enhance production performance and product quality (Mwacharo, 2013). Lean manufacturing (LM) is a profound system designed to enhance every manufacturing industry's efficiency by reducing waste through internationally recognized tools and techniques (Badan Pusat Statistik, 2021). The concepts of LM can make it possible to use their resources effectively and increase their competitiveness. According to (Deif & ElMaraghy, 2014) and (Jilcha & Kitaw, 2015), LM is characterized by doing more with less. It focuses on reducing/eliminating waste in order to increase productivity and maximize customer values (Belekoukias et al., 2014). The lean manufacturing used in this research refers to the Toyota Production System (TPS), combined with the Define, Measure, Analyze, Improve, and Control (DMAIC) methodology from six sigma as a model for measuring and improving quality and processes. In the Define phase, the production process is depicted using Process Activity Mapping (PAM) to identify waste. In the Measure phase, wasteful elements with the highest importance or critical waste are identified, and their sigma values are calculated.

In the Analyze phase, problem analysis is conducted using Failure Modes and Effects Analysis (FMEA). FMEA is usually conducted through cross-functional team of expert with different backgrounds to determine failure mode's risk orders and crucial failures that should be improved for the performance of the overall systems (Lo et al., 2019). Traditionally, risk assessment in FMEA is performed by developing a metric known as the risk priority number (RPN). It is computed by multiplying three risk factors, namely severity (S), probability of occurrence (O), and probability of detection (D) for each of the failure modes (Xiao et al., 2011)(Panchal et al., 2019). According to (Huang, et al., 2020), based on RPN results, the risk order rankings of all failure modes are identified, and then rational control actions are developed to maintain the quality and reliability of the subject system. As an important early preventive technique, FMEA has been frequently used to provide valuable risk information. Therefore, the higher RPNs imply more critical failure modes and more attention to be paid for improving system performances (Boral et al., 2020).

However, the conventional RPN method has been criticized for numerous inherent limitations that weaken its effectiveness. According to (Catelani et al., 2018)(Huang et al., 2017)(Liu et al., 2019) (Liu et al., 2017) and (Wang et al., 2018), the relative weights of RPN elements and FMEA experts are not considered, different evaluation sets of RPN elements may yield the same RPN result, only the three RPN elements are considered, and the arithmetical formula of RPN is too simplistic and is strongly sensitive to assessments' variations, which may not make a precise depiction of a system's risk. In traditional FMEA, the RPN system is used to rank improvement priorities, but this approach has several limitations. First, it assumes that the three factors—severity, occurrence, and detection—have equal importance, which can introduce bias since there is no relative weighting among them. Second, different activities can yield the same RPN, even though their risk implications may differ, as shown in an example where two events have identical RPNs despite differing risk profiles. Third,

the traditional RPN calculation does not account for indirect relationships between components (Kumru et al., 2013). The fuzzy approach addresses these issues by allowing for more accurate risk assessments and enabling complex evaluations (Sun et al., 2019). It enhances the traditional RPN calculation by converting it into fuzzy-RPN values, using membership functions to make risk assessments clearer and more representative (Nilay et al., 2019). To overcome these limitations, this study integrates Fuzzy FMEA, which employs Fuzzy Set (FS) theory to better capture the ambiguities and uncertainty in expert assessments (Lakshmi & Baskar, 2019). In the Improve phase, proposals and alternative improvement designs are presented based on the RPN ranking order, validated by the experts. Lean Six Sigma focuses on waste reduction and process efficiency, which are essential in a sector where minor inefficiencies can lead to substantial costs and risks. Meanwhile, Fuzzy FMEA enhances risk assessments by capturing the inherent uncertainties in expert evaluations, allowing for a more accurate understanding of potential failures. This combination enables pharmaceutical companies to streamline operations while ensuring consistent quality and effective risk management, ultimately fostering a resilient manufacturing environment capable of meeting both regulatory standards and market demands.

