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EVALUATION OF THE QUALITY ASSURANCE SYSTEM FOR HERBAL PRODUCT MANUFACTURING AT PT. X BASED ON GOOD TRADITIONAL MEDICINE MANUFACTURING PRACTICES (CPOTB)

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ABSTRACT

Background: Herbal products require a proper quality assurance system to ensure consistent manufacturing and compliance with safety and quality standards. The quality assurance system is crucial for overseeing the entire production process, starting from the acquisition of raw materials to the distribution of finished products. **Objective:** This research aims to assess the implementation of a quality assurance system in the manufacturing of herbal products at PT. X based on CPOTB. **Methods:** This study employed a qualitative descriptive approach using a case study methodology. Data were collected through observations, interviews, and document reviews, which included standard operating procedures, batch production records, testing documents, equipment logbooks, and quality control records. The assessment focused on the quality management system, raw material oversight, staff, infrastructure and machinery, manufacturing methods, warehousing, and record-keeping. **Results:** The findings indicated that PT. X has established a cohesively integrated quality assurance system by fostering collaboration between the QA and QC divisions, despite facing challenges related to dual functional roles in the absence of a separate R&D department. Cross-contamination risks are addressed from both facility and production perspectives through the implementation of a structural three-zone workflow (Black, Green, and Gray Areas), supported by integrated HEPA filtration and Reverse Osmosis (RO) water systems. Additionally, quality control in the industry is rigorously maintained through strict adherence to instrument logbook regulations, effective batch-tracking methods for addressing complaints and product recalls, and a thorough and organized documentation system. **Conclusion:** PT. X requires strategic enhancements in structural aspects concerning personnel dual roles and the modernization of equipment. However, its comprehensive documentation, standardized internal audits, and strong environmental controls indicate that the facility's quality management aligns effectively.

Keywords: CPOTB; Herbal preparations; Quality Assurance; Documentation; Quality system

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INTRODUCTION

Herbal medicinal products are derived from plant resources for the treatment and well-being of mankind. It is essential that the quality of herbal medicines is controlled to the same extent as that of chemically synthesized medicines. Unfortunately, the regulatory norms for herbal products are not as strict as those for synthetic drugs [1]. This discrepancy leads to a decline in the quality standards of herbal products due to intentional and sometimes unintentional adulteration, spurious drugs, drug substitution, and various other factors that compromise the quality of herbal materials marketed and consumed for healthy living. Consequently, this situation poses hazardous effects on consumer health. Therefore, it is crucial to establish and maintain quality standards for herbal drugs and products for the betterment of mankind[2].

The increasing use of herbal products has heightened attention to their quality, safety, and efficacy. Consistent quality and standardization of herbal products are vital to ensuring their safety, efficacy, and reproducibility. The implementation of strict quality control and quality assurance protocols is necessary to protect consumer health by minimizing the risks of contamination, adulteration, and the presence of hazardous substances. Additionally, quality control helps maintain the consistency of the composition and potency of herbal products through standardized manufacturing processes and appropriate testing methods, allowing for the monitoring and control of active compound levels to ensure that products provide consistent therapeutic effects [3].

Quality assurance (QA) encompasses all measures designed to ensure that traditional medicines are produced to a quality standard appropriate for their intended use. In Indonesia, the implementation of a quality assurance system in the natural medicine industry is based on the Cara Pembuatan Obat Tradisional Yang Baik (CPOTB), which provides guidelines governing all aspects of traditional medicine manufacturing to ensure that the resulting products consistently meet established quality requirements. GMP-TM covers various important aspects, including quality management, personnel, buildings and facilities, equipment, sanitation and hygiene, production, quality control, documentation, and storage [4].

In implementing the latest CPOTB requirements, the Indonesian Food and Drug Administration (BPOM) must assess, guide, and assist Indonesia in adhering to these standards to ensure that the quality of produced products meets the necessary requirements and aligns with the goal of accelerating self-reliance and the development of domestic raw material production, including active ingredients or raw materials for traditional medicines [5].

Although the CPOTB regulations have been updated by BPOM to accelerate industrial self-reliance, in reality, many small-scale traditional medicine industries still face significant constraints, such as limited infrastructure, conventional manufacturing equipment, and dual-role personnel arrangements due to limited organizational structures. To illustrate, a previous study mapping CPOTB implementation across 98 small-scale traditional medicine industries (UKOT) in Central Java revealed that only 5 UKOTs fully complied with all aspects, whereas 63 UKOTs only met the basic Phase I requirements, and 19 UKOTs failed to meet the standards entirely. This clear discrepancy highlights the need for further evaluation on how resource-constrained facilities manage to align their operations with standard quality guidelines [4].

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It is important to evaluate the quality assurance system to determine the alignment between established procedures and actual operations in the field. Evaluation is also necessary to identify aspects that are functioning well and those that require improvement. Based on this description, this study aims to evaluate the quality assurance system for the production of herbal preparations at PT. X in accordance with CPOTB.

