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

Hayu Kartika, Titiaizzati, Didi Junaedi

Department Teknik Industri, FakultasTeknik, Universitas Mercu Buana, Jakarta, Indonesia

Email : hayu.kartika [at]mercubuana.ac.id, titia.izzati [at]mercubuana.ac.id, didi.junaedi [at]mercubuana.ac.id

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).
4. Analyzing causes: Analyzing the causes of problems using method 5 W looking for the subject matter.
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

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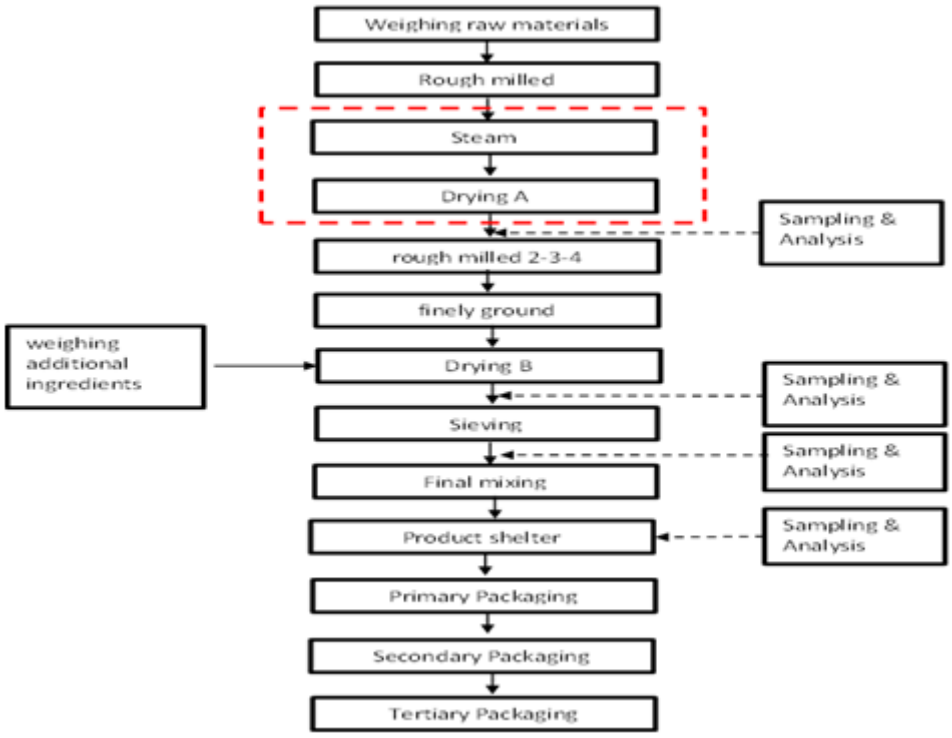
3. Data Collection and Processing

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.



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 3x103 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 15.7x103 col/g and in February at 15.07x103 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 x 102 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 x 102 col/g and in February of 5.67 x 102 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:

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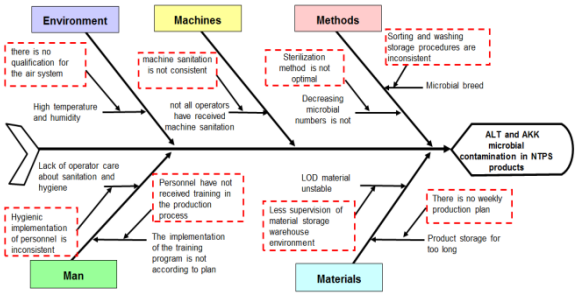

Figure 2: Fishbone diagram

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

Table 1: Root Cause

Main Problem	Factors	Why 1	Why 2	Why 3	Why 4	Why 5
The cause of the increament of ALT and AKK microbial contaminatio n in NTPS products	Man	Lack of operator care about sanitation and hygiene	The hygienic implementation of personnel is inconsistent			
		Personnel have not received training	The implementation of the training program is not according to plan	Lack of supervisory control in the training program created		
	Materials	Material LOD is not stable	The nature of hygroscopic simplicic material			
		Storage of bulk products is too long	The number of product queues that must be processed	production planning is not going well	Do not have an annual production plan	
	Methods	Sterilization method	The sterilization method is not effective	Does not reduce microbial contaminatio n optimally	The process is not constant	Temperat ure is not stable and long time
		Procedure for storing, sorting and washing	Not exactly	The possibility of microbial breeding	Unhygienic	
	Machine	Machine sanitation is not consistent	Not all operators have received machine sanitation	Not yet running employee training program	Lack of supervisory control on the programs made	
	Environment	High temperature and humidity	Air conditioning has not been able to run properly	Air conditioning has not yet been qualified	Improvement s to the air system are still needed	