2. Literature Review

In addressing waste problems in operational activities in the pharmaceutical industry, several previous studies have utilized the Lean Six Sigma approach. (Rahman et al., 2010) made efforts to minimize waste in the packaging process of cram product at company's laboratories. The research aimed at continuous improvement in the production process. In this study, the first step involved identifying nine types of waste using the E-DOWNTIME acronym, followed by measuring their sigma values. The factors causing waste were then analyzed using root cause analysis, and improvement suggestions were provided, including facility layout concepts. (Hasanah et al., 2020) applied lean manufacturing to enhance production outcomes and reduce lead time by identifying and working to reduce waste in a pharmaceutical company. The method involved calculating takt time in production activities to determine the ideal production time to meet consumer demand. Critical waste was identified using Failure Modes and Effects Analysis (FMEA) to calculate the Risk Priority Number (RPN), followed by providing several improvement suggestions.

FMEA itself is a helpful tool for analyzing factors influencing waste. Its use can help identify the root causes of waste that require primary attention. In a study by (Lakshmi et al., 2019), the identification of potential waste in the production process of liquid soap bottles was analyzed using FMEA to reduce the risk of production failure. The determination of critical components for waste management was based on the RPN value, calculated from detection, occurrence, and severity for each cause. FMEA serves as a forward-looking risk analysis tool used across various sectors to mitigate known or potential product failures. In the traditional FMEA model, the Risk Priority Number (RPN) is utilized to gauge the level of risk associated with each failure mode. This is computed by multiplying the crisp assessment values of three RPN elements (or risk elements), occurrence (O), severity (S), and detection (D) corresponding to the failure mode. A 10-point scale is employed to quantify the risk associated with each RPN element. A higher RPN score indicates a greater impact of the respective failure mode on the system (Ellianto et al., 2015). However, the conventional RPN method has been criticized for numerous inherent limitations that weaken its effectiveness (Huang et al., 2020).

Actions derived from FMEA analysis were then evaluated using a fuzzy approach to obtain a prioritized sequence of more critical interventions. Evaluating the RPN values from FMEA analysis using the fuzzy approach required input from stakeholders. (Catelani et al., 2018) initially presented a fuzzy logic-based FMEA approach for dealing with some of the drawbacks in the traditional method of strictly numerical evaluation. Another research conducted by (Bowles et al., 1995) proposed a fuzzy version of the technique for order preference by similarity to ideal solution (TOPSIS) to find risk priority ranking of the failure modes in FMEA. (Braglia et al., 2003) provided a comprehensive survey

of the improvement risk evaluation methods for FMEA. From the previous research it could be seen that the use of the fuzzy approach in FMEA can help improve the accuracy of risk assessments and also enable more complex risk evaluations (Sun et al., 2019). The risk values obtained from calculating factors in FMEA, represented by RPN, are transformed into fuzzy-RPN values using membership functions corresponding to the risk categories used. Membership functions are employed to convert risk values into a more understandable and representative form, enabling the determination of appropriate risk control measures. The result of the FMEA evaluation using the fuzzy approach is the fuzzy-RPN value, which is then ranked to obtain a prioritized sequence of improvement suggestions that are more objective and independent (Nilay et al., 2019).

3. Method

3.1. Data Collection

In the data collection stage, data on the company's current state is collected to identify problems with the focus object. In this stage, the genchi genbutsu method or direct observation employed to the focus object and engages in discussions with stakeholders involved in the production process.

3.2. Data Processing

In the data processing stage, a detailed and systematic depiction of the production process, Define stage, and Measure stage of the DMAIC methodology in Six Sigma is carried out. This stage includes the Define process to identify potential problems during the production process, identifying the flow of information and materials in the production process, mapping time and activities in the production process using Process Activity Mapping (PAM), and identifying waste in the production process based on the depictions of the production process and PAM. Subsequently, in the Measure stage, data processing and calculations are conducted to identify critical waste in the production process, followed by the calculation of sigma values for the detected critical waste.

