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HACCP design in the production of rapet wangi Madura herbal medicine at PT. Firdaus Kurnia Indah

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ABSTRACT

PT. Firdaus Kurnia Indah is one of the traditional herbal medicine industries in Bangkalan. One of the herbal medicine products with the highest demand is rapet wangi. News about traditional herbal medicine that is added with hazardous chemicals can cause complaints that are very detrimental to health. Therefore, it is necessary to carry out material inspection and monitoring of the process of making traditional herbal medicine that is free from the dangers of chemicals. The method for identifying hazards in the production process was by using the HACCP (Hazard Critical Control Point) method. The application of HACCP in the process of making herbal rapet wangi produces critical control points (CCP) in the drying process and the printing process. In herbal rapet wangi products, it can be seen that the critical control points (CCP) are in the drying process and the printing process. In the drying process where the risk of contamination of pathogenic microbes is very high. The risk of contamination of pathogenic microbes is very high because it is feared that the microbes will not die even though they have been heated. In the process of forming herbal medicine, there is a risk of cross-contamination from workers and equipment because when forming herbal medicine it is round, does not use gloves, and does not use hair coverings.

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INTRODUCTION

Madura herbal/traditional medicine (*Jamu*) has been renowned for generations due to its traditional recipes passed down from ancestors. The Madura herbal industry has continued to grow year after year, along with the increasing variety of herbal products being produced. Madura herbal products are primarily intended for women, as most consumers of these products are female, whether they are unmarried or married. Some well-known Madura herbal products related to women consist of *empot-empot*, Madura stick, Tightening and Fragrant Herbal Mix, Slimming and Firming Herbal Mix, raw herbal scrub, Curvy Herbal Mix, and cooling powder. Among these various types, rapet wangi herbal medicine is the most in demand, with an annual demand of approximately 1,080 bottles, surpassing that of other herbal products. Rapet wangi herbal medicine is an herbal concoction believed to tighten female intimate organs, firm vaginal muscles, and help treat vaginal discharge.

The raw materials or natural traditional plants used to produce *galian rapet wangi* (Tightening and Fragrant Herbal Blend or Rapet Wangi Herbal Formula) herbal medicine consist of narrow-leaved peacock ginger (*Kaempferia angustifolia R*), Gall Oak (*Quercus gellac*), Java ginger (*Curcuma domestica*), Parameria Bark (*Parameria cortex*), and other complementary herbal ingredients. These ingredients are mixed, ground, and then shaped into round forms or placed into capsules before being packaged in plastic bottles. The production process of Rapet Wangi herbal medicine must comply with CPOTB (Good Manufacturing Practices for Traditional Medicine) standards to ensure the product's efficacy, safety, and quality. CPOTB encompasses all aspects of traditional medicine manufacturing to guarantee that the products meet quality standards following their intended use (BPOM 2021)

To ensure the quality and safety of rapet wangi formula herbal products, standardized guidelines are required. This aligns with consumer demands, requirements, and the increasing awareness of food safety and quality (Mamuaja 2016). The rise of counterfeit herbal/traditional medicines, along with the lack of information about their ingredients, side effects, and proper dosage, has contributed to the declining interest in traditional herbal medicine (Farida dan Fauziyah, 2020).

Reports have surfaced regarding traditional herbal medicines being adulterated with harmful chemical substances such as sildenafil citrate, phenylbutazone, mefenamic acid, and prednisone, which can pose serious health risks (BPOM 2006). The side effects of consuming herbal products contaminated with these chemicals are liver damage, kidney failure, stomach infections, intestinal bleeding, headaches, facial blood vessel dilation, and even death (BPOM 2006).

In addition, one of the challenges faced by the herbal medicine industry, including PT. Firdaus Kurnia Indah, is that the production process still relies heavily on manual labor. Tasks such as mixing herbal ingredients, shaping herbal granules, and packaging are still conducted by hand, increasing the risk of bacterial contamination. Moreover, there is no established Standard Operating Procedure (SOP) or use of Personal Protective Equipment (PPE) among employees. Therefore, it is essential to analyze potential hazards in the production process. One method that can be implemented is the Hazard Analysis and Critical Control Point (HACCP) system.

