# A Feasibility Study for Quality Control Testing on Raw Materials Used in Natural Products in Malaysia

Tan Hooi Tien[1], Nurul Azeera binti Hasnan[2], Wan Najbah Nik Nabil[2], Siti Fatimah binti Idris[2], Seetha Ramasamy[2]

[1]New Drug Product Section, Centre of Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia.
[2]Complementary and Alternative Medicine Section, Centre of Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia.

**Abstract**

**Introduction:** In Malaysia, quality control (QC) testing of finished products is compulsory for the registration of natural products. However, there was minimal control on the quality of raw materials.
**Objective:** This study aimed to assess the feasibility of implementing the requirement of QC testing on raw materials by Malaysian natural product manufacturers.
**Methods:** A cross-sectional study was carried out among natural product manufacturers in Malaysia using an online questionnaire on the Google platform from 15th July to 30th August 2023. The 50-question questionnaire was developed and revised based on the experts' feedback. The data collected via the Google platform were exported into Microsoft Excel for further processing.
**Results:** Out of 156 potential participants, 72 responded to the questionnaire, resulting in a response rate of 46.15%. Of the 72 respondents, 61.1% of them reported conducting QC testing on the raw materials used. The majority (65.3%) acknowledged the importance of testing raw materials. Primary QC tests conducted included organoleptic (97.4%), moisture content (53.8%), microbial limit content (30.8%), and heavy metal testing (23.1%). Of the 44 manufacturers with QC testing facilities, only 8 claimed their testing facility were accredited, and 23 of them followed standard reference methods for identification testing. In real-world practice, despite most respondents (72.2%) realised the necessity of identification tests to ensure the safety of product (38.9%), nearly half (43.1%) disagreed and 29.2% hesitated with implementing mandatory QC testing on raw materials for natural product registration, due to budget constraints (58.8%), whereas 27.8% agreed.
**Conclusion:** It may be feasible to implement QC testing on raw materials for registration of natural products, if a phased approach is proposed. Current gaps could be potentially addressed by incorporating industry engagement, targeted training for regulators and manufacturers, and the expansion of testing infrastructure.
**Keywords:** Raw Material, Quality Control, Natural Product

**NMRR ID:** NMRR-23-01134-8JO
**Corresponding author:** Seetha Ramasamy
Complementary and Alternative Medicine Section, Centre of Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Prof Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor, Malaysia.
Email: seetha@npra.gov.my

## Introduction

Globally, the natural product market is experiencing remarkable growth. The global herbal medicine market size was valued at USD 233.08 billion in 2024. It was expected to expand to USD 251.25 billion in 2025 and projected to reach USD 437 billion by 2032, registering a compound annual growth rate (CAGR) of 8.23% over the forecast period (1). With the expansion of global market for herbal medicines, the safety and quality of herbal medicines become a primary concern for health authorities, industries and public. Considering this, the World Health Organization (WHO), since 2003, had urged the Member States to ensure the safety and quality of herbal medicines, including the raw material (2). It is essential to ensure that plant materials used in herbal formulations are of high quality, free from contaminants, and accurately identified (3). According to the "WHO Global Report on Traditional & Complementary Medicine 2019", 83 out of 179 WHO Member States reported having Good Manufacturing Practices (GMP) in place for manufacturing herbal

medicines. The GMP standards specify the need for QC of raw materials which includes proper identification (4). Reflecting these, the Therapeutic Goods Administration (TGA) in Australia and European Medicines Agency (EMA) emphasise identity testing using macroscopic, microscopic, and chromatographic methods to authenticate herbal materials. Specifications should be based on recognised pharmacopeia standards and include contaminant limits (5, 6).

