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Research

Assessment of a quality assurance practices in the production Of herbal medicines

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Abstract

Background: The production of herbal medicines is increasingly significant in global healthcare, yet it faces challenges related to quality assurance (QA) practices. Issues such as contamination, adulteration, and inconsistent regulations hinder the credibility of these products in the market.
Objective: This study aims to assess the current QA practices in the production of herbal medicines, identifying challenges and proposing improvements to enhance safety and efficacy
Approach: A mixed-methods research design was employed, combining qualitative and quantitative approaches. Qualitative data were gathered through case studies and interviews with industry experts, regulatory authorities, and manufacturers, while quantitative data were collected via structured surveys and laboratory testing of samples. The study involved 57 manufacturers and analyzed 30 samples, focusing on adherence to established quality standards
Result: The findings revealed that 70% of medium-scale operations met quality standards, but small-scale units faced significant financial constraints, with 60% lacking funds for necessary QA upgrades. The study highlighted the need for scale-specific interventions to improve QA practices and market trust.
Conclusion: The research underscores the importance of regulatory harmonization, technological adoption, and resource support to ensure the safety and efficacy of herbal medicines, ultimately benefiting the 80% of the global population that relies on these products.

Keywords: Quality Assurance, Herbal Medicines, Production Practices, Quality Control, Mixed-Methods Research.

INTRODUCTION

Herbal medicines are a significant part of traditional medicine, which has been the basis of some medicine systems like Ayurveda, Traditional Chinese Medicine (TCM), Unani, etc. [1]. Restoring to the WHO declares those herbal medicines are used by roughly 80% of the total population for ultimately healthcare needs, especially in developing countries where people do not have easy access to modern medicine [2]. The growing popularity of herbal medicines can be attributed to their supposed health benefits, low cost, and low incidence of adverse effects in relation to synthetic pharmaceuticals [3].

Importance of Quality Assurance in Herbal Medicines

The use of herbal drugs is increasing, but their quality, safety, and effectiveness face significant challenges. Unlike synthetic drugs, which have strict production controls, herbal medicines can vary greatly due to different raw materials and preparation methods. This variability can lead to inconsistent effects, contamination risks, and potential adulteration, such as the use of synthetic drugs or cheaper substitutes. Quality assurance is complicated by differing regulations across countries, particularly in developing nations. To address these challenges, an integrated approach with strict monitoring, modern analytical techniques, and international standards is needed to enhance the safety and efficacy of herbal products and restore public trust.

Regulatory Challenges in Herbal Medicine Production

There is significant variation in how countries oversee herbal medicines, resulting in different standards for quality and safety. Countries like the USA have established regulations, such as Good Manufacturing Practices (GMP) enforced by the FDA, to ensure compliance with production processes and safety monitoring. In contrast, many developing nations have weak regulatory policies, allowing substandard herbal products that pose health risks. Inconsistent international regulations can lead to public health issues, including mislabeling and contamination.

To address these challenges, global harmonization of herbal medicine regulations is necessary. Organizations like the WHO and ICH are working to set common quality control standards worldwide, which would ensure that herbal medicines are safe and effective globally. Improving testing procedures and enhancing the supply chain's transparency are key steps for consumer safety and confidence in herbal products.

Moreover, herbal medicines face risks of contamination and adulteration, which can occur during various stages of production. Common contaminants include heavy metals and pesticides, while adulteration involves adding inferior substances. Advanced quality control techniques, such as DNA barcoding and chromatographic methods, help identify adulterants. Establishing global standards and cooperation between regulatory agencies will enhance safety and efficacy in the herbal medicine market.

Aim & objectives

Aim: Assessment of A Quality Assurance Practices In The Production of Herbal Medicines

Objectives

1. To assess the quality assurance practices in the production of herbal medicines.
2. To identify the challenges and gaps in current QA practices.
3. To propose recommendations for improving quality assurance in the herbal medicine industry.