A good manufacturing process must go through several stages, from start to finish, to properly implement the HACCP system (Panghal et al. 2018). HACCP is also one of the mandatory documents required when applying for Indonesian Food and Drug Authority (Indonesian FDA)/BPOM distribution permits. HACCP is a preventive system to ensure food safety. It aims to protect products, correct errors, reduce costs due to defective products and minimize excessive control over the final product (Widodo et al. 2022). HACCP is a food safety assurance system that uses a mathematical approach to identify potential hazards and establish control systems to prevent them (Fakhmi et al. 2014). The key to HACCP is hazard anticipation and identifying critical control points. The HACCP system serves as a monitoring and control tool focused on food safety assurance, particularly in eliminating hazards—whether microbiological (biological), chemical, or physical—by prevention and anticipation rather than relying solely on inspection.

The implementation of CPOTB and HACCP in the production process of Rapet Wangi Madura

herbal medicine can improve the quality of the product and facilitate the herbal medicine industry in obtaining distribution permits from the Indonesian FDA, as well as obtaining SNI certification. One of the requirements for obtaining SNI certification is that the industry has implemented HACCP. Having SNI and Indonesian FDA certifications can enhance consumer trust and safety in consuming Rapet Wangi Madura herbal medicine and increase competitiveness in the rapidly growing Madura herbal medicine industry. This research aims: (1) To analyze hazards (Hazard Analysis) in the production process of Madura Rapet Wangi herbal medicine (2) To determine critical control points (CCP) in the production of Madura Rapet Wangi herbal medicine (3) To control detected hazard risks preventively in the Madura Rapet Wangi herbal medicine produced by PT. Firdaus Kurnia Indah, located in Bangkalan, Madura.

METHOD

Research Method

This research is a descriptive qualitative study conducted at PT. Firdaus Kurnia Indah, located on Jln. KH. Lemah Duwur Gg. IX No. 16, Pejagan, Bangkalan District, Bangkalan Regency. The research was carried out from June to October 2022. The research used the Hazard Analysis Critical Control Point (HACCP) document and a decision tree diagram to determine critical control points of potential hazards at each stage of the Madura Rapet Wangi herbal medicine production process.

The HACCP document was created and adjusted to the conditions of the Madura herbal medicine industry. Hazard identification was obtained through observation and direct interviews with the owner of PT. Firdaus Kurnia Indah. The identified hazards were then tabulated in a table along with their sources, risk levels, and preventive actions. The risk level was determined based on the severity of the consequences caused by a hazard and the frequency of its possible occurrence (Nanang, 2014).

The determination of Critical Control Points (CCP) was conducted at each production stage, with markers assigned to the CCP. These CCPs were subsequently improved with appropriate recommended actions to eliminate hazard points as early as possible. The research stages can be seen in Figure 1.