Malaysia, recognised as one of the twelve most biodiverse countries in the world, serves as a global hub for natural products in which they have contributed significantly to the country gross domestic product (GDP) (7). In Malaysia, the category of natural products includes traditional medicines, herbal products, homeopathic medicines, natural products with modern claim and natural products with therapeutic claim (8). Natural products were regulated under the Control of Drugs and Cosmetic Regulations (CDCR) 1984. According to these regulations, all natural products must be registered with the Drug Control Authority (DCA), with some exceptions such as extemporaneous preparations, traditional preparations that are produced solely through the drying process, traditional medicines used as food, spices or flavouring of food that do not have any medicinal claim, as well as traditional preparations used solely for cosmetic purposes (8, 9). For natural product registration in Malaysia, safety and quality testing evidence, such as organoleptic, disintegration, uniformity of weight, microbial contamination test and heavy metal contamination tests, are mandatory for finished products (8). However, there is minimal control on the quality of raw materials, indicating gaps to strengthen the QC for raw materials used in natural products.

The quality of natural products depends on the starting materials (raw materials), manufacturing process, building, equipment and personnel involved. It is important to recognise that QC shall not rely solely on finished product testing but to be built into the product (10). The identification and quantification of active ingredients play a crucial role in addressing challenges such as adulteration, misidentification, and quality inconsistency within the herbal medicine industry (3). Chapter 6 (QC) of the Malaysian Guidelines on GMP for Traditional Medicines and Health Supplements (TMHS) specifies that the identity and quality of starting materials, including the raw materials, shall be tested (10). Recognising the significance of QC testing for raw materials and aligning with the guidelines, the National Pharmaceutical Regulatory Agency (NPRA) intended to enhance QC testing requirements for raw materials of natural products for product registration purpose. Given the importance of understanding manufacturer's awareness and readiness before implementing more rigorous QC requirements, this study was carried out to determine the feasibility of performing QC testing on herbal raw materials by natural product manufacturers in Malaysia.

## Method

This was a cross-sectional study conducted among natural product manufacturers in Malaysia. The study was registered with the National Medical Research Register (NMRR ID-23-01134-8JO) and approved by the Medical Research and Ethics Committee (MREC), Ministry of Health, Malaysia.

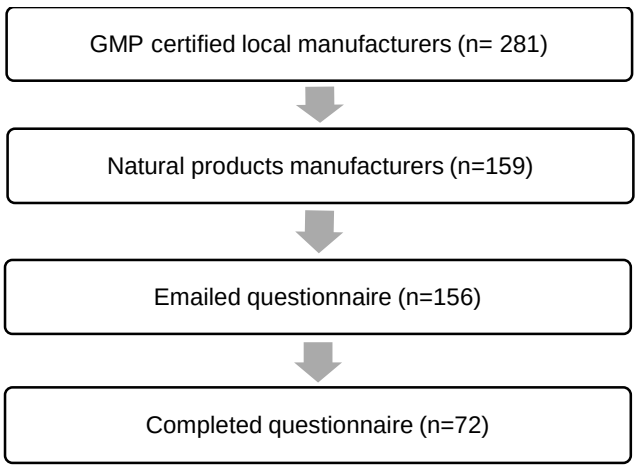


Figure 1: Study flow

The targeted respondents were identified from an updated list of local manufacturers with GMP certification provided by the Centre of Compliance and Quality Control, NPRA. These manufacturers produce a variety of products, including pharmaceuticals, natural products, health supplements, and/or cosmetics. The inclusion criteria for this study were limited to local manufacturers who produced natural products. Manufacturers who produced pharmaceutical products, health supplements and cosmetics were excluded from this study. The study identified 159 natural product manufacturers out of 281 GMP certified local manufacturers. However, three of these manufacturers lacked email addresses in the database and could not be reached for participation. As a result, the number of potential participants decreased to 156 (Figure 1).

The initial draft of the questionnaire was developed by the Committee on Strengthening Quality Control Testing of Natural Products (JKPPKKPS). The questionnaire was distributed to the members of JKPPKKPS to collect feedback with the aim of improving the questionnaire's content and readability. Following the feedback, the questionnaire was revised and reviewed by officers from the Complementary and Alternative Medicine Section, Centre of Product Evaluation and Cosmetic, NPRA for further evaluation on its clarity, comprehensiveness, and suitability. Subsequent revisions were made based on feedback from the NPRA Research and Development (R&D) Committee to ensure better alignment with the study objectives and to facilitate clearer comprehension by participants. The translation process was carefully managed to preserve the instrument's accuracy and relevance. The survey questions were developed in both Malay and English to ensure inclusivity and allow participation from individuals literate in either language. Following this, the link to the final version of the online questionnaire was sent via email to 156 manufacturers as an invitation to participate in this study. The questionnaire, hosted on the Google platform, was open from 15$^{th}$ July to 30$^{th}$ August 2023.