Research methodology

A mixed-methods research design has been adopted, combining both qualitative and quantitative research approaches. The qualitative aspect includes case studies and interviews with industry experts, regulatory authorities, and manufacturers, providing an in-depth understanding of existing challenges and best practices [37]. The quantitative aspect involves structured surveys, laboratory testing, and statistical analysis of collected data to assess adherence to established quality standards in herbal medicine production.

Primary data collection

Surveys

A structured questionnaire was developed to comprehensively assess the implementation of quality assurance measures in the herbal medicine industry. The questionnaire was distributed to:

Herbal medicine manufacturers

Quality control personnel

Regulatory authorities (e.g., WHO, FDA, AYUSH, EMA)

The survey aimed to assess quality assurance in herbal medicine by examining raw material selection, manufacturing compliance, testing methods, regulatory adherence, and future challenges. It included multiple-choice, Likert scale, and open-ended questions for data collection. The target was 60 manufacturers of varying sizes, using digital forms for accurate data entry.

Preparation: Questionnaire validated by three pharmaceutical experts for content clarity.

Distribution: Conducted over 6 weeks by trained research assistants visiting manufacturing sites.

Collection: Achieved a 95% response rate (57/60), with follow-ups via phone for non-responders.

Interviews

Semi-structured interviews were conducted with manufacturing heads, QA managers, regulatory officials, quality control scientists, and herbal practitioners. They discussed challenges in herbal formulation quality, regulatory frameworks, testing methods, and traditional quality practices. Interviews were recorded, transcribed, and analyzed for insights into quality assurance in herbal medicine.

Direct Observations

Laboratory Analysis

Microbial Load Assessment

Process: Samples (1 g each) were homogenized in 9 mL sterile saline, serially diluted (10^{-1} to 10^{-5}), and plated on nutrient agar (TAMC) and Sabouraud dextrose agar (TYMC). Plates were incubated at 37°C for 48 hours (TAMC) and 25°C for 5 days (TYMC). Colonies were counted using a digital colony counter (HiMedia LA660) [4].

Standards: WHO limits (TAMC $\leq 10^5$ CFU/g, TYMC $\leq 10^3$ CFU/g).

Controls: Sterile saline blanks ensured no contamination.

Heavy Metal Quantification

Process: Samples (2 g) were digested with 10 mL concentrated nitric acid (Merck, 65%) in a microwave digester (Milestone ETHOS One) at 180°C for 20 minutes. Digests were diluted to 50 mL with deionized water and analyzed via Atomic Absorption Spectroscopy (AAS, Agilent 240FS AA) with hollow cathode lamps (Pb: 283.3 nm, as: 193.7 nm, Cd: 228.8 nm). Calibration used certified standards (0.1–10 ppm, $R^2 = 0.998$) [5].

Standards: WHO limits (Pb ≤ 10 ppm, As ≤ 3 ppm, Cd ≤ 1 ppm).

Controls: Blank digests verified baseline accuracy.

Testing was performed in triplicate, with equipment calibrated daily (e.g., HPLC retention time RSD < 2%).

Active Constituent Analysis

Process: Samples (0.5 g) were extracted with 20 mL methanol (HPLC-grade, Sigma-Aldrich) via ultrasonication (Elma S 30H, 37 kHz, 30 min), filtered (0.45 µm syringe filter), and analysed using High-Performance Liquid Chromatography (HPLC, Waters Alliance e2695). A C18 column (250 mm × 4.6 mm, 5 µm) with a methanol: water (60:40) mobile phase at 1 mL/min and UV detection (254 nm) was used. Peaks were quantified against standards (withanolides, gallic acid, ursolic acid; Sigma-Aldrich) [6].

Standards: Indian Pharmacopoeia (e.g., withanolides ≥ 2.5% w/w).

Controls: Solvent blanks ensured no interference.

Secondary data collection

Secondary data were collected through an extensive review of existing literature, regulatory frameworks, and industry reports to provide a comprehensive understanding of quality assurance practices in herbal medicine production [7]. The sources of secondary data included:

Scientific Journals, Books, and Research Papers:

Peer-reviewed articles and books on herbal medicine quality assurance were reviewed to identify best practices, emerging trends, and research gaps in quality control methodologies.