3.3. Data Analysis and Interpretation

In the Analyze phase, this study will focus on identifying critical waste within the production process in the pharmaceutical industry. The process consists of several essential steps: initially, the root causes of critical waste will be determined using the Five Whys analysis method, which enables a comprehensive investigation of issues through a series of up to five iterative questions. Subsequently, a FMEA will be performed, informed by the findings from the Five Whys, and enhanced by incorporating a fuzzy logic approach to improve risk assessment accuracy. Fuzzy offers a more realistic framework compared to classical methods by handling imprecise data through mathematical data processing (Silva et al., 2014). To determine fuzzy numbers for each factor in FMEA the triangular fuzzy set is employed, the triangular fuzzy set method is utilized, refers from the framework established by (Wang et al., 2009). This approach adheres to a scale of 1 to 10, consistent with traditional FMEA metrics, allowing for seamless integration of qualitative assessments into quantitative analyses. For the severity factor, linguistic terms such as "none" to “very dangerous” are mapped to fuzzy sets, which represent the potential impact of issues on production processes. Similarly, for the occurrence factor, terms ranging from "never" to "very often" define the likelihood of an issue occurring, while the detection factor uses terms from "certain" to "not detectable" to evaluate the ease of identifying issues. Each fuzzy value is derived from a corresponding membership function that translates qualitative assessments into quantitative representations. Finally, fuzzy-RPN calculations aggregate these factors to prioritize improvement recommendations effectively.

In the Improve stage, optimal alternative improvement recommendations are formulated for implementation by the company. Each proposed alternative improvement recommendation is validated with stakeholders to obtain recommendations that align with the company's needs and conditions.

4. Results and Discussion

4.1. Process Activity Mapping

In designing PAM, the method used involves direct observation of each production process, documenting all activities occurring in each process. Subsequently, validation is carried out with stakeholders in each process to enhance the accuracy of the results. Each activity in the production process is classified into three categories: Value-Added (VA) activities, Essential but Non-Value Added (ENVA) activities, and Non-Value Added (NVA) activities. Additionally, each Based on the comprehensive analysis of the entire drug production process using PAM.

Table 1. Process Activity Mapping (PAM) Recapitulation

Activity					Classification Activity					
					VA		ENVA		NVA	
Activity	Number of Activity	Percentage	Time (minute)	Percentage of Activity Time	Activity Time (minute)	Activity Percentage	Activity Time (minute)	Activity Percentage	Activity Time (minute)	Activity Percentage
Operation	25	23%	5,370.34	62%	5,309.67	98%	0.67	0%	60.00	2%
Delay	27	24%	243.11	3%	20.08	0%	147.83	48%	75.20	3%
Transportation	46	41%	168.51	2%	16.49	0%	69.44	22%	82.58	3%
Storage	4	4%	2,700.00	31%	-	0%	-	0%	2,700.00	92%
Inspection	9	8%	165.25	2%	70.00	1%	91.25	30%	4.00	0%
Total	**111**	**100%**	**8,647.21**	**100%**	**5,416.24**		**309.19**		**2,921.78**	
Activity Classification Percentage					**63%**		**4%**		**34%**	

Based on the summary of PAM in Table 1, it can be observed that there are a total of 111 activities in the production process. The breakdown of activities reveals that VA activities last for 5.416 minutes, accounting for 63% of the total activities, ENVA activities last for 309 minutes, representing 4% of the total activities, and NVA activities last for 2,921 minutes, making up 34% of the total activities. When categorized by activity type, the percentages for each activity are as follows: 23% for operation activities, 24% for delay activities, 41% for transportation activities, 4% for storage activities, and 8% for inspection activities.

4.2. Critical Waste

The waste identification process obtained during field observations and PAM identification, a total of 37 activities were identified as causing waste based on the verification and validation process with stakeholders. Using the identified waste data, the next step is to determine critical waste in the drug production process. To determine critical waste, the genba shikumi is employed, consisting of four matrices: the waste matrix, correlation matrix, priority matrix, and absolute importance matrix.

Based on the waste matrix, it was found that the most prevalent types of waste are waiting, motion, and transportation. The primary cause of waiting waste is the staging process, such as staging in pre-production, pre-printing staging, and pre-packaging staging. The high occurrence of motion waste is attributed to numerous preparations in each process confirmed by workers, which can be reduced or even eliminated. Suboptimal production floor layout results in significant material and worker movements, contributing to the high occurrence of transportation waste. The second step in identifying critical waste is designing the correlation matrix. The correlation values between the identified observed problems will be summed up to form the correlation vector value. The third step in identifying critical waste is designing the priority matrix. In designing the priority matrix, observed problems, which are problems in the drug production process, can be identified for their relevance to Key Performance Indicators (KPIs) in the production process. The KPIs used encompass aspects of productivity, budget control, rework reduction, product availability realization, and reject rate reduction. These KPIs constitute the core of the Production Manager's KPIs provided by the General Production Manager. The values of the correlations between the identified observed problems and KPIs will be summed up to form the priority vector value.