The questionnaire comprised of 50 questions, encompassing both close-ended and open-ended formats. It started with a participant information sheet (PIS) and a request for informed consent. Only participants who provided consent would proceed to answer the questionnaire, which was divided into four domains: i) manufacturers' characteristics; ii) manufacturers' awareness on QC testing of raw material; iii) feasibility of QC testing of raw material in terms of technical aspects, human resources, and market demand; and iv) manufacturers' preparedness regarding the implementation of QC testing for raw material. The responses were kept anonymous to encourage open and honest feedback from the participants.

The data collected from the Google platform were compiled into Microsoft Excel worksheet. Quantitative data were organised and presented in frequency (n) and percentages. The qualitative responses from open-ended questions exhibiting similar meaning and context were aggregated and expressed as frequency (n) and percentages. The data were subsequently presented alongside the corresponding quantitative findings.

## Results

Out of 156 potential participants, 72 responded to the questionnaire, resulting in a response rate of 46.2%. The background characteristics of the respondents were reported in Table 1. More than half of the manufacturers focused only on producing natural products (69.4%), had over 10 years of experience in manufacturing finished products (72.2%) and conducted in-house QC testing for raw material (61.1%).

Apart from their core activity of manufacturing natural products, 15.3% of manufacturers also imported raw materials, and approximately 9.7% provided laboratory service to others. The raw materials that they used were primarily in powder form (62.5%) and sourced locally (88.9%). For imported raw materials, the majority came from China (92.5%), followed by India (43.4%), and Taiwan (22.6%).

Table 1: Background characteristics of the respondents (n=72)

| Background characteristics | n (%) |
|---|---|
| Other services besides manufacturing natural products * | |
| None | 50 (69.4) |
| Raw material importer | 11 (15.3) |
| Raw material supplier | 8 (11.1) |
| Raw material manufacturer | 6 (8.3) |
| Laboratory service | 7 (9.7) |
| Product registration service, export product | 1 (1.4) |
| Years of experience as manufacturer of finished product | |
| 3 – 5 years | 6 (8.3) |
| 6 – 10 years | 13 (18.1) |
| > 10 years | 52 (72.2) |
| Not applicable (inactive or manufacture raw materials) | 1 (1.4) |
| Conduct In-house QC testing for raw materials | |
| Yes | 44 (61.1) |
| No | 28 (38.9) |
| Source of raw materials * | |
| Local | 64 (88.9) |
| Imported | 45 (62.5) |
| Self-produced | 9 (12.5) |
| Country of origin for imported raw material (n=53) * | |
| China | 49 (92.5) |
| India | 23 (43.4) |
| Taiwan | 12 (22.6) |
| US | 8 (15.1) |
| Australia | 3 (5.7) |
| Indonesia | 2 (3.8) |
| Others: Thailand, Japan, Korea, South Africa, Brazil, Sri Lanka | 6 (11.3) |
| Form of raw materials * | |
| Powder | 45 (62.5) |
| Extract powder | 36 (50.0) |
| Crude | 35 (48.6) |
| Liquid or oil | 23 (31.9) |
| Extract liquid | 13 (18.1) |
| Standardised extract | 12 (16.7) |

* Multiple responses were allowed for these questions.

Manufacturers' awareness on QC testing of raw material

Manufacturer awareness on QC testing of raw material was presented in Table 2. Majority of the manufacturers (n=47, 65.3%) recognised the importance of testing raw materials, highlighting the need to verify the correct supply of materials (80.9%) and detect any adulterants (59.6%). Conversely, among those who deemed such testing unimportant (n=18, 25.0%), nearly all cited cost restraints (94.4%) and considered raw material supplier documentation to be sufficient (72.2%). When suppliers could not provide COA for raw materials, 75.0% of manufacturers conducted QC testing on the raw materials. Majority of manufacturers (73.6%) were aware of standard methods available for identifying herbs.