Regulatory Reports and Guidelines:

Official publications from global and national regulatory bodies such as WHO, FDA, EMA, and AYUSH were examined to assess regulatory frameworks, compliance requirements, and industry standards for herbal medicine production [8].

Pharmacopoeias and Standard Operating Procedures (SOPs):

Herbal pharmacopeias and SOPs were analyzed for testing methods and safety measures. The data helped benchmark QA practices, identify regulatory gaps, support primary findings, and guide improvement recommendations.

Data analysis

Quantitative and qualitative analyses were conducted using SPSS and Microsoft Excel to evaluate survey and laboratory data. Key trends in quality assurance (QA) practices were identified, and expert interviews revealed challenges in QA. Laboratory samples of herbal medicines were compared to standards to assess compliance, with statistical tests analyzing differences in QA among manufacturers.

Ethical considerations

Ensuring ethical compliance is a critical component of this research on quality assurance practices in herbal medicine production. Ethical considerations were carefully implemented to protect the rights and interests of participants and ensure the integrity of the research process [9]. The following procedures were followed to adhere to ethical standards:

Informed Consent

Before participating in the study, all survey respondents and interviewees were provided with a detailed participant information sheet outlining the research objectives, methodology, potential risks and benefits [10].

- Participants were given the opportunity to ask questions and seek clarifications before consenting.
- A written consent form was obtained from each participant, ensuring voluntary participation with the right to withdraw at any stage without consequences.
- In cases where participants were unable to provide written consent, verbal consent was recorded for documentation.

Confidentiality

Confidentiality of participant information was maintained by following strict data security protocols [11].

- Personal identifiers such as names, job titles, and company names were excluded from survey responses and interview transcripts.
- Data was securely stored in password-protected electronic files and, where applicable, physical documents were kept in locked cabinets.
- Only authorized members of the research team had access to the raw data, ensuring no unauthorized use or distribution.

Institutional Approval

Prior to data collection, the study underwent an ethics review process to ensure compliance with regulatory and ethical guidelines.

A research proposal was submitted to the Institutional Review Board (IRB) detailing the research objectives, methodology, and ethical safeguards.

The IRB conducted a thorough review to evaluate the potential risks to participants and ensure that the research adhered to established ethical standards.

Ethical clearance was granted before surveys, interviews, and laboratory data collection commenced.

Compliance with Regulatory Guidelines

The study strictly adhered to international and national regulatory guidelines for ethical research, ensuring fairness and scientific validity [12].

- The research was conducted in accordance with ethical frameworks established by WHO, FDA, EMA, and AYUSH.
- Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) standards were followed in laboratory analysis and testing.
- The study aligned with data protection laws, ensuring that participant information was handled responsibly and securely.

Interviews and expert opinions

1.1. Dr. Sanjay Verma, Head of R&D at Dabur India Ltd., oversees product formulation and quality control in herbal medicine. He ensures that products meet global standards like WHO-GMP and AYUSH guidelines. Key challenges include variability in raw materials, contamination, and regulatory compliance. His team uses advanced analytical techniques, conducts supplier audits, and implements AI-driven quality controls to address these challenges.

1.2. Dr. Priya Nair, Lead Pharmacognosist at Zandu Pharmaceuticals, focuses on the identification and standardization of herbal drugs. Her team employs DNA barcoding and HPTLC fingerprinting to verify authenticity and quality, along with testing for microbial and heavy metal contamination. Zandu addresses adulteration by tracing suppliers, screening for contaminants, and training farmers on ethical practices.

1.3. Mr. Rakesh Gupta, a Senior Inspector at FDA India, is responsible for ensuring compliance in herbal medicine manufacturing. He identifies common issues like inadequate GMP compliance and mislabeling. The FDA conducts facility audits, enforces strict labeling, and recalls unsafe products. Gupta recommends using blockchain for traceability, enhancing collaboration with industry, and raising public awareness about herbal quality.

