Analysis of Quality Improvement of Herbal Medicine Products from Microbial Contaminants Using the PDCA Method with the QCC Approach

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Abstract: This research aims to analyse the quality improvement of herbal medicine from microbial contaminants. There are 2 types of microbial contamination found in many traditional drinks, namely: bacteria (TPN) and fungi (AKK). Therefore, it is necessary to improve the quality and process of herbal medicine using the PDCA method. QCC approach is conducted in one of the herbal medicine producers in Indonesia. Through these improvements, the results of a significant reduction in microbial contamination in the powdered herbal products are obtained. ALT values before repair were 15 x 103 col/g and AKK 5.6 x102 col/g to 5.58 x 103 col/g for ALT and 0.9 x102 col/g for AKK after repair.

Keywords: Quality, PDCA, microbial contamination

1. Introduction

The pharmaceutical and cosmetic industries, including the traditional medicine industry, are one of the mainstay sectors because they are the main drivers of the economy in the future in Indonesia. In Indonesia alone there are 986 herbal medicine industries from 102 traditional drug industries and the rest are included in traditional medicine small businesses.

There are problems that often arise in the processing of traditional medicines, namely contamination. In general, the meaning of contamination is the placement of material that is not important in a person's body, environment, food or other ingredients and according to world health organizations, contamination can be caused by chemicals, biological or radio nuclear [1]. One of row materials that often researched to avoid contamination is water. Several studies on groundwater in densely populated areas and industries have been carried out [2-12]. This is very important to avoid contamination of home-industries of herbal products. The microbial problem in drinks is divided into two groups, namely: Products have general organism growth or contamination resulting in decay and products experiencing pathogenic contamination in production so that the product becomes toxic [13].

In this study, we will discuss the improvement and control of the quality of herbal powder products as one of the traditional drinks in order to reduce microbial contamination according to the standard limits allowed by the Indonesian National Standard (SNI). Quality control is needed here as an effort to improve and maintain products in accordance with predetermined product specifications [14]. The method used in this study uses the PDCA method (Plan, Do, Check and Action), using the PDCA method that is able to systemize continuous action within an industry [15, 16]. To make quality improvements effective, the Quality Control Circle (QCC) approach is also used. QCC is more effective in improving quality because the process of implementing repairs can be done directly by the operator concerned so that it can reduce the cause of the decline in quality (defect) and increase improvement significantly [17-19].

2. Research Methodology

2.1. Data Collection and Processing

At this stage, the method used in this study is using PDCA with QCC (Quality Control Circle) by applying 8 steps, namely [20]:

1. Looking for the main problem using a check sheet
2. Discussion of the causes of microbial contamination: finding the position of the cause of the increase in microbes in the product.
3. Looking for causes: analyze the causes by using fishbone diagrams fishbone diagrams. Fishbone diagrams to specify and find the root causes of the problems of each factor -4 M (man, method, material, machine) +1 E (environment).
5. Improvement plan (countermeasure plan: existing improvement plan using problem solving goals with 5W + 1H (What, When, Where, Who, Why and How) is an investigation and research on problems that occur in the production process.
6. Improvements: Improvement plans that have been made, then implemented and analyzed accurately whether they can solve the problems that have been determined
7. Examine results
8. Carry out standardization
3. Data Collection and Processing

Data Collection

Data collection by observing the results of microbial contamination seen from the Total Plate Number (ALT), namely for bacteria and the Fungal Fungus (AKK) number, which is for mushrooms. There are 7 types of product types of herbal medicine powder preparations, namely: MP, HFS 1g, NTPS, KHS, WKP, SHP, and PLP. Sampling is taken from several processes along with a picture of the flow of the production process and sampling.

From several sampling, it was found that microbial contamination had the greatest effect and there was a significant increase in contamination during the Steam process.

![Flowchart of production process](image)

Source: observation of production flow

**Figure 1**: Production Process Flow

Obtained contamination results in the Steam process contamination has occurred that is large enough to affect the final product. Data contamination is as follows:

1. Total Plate Number (ALT) Data

Tests are carried out and taken in January - February 2019. Tests were carried out in 17 times sample testing in 1 month.

Obtained from the test results according to the limits of the Indonesian National Standard (SNI) [21, 22], for traditional beverage powder the maximum plate number value of the maximum limit is allowed is $3 \times 10^3$ colonies / g from the table above almost all products of the total plate value are still under SNI allow mainly products from NTPS with an average value of product contamination in January of $5.61 \times 10^2$ col/g and in February of $5.67 \times 10^2$ col/g.

2. Numbers of Yeast Mushroom (AKK) data

The test results according to the limits of the Indonesian National Standard (SNI) for traditional beverage powder the maximum permissible mold yeast value is $1 \times 10^2$ colonies / g from the table above almost all products of the total Plate value values are still under allowed SNI, seen from the table above the products from NTPS which are the most dominant with an average value of product contamination in January of $5.61 \times 10^2$ col/g and in February of $5.67 \times 10^2$ col/g.