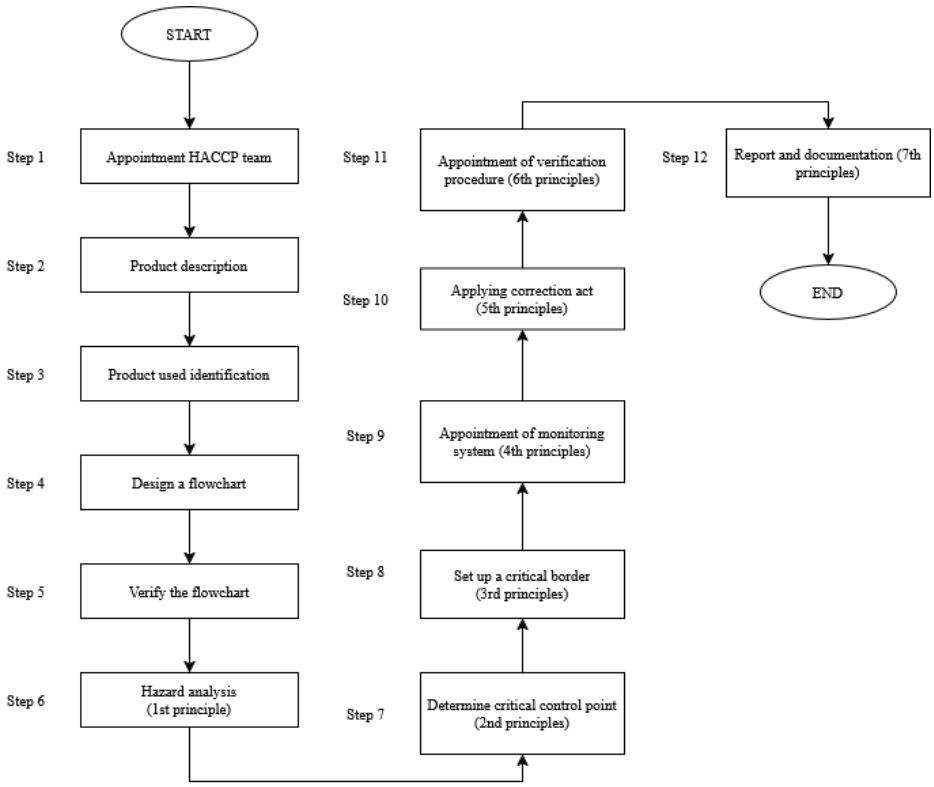

Figure 1 Research flowchart

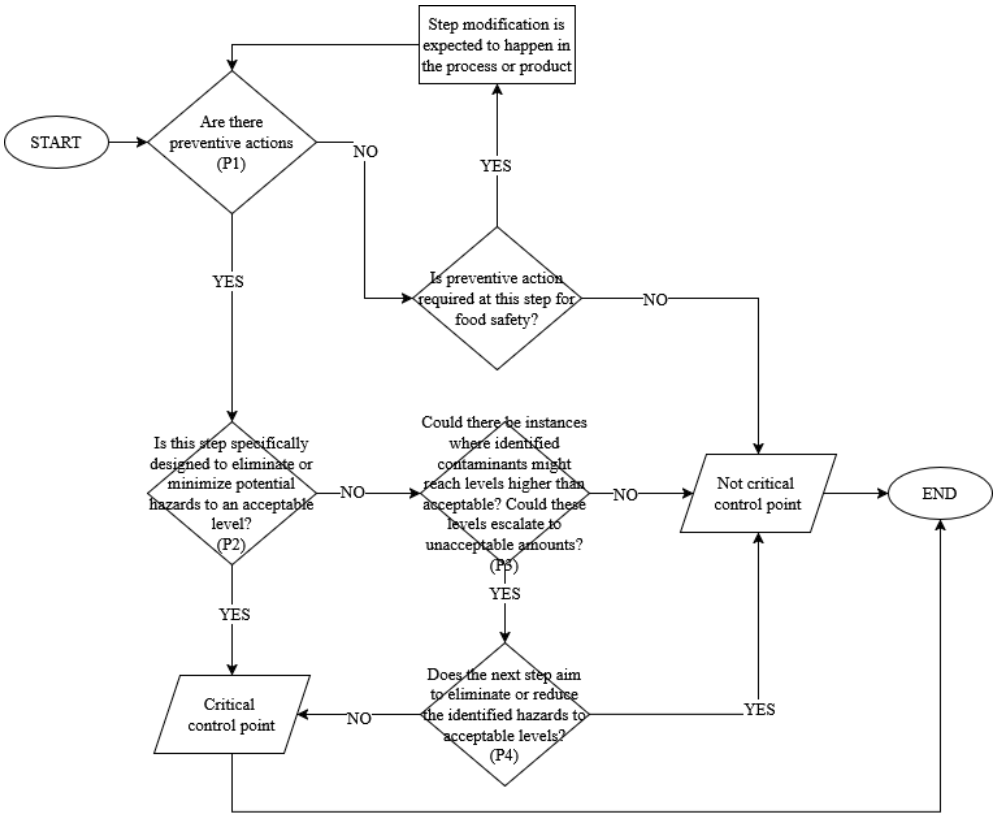

Figure 2 Flow diagram for determining critical control points (CCP)

The Implementation of HACCP in the Madura Herbal Medicine Industry

The Hazard Analysis Critical Control Point (HACCP) process in the production of Jamu Madura Galian Rapet Wangi follows the Guidelines for HACCP Plan Preparation (BSN-Guideline 1004-1999). The process involves listing raw materials and supporting ingredients, creating a production process flowchart, determining risk levels, and applying the CCP decision tree. The HACCP system is implemented based on seven principles recommended by the Indonesian National Standard (SNI 1998), issued by BSN (1999). These principles are as follows:

1. Hazard Analysis and Risk Determination along with Preventive Measures Identification and determination of critical control points (CCP) in the production process.
2. Establishing Critical Limits for Each Identified CCP.
3. Developing Monitoring Procedures and Requirements for CCP Supervision.
4. Establishing Corrective Actions for Deviations from Critical Limits.
5. Implementing an Effective Procedure for Data Recording and Storage (Record Keeping).
6. Establishing a Procedure for Verification.