1.4. Dr. Rajesh Kumar, Quality Control Manager at Himalaya Wellness Company, oversees the entire QA process and ensures compliance with regulations. He faces challenges from variability in raw materials and uses stringent supplier qualification, advanced testing methods, and standardization processes to maintain product consistency.

1.5. Mr. Anil Sharma, Senior Regulatory Officer at the Ministry of AYUSH, formulates policies for herbal medicine quality control. Challenges include inconsistent global regulations and adulteration. The Ministry is strengthening GMP enforcement, encouraging research partnerships, and developing stricter labeling requirements to improve quality in herbal medicine production.

1.6. Dr. Meera Nair, a Senior Scientist at the Central Drugs Testing Laboratory (CDTL), oversees the testing of herbal medicines for contamination, including heavy metals and microbial growth. Common contaminants include lead, arsenic, microbial growth, and pesticide residues. The laboratory utilizes techniques like HPLC, GC-MS, FTIR spectroscopy, and DNA barcoding for quality control.

1.7. Mr. Vivek Sharma, Quality Control Manager at Patanjali Ayurved Ltd., ensures that herbal products meet safety and quality standards. He faces challenges like raw material variability, microbial risks, and regulatory compliance. To address these, he conducts supplier audits, microbial testing, and utilizes advanced analytical methods. The company adheres to good manufacturing practices and regulatory audits.

1.8. Ms. Neha Joshi, Quality Control Manager at Dabur India Ltd., focuses on product safety and efficacy through rigorous testing. Key concerns include herbal adulteration, chemical residues, and stability issues. Dabur uses advanced authentication methods, pesticide residue analysis, and conducts stability studies to ensure the quality of their herbal medicines.

RESULTS AND DISCUSSION

QA Practices Assessment

Survey Results

Survey responses from 57 manufacturers indicated an overall GMP compliance rate of 68.4% (39/57, mean = 3.7 ± 0.8). Scale-wise:

Large-scale: 93.3% (14/15, mean = 4.6 ± 0.4).

Medium-scale: 70% (14/20, mean = 3.8 ± 0.6).

Small-scale: 52% (13/25, mean = 3.2 ± 0.9).

ANOVA showed significant differences ($F(2,54) = 12.34$, $p < 0.001$), with large-scale outperforming small-scale ($p < 0.001$). Detailed findings:

Raw Material Testing: 63.2% (36/57) tested regularly (weekly/biweekly), with 100% (15/15) large-scale, 75% (15/20) medium-scale, and 40% (10/25) small-scale compliance.

Process Validation: 71.9% (41/57) validated critical steps (e.g., drying, milling), with 93.3% (large), 80% (medium), and 52% (small).

Equipment Maintenance: 66.7% (38/57) followed schedules, highest in large-scale (100%).

Documentation: 78.9% (45/57) maintained records, with completeness at 93.3% (large), 85% (medium), and 60% (small).

Training: 68.4% (39/57) trained staff annually, ranging from 100% (large) to 48% (small).

Interview findings

Key issues in herbal medicine quality control include raw material variability and contamination. Solutions highlighted by professionals include advanced phytochemical analysis, authenticity methods like DNA barcoding, facility audits, and stricter labeling regulations. Emphasis on analytical methods and safety studies is crucial for ensuring product efficacy and compliance.

Case Study Insights

To provide a deeper understanding of QA practices and their practical implementation, five case studies were conducted across manufacturers of varying scales: two small-scale (S1 and S2), two medium-scale (M1 and M2), and one large-scale (L1). These case studies involved direct observation of production facilities, review of QA documentation, and assessment of physical conditions, offering a granular view of how survey-reported practices translate into operational realities and influence laboratory outcomes. Below are the detailed findings for each case study.

Small-Scale Manufacturer S1: Rudimentary QA with Significant Gaps

Facility Overview: Located in a rural area of Chittorgarh, Rajasthan, S1 is a family-run operation producing Ashwagandha capsules (50 kg/month) with a turnover of ₹40 lakh annually. The facility spans 200 sq. ft., with a single production room and an adjacent storage area.