METHODS

This study employed a qualitative descriptive method using a case study approach. This approach was utilized to obtain an overview of the implementation of the quality assurance system in the production process of herbal preparations at PT X. The research was conducted in June 2026 at PT. X Industries. The research subjects included the implementation of the quality assurance system in areas such as raw material control, production operations, quality facilities, equipment, documentation control, storage, and personnel.

Primary data were collected through observations of production areas and processes, as well as interviews with relevant personnel from the QA, QC, production, and supervisory departments. Secondary data were gathered through a review of documents, including standard operating procedures, batch production records, packaging records, quality testing records, raw material receipt documents, equipment logbooks, training documents, and internal audit results.

The research instrument consisted of a checklist developed based on the CPOTB criteria. Data were analyzed descriptively through the stages of data reduction, grouping of information based on evaluation aspects, comparison with CPOTB requirements, and drawing conclusions[6].

This study was conducted with the official institutional permission and approval from the management of PT X, ensuring compliance with data confidentiality and corporate regulations.

RESULTS

1. Evaluation of Quality Management Implementation

The quality management system at PT. X is predicated upon a closely-knit functional cooperative relationship among the various departments. Quality Assurance (QA) and Quality Control (QC) are pivotal in ensuring, acquiring, and sustaining the consistent quality of herbal products. Within its organizational framework, QC is strategically positioned as an integral operational component within the QA system, which encompasses a broader scope of supervisory responsibilities. The company is presently devoid of a dedicated divisional structure for Research and Development (R&D), as the industry's capacity is still perceived to be on a small-scale. All duties pertaining to product innovation, the development of new formulations, and other related aspects remain developmental in nature. The product is managed functionally by the designated technical pharmacist in conjunction with the QC manager.

2. Evaluation of the Implementation of Personnel Aspects

The rules about who can work at PT. X are made to fit the size of the company's food business, which is part of the Household Food Industry. When PT. X hires people to work in production, they do not require a diploma or special training in health. Instead, they care more about the skills people have when it comes to working with plants. The people in charge of the work are led by one pharmacist, who is in charge of the technical part, and they work with a QC manager to make sure everything meets the quality

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standards. PT. X makes sure people keep themselves clean at the factory. They have training programs and health checks for all employees. They also require everyone to wear clothes when they are working in the production area. PT. X does this to keep everything safe.

3. Evaluation of the Implementation of Building and Facility Aspects

The building that PT. X uses to make things is really old. It is divided into rooms where they do their work. This is a problem because the building is not big enough. There is not enough space for the people who work there to move around. When they add machines, it gets crowded really fast. Even though the space is limited, they have found a way to keep people from getting in each other's way. They have divided the area into three parts: the Black Area, the Green Area, and the Gray Area. This helps prevent things from getting mixed up. In the room where they make things, which is called the Gray Area, they have a special air conditioning system. This system uses a lot of equipment like filters, super fine filters called HEPA tools to check the air, and special water that is really clean. They make this clean water using a process called osmosis, or RO for short.

4. Evaluation of Equipment Aspect Implementation

The utilization rate of production machinery and equipment at PT. X is generally considered to be still conventional and in need of systematic modernization. As a concrete example in the field, the process of applying labels to product packaging (labeling) is still performed manually by human labor and has not yet utilized automated machines based on direct printing technology. The main heating system equipment and several other production instrument components have also been identified as still requiring technological upgrades, although gradual improvements to a small portion of this equipment have already begun. From an operational oversight perspective, PT. X implements a highly disciplined equipment documentation system, in which every machine is required to have a logbook detailing its usage history, including the equipment's condition prior to use, duration of operation, and records of cleaning procedures.

5. Evaluation of the Implementation of Production Aspects

The herbal medicine production process at PT. X follows a linear and logical sequence in accordance with a series of SOPs that are standard in this industry. This series of work processes begins with the collection of raw materials, weighing of raw materials, extraction, drying of the extract, mixing, filling of containers, and concludes with the packaging of the finished product. The variety of dosage forms currently produced by the company is still very limited to topical forms (herbal oils or creams) and non-solid oral formulations (instant drink powders and herbal tea blends). PT. X has not yet been able to produce traditional medicines in solid forms, such as tablets, due to the high investment costs for tablet compression machines, and has not yet developed liquid formulations in the form of herbal syrups due to challenges related to internal formula compatibility.

6. Evaluation of the Implementation of Internal Audit Aspects

PT. X has an independent internal audit system that ensures compliance by periodically conducting audits quarterly or annually of operations. The internal assessment is done through regular coordination meetings between the Pharmacist in Charge (QA representative) and QC Manager. These audits focus on

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identifying technical gaps in production, evaluating workforce capabilities, and overcoming physical space constraints to establish if the facility is set up to accommodate new equipment. Management then uses the feedback produced by these internal reviews as a platform for ongoing successes in facility improvement.

7. Product Complaint Handling Evaluation

This is the process for addressing customer complaints or feedback at PT. X is fully managed by the QC division. The company provides clear and open communication channels through which customers can report any issues relating to the physical quality of products purchased from the market. Once an official report is received with a sample attached, the QC team is authorised to conduct an immediate, thorough investigation on the production floor. The team records the history of each complaint in their quality files in order to pinpoint the source of the issue and establish whether it is due to natural variance in the raw herbs or an error during production.

