Improvement of DEET level of product X using Deming cycle (PDCA Method) in PT Z

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Abstract. DEET is a complex compound that is used as an active ingredient in the manufacture of insect repellent products. PT Z is one of the sub-contracting companies that manufacture mosquito coils from PT XYZ with product X. PT Z received complaints from PT XYZ claiming that DEET levels in a tested batch were below the specified specifications. PT Z needs to conduct an internal assessment and investigation to find the cause of the release of DEET levels from the specification range. The research was carried out with a Deming cycle, namely the sub-stage PDCA method. Based on the results of the investigation, the decrease in DEET levels is caused by the inhomogeneity of DEET because the mixing process is only done in 5 minutes, so it is necessary to optimize the mixing time. Both parties have agreed on corrective and preventive actions in the form of a re-validation process by determining the best mixing time, which is 20 minutes, which produces a DEET level of 32.58%. Validation is carried out for three consecutive batches with all batches showing DEET results that meet the specified product specifications.

Keywords: DEET, Deming Cycle, PDCA, customer

1. Introduction
Customers are the essential elements of every line of business. Customers are also a determining factor for the existence of a company. It is from customers that the source of the company's revenue comes from. The more customers, the more income opportunities are obtained. The more the frequency of purchases, the more opportunities for increased income. Customer satisfaction is one crucial factor that must be considered by the company because customers are the reason why a company exists and operates. According to Philip Kotler and Kevin Lane Keller [1], customer satisfaction is a feeling of pleasure or disappointment someone who appears after comparing the performance (results) of products thought to the expected performance. If the benefits provided exceed consumer expectations, consumers would feel satisfied, while vice versa, if less than expectations, they will feel disappointed. With a high level of satisfaction, it will further increase consumer loyalty to the company/product. Older consumers can be maintained and more often make repeat purchases (repeat buying) on these products. The selection of the best marketing strategy is a decision-making process with various criteria involving many criteria and alternatives, one of the criteria being taken into consideration is customer loyalty [2]. In the manufacturing world, of course, customer satisfaction with the output produced is the main thing...
that is maintained. Product reputation in the market must be maintained as well as possible to maintain consumer loyalty. A brand owner can hold subcontractors to take part in manufacturing the product, both the entire process and only part of the process. The contact provider company must ensure that the contract recipient company consistently produces quality products to retail consumers, and all complaints can be resolved and resolved.

DEET or diethyltoluamide is the most common active ingredient in insect repellents. Applied to skin or clothing and protects against mosquitoes and various other insects [3]. DEET concentrations in products can range from less than (<) 10% to almost 100%. A concentration of 10% to 30% percent is recommended for infants and children. DEET should not be used in children under two months [4]. DEET is often sold and used in sprays or lotions in concentrations of up to 100%. The Consumer Report found a direct correlation between DEET concentration and hours of protection against insect bites. 100% DEET was found to offer protection for up to 12 hours, while some low concentration DEET formulations (20% - 34%) offered 3-6 hours protection [5].

In 2020, PT Z as a sub-contractor received a complaint from PT XYZ stating that the DEET levels in one of the X product batches showed the laboratory testing results below the Lower Specification Limit. Therefore, it is necessary to conduct a collaborative investigation to remedy the problem. The investigation is carried out with a Deming cycle, namely the PDCA (Plan-Do-Check-Act) method. PDCA (Plan, Do Check, Act) is a four-step problem-solving process commonly used in quality control [6]. In its development, the PDCA analysis methodology is more often referred to as the "Deming cycle." This is caused because Deming is a person who popularized its use and implemented its application. The stages in the PDCA cycle are developing a plan (plan), carrying out a plan (do), checking the results achieved (check), and taking action (action) [7]. By conducting this research, it is expected that the Company can reduce/avoid the cost of replacing X batches of failed products from PT XYZ in the future and reduce the number of complaints substantially from PT XYZ.