Hazard Analysis and Risk Determination along with Preventive Measures

The first approach in the HACCP concept is hazard analysis related to all aspects of the product being produced. This examination or analysis of hazards must be carried out as a primary step to identify all potential hazards that may occur when food products are consumed. The hazard analysis must be comprehensive and realistic, covering everything from raw materials to the final consumer. Hazards in food are classified into three categories:

a) Biological/Microbiological Hazards caused by pathogenic bacteria, viruses, or parasites can lead to poisoning, infectious diseases, or infestations. For instance, there are *E. coli* pathogenic, *Listeria monocytogenes*, *Bacillus* sp., *Clostridium* sp., Hepatitis A virus, etc.
b) Chemical Hazards due to ingestion of natural toxins or toxic chemicals, such as aflatoxins, histamine, mycotoxins, shellfish toxins, pyrrolizidine alkaloids, pesticides, antibiotics, growth hormones, heavy metals (Pb, Zn, Ag, Hg, cyanide), preservatives (nitrites, sulfites), artificial colorants (amaranth, rhodamine B, methanyl yellow), lubricants, sanitizers, etc.

c) Physical Hazards are due to the presence of foreign objects that should not be found in food, such as glass shards, wood pieces, gravel, metal, insects, bone fragments, plastic, body parts (hair), scales, spines, skin, etc.

To ensure that hazard analysis effectively provides complete and accurate information about potential hazards, it must be conducted systematically and in an organized manner.

There are three key elements in hazard analysis:

1. Forming an HACCP Team
2. Defining the Product: Understanding how the product is consumed and identifying any negative characteristics that need to be controlled.
3. Identifying Hazards at Critical Control Points by preparing a detailed process flow diagram that accurately reflects the actual conditions to ensure a safe product.

Identification and Determination of Critical Control Points (CCP) in the Production Process

Hazard identification is the stage where potential hazards throughout the production process are assessed (Dian Rachmadia et al. 2018). Critical control points (CCP) are defined as specific locations, steps, or procedures within the process where, if not properly controlled, food safety risks, spoilage, or economic losses may occur. CCPs are determined after identifying potential hazards in each production stage using a flowchart and answering key questions such as: "Does critical hazard control occur at this stage or another?" and "If control fails at this stage, does it directly lead to an unwanted hazard, spoilage, or economic loss?" It is important to note that a control point (CP) is not the same as a critical control point (CCP). The systematic method for identifying and recognizing CCPs can be carried out using the CCP Decision Tree method, as illustrated in Figure 2.

Establishing Critical Limits for Each Identified CCP

Once all CCPs and their associated control parameters have been identified, the HACCP team must set critical limits for each CCP. Critical limits for biological/microbiological, chemical, and physical hazards vary for different types of products. A critical limit is defined as the acceptable tolerance threshold to mitigate hazards, ensuring that the control point can effectively and accurately manage health risks (Motarjemi and Warren 2023). These established critical limits must not be violated or exceeded. If a critical limit is breached and the critical control point is lost, it may pose a health hazard to consumers (Motarjemi and Warren 2023). Identified critical control points serve as benchmarks for all similar production processes, ensuring product safety and enhancing consumer confidence (Nahemiah et al. 2014). The instance of critical limits that should be set to prevent hazards are Maximum temperature and time for thermal processing, Maximum temperature for maintaining refrigeration conditions, Specific temperature and time for commercial sterilization, Permissible pesticide residue levels in food ingredients, Maximum allowable pH level, Maximum filling weight, Maximum permissible viscosity, and so on.