From the priority matrix result, it can be determined that the highest priority vector value is associated with the observed problem related to improper machine setup in the printing process, which can lead to a high number of defective products. This is connected to all KPI values because defective products undergo rework, and if rework is not possible, they are rejected. Defective products also affect the realization of product availability and productivity rates, and all of these factors contribute to an increase in production costs. A similar situation occurs with the observed problem related to improper initial setup of the packaging machine, which can impact all KPI values.

The final step in identifying critical waste is designing the absolute importance matrix. In designing the priority matrix, the values of the waste vector, correlation vector, and priority vector will be summed up to generate the absolute importance vector value. Based on the absolute importance vector value, the severity level of each observed problem can be determined. The result of this absolute importance matrix is the ranking of observed problems based on their severity level, revealing which ones constitute critical waste in the production process. Table 2 shows the List of Observed Problems Identified as Critical Waste.

Table 2. List of Observed Problems Identified as Critical Waste

No	Observed Problems	Vector of Absolute Interest
1	Setting the initial packaging machine incorrectly can cause defects in the product and packaging	10
2	Storing raw materials in the staging area to wait for production	8
3	Store the VAT barrel containing bulk Drug X in the staging room to wait for its turn to be printed	8
4	Setting the printing machine incorrectly can cause defects in the product	8
5	Waiting for the arrival of raw material shipments from the raw material warehouse	8

4.3. Calculation of Sigma Value for Critical Waste

After identifying critical waste based on the ranking of the absolute importance matrix, the next step is to calculate the sigma value for critical waste. The purpose of calculating the sigma value for critical waste is to assess the performance of the existing conditions in the production process. Table 3 show the critical waste in the production process based on muda matrix.

Table 3. Critical Waste in the Production Process Based on Muda Matrix

Observed Problems	Waste
Performing an initial setup of the packaging machine that is not appropriate can result in defects in the product and its packaging	. Waiting . Defect
Storing raw materials in the staging area to await their turn in production	. Waiting
Storing VAT barrels containing the input of the drug in the staging area, waiting for the printing turn	. Waiting
Performing an improper setup of the printing machine can result in defects in the product	. Waiting . Defect
Waiting for the arrival of raw material shipments from the raw material warehouse	. Motion . Waiting

4.3.1. Waste Waiting

Waste waiting is the primary critical waste that occurs in the drug production process based on genba shikumi results. Based on direct observation and discussions in the field, the majority of waiting waste occurs in the staging process, making the Critical-to-Quality (CTQ) for waiting waste the total staging time generated during the drug production process. Table 4 shows the calculation of the sigma value for Waste waiting. Based on Table 4, it is known that waiting waste has a sigma value of 1.98. The total staging time of 2730 minutes is considered to have a significant impact on the overall

production process time, which can lead to schedule delays and failure to meet the target demand. Therefore, an improvement in the sigma value for waiting waste is necessary.

Table 4. Sigma Value for Waste Waiting

Step	Action	Result	Unit
1	The production process	Production Process Time	
2	Total availability time	8647.21	Minute
3	Total staging time	2730	Minute
4	Calculate the failure rate	0.315708766	Proportion
5	Number of CTQs	1	
6	Probability of failure rate per CTQ	0.315708766	DPO
7	Calculating DPMO	315708.7662	DPMO
8	**Convert DPMO to sigma value**	**1.98**	**Sigma**

4.3.2. Waste Defect

Defect waste is the second most critical waste that occurs in the drug production process based on the genba shikumi results. The total calculated defects are primary packaging defects, specifically strips containing the drug. Based on Table 5, it is known that there are seven Critical to Quality (CTQ) factors for defect waste, with a total of 172,490 defective strips during the year 2022. The sigma value for defect waste is already relatively high. Pharmaceutical industry companies aim to achieve zero defects. Therefore, improving the quality of the production process is crucial to reaching this target.