2. Methodology

This type of research is a case study where the research is carried out on product X to see the cause of the decrease in DEET levels based on the collection of relevant data and efforts that must be made to correct the problem. The place of research was conducted at PT Z in a personal care facility. The purpose of the research phase is to formulate steps to be carried out in the implementation of this case study. These steps include data collection, problem-solving analysis, and implementation/improvement efforts. Planning stages can be seen in the Figure 1.
2.1 Data type

2.1.1 Primary data
Primary data in this study were obtained directly from the field through direct observation.

2.1.2 Secondary data
Secondary data is supporting data from primary data that is data or sources obtained from reading material. Secondary data in this study were obtained from company data, namely: Product Specifications X, MSDS material formulation, MMI, product X documents, as well as company Work Procedures and Instructions. Besides that, from reference books and other information related to research.
2.2 Data processing and analysis methods

2.2.1 Problem root investigation
Finding the root cause of the problem in this case study is the five-step RCA (a method that integrates Fish Bone Analysis, and five whys analysis). The five-step RCA is a useful tool for problem-solving by identifying the root cause of a problem clearly and systematically.

2.2.2 Determination of Corrective Action & Preventive Action
The determination of improvement is based on the CAPA taken. Corrective action is an action to eliminate the cause of a discrepancy and prevent repetition. Preventive action is an action to eliminate the cause of the non-conformity, so it does not occur.

2.2.3 Evaluation of improvement results
The completed CAPA must be monitored for the effectiveness of the CAPA. Monitoring is carried out to determine whether the CAPA does solve the problems that occur or not. The success of CAPA effectiveness is determined by several crucial factors, including:
• Compliance with the root of the problem specified
• CAPA conformity taken under RCA
• Understanding of personnel implementing the approved CAPA
• Processes that are reviewed are based on effectiveness checks carried out

2.2.4 Evaluation of Improvement Results
The outcome of implementing improvements in the manufacturing process is achieving PT XYZ’s customer satisfaction with the services provided by PT Z in overcoming problems identified in product X related to DEET levels.

3. Result and discussion
3.1 Problem investigation & determination of root problems
The investigation is carried out by looking at all available secondary data. Based on the assessment of product specifications X, DEET content for product X has a DEET Lower Specification value of 14.25% and a DEET Upper Specification value of 15.75%. The assessment is also carried out on the production process of product X compared with the customer’s dossier. The customer dossier does not specify the mixing time and is determined based on the validation process. The results of the first process validation concluded the mixing time was 5 minutes in the DEET stage in Ethanol. Table 1 shows the ongoing production process.

| No. | Description |
|-----|-------------|
| 1   | Transfer Ethanol into the Main Mixing Tank according to the formulation |
| 2   | Transfer the DEET material in the Main Mixing Tank according to the formulation & mix the Ethanol Material with DEET for 5 minutes |
| 3   | Add Takasago material according to the formulation |
| 4   | Perform additional mixing for 5 minutes |
| 5   | Add demin water according to the formulation while the main mixer tank’s mixing blade is turned on |
| 6   | Mix until homogeneous for 30 minutes |
Based on the results of investigations conducted, it was determined internally and the customer that the primary root cause of the decrease in DEET levels was short mixing time to homogenize DEET in Ethanol, which was only 5 minutes.

### 3.2 Problem Investigation and Problem Root Determination

Corrective & Solution Measures (CAPA) taken are repeating the validation of the manufacturing process and optimizing the timing of mixing DEET material in ethanol to achieve the appropriate homogeneity. The mixing time in this validation is planned to take 30 minutes. Sampling was carried out from the main mixer tank at specified intervals, namely minutes 10, 15, 20, and 30, when the DEET mixing stage was in ethanol. The implementation of the action was carried out on February 21, 2020, which was attended by representatives of PT XYZ and PT X. Table 2 shows the results of the recapitulation of the data validation of the process.