8. Product Recall Evaluation

In the event of a product requiring withdrawal from the market, the recall mechanism is placed under the sole jurisdiction of the Quality Assurance (QA) division. In the event of a customer complaint that reveals a significant quality defect affecting an entire batch, the QA team is required to immediately initiate emergency recall protocols. In order to achieve this objective, the company has established a collaborative relationship with external distribution networks, leveraging their document tracking system to accurately identify batch numbers and locate the affected products. This recall process serves as a critical safety net, safeguarding consumer health while ensuring the company maintains its legal standing and industry credibility.

9. Evaluation of the Implementation of Documentation Aspects

The documentation system at PT. X adheres to the prevailing principle of contemporary pharmaceutical manufacturing: The maxim "Write what you do, and do what you write" encapsulates the notion that one's actions and aspirations should be in alignment with their literary output. It is imperative that each activity on the floor is meticulously documented, from the preliminary upstream setups to the concluding post-production cleanups, in accordance with the established SOP guidelines. The quality archives are organised meticulously and comprise machine logs, ingredient approval sheets, and official Certificates of Analysis (COA) from verified vendors, along with final product certificates issued by an independent laboratory in Surabaya. In the context of packaging labels, PT. X adopts a language that is not subject to change. Benefit claims are strictly limited to statements of empirically proven "efficacy", avoiding any definitive medical "indication" claims.

DISCUSSION

Following direct assessments of the manufacturing site and a comprehensive review of the SOP documents, it is evident that PT. X's quality management system and staff aspects exhibit consistent functional modifications, yet they continue to encounter challenges due to intersecting organizational frameworks. The proactive QA team, working alongside the reactive QC team on the production floor, has effectively minimized human errors and aims to design operational controls to prevent human errors during the compounding process. However, further quantitative verification is needed to evaluate its direct impact on the homogeneity

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of the herbal mixtures. However, operating without a distinct R&D team necessitates that the QC manager undertake additional QA documentation, resulting in a dual-role arrangement that demands meticulous oversight to guarantee that the product release process remains entirely autonomous. On a brighter note, employing production personnel with agricultural experience and providing them with technical training, health assessments, and strict uniform policies constitutes a commendable approach to mitigating biological contaminants. This framework meets the personnel standards stipulated in current regulations, which indicate that organizations must maintain an adequate number of qualified staff to facilitate smooth and predictable quality assurance processes. [4].

By conducting an assessment of the structure, amenities, apparatus, and workflow of production, it is evident that PT. X operates within the constraints of an aging building where the layouts impede movement when new production equipment is introduced. Despite these confined conditions, the facility adeptly addresses cross-contamination concerns through a stringent three-zone system (black, green, and gray areas) alongside HEPA filtration, particle monitoring devices, and a reverse osmosis (RO) water setup. There is a need for updates on the equipment aspect, as essential functions such as label application are still performed manually. The team successfully maintains adherence to regulations with meticulous machine record-keeping and a clear, linear production pathway (progressing seamlessly from weighing to packaging), ensuring their topical blends and non-solid oral beverages meet quality standards. This method relates directly to the physical facility criteria outlined in the guidelines, which emphasize that manufacturing spaces and equipment must be crafted, situated, and consistently serviced using validated methods to minimize contamination and facilitate cleaning [4].

This study relies primarily on qualitative data obtained through interviews, standard operating procedure (SOP) reviews, and direct visual observations during the audit period. Due to logistical constraints, objective quantitative data such as environmental particle monitoring scores, microbiological contamination tests, batch deviation rates, and product quality testing outcomes were not collected. Consequently, while the structural and procedural frameworks align with CPOTB guidelines, the definitive operational effectiveness of these systems remains to be verified through future quantitative and longitudinal studies.

CONCLUSION

This study evaluated the quality assurance system for herbal product manufacturing at PT. X in alignment with Good Traditional Medicine Manufacturing Practices (CPOTB) guidelines. Based on qualitative observations, document reviews, and personnel interviews, PT. X has established operational and procedural mechanisms to support quality assurance across major manufacturing stages. Key implemented practices include structured Standard Operating Procedures (SOPs) for batch processing, raw material verification, and physical environmental controls such as a three-zone air classification system and Reverse Osmosis (RO) water treatment. However, areas requiring operational strengthening remain, particularly regarding the formal integration of research and development workflows and long-term process validations. As this evaluation was conducted using a qualitative descriptive design without a formal quantitative scoring framework or laboratory quality testing, these findings reflect procedural alignment rather than verified overall regulatory compliance. Future quantitative audits and

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empirical environmental monitoring are recommended to comprehensively assess operational compliance.

CONFLICT OF INTEREST

There are no conflicts of interest in this research. This research article was written independently. All authors have no financial or personal relationships with other individuals or organizations that could inappropriately influence this research.

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