Table 5. Sigma Value for Waste Defect

Step	Action	Result	Unit
1	The production process	Defect product	
2	Total availability time	61,600,000	Minute
3	Total defect product	172,490	Minute
4	Calculate the failure rate	0.0028	Proportion
5	Number of CTQs	7	
6	Probability of failure rate per CTQ	0.0004	DPO
7	Calculating DPMO	400.023	DPMO
8	**Convert DPMO to sigma value**	**4.85**	**Sigma**

4.3.3. Waste Motion

Waste motion is a wasteful activity of workers that adds little or no value to the production process. This motion waste can impact the high lead time of the process, making the CTQ for waste motion the total NVA time in the production process. Table 6 shows the calculation of the sigma value for waste motion. The result of the sigma value for waste motion still needs improvement, which can be achieved by making enhancements to reduce NVA in the production process.

Table 6. Sigma Value for Waste Motion

Step	Action	Result	Unit
1	The production process	Production process	
2	Total availability time	8647.21	Strip
3	Total NVA time	2929.78	Strip
4	Calculate the failure rate	0.3388	Proportion
5	Number of CTQs	1	
6	Probability of failure rate per CTQ	0.3388	DPO
7	Calculating DPMO	338812.2	DPMO
8	**Convert DPMO to sigma value**	**1.92**	**Sigma**

4.4. Failure Modes and Effects Analysis (FMEA)

The analysis phase involve analyzing the root cause of critical waste using the five whys analysis method. Subsequently, analyzing critical waste based on the results of the five whys analysis using Failure Modes and Effects Analysis (FMEA) to determine the Risk Priority Number (RPN), which is then evaluated using a fuzzy approach.

The identification process of the main root causes of critical waste that have been identified, further analysis will be conducted to determine the values of severity, occurrence, and detection factors. The values of these three factors are obtained from interviews and discussions with the Production Manager. The values of each failure factor are then multiplied to generate the Risk Priority Number (RPN). To identify the values of severity, occurrence, and detection factors, it is necessary to establish criteria standards. Criteria standards for the three factors, severity, occurrence, and detection, are obtained based on discussions with several respondents directly involved in the production process. Based on the analysis of the 20 problems using the 5 Whys method, RPN values were obtained for each problem, and RPN scores above 70 were selected. Consequently, a total of 6 problems were identified, as indicated in Table 7.

Table 7. Problems with The Highest RPN Scores

Problem Code	Problems	S	O	D	Risk Priority Number
R7	The number of machines for the granulation to lubrication process is still insufficient	4	6	5	120
R12	The number of packaging machines is still insufficient	4	6	5	120
R8	The number of workers is less	3	6	5	90
R10	The printing process for other products is ahead of schedule	7	3	4	84
R14	The human error factor from the operator when printing samples to be submitted to IPC	8	2	5	80
R9	Based on CPOB, a pharmaceutical product must not be contaminated with product contents other pharmacies	7	5	2	70

4.5. Fuzzy-FMEA

In determining the fuzzy numbers for the importance weights of all factors, a set of fuzzy numbers is used, employing a scale from 0 to 1. Subsequently, linguistic scales defined as very low, low, moderate, high, and very high are utilized. The references used in determining the degree of membership in the fuzzy set are based on research conducted by (Wang et al., 2009). Next, aggregation calculations of fuzzy number assessments for each factor in FMEA are conducted. The aim is to combine all membership degrees so that the output will be a number that changes linearly with respect to the input variables. Equations (1), equation (2), and equation (3) illustrate the formulas used to perform the aggregation calculations of fuzzy number assessments for severity, occurrence, and detection factors.

$$R_1^S = \frac{1}{n}\sum_{j=1}^{m} h_j R_{ij}^S = \left(\sum_{j=1} h_j R_{ijL}^S, \sum_{j=1} h_j R_{ijM}^S, \sum_{j=1} h_j R_{ijU}^S\right) \quad (1)$$

$$R_1^O = \frac{1}{n}\sum_{j=1}^{m} h_j R_{ij}^O = \left(\sum_{j=1} h_j R_{ijL}^O, \sum_{j=1} h_j R_{ijM1}^O, \sum_{j=1} h_j R_{ijM2}^O, \sum_{j=1} h_j R_{1jU}^O\right) \quad (2)$$

$$R_i^D = \frac{1}{n}\sum_{j=1}^{m} h_j R_{ij}^D = \left(\sum_{j=1} h_j R_{ijL}^D, \sum_{j=1} h_j R_{ijM}^D, \sum_{j=1} h_j R_{1jU}^D\right) \quad (3)$$