Table 2: Manufacturers' awareness on QC testing of raw materials # (n=72)

| Awareness on QC testing of raw materials | n (%) |
|---|---|
| Important to test the raw materials (n=72) | |
| Yes | 47 (65.3) |
| No | 18 (25.0) |
| Unsure | 7 (9.7) |
| Reasons of being important (n=47) * | |
| Ensure the supply of correct raw materials. | 38 (80.9) |
| Adhere to regulatory requirement. | 31 (66.0) |
| Ensure no adulterant. | 28 (59.6) |
| Ascertain the content of raw materials. | 27 (57.4) |
| Ensure free from contamination by heavy metals, microbes or chemicals. | 2 (4.3) |
| Reasons of being not important (n=18) * | |
| It incurs cost. | 17 (94.4) |
| Suppliers have provided sufficient documentation. | 13 (72.2) |
| It will delay manufacturing plan. | 12 (66.7) |
| Wastage of raw materials. | 6 (33.3) |
| Finished product will be tested. | 5 (27.8) |
| It is not a regulatory requirement. | 4 (22.2) |
| CoA provided by suppliers of raw materials (n=72) | |
| Yes | 55 (76.4) |
| No | 12 (16.7) |
| Occasionally | 5 (6.9) |
| Conduct QC testing for raw materials if CoA is not provided by the supplier (n=72) | |
| Yes | 54 (75.0) |
| No | 18 (25.0) |
| Aware of the standard methods for identifying herb (n=72) | |
| Yes | 53 (73.6) |
| No | 19 (26.4) |

* Multiple responses were allowed for these questions. Abbreviation: CoA = Certificate of Analysis.
# The complete responses for Domain 2 Manufacturers' awareness on QC testing of raw material can be found in the Appendix.

Feasibility for conducting QC testing on raw material

The feasibility for manufacturers performing QC testing on raw materials was assessed across three dimensions: technical, personnel competency and market demand as presented in Table 3. In terms of technical feasibility, 46 out of 72 manufacturers (63.9%) possess QC testing facilities, but only eight among them were accredited. The primary QC testing conducted by these manufacturers was organoleptic testing (97.4%), moisture content (53.8%) and microbial limit content (30.8%). When inquiring about the accreditation of both the manufacturers' laboratory (Question 2) and the outsourced laboratory (Question 5), many respondents were unable to identify the correct accreditation body (please refer to the complete responses in Appendix).

In terms of personnel competency, a significant number of manufacturers responded that a bachelor's degree (34.7%) and diploma (34.7%) were the minimum qualifications required to conduct QC testing. Most still relying on manual analysis by humans (66.7%). Regarding market demand feasibility, 72.2% of manufacturers agreed with the necessity of conducting identification tests for raw materials in natural products to ensure the safety (38.9%) and quality (22.2%) of finished products. However, 26.4% of manufacturers, while acknowledging the importance of such tests, were unwilling to conduct them.

Table 3: Feasibility for conducting QC testing on raw materials from the manufacturers' perspective # (n=72)