Production Process: Raw Ashwagandha roots are sourced from local farmers, manually cleaned with tap water, air-dried on tarps (30–35°C, 8–10 hours), and ground using a domestic grinder. Capsules are filled using a hand-operated machine (100 capsules/hour). No sterilization step is included.

Compliance Analysis

This section provides a thorough assessment of how well 30 herbal medicine samples 12 from small-scale producers, 10 from medium-sized manufacturers, and 8 from large-scale manufacturers comply with defined quality requirements, including levels of active constituents, heavy metal concentration, and microbial load. In order to evaluate how well QA procedures ensure safety, purity, and efficacy, the analysis combines survey data, test results, and case study insights. A detailed picture of compliance patterns across production scales is provided by the subsections that are dedicated to each parameter, each of which contains particular results, statistical comparisons, and consequences.

Microbial Load

Total Aerobic Microbial Count (TAMC)

With an overall mean of $7.8 \times 10^4 \pm 2.9 \times 10^4$ CFU/g, 63.3% (19/30) of the 30 examined samples met the WHO standard of TAMC < 10^5 CFU/g. Results on a scale showed notable variability:

Small-Scale: Only 33.3% (4/12) were compliant, with a mean TAMC of $1.9 \times 10^5 \pm 4.2 \times 10^4$ CFU/g (range: 1.4×10^5–2.5×10^5 CFU/g). Non-compliant samples included S1 (2.2×10^5 CFU/g) and S2 (1.7×10^5 CFU/g), reflecting poor storage (28°C, 70% RH) and infrequent testing (monthly).

Medium-Scale: 70% (7/10) met the standard, with a mean of $8.9 \times 10^4 \pm 3.1 \times 10^4$ CFU/g (range: 6.5×10^4–1.3×10^5 CFU/g). M1 (8.5×10^4 CFU/g) and M2 (9.2×10^4 CFU/g) were compliant, aided by autoclaving and biweekly testing, though one sample (1.3×10^5 CFU/g) exceeded due to inconsistent sterilization. Large-Scale: 100% (8/8) complied, with a mean of $5.5 \times 10^4 \pm 1.8 \times 10^4$ CFU/g (range: 4.0×10^4–7.2×10^4 CFU/g). L1's samples (e.g., 5.0×10^4 CFU/g) benefited from gamma irradiation and weekly in-house testing.

Statistical Analysis: One-way ANOVA showed significant differences across scales ($F(2,27) = 14.56$, $p < 0.001$), with post-hoc Bonferroni tests confirming small-scale TAMC was higher than large-scale ($p < 0.001$) and medium-scale ($p = 0.008$).

Total Yeast and Mold Count (TYMC)

100% (30/30) complied with As ≤ 3 ppm, with a mean of 1.0 ± 0.5 ppm (range: 0.4–2.2 ppm). No scale differences (ANOVA, $F(2,27) = 1.12$, $p = 0.34$), suggesting minimal As contamination risk across sources.

Cadmium (Cd)

100% (30/30) met Cd ≤ 1 ppm, with a mean of 0.5 ± 0.2 ppm (range: 0.2–0.8 ppm). Uniform compliance indicates effective soil management by suppliers.

70% (21/30) of samples met the WHO TYMC limit of ≤ 10^3 CFU/g, with an overall mean of $1.1 \times 10^3 \pm 0.7 \times 10^3$ CFU/g. Scale-wise: Small-Scale: 50% (6/12) were compliant, with a mean of $2.3 \times 10^3 \pm 0.9 \times 10^3$ CFU/g (range: 1.2×10^3–3.0×10^3 CFU/g). S1 (2.5×10^3 CFU/g) and S2 (2.0×10^3 CFU/g) exceeded due to moldy storage conditions (70% RH, 10% fungal growth observed). Medium-Scale: 80% (8/10) complied, with a mean of $1.4 \times 10^3 \pm 0.6 \times 10^3$ CFU/g (range: 9.0×10^2–2.1×10^3 CFU/g). M2 (1.5×10^3 CFU/g) was non-compliant, linked to dusty shelves and biannual testing. Large-Scale: 100% (8/8) met the limit, with a mean of $7.8 \times 10^2 \pm 2.5 \times 10^2$ CFU/g (range: 5.0×10^2–9.5×10^2 CFU/g), reflecting L1's HEPA-filtered storage (50% RH).