Where, R is set of fuzzy numbers for each risk on factors S, O, D. Then, h is relative importance weight of each evaluator, i is risk 1, risk 2, etc. (i = 1, 2... n), and j is evaluator 1, evaluator 2, etc. (j = 1, 2..., m).

4.5.1. Aggregation of Fuzzy Number Assessments for Each Problem

Based on the RPN ranking from FMEA, aggregation of fuzzy number assessments for each problem on severity, occurrence, and detection factors is conducted to form a set of fuzzy numbers.

Subsequently, fuzzy number assessments are made using (1) for problems on severity factors, (2) for problems on occurrence factors, and (3) for problems on detection factors. For example, the calculation of the occurrence fuzzy number value for an problem with code R1 is obtained as follows.

$$R_1^0 = \frac{1}{4}(1 + 2 + 3 + 4)$$

$$R_1^0 = 2.5$$

The R1 problem has an occurrence value of 2, the fuzzy number set used to calculate the R value for problems on the occurrence factor is {1, 2, 3, 4}. These membership degrees will serve as input in the calculation formula.

4.5.2. Aggregation of Importance Weights for Each Factor in FMEA

After aggregating fuzzy number assessments for each problem, the next step is to aggregate the importance weights for each factor in FMEA, namely severity, occurrence, and detection factors. Subsequently, importance weights for each factor are assessed using (4) for severity, (5) for occurrence, and (6) for detection factors. From these assessments, the weights for each factor are then averaged to determine their percentages.

$$W_1^S = \frac{1}{n}\sum_{j=1}^{m} h_j W_{ij}^S = (\sum_{j=1} h_j W_{ijL}^S, \sum_{j=1} h_j W_{ijM}^S, \sum_{j=1} h_j W_{ijU}^S) \quad (4)$$

$$W_1^O = \frac{1}{n}\sum_{j=1}^{m} h_j W_{ij}^O = (\sum_{j=1} h_j W_{ijL}^O, \sum_{j=1} h_j W_{ijM}^O, \sum_{j=1} h_j W_{ijU}^O) \quad (5)$$

$$W_1^D = \frac{1}{n}\sum_{j=1}^{m} h_j W_{ij}^D = (\sum_{j=1} h_j W_{ijL}^D, \sum_{j=1} h_j W_{ijM}^D, \sum_{j=1} h_j W_{ijU}^D) \quad (6)$$

Where, W is set of importance weights for factors S, O, D. Then, h is relative importance weight of each evaluator, i is risk 1, risk 2, etc. (i = 1, 2... n), and j is evaluator 1, evaluator 2, etc. (j = 1, 2..., m). For example, the calculation of the W detection for the problem with code R1 is obtained from the following calculation.

$$W_1^D = \frac{1}{3}(0.25 + 0.5 + 0.75)$$

$$W_1^D = 0.5$$

The R1 problem has a detection value of 5, the fuzzy number set used to calculate the W value for the problem's weight on the detection factor is {0.25, 0.5, 0.75}. After obtaining all the weight values for the problems on the three factors, the average weight for each factor can be determined. The severity factor has an average weight of 0.38333 or 39.83% of all factors, the occurrence factor has an average weight of 0.23333 or 24.24% of all factors, and the detection factor has an average weight of 0.34582 or 35.93% of all factors.