Prevention Plan

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

Table 2: Reconstruction or repair plan

Factors	What		Why	How	Where	Who	When	How Much
	Problem	Effects	Causes	Improvement	Place	PIC	Time	Cost
Man	The hygienic implementation of personnel is inconsistent	Microbial contamination	Lack of operator care in hygienic attention before consulting products	Before entering the production room operators wash their hands and use gloves and use special clothing	Production room	Production department	Feb-19	Rp 0
	Personnel have not received training in the production	Microbial contamination	lack of supervision control in the training program created	Ensure employees and personnel attend training and understand work procedures	Production room	Production department	Feb-19	Rp 0
Materials	Less supervision of warehouse storage materials	Microbial contamination	Hygroscopic material properties	Make a warehouse with controlled temperature <25° by filling in the form of monitoring the warehouse temperature at the controlled temperature	Warehouse	Warehouse	Feb-19	Rp 0
	Do not have a weekly production plan	Microbial contamination	Do not have an annual production plan so that it cannot be done scheduling breakdown for weekly production	Carry out production planning including controlling raw material inventories	Production room	PPIC Department	Mar-19	Rp 0
Methods	Sterilization method is not optimal	Microbial contamination is not according to	The steam temperature is unstable and requires a long time	Improve the method of sterilization with gamma radiation	BATAN - National Atomic Energy	R&D and production department	Mar-19	Rp 250.000
	The procedure for storing, sorting and washing is inconsistent	Microbial contamination	Unhygienic	The implementation of work instructions must always be socialized, pointed in the related and implemented section	Production room	PPIC Department	Mar-19	Rp 0
Machine	Machine sanitation is not consistent	Microbial contamination	lack of supervision control in the training program	Ensure employees and personnel attend training and understand work procedures	Production room	Training Department	Feb-19	Rp 0
Environment	There is no qualification for the air system	Microbial contamination	There is no good air system	Make room layout and keep cross contamination on the product	Production and Warehouse Room	Warehouse and Production Department	Mar-19	Rp 5.000.000

B. Implementation Stage (Do)

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

Table 3: Implementation of Repair

Factors	Before Improvement	After Improvement
Man	Operators do not use gloves and use special clothing	Get used to standard production clothing and gloves 
	Employees do not attend training and are in accordance with work procedures	Make training schedules and attendance attendance training and provide penalties if not training
Materials	Warehouse temperature is under control <25* ada there is no monitoring of warehouse temperature	Fill in the controlled warehouse temperature monitoring form by looking at the temperature gauge in the warehouse
	There is no production planning so that material buildup occurs which makes the quality of the material decrease	Make production planning
Methods	The optimal sterilization method still uses the steam process	Change the sterilization method using 7.5 kGy dose gamma ray radiation
		Changes in Production Flow (see figure 5)
	Sorting and sterilization methods are inconsistent	Dissemination of work instructions and attachment of work methods in each part of
Machine	Machine sanitation is not consistent	Personnel are given training and undergo and understand work procedures
Environment	There is no environmental system qualification	Change HVAC air system (Heating, Ventilating and Air Conditioning)

For the method factor by changing the Steam method with the use of gamma radiation, the production flow changes to the following:

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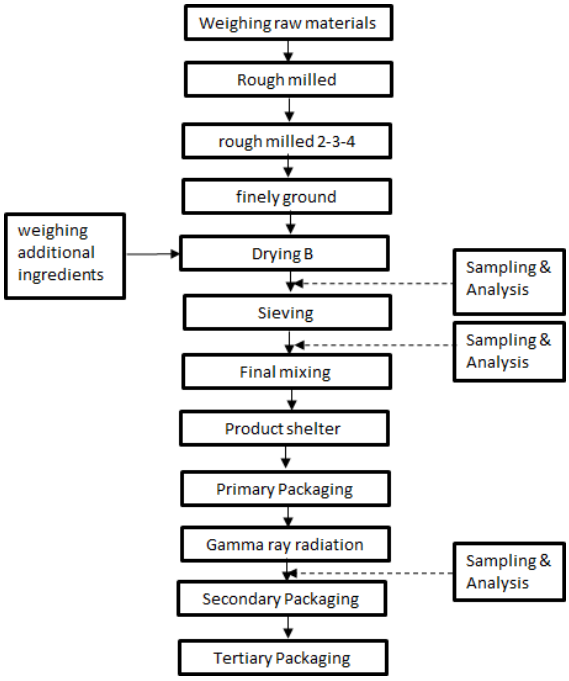

Figure 3: Improvement of Production Flow

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 4: Improvement of QCDSM

No.	Factors	Before Improvement	After Improvement	Efficiency
1	Quality	average test results - ALT Number 15 x 10^3 col/g - ALT Number 5.67 x 10^4 col/g	average test results - ALT Number 5.58 x 10^3 col/g - ALT Number 0.9 x 10^2 col/g	Decreasing the results of testing of microbial contamination can extend the period of Exp. Date from NTPS products
2	Delivery	There are no delivery fees	There are no delivery fees	
3	Safety	The gas turnover process can cause work accidents if it is not installed properly	Does not affect workplace accidents	
4	Morale	The operator makes a gas change for the steam process	The operator is comfortable because there is no gas change	
5	Cost	Number of operators: 27 man/batch	Number of operators: 23 man/batch	
		Use of working hours: 54.27 hour/batch	Use of working hours: 46.93 hour/batch	
		Use of working hours: 6.78 hour/batch	Use of working hours: 5.37 hour/batch	
		electricity consumption: 455.49 kwh/batch	electricity consumption: 272.99 kwh/batch	
		gas consumption: Rp 125,000 /batch	no gas usage	
			the cost of gamma rays 1 batch = Rp 250,000, production rate per month 17 batch = Rp 250,000x17 = Rp 4,250,000	
		Cost for employee salaries	Cost for employee salaries	
		Rp 21,321.43 x 6.78 hours = Rp 1,157,042.86 = Rp 1,157,042.86	Rp 21,321.43 x 5.37 hours = Rp 915,400.00 = Rp 915,400.00	cost savings
				Rp 241,642.86
		total payment of employee salaries	total payment of employee salaries	
		27xRp 1,157,042.86 =Rp 31,240,157.22	23 x Rp 915,400.00 = Rp 21,054,200	
		Rp 31,240,157.22	Rp 21,054,200	Rp 10,185,957.22
		electricity usage fees	electricity usage fees	
		1 batch total production Kwh : 455.59 x	1 batch total production Kwh : 272.99 x	
		Rp 1,050 = Rp 478,263.84 + Rp 125,000 =	Rp 1,050 = Rp 286,636.04	
		Rp 603,263.84	Rp 286,636.04	Rp 316,627.8

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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