Statistical Analysis: ANOVA indicated significant variation ($F(2,27) = 10.23$, $p < 0.001$), with small-scale TYMC higher than large-scale ($p < 0.001$).

Heavy Metal Content

Lead (Pb)

86.7% (26/30) of samples met the WHO limit of Pb ≤ 10 ppm, with an overall mean of 4.5 ± 2.6 ppm. Scale-wise:

Small-Scale: 66.7% (8/12) compliant, mean = 6.8 ± 3.5 ppm (range: 3.2–15.1 ppm). Four exceedances (11.2 ppm S2, 12.5 ppm, 13.8 ppm S1, 15.1 ppm) tied to uncertified rural suppliers (case study S1, S2).

Medium-Scale: 100% (10/10) compliant, mean = 3.9 ± 1.8 ppm (range: 2.0–6.5 ppm), reflecting certified sourcing (M1, M2).

Large-Scale: 100% (8/8) compliant, mean = 2.5 ± 1.2 ppm (range: 1.5–4.0 ppm), due to GACP suppliers (L1).

Arsenic (As)

100% (30/30) complied with As ≤ 3 ppm, with a mean of 1.0 ± 0.5 ppm (range: 0.4–2.2 ppm). No scale differences (ANOVA, $F(2,27) = 1.12$, $p = 0.34$), suggesting minimal As contamination risk across sources.

Cadmium (Cd)

100% (30/30) met Cd ≤ 1 ppm, with a mean of 0.5 ± 0.2 ppm (range: 0.2–0.8 ppm). Uniform compliance indicates effective soil management by suppliers.

Correlations

Supplier Certification: Negative correlation with Pb ($r = -0.71$, $p < 0.01$); certified suppliers (L1, M1) averaged 2.5–3.9 ppm vs. 6.8 ppm for uncertified (S1, S2).

Testing Frequency: $r = -0.65$, $p < 0.05$; weekly Pb checks (L1) ensured compliance vs. biannual (S2).

Active Constituent Analysis

Ashwagandha (Withanolides)

Of 12 Ashwagandha samples, 66.7% (8/12) met the Indian Pharmacopoeia standard of withanolides ≥ 2.5% w/w, with an overall mean of 2.6 ± 0.5% w/w.

Small-Scale: 50% (3/6) compliant, mean = 2.3 ± 0.4% w/w (range: 1.8–2.7%). S1 (2.1%) and two others (1.8%, 2.2%) failed due to uneven drying (8–10 hours, S1 case study).

Medium-Scale: 75% (3/4) compliant, mean = 2.6 ± 0.3% w/w (range: 2.2–2.9%). M1 (2.6%) succeeded, but one (2.2%) fell short.

Large-Scale: 100% (2/2) compliant, mean = 2.8 ± 0.2% w/w (range: 2.7–2.9%), due to precise drying (L1, 3 hours).

Triphala (Gallic Acid)

70% (7/10) of Triphala samples met gallic acid ≥ 1.5% w/w, with a mean of 1.7 ± 0.4% w/w.

Small-Scale: 50% (2/4) compliant, mean = 1.4 ± 0.3% w/w (range: 1.2–1.7%). S2 (1.3%) failed, linked to high moisture (12%, case study).

Medium-Scale: 83.3% (5/6) compliant, mean = 1.8 ± 0.3% w/w (range: 1.4–2.0%). One (1.4%) was non-compliant.

Large-Scale: 100% (1/1) compliant, mean = 1.9% w/w (L1).

Tulsi (Ursolic Acid)

87.5% (7/8) met ursolic acid ≥ 0.5% w/w, with a mean of 0.6 ± 0.2% w/w.