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| **A) Technical Aspect** | |
| Availability of QC testing facilities for raw material (n=72) | |
| Yes | 46 (63.9) |
| No | 26 (36.1) |
| Accreditation of QC testing facilities (n=41) | |
| Yes | 8 (19.5) |
| No | 33 (80.5) |
| Outsourcing QC testing of raw materials (n=72) | |
| Yes | 48 (66.7) |
| No | 24 (33.3) |
| Accreditation of the outsourced laboratory (n=48) | |
| Yes | 45 (93.8) |
| No | 3 (6.3) |
| Types of in-house QC testing available (n=39) * | |
| Organoleptic testing | 38 (97.4) |
| Moisture content | 21 (53.8) |
| Microbial limit test | 12 (30.8) |
| Heavy metal test | 9 (23.1) |
| Identification testing | 6 (15.4) |
| Assay of standardised compound | 2 (5.1) |
| Ash content | 2 (5.1) |
| Pesticide and herbicide residue | 1 (2.6) |
| Aflatoxin | 1 (2.6) |
| Types of in-house QC testing available to identify raw material (n=72) * | |
| Physical or macroscopic examination | 49 (68.1) |
| Chemical testing | 6 (8.3) |
| Thin layer chromatography | 3 (4.2) |
| High performance layer chromatography | 3 (4.2) |
| Others | 6 (8.4) |
| Following standard reference procedure for identification test methods (n=72) | |
| Yes | 23 (31.9) |
| No | 2 (2.8) |
| Unsure | 14 (19.4) |
| Not applicable as doesn't have a laboratory | 33 (45.8) |
| **B) Personnel Competency** | |
| Minimum qualification level for personnel conducting QC testing (n=49) | |
| Bachelor degree | 17 (34.7) |
| Diploma | 17 (34.7) |
| SPM level or equivalent | 14 (28.6) |
| Below high school | 1 (2.0) |
| Analysis of QC results (n=42) | |
| Manually by human analysts | 28 (66.7) |
| Both manually and through computerisation | 12 (28.6) |
| Computerised through applications or tools | 1 (2.4) |
| Based on the CoA from Allied Chemists Laboratory | 1 (2.4) |
| Frequency of continuous training for QC testing personnel (n=62) | |
| Never | 11 (17.7) |
| 1 – 2 times yearly | 47 (75.8) |
| 3 – 6 times yearly | 4 (6.5) |
| **C) Market Demand** | |
| Necessary to conduct identification testing for raw materials (n=72) | |
| Yes | 52 (72.2) |

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| No | 20 (27.8) |
| Reasons for necessary to conduct identification testing (n=46)* | |
| To ensure product safety (e.g. avoid adulteration) | 28 (38.9) |
| To improve the quality of finished products | 16 (22.2) |
| To prevent use of raw material contaminated by heavy metal | 1 (1.4) |
| Required for finished product testing | 1 (1.4) |
| Reasons for not necessary to conduct identification testing (n=20)* | |
| Important for quality, but lack of resource to enforce it | 1 (1.4) |
| Identification test is crucial, but unwilling to conduct it | 19 (26.4) |
| Delay production and increase cost | 4 (5.6) |
| Important for quality, but lack of resource to enforce it | 1 (1.4) |
| Use natural materials | 1 (1.4) |
| No benefit of testing raw materials as the testing of the finished product is the conclusion. | 1 (1.4) |
| Are the time and cost required for raw material identification testing to ensure safety and quality of natural products justified? (n=72) | |
| Yes | 19 (26.4) |
| No | 21 (29.2) |
| Maybe | 32 (44.4) |

* Multiple responses were allowed for these questions. Abbreviation: QC = quality control.
# The complete responses for Domain 3 Feasibility for conducting QC testing on raw material can be found in the Appendix.

Manufacturers' preparedness on implementing QC testing for raw material

Among the respondents, a significant portion (43.1%) expressed disagreement with the implementation of QC testing on raw materials for product registration. The primary reasons for disagreement or uncertainty were constraints in resources such as budget (58.8%) and manpower, facilities and time (7.8%) (Table 4).

Table 4: Manufacturers' preparedness on implementing QC testing for raw materials (n=72)

| Preparedness | n (%) |
|---|---|
| Agree to implement QC testing on raw materials (n=72) | |
| Yes | 20 (27.8) |
| No | 31 (43.1) |
| Maybe | 21 (29.2) |
| Reason for disagreeing or unsure about the implementation of QC testing (n=51) | |
| Budget constraint | 30 (58.8) |
| Not cost effective | 12 (23.5) |
| Manpower, facility and/or time constraint | 4 (7.8) |
| Other reasons | 5 (9.8) |
| Time needed to set up a facility to conduct the test (n=67) | |
| < 1 year | 1 (1.5) |
| 1 – 3 years | 27 (40.3) |
| 4 – 5 years | 14 (20.9) |
| > 5 years | 25 (37.3) |
| Limiting factors in implementing QC testing on raw materials (n=68) * | |
| Cost for setting up the facility | 66 (97.1) |
| Insufficient qualified personnel | 51 (75.0) |
| Insufficient technology | 43 (63.2) |
| The product must meet the contracting company's requirement | 22 (32.4) |
| Cost of hiring qualified personnel | 2 (2.9) |
| Delaying production process | 1 (1.5) |
| Difficulty in findings stable suppliers for reagents, and contractors for equipment maintenance. | 1 (1.5) |
| Limited cash flow without improvement in sales | 1 (1.5) |

* Multiple responses were allowed for these questions.