**Table 2. Recapitulation of Revalidation Data & Determination of the Time of Mixing DEET in Ethanol**

| No | Production process                                                                 | Batch Re-Validation | Batch Number 240201 |
|----|-------------------------------------------------------------------------------------|---------------------|---------------------|
|    |                                                                                     | Begin the Process   | End of Process      | Processing Time | DEET levels    |
| 1  | Transfer Ethanol into the Main Mixing Tank according to the Formulation             | 10:16               | 10:22               | 6 min           | No sampling    |
| 2  | Transfer the DEET Material in the Main Mixing Tank according to the Formulation & Mix the Ethanol Material with DEET for 30 minutes | 10:25               | 10:35               | 10 min*         | 28.82%         |
|    |                                                                                     | 10:25               | 10:40               | 15 min*         | 30.14%         |
|    |                                                                                     | 10:25               | 10:45               | 20 min*         | 32.58%         |
|    |                                                                                     | 10:25               | 11:55               | 30 min*         | 31.60%         |
| 3  | Add Takasago Material according to the Formulation                                 | 11:06               | 11:09               | 3 min           | No sampling    |
| 4  | Do additional mixing for 5 minutes                                                   | 11:09               | 11:14               | 5 min           | No sampling    |
| 5  | Add the Demin Water according to the Formulation while the Mixing Blade of the Main Mixer Tank is turned on | 11:21               | 11:42               | 21 min          | No sampling    |
| 6  | Mix until homogeneous for 30 minutes                                                 | 11:42               | 11:50               | 8 min*          | 14.61%         |
|    |                                                                                     | 11:42               | 12:00               | 18 min*         | 14.52%         |

*: Sampling Taken

Based on the re-validation data obtained, the best mixing time for the transfer and mixing of DEET material into ethanol is 20 minutes, with a yield of 32.58%. Determination of the best time is to see the factor of high levels of DEET obtained. DEET material transfer in ethanol and its mixing process is a critical process parameter (Critical Process Parameter) in making product X, so many things must be considered, namely:

- Material transfer into the mixing tank is carried out slowly together with stirring activities using a mixing blade mixer.
- The DEET material weighing container is rinsed with the remaining demin water to ensure all DEET material is completely dissolved.
3.3 Output Evaluation Results
Based on three batches (No, batch 240201, 24020202, 24020303) that have been manufactured from February 21, 2020, to February 25, 2020, the DEET content results meet the requirements of the specification with detailed data can be seen in the Table 3.

| Batch 24020101 | Batch 24020202 | Batch 24020303 |
|----------------|----------------|----------------|
| Sampling Time  | Test result    | Sampling Time  | Test result    | Sampling Time  | Test result    |
| 13:10          | 14.52%         | 17:56          | 14.69%         | 10:45          | 14.31%         |

Figure 2. Product Testing Graph with DEET Parameters Using GC-MS

The test was carried out at the PT XYZ customer laboratory due to the limited equipment owned by PT Z. The test was carried out using the Gas Chromatography-Mass Spectrometry (GC-MS) instrument as shown in the Figure 2. The GC / MS instrument separates chemical compounds (GC analyte) and identifies analytes at the molecular level (referred to as MS). GC-MS is one of the most accurate testing instruments for analyzing product X samples to determine DEET levels. GC works on the principle that compound compounds will separate into individual substances when heated to a specific temperature. The heated gas has flowed through the column with a mobile phase in the form of inert gas (such as helium, nitrogen, etc.). When a separate substance comes out of the column opening, it will flow into MS. MS can identify compounds with molecular mass analytes.

3.4 Output Evaluation Results
PT XYZ has responded to improvements in the manufacturing process for product X. PT Z has achieved customer satisfaction with service as a sub-contractor provided in terms of product quality and can make improvements to the manufacturing process. In this case, PT XYZ will make changes to the mixing time, which was initially 5 minutes to 20 minutes in product X dossier.

4. Conclusion
End-to-end processes have been reviewed in the manufacturing process of product X at PT Z, which can affect DEET levels. Based on the analysis of the problem and the investigation of the root of the problem that has been done, it can be determined that the low levels of DEET in product X are caused by the less mixing time of ethanol material with DEET. CAPA carried out internally by PT Z is to re-validate the process by seeing the most optimum mixing time to
homogenize the ethanol material with DEET. The output evaluation results show a correlation between the time of mixing DEET material in ethanol. Three batches have been tested in succession with Batch 240201 with DEET of 14.52%, Batch 240202 with DEET of 14.69%, and Batch 240203 of 14.31%. The outcome of the improvement of this problem is that PT XYZ expressed satisfaction with the services provided by PT Z regarding problem solving and improvements in the manufacturing process of product X.

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