Small-Scale: 66.7% (2/3) compliant, mean = 0.5 ± 0.1% w/w (range: 0.4–0.6%). One (0.4%) failed.

Medium-Scale: 100% (4/4) compliant, mean = 0.6 ± 0.1% w/w (range: 0.5–0.7%), with M2 at 0.5%.

Large-Scale: 100% (1/1) compliant, mean = 0.7% w/w (L1).

Comparative Analysis Across Parameters

Small-Scale: Lowest compliance (33.3% TAMC, 50% TYMC, 66.7% Pb, 50–66.7% potency), driven by manual processes, poor storage (S1, S2 case studies), and low survey scores (e.g., 40% testing).

Medium-Scale: Moderate compliance (70–80% microbial, 100% metals, 75–100% potency), reflecting semi-automation (M1) and partial testing (M2), with survey scores of 70–80%.

Large-Scale: Full compliance across all parameters, supported by automated systems, weekly HPLC (L1 case study), and 100% survey adherence.

Implications for QA Practices

Microbial Safety: Large-scale's sterilization (gamma irradiation) vs. small-scale's lack thereof explains the 66.7% TAMC gap.

Heavy Metals: Supplier certification is critical, with small-scale's 33.3% Pb non-compliance highlighting sourcing risks.

Potency: Precise process control (drying, milling) and trained staff are key, as seen in L1's 100% vs. S1's 50% compliance.

Identified Gaps

Quality assurance (QA) practices observed across the 57 surveyed manufacturers and 30 tested herbal medicine samples, as corroborated by five case studies (S1, S2, M1, M2, L1). The gaps are categorized into contamination sources, process weaknesses, resource disparities, and regulatory shortcomings, reflecting systemic and operational challenges that undermine compliance with microbial, heavy metal, and active constituent standards. Each gap is substantiated with specific data and linked to its impact on product quality, providing a foundation for targeted recommendations.

Microbial Contamination

Microbial contamination was a major issue, with 36.7% of samples failing WHO TAMC limits and 30% exceeding TYMC limits. Inadequate raw material screening and poor storage conditions contributed significantly, as 80% of non-compliant samples came from units with infrequent testing. Small-scale units often lacked regular testing and sterilization, leading to high microbial counts. Heavy metal exceedances were found, particularly lead, in 33.3% of small-scale samples, mainly due to unverified suppliers and infrequent testing. Small and medium-scale units faced testing deficiencies and validation gaps, with many lacking proper testing equipment and sterilization protocols. This resulted in substantial non-compliance in microbial and potency levels among these units.

Resource Disparities

Equipment Limitations

Resource gaps led to quality assurance (QA) issues across different scales of operation. Small-scale units had high error rates due to outdated manual tools, while medium-scale units improved with some automation but still faced limitations. Large-scale operations achieved full compliance with advanced equipment. Training was inadequate in small-scale settings, linking low training rates to more errors. Financial constraints in smaller units hindered testing and equipment upgrades, while larger units had the resources for necessary quality improvements. Regulatory oversight was inconsistent, with small and medium-sized units lacking standardized QA guidelines, impacting their compliance and testing practices significantly.

Discussion

The findings from the assessment of quality assurance (QA) practices in herbal medicine production, drawing on survey responses from 57 manufacturers, laboratory analysis of 30 samples, and detailed insights from five case studies (S1, S2, M1, M2, L1). The results reveal a spectrum of QA effectiveness influenced by scale, resources, and regulatory oversight, with significant implications for product safety, efficacy, and consistency. The analysis is structured to explore methodology-result linkages, align findings with existing literature, assess practical and theoretical implications, and address limitations, providing a robust foundation for understanding QA challenges and opportunities in the herbal medicine sector.

Methodology-Results Synergy

The mixed-methods approach, using surveys, lab testing, and case studies, revealed strong links between QA practices and outcomes. A survey showed a GMP adherence rate of 68.4% among manufacturers, which aligns with high compliance rates in laboratory tests. Large-scale units demonstrated better compliance due to regular testing and trained staff, while small-scale units struggled with both compliance and testing frequency. Case studies supported these findings, showing that automated systems led to better outcomes compared to manual processes in less controlled environments. The study echoes prior research, emphasizing the importance of proper storage, training, and preventive measures in quality assurance in herbal medicine production.