When responding to an open-ended question about suggestion for implementing QC testing on raw materials, respondents proposed a phased approach, starting with simple testing rather than full-scale implementation. There were also suggestions for a grace period (at least 3 years) to allow time for the manufacturers to establish testing facilities (results not presented in Table 4).

**Discussion**

In order to establish quality standards and specifications for herbal materials, a guideline of Quality Control Methods for Medicinal Plant Material has been published in 1998 by WHO (3). The majority of adverse events reported in relation to the use of herbal products and medicines are attributable to poor quality of the product. Hence, to promote the safety of herbal medicines, new guidelines pertaining to quality assurance and control have been consistently developed over the years to update existing ones (3). The findings of this study suggested the feasibility of QC testing on raw materials and provided valuable insights into the practices and challenges faced by local natural product manufacturers. The background information indicated that a significant proportion of manufacturers have over a decade of experience in producing natural products, suggesting a well-established local industry with substantial knowledge and operational capacity. The capacity beyond manufacturing, such as providing laboratory services (9.7%) may be driven by the need to control product quality and cater to the registration requirements prior to be marketed. The manufacturers primarily sourced raw materials locally (88.9%) which might imply that local supply chain for raw material is sufficiently mature to support the sustainability and quality of natural products.

The effort to strengthen QC testing for Natural Products falls under Strategic Thrust 3, Strategy 1 (Strengthen Governance and Regulatory Control), Initiative 4 of the Ministry of Health Malaysia (MOH) Pharmaceutical Services Programme (PSP) Strategic Plan 2021-2025 with the objective of strengthening the QC requirement in ensuring raw materials used in natural products manufacturing were identified and authenticated before they were released into market. The initiative included the recognition of private laboratories that were able to conduct identification and authentication tests for herbal raw materials and enforcement on the requirement to submit certificate of analysis (COA) for raw materials from the suppliers and manufacturers of finished product during product registration (11). In preparation for the prospective implementation of QC testing on raw materials for natural product registration, NPRA's Committee on Strengthening Quality Control Testing of Natural Products organised a series of awareness programmes including two virtual workshops in 2021 and one physical workshop in 2023. These workshops attracted a broad audience (approximately 100 participants per virtual session and 150 for the physical session). During the Q&A sessions and post workshop feedback, it became evident that some manufacturers remained unfamiliar with the purpose and requirements of QC testing. Following the awareness programmes, this study was undertaken to assess the feasibility of manufacturers conducting QC testing on raw materials. Many of the manufacturers acknowledged the importance of QC testing to verify raw material authenticity and detect adulterants. When COA for the raw material was not provided by the supplier, a significant portion of them would conduct QC testing on the material, thus displaying their proactivity in quality assurance of the raw material. Additionally, most of the manufacturers were aware of available standard references or methods for herbal raw material identification. These findings indicate that the awareness programmes might have contributed to the improved awareness on quality assurance practices among the industry players.

Looking at the technical aspects for QC testing, even though some manufacturers reported having QC testing facilities, which indicated the availability of technical capability, these facilities may not fully meet the quality standards required by accreditation bodies. This limitation is likely attributed to the high costs associated with obtaining accreditation, which typically involves meeting minimum requirements for equipment, qualified personnel, and facility infrastructure. Such financial and logistical demands can pose significant barriers, particularly for smaller institutions or those operating with limited budgets (12). The survey respondents also highlighted that budget restraints remained the largest challenge in conducting QC tests for raw materials, followed by shortage in qualified personnel and technology deficiency, which both require financial investment as well.