In addition to pesticide residue limits from agricultural commodities, critical limits must also be established for other chemical substances that could pose chemical hazards. The HACCP team must adhere to established regulations as guidelines for setting critical limits in herbal medicine production, including chemicals used in packaging materials that come into contact with the product. All critical limits for each CCP must be documented. This documentation must clearly explain the acceptability of each critical limit and be maintained as part of the formal HACCP plan. CCP processes must be carried out correctly according to SSOP (Sanitation Standard Operating Procedures) to eliminate potential hazards. Any negligence in performing critical processes may introduce hazards into the production system. Although control points (CPs) do not qualify as CCPs, they still require monitoring to prevent potential hazards (Yuniarti et al. 2015)

RESULTS AND DISCUSSION

Formation of the HACCP Team

The HACCP team consists of members with diverse experiences and professional backgrounds, including production staff, pharmacists, quality control (QC), and quality assurance personnel. The team comprises five members responsible for planning, implementing, and developing the HACCP system for Rapet Wangi Herbal Medicine. The composition of the HACCP team is presented in Table 1.

Table 1 HACCP team formation

No	Name	Position	Duties	Workshop
1	Niken M	Chairperson	Designing and overseeing the implementation of HACCP throughout the production process	HACCP; CPPOB
2	Salha Safira	Vice Chairperson	Ensuring the proper implementation of the HACCP system	HACCP; CPPOB
3	Firdaus Alhinduan	Members	Ensuring critical points are controlled and guaranteeing product quality	HACCP; CPPOB
4	Debirotul Auliya	Members	Identifying potential hazards in each process	HACCP; CPPOB

Table 2 Product description of rapet wangi herbal medicine

Specifications		Information
Product Name	:	Rapet Wangi
Raw Materials	:	Gall Oak, young areca nut, turmeric, pomegranate, pure honey, Parameria Bark
Processing	:	Drying, Grinding, and Molding
Type of Packaging	:	PET plastic bottle, brand Sopra, type Square N35
Product Characteristics	:	Physical: Solid with a normal aroma Chemical Biological
Shelf Life	:	24 months
Distribution	:	Using two-wheeled and four-wheeled vehicles
Product Usage	:	Direct consumption
Consumers	:	Women aged 20 years and above.

Product Description and Usage

The description and characteristics of Rapet Wangi Herbal Medicine produced by PT Firdaus Kurnia Indah are illustrated in Table 2.

This herbal medicine is intended exclusively for women aged 20 years and older. It is not recommended for pregnant women, as it may affect fetal conditions. Rapet Wangi Herbal Medicine can be consumed directly (ready-to-drink) and is recommended to be taken twice a day, 2-3 capsules per dose. However, it is not advisable to consume this herbal medicine simultaneously with chemical drugs. A minimum interval of 2 hours is required to avoid potential drug interactions.

The conditions at PT Firdaus Kurnia Indah, based on the Sanitation Standard Operating Procedure (SSOP), are presented in Table 3. Based on the SSOP assessment in Table 3, several deviations were identified that may pose potential hazards to the Rapet Wangi herbal medicine product. Therefore, the next step is to determine the critical hazard points in the production process.

Production Process Flowchart

The production process involves converting raw materials into finished products. The production flow of Rapet Wangi Herbal Medicine at PT Firdaus Kurnia Indah is illustrated in Figure 3.

Flowchart Verification

The verification of the production flowchart for Rapet Wangi Herbal Medicine has been aligned with industrial conditions, covering the following stages: raw material reception, washing, draining, drying for 2 hours, grinding using a machine, storage of ground materials, mixing according to specified measurements, manual formation into round granules, drying using an oven, packaging and labeling, and product storage.

Hazard Analysis

Based on observations, in the production process of rapet wangi herbal medicine, there is a hazard analysis at each stage. In the first stage of production, which is the reception of raw materials, the identified potential hazards are pathogenic mold microbes and foreign objects such as unusable plant parts (stems, leaves). The cause of these hazards is contamination during handling, distribution, and poor sorting of raw material supplies. At this stage, the hazard is not significant, so the raw material reception stage is not classified as a Critical Control Point (CCP). The second stage is the washing of raw materials, where the identified hazards include pathogenic microbes and dust originating from water contaminated by employees and the environment during washing. However, this hazard is not significant, so the washing stage is not classified as a CCP. The stages classified as CCPs are the drying and formulation stages of herbal medicine. The formulation stage involves molding the herbal medicine into granules, which is conducted by hand. In the drying and formulation stages, the identified hazards include pathogenic microbes and metal contamination caused by contaminated grinding equipment or machines and cross-contamination from employees, as the herbal medicine formulation process is performed by hand.