Practical Implications

Scale-Specific Challenges

Systemic obstacles that small-scale units must overcome include manual procedures, little testing (40%) and inadequate storage (70% RH), which contribute to 33.3% Pb and 66.7% microbiological non-compliance. Semi-automation improves microbiological compliance in medium-scale units by 70–80%; nonetheless, progress is limited by uneven sterilization (e.g., M2: TYMC 1.5×10^3 CFU/g) and a lack of HPLC. Large-scale units use resources and automation to create a standard with complete compliance (e.g., L1's ₹50 lakh setup). This gradient recommends customized interventions: mid-tier improvements (like HPLC subsidies) for medium-scale, long-term investment for large-scale, and inexpensive instruments (like portable microbial kits) for small-scale.

Consumer Safety and Market Trust

While 33.3% Pb exceedances (e.g., S2: 11.2 ppm) threaten long-term toxicity, 36.7% TAMC and 30% TYMC failures in small-scale samples (e.g., S1: 2.2×10^5 CFU/g) provide health hazards (e.g., infections). Inadequate potency (e.g., S1: 2.1% withanolides) compromises effectiveness and damages customer confidence. Given that 80% of people worldwide use herbal medicines, large-scale consistency (100% compliance) emphasizes how standardized QA may improve market confidence (WHO).

Economic and Policy Considerations

Compared to L1's ₹5 crore capacity, small-scale units' financial limitations (₹40–45 lakh turnover) point to cost obstacles to QA improvements (e.g., HPLC: ₹4,00,000). This is made worse by regulatory loopholes (biennial audits for S1), which show that in order to level the playing field and support India's AYUSH industry growth objectives, subsidies and stronger enforcement are required.

Theoretical Implications

QA vs. QC Framework

The results validate the QA-QC dichotomy proposed by Yau et al. (2015): proactive QA (weekly HPLC, training) assures quality, whereas reactive QC (e.g., S2's outsourced testing) fails to prevent contamination. This highlights the necessity of a preventative QA methodology in the manufacturing of herbal medicines.

Scale and Quality Nexus
The study presents a scale-quality nexus in which compliance is directly predicted by the availability of resources (training, equipment) (r = -0.82 for testing frequency, r = 0.79 for documentation). Future studies on resource allocation in the traditional medicine sectors can be guided by this theoretical framework.

Standardization Challenges
Variability in testing (TLC vs. HPLC) and drying (S1: 8–10 hours vs. L1: 3 hours) underscores the challenge of standardizing herbal production, bolstering the demand for phytochemical consistency through advanced analytics made by Govindaraghavan et al. (2015).

Limitations
Sample Size and Scope
Although the 57-manufacturer survey and 30-sample lab analysis are reliable for Rajasthan, its applicability to India's varied herbal industry is limited. Their gaps could be overrepresented by small-scale dominance (12/30 samples), which could understate medium- and large-scale variability.
Methodological Constraints
Because of its lesser sensitivity, TLC may overlook tiny pollutants, hence relying on it in small/medium-scale units (e.g., S1, M2) instead of HPLC in L1 may induce analytical bias. Seasonal variation study (e.g., monsoon humidity effects on TYMC) was not possible due to the 6-week lab testing duration.

CONCLUSION

This study assesses quality assurance (QA) practices in herbal medicine production in Rajasthan, India. Large producers meet QA standards fully due to advanced technology and trained staff. In contrast, small and medium producers struggle with compliance due to limited resources and inconsistent practices. The research emphasizes the need for targeted interventions to enhance safety and trust in herbal medicines. Recommendations include subsidies for medium-scale units, affordable testing for small-scale producers, and continuous investment for larger operations, aiming to improve QA practices globally.

Conflicts of Interest
The authors declare that there are no conflicts of interest, whether financial or otherwise.

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