4.2.1. Calculation of Fuzzy-RPN

The next stage involves calculating the fuzzy-RPN value. The values used in the fuzzy-RPN calculation are derived from the aggregation calculation results of fuzzy number assessments for each problem and the aggregation calculation results of importance weights for each factor in FMEA. Equation 7 depicts the formula utilized in performing the fuzzy-RPN calculation.

$$FRPN_i = R_i^{S\frac{w^S}{w^S+w^O+w^D}} \times R_i^{O\frac{w^O}{w^S+w^O+w^D}} \times R_i^{D\frac{w^D}{w^S+w^O+w^D}} \quad (7)$$

An example calculation of the fuzzy-RPN value for the R1 problem is obtained from the following calculation. The highest ranking of Fuzzy-RPN is obtained based on Table 8.

$$FRPN_1 = 5^{\frac{0,38333}{0,38333+0,23333+0,34582}} \times 2.5^{\frac{0,23333}{0,38333+0,23333+0,34582}} \times 5^{\frac{0,34582}{0,38333+0,23333+0,34582}}$$

Table 8. Problems with The Highest Fuzzy-RPN Scores

Problem Code	Problems	Average Importance Weight S	Average Importance Weight O	Average Importance Weight D	FRPN
R14	The human error factor from the operator when printing samples to be submitted to IPC	2.29	1.25	1.78	5.10
R2	The operator forgot to calibrate the packaging machine every two weeks	2.29	1.07	1.90	4.68
R7	The number of machines for the granulation to lubrication process is still insufficient	1.74	1.48	1.78	4.57
R12	The number of packaging machines is still insufficient	1.74	1.48	1.78	4.56
R10	The printing process for other products is ahead of schedule	2.17	1.25	1.65	4.46
R1	There is no standard procedure for operating the packaging machine settings	1.90	1.25	1.78	4.23

4.6. Comparison of the Highest Score Values of RPN FMEA and Fuzzy-RPN

Based on the calculation results of FMEA RPN and Fuzzy-RPN, the composition of the top-ranking problems in FMEA and the results of the fuzzy-RPN evaluation did not change significantly. However, problems with codes R8 and R9, which previously occupied the fourth and fifth positions in FMEA, did not appear in the rankings of the fuzzy-RPN evaluation. These two problems were replaced by problems with codes R2 and R1. This could occur because in the RPN evaluation using the fuzzy method, there is weighting for each severity, occurrence, and detection factor. For the weighting calculation results for each factor, it is known that the weight value for the severity factor is 0.38333, for the occurrence factor is 0.23333, and for the detection factor is 0.34583. The severity factor has a higher weight than the other factors, the weight of the detection factor is also not significantly lower compared to the severity factor, and the occurrence factor has the lowest weight among the other factors.

Furthermore, based on the FMEA analysis results, it is known that the R1 problem has a severity value of 5, an occurrence value of 2, and a detection value of 5. It is the moderate yet relatively high severity and detection values that make the R1 problem have a high fuzzy-RPN value. Meanwhile, for the R2 problem, which has a severity value of 8, an occurrence value of 1, and a detection value of 6, it is the severity value of 8 that makes the R2 problem has a high fuzzy-RPN value. After conducted the validation results from the production manager, the fuzzy-RPN rankings are then used as the basis for designing alternative improvement suggestions in the subsequent sections. According to the validation process with the production manager, the fuzzy-RPN ranking resulting from the RPN evaluation using fuzzy methods are more necessary for the company to initiate improvement efforts.

4.7. Improvement

Alternative improvement suggestions can be determined for future implementation by the manufacturing company. Based on the suggestions for the top six problems shown in Table 9, each reason in determining improvement recommendations is explained. In R14 and R2, the configuration applied to the printing machine for tablet printing process is influenced by the analysis results conducted by the IPC on the condition of the product feed from granulation to lubrication processes.

Each product batch has slightly different conditions, thus the machine must adjust its speed and compression force to ensure the final product feed in the form of tablets does not experience defects. Inaccurate sampling activities for submission to the IPC may lead to errors in the IPC's analysis of the product feed from a batch, thus affecting the duration of the printing machine operation. To address problems R14 and R2, the implementation of a quality form can be applied. Implementing machine calibration activity documentation cards can also assist in controlling the details of calibration actions on the machine. Documentation is performed after the operator performs machine calibration activities by filling out the machine calibration documentation card and reporting it to the supervisor or assistant manager.