Data processing

A. Stage of Planning

In the process of collecting data, the results are 7 types of herbal products that have the highest levels of microbial contamination in NTPS type products. At this stage an analysis of the causes of microbial contamination will be carried out.

Analysis of causes

At this stage all the drying factors are evident if the problem is explained by five factors: machine, material, method, human and environment besides sterilization from method factors but there are other factors that cause contamination. Can be seen from the fishbone diagram below:
Figure 2: Fishbone diagram

In order to be more clearly visible at the root of the problem, Root Cause is done with a 5Why analysis

<table>
<thead>
<tr>
<th>Main Problem</th>
<th>Factors</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Low of operating time during production</td>
<td>The operating time is not enough</td>
<td>Increase the operating time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance</td>
<td>Poor of personnel attitude</td>
<td>The attitude of personnel is not good</td>
<td>Improve the personnel attitude</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td>Material is not stable</td>
<td>The material is not in a good state</td>
<td>Replace the material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>Utilization method is not effective</td>
<td>The method is not effective</td>
<td>Change the method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevention</td>
<td>Does not prevent microbial contamination</td>
<td>Microbiological contamination is not prevented</td>
<td>Prevent microbial contamination</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prevention Plan**

The mitigation plan will be carried out to reduce microbial contamination based on Root Cause analysis.

**Table 2: Reconstruction or repair plan**

<table>
<thead>
<tr>
<th>Factors</th>
<th>Before Improvement</th>
<th>After Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Man</td>
<td>Operators do not use gloves and special clothing</td>
<td>Operators use standard production clothing and gloves</td>
</tr>
<tr>
<td>Workers</td>
<td>Employees do not attend training and are not in accordance with work procedures</td>
<td>Employees undergo training and are in accordance with work procedures</td>
</tr>
<tr>
<td>Materials</td>
<td>Warehouse area is under control with 25°C and there is no monitoring of warehouse temperature</td>
<td>Temperature in the warehouse is controlled</td>
</tr>
<tr>
<td>Methods</td>
<td>The optimal sterilization method still uses the steam process</td>
<td>Changes the sterilization method using 7.5 kGy dose of gamma ray radiation</td>
</tr>
<tr>
<td>Machine</td>
<td>Machine sanitation is not consistent</td>
<td>Make production planning that material build-up occurs which makes the quality of the material decrease</td>
</tr>
<tr>
<td>Environment</td>
<td>There is no environmental system qualification</td>
<td>Change Hi-Vac air system (heating, ventilating and air conditioning)</td>
</tr>
</tbody>
</table>

**B. Implementation Stage (Do)**

This stage is a follow-up of the improvements made in Table 3 below:

**Table 3: Implementation of Repair**

<table>
<thead>
<tr>
<th>Factors</th>
<th>Before Improvement</th>
<th>After Improvement</th>
</tr>
</thead>
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</tr>
</tbody>
</table>

For the method factor by changing the Steam method with the use of gamma radiation, the production flow changes to the following:
C. Checking Stage (Check)

The results obtained from the improvements and countermeasures by looking at 5 factors, namely Quality, Cost, Delivery, Safety and Moral (QCDSM). Of the five factors described in Table 4.

<table>
<thead>
<tr>
<th>No.</th>
<th>Factors</th>
<th>Before Improvement</th>
<th>After Improvement</th>
<th>Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Quality</td>
<td>&lt;ALT number 1.3 x 10⁻⁶</td>
<td>&lt;ALT number 1.3 x 10⁻⁶</td>
<td>0%</td>
</tr>
<tr>
<td>2</td>
<td>Cost</td>
<td>&lt;103.67</td>
<td>&lt;103.67</td>
<td>0%</td>
</tr>
<tr>
<td>3</td>
<td>Delivery</td>
<td>&lt;103.67</td>
<td>&lt;103.67</td>
<td>0%</td>
</tr>
<tr>
<td>4</td>
<td>Safety</td>
<td>&lt;103.67</td>
<td>&lt;103.67</td>
<td>0%</td>
</tr>
<tr>
<td>5</td>
<td>Moral</td>
<td>&lt;103.67</td>
<td>&lt;103.67</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Table 4: Improvement of QCDSM**

D. Acting Phase (Action)

In order for these results to be optimal and not to have the same error, after repairs are carried out it is necessary to have an evaluation and standardization.

One of the processes in standardization procedures is the need for validation, this is intended as proof that each process is carried out according to procedures or mechanisms that are carried out in all parts of production in the form of supervision that can be accounted for so that it will achieve the expected standards.

4. Conclusion

From the results and discussion contained in the research above, the conclusions that can be drawn are:

1. From the results of the highest sampling of microbial contamination occurring in NTPS products with an average value of ALT contamination of 15 x 10³ col/g and for AKK contamination of 5.67 x 10² col/g.
2. From the results of the analysis carried out with the PDCA method with the QCC approach, several efficiency results were carried out, namely:
   a. reduce microbial contamination so as to increase product expiration
   b. improve the safety of workers in the production section
   c. can save costs (costs for the company)

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