Table 3 Identification of PT Firdaus Kurnia Indah's Compliance with SSOP Implementation

No	SSOP Aspect	Aberration
1	Water Safety	Complies with the required water quality standards
2	Condition/Cleanliness of Food-Contact Surfaces	Use of trays as drying containers for herbal medicine raw materials. Containers used for mixing herbal medicine powder with honey
3	Prevention of Cross-Contamination	Risk of contamination from workers who do not use PPE (Personal Protective Equipment).
4	Worker Hygiene	Limited availability of handwashing stations in the production area
5	Prevention and Protection from Adulteration	Hazardous chemicals are stored away from the production area
6	Proper Labeling and Storage	Packaging labels do not yet include production date, net weight, and complete composition details.
7	Employee Health Control	No regular health check-ups were conducted for workers
8	Pest Control	No protective barriers to prevent insects from entering the production area

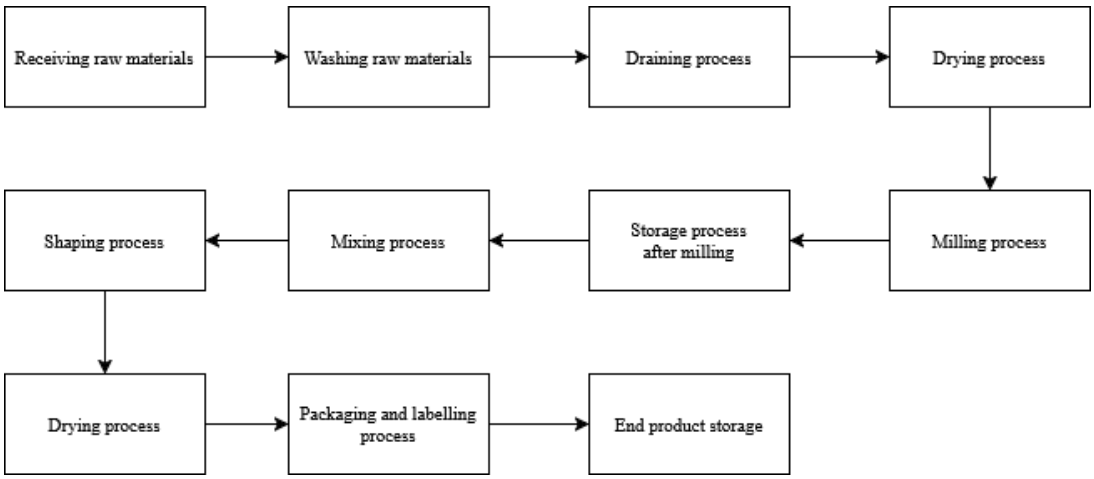

Figure 3 Production process of rapet wangi herbal medicine in granule form

Table 4 Hazard Identification in the Rapet Wangi Herbal Medicine Production Process

No	Process Stages	Potential Hazards	Causes of Hazards
1	Raw Material Reception	Pathogenic microbes, mold	Contamination during handling and raw material distribution
	Washing	Foreign objects (e.g., unusable plant parts)	Poor sorting and contamination from suppliers
2	Draining Process	Pathogenic microbes	The water used does not meet clean water quality standards
	Drying Process	Dust	Contamination from employees and the environment
3	Grinding Process	Pathogenic microbes	Cross-contamination from employees and raw material containers
	Storage Process	Dust	Contamination from employees and the environment
4	Ingredient Mixing	Pathogenic microbes	Microbes from previous contamination that survive the heating process
	Process Formulation Process	Metal contamination	Cross-contamination from drying equipment
5	Drying of Final Dosage Form	Pathogenic microbes	Contamination from previously milled materials
	Packaging and Labeling Process	Metal contamination	Contamination from grinding equipment
6	Final Product Storage	Mold	Cross-contamination from storage areas
7	Raw Material Reception	Pathogenic microbes	Cross-contamination from workers and equipment
8	Washing	Metal contamination	Contamination from machines used in processing
	Draining Process	Pathogenic microbes	Cross-contamination from workers and equipment
9	Drying Process	Dust	Contamination from employees and the production area environment
10	Grinding Process	Pathogenic microbes	Bacterial growth due to previous contamination and contamination from packaging materials
	Storage Process	Dust	Cross-contamination from packaging materials
11	Ingredient Mixing Process	Mold	Cross-contamination from storage areas and damaged products