Table 9. Improvement Suggestions

Problem Code	Problems	Suggestions
R14	The human error factor from the operator when printing samples to be submitted to IPC	Designing quality forms for raw products before printing and inspection forms for the printing process.
R2	The operator forgot to calibrate the packaging machine every two weeks	Documenting calibration results on the inspection form and on the board in front of the machine room
R7	The number of machines for the granulation to lubrication process is still insufficient	Analysis and calculation of the utilization of granulation to lubrication machines to determine the necessity of current machine investment
R12	The number of packaging machines is still insufficient	Analysis and calculation of the utilization of printing machines to determine the necessity of current machine investment
R10	The printing process for other products is ahead of schedule	Comprehensive adjustment of production schedules by implementing the Shortest Processing Time (SPT) scheduling method
R1	There is no standard procedure for operating the packaging machine settings	Designing an orthogonal array experiment to determine optimal settings on the packaging machine.

Alternative improvement suggestions that can be provided for R7 and R12 involve investing in machines for the granulation to lubrication process to reduce production queues for R7 problem and investing in printing machines for R12 problem. However, in determining the appropriate alternative improvement suggestions to be implemented by the company, there are several crucial factors to consider. The existing production space conditions, which are already quite full, make decisions to invest in additional machines need to be carefully considered. Additionally, the considerable investment value also greatly influences the decision to add machines. To determine the decision to invest in machines, analysis and calculation of machine utilities are required to understand the existing conditions of the machinery owned by the company.

For R10 problem, scheduling of the printing process is conducted to plan and control schedules while considering resource allocation and existing resource capacity. In determining the most optimal printing process scheduling, there are several objective criteria that need to be considered, namely reducing completion time and customer waiting time. The method that can be applied is using the Shortest Processing Time (SPT) scheduling method.

Lastly, for R1 problem, in operating the packaging machine, initial setting errors by the operator can result in defects in the strip and tablet products. Defects in products that can occur from errors in machine packaging settings include leaking strips, overlapping aluminum foil pieces, and tablets in aluminum foil that are not intact, double, wrinkled, and empty. Alternative improvement suggestions that can be provided are by implementing orthogonal array experiments to determine optimal settings on the packaging machine. Orthogonal array is a method in the Taguchi concept used to design experiments efficiently with the aim of obtaining maximum information about all factors affecting a parameter, but with minimal number of experiments required.

This research implements the studies of (Kumru et al., 2013) that applied Fuzzy FMEA in public hospitals, and (Nilay et al., 2019) that utilized the method in pharmaceutical quality control, showcasing the adaptability of Fuzzy FMEA across different sectors. Additionally, it aligns with (Lakshmi et al., 2019) and (Hasanah et al., 2020) that emphasized the integration between Lean and FMEA in reducing waste and improving efficiency in the pharmaceutical industry. By integrating these approaches, this study not only confirms earlier findings but also provides new insights for improving production processes through a clearer risk evaluation framework, significantly contributing to the field of operational excellence.

5. Conclusion

Based on the comprehensive analysis of the entire production process using PAM, it was revealed that VA activities contribute about 63% of total production activities, while NVA and ENVA activities contribute approximately 34% and 4%, respectively. NVA activities were identified as the main sources of waste in the production process. A total of 37 waste-causing activities were identified, with 33 classifieds as NVA, 1 as ENVA, and 3 additional activities identified through discussions with Production Managers. Subsequently, through further identification using the genba shikumi method, five critical waste-causing activities were determined: inadequate machine packaging setting standards, operator oversight in machine calibration, low machine count in granulation and lubrication processes, insufficient packaging machinery, and delays in raw material delivery. These were ranked based on their fuzzy-RPN values, with the highest-ranked being human error during sample printing (R14), followed by other identified problems. This research has significant practical implications for the pharmaceutical industry by providing a structured approach to identifying and mitigating waste in production processes. Other companies can apply these findings by adopting the Lean and Fuzzy FMEA framework to analyze their own operations, which will help them to identified non-value-added activities and improve efficiency by prioritizing the most critical issues based on their weighted importance. Future research could explore the application of the Fuzzy FMEA framework in other industries, both manufacture and service industries. Additionally, studies could investigate how this approach performs under varying conditions, such as different production scales or technological advancements. Research could also focus on longitudinal studies that track the long-term impacts of implementing the proposed improvements on operational efficiency and financial performance.

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