Pathogenic microbes may arise due to employees' lack of knowledge regarding the appropriate drying temperature and inadequate attention to equipment and workspace cleanliness. The potential hazard in herbal medicine includes contamination by pathogenic microbes and mold (Saputro 2019). Based on Prabandari (2023), the pathogenic microbes found in herbal medicine are *Escherichia coli* and *Staphylococcus aureus*, while the identified mold species in herbal medicine include *Aspergillus niger* and *Aspergillus flavus*. Bacterial contamination during the herbal medicine production process may originate from production equipment. Mold/yeast may come from rhizomes and insufficiently cleaned rhizome washing processes. Rhizomes grow in soil, which serves as a natural habitat for mold, especially in moist soil conditions.

Escherichia coli bacteria can cause health issues in humans, such as diarrhea (Nataro and Kaper 1998). The danger of mold contamination is aflatoxin, a secondary metabolite compound that poses a health risk to humans. The secondary metabolites produced by mold are carcinogenic, mutagenic, and teratogenic (Erami et al. 2007). Aflatoxin-producing mold contamination is commonly found in food and feed derived from agricultural products (Sukmawati et al. 2018). According to Dharmaputra et al (2010), consuming food contaminated with aflatoxin can lead to cancer in human tissues, particularly liver cancer.

Other hazards arise from rust and dirt adhering to drying equipment. Cross-contamination from employees occurs because they do not use personal protective equipment (PPE) and fail to wash their hands before the herbal medicine formulation process. This contamination occurs significantly, making this stage a CCP (Critical Control Point). The hazard identification for rapet wangi herbal medicine can be seen in Table 4.

The Determination of Critical Limits, Critical Point Monitoring, Corrections, Verification, and Records

The critical limit for the drying stage is setting the drying temperature between 50°C to 60°C to prevent the growth of pathogenic microbes. Meanwhile, the critical limit for the herbal medicine formulation process involves regular inspections of employees, equipment, and the workspace before production begins. Employees must wear personal protective equipment (PPE) during the herbal medicine formulation process. The Critical Control Points (CCP) are identified during the drying process and formulation process. The next steps involve establishing critical limits, monitoring critical points and CCPs, implementing corrective actions, verification, and documentation, which are detailed in Table 5.

Table 5 Determination of critical limits, critical point monitoring, ccp, corrective actions, verification procedures, and documentation at PT Firdaus Kurnia Indah

No	Step	Critical Limit	Monitoring	Corrective Action & Corrective Measures	Verification	Records
1	Drying Process	Minimum drying temperature 50°C to 60°C	The operator ensures the machine is preheated and monitors the inlet & outlet temperature of the Simplicia	If the required temperature is not reached, the operator extends the heating time	Drying machine inspection Final product testing Internal audit	- Test result report - Internal audit report
2	Formulation Process	Regular inspection of personnel, equipment, and workspace before use	Ensure personnel are clean and sterile, and verify the condition of equipment and workspace before use	If personnel, equipment, or workspace do not meet requirements, additional time must be allocated to correct deficiencies according to company SOPs	- Regular personnel inspection - Equipment and workspace inspection before use - Final product testing - Internal audit	- Personnel, equipment, and workspace inspection form - Test result report - Internal audit report

CONCLUSION

Based on the HACCP (Hazard Analysis and Critical Control Points) implementation analysis conducted in the Madura Herbal Medicine industry, specifically at PT. Firdaus Kurnia Indah for the rapet wangi herbal medicine product, the Critical Control Points (CCP) are found in the drying and formulation processes. During the drying process, the risk of pathogenic microbial contamination is high, as there is concern that the microbes may not be eliminated despite the heating process. In the formulation stage, the risk of cross-contamination from workers and equipment is significant because employees do not use gloves or hair covers when shaping the herbal medicine into granules.

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