The most common QC tests conducted on raw materials include organoleptic testing, moisture content, microbial limit and heavy metal testing. These are the existing tests required to be conducted on finished product. In contrast, identification test is not made compulsory in the current registration requirements, thus leading to relatively low availability of testing facilities. The implementation of mandatory

regulatory requirement could potentially improve the adherence of the industry to include identification test as part of the raw material QC testing as per the TMHS GMP guideline. Among the facilities that performed identification testing, the most common tests were macroscopic examination and chemical testing, while less than 5% mentioned other methods such as thin layer chromatography or chemical profiling. While macroscopic examination commonly serves as the initial step in identifying an entire plant, variations in phenotypic features can occur due to factors such as growing conditions and the age of the plant at the time of harvesting. Macroscopic examination becomes impractical when dealing with herbal materials in powdered form, necessitating microscopic examination to be supplemented by chromatographic evidence (13).

With respect to the capacity of personnel in conducting QC testing, most manufacturers equipped with testing facilities agreed to put more emphasis on employing skilled personnel to maintain quality product. Majority of them recognised the need for personnel with at least a diploma or bachelor's degree to conduct QC testing. QC personnel in manufacturing facilities should have the expertise to conduct tests to identify the raw materials as well as to detect adulteration, fungal growth, infestations, and non-uniformity when receiving and inspecting the raw materials (10). On the other hand, many of the tests were conducted manually, with only a minority utilising computer-based applications as analytical tools. This may be due to limited financial and technological resources required to implement advanced analytical technologies. In addition, it was concerning that some manufacturers did not provide continuous training to their employee as it is crucial to maintain the competency level of personnel and to enhance the standards of QC testing in the local facilities.

Market feasibility is one of the key determining factors when it comes to developing QC testing workflow and facilities. Despite a strong recognition on the importance of identification testing to ensure the safety and quality of finished products, respondents generally expressed disagreement or uncertainty regarding its value, primarily due to the concerns over cost and resource constraints. Respondents were worried that high testing cost would lead to higher product prices and risks of market loss, especially for products with multiple active ingredients. These concerns may be addressed by having a more extensive cost-benefit analysis to demonstrate the long-term value of QC testing for raw materials in ensuring compliance with regulatory requirements, thereby enhancing the credibility of natural products and facilitating access to new markets. Furthermore, if the implementation of mandatory raw materials QC testing is done in a staged manner, as suggested by the respondents, local manufacturers would have additional time to prepare for the investment of establishing more extensive testing facilities. This would also allow planning in the aspects of budgeting, personnel and other relevant resources, ultimately to comply with the regulatory requirements. The authority may also consider gradual adaptation, beginning with voluntary compliance and progressing toward mandatory enforcement.

One limitation of this study is that the questionnaire was not pilot-tested to assess its reliability, primarily due to time and resource constraints. Expert consultation is a recommended approach to improve the design and content of surveys when pilot testing is not feasible (14). To mitigate this limitation, the questionnaire was carefully reviewed to improve its clarity, comprehensiveness, and suitability. Another limitation includes missing or incomplete data for some questions, particularly those that were not compulsory to be answered and those that allowed multiple responses, which resulted in varied number of responses from the same group of respondents. This may limit the reliability of the findings and complicate the results. In order to address this issue, detailed information on the number of responses was stated in the result tables to clarify the extent of data coverage. Other than that, the low survey response rate may impact the generalisability of its findings on QC testing feasibility. It may also potentially introduce response bias favouring more proactive manufacturers with established testing facilities and higher awareness. However, the responses still reveal significant industry trends, such as the utilisation of locally sourced raw materials and a strong emphasis on quality assurance, which may be valuable for policy planning. Future studies should aim for higher participation rate and broader stakeholder engagement to strengthen the generalisability and quality of evidence.

## Conclusion

This study indicated that most manufacturers were generally aware of, and committed to QC testing on raw materials. However, financial and technical restraints continue to pose significant challenges in the process whereby addressing them is crucial for the effective implementation of QC testing on raw material to ensure

safety and quality of natural products. Based on the findings of this study, the implementation of QC testing for raw materials as part of the natural product registration process is considered feasible through a phased approach to facilitate a smooth and non-disruptive transition for all stakeholders. By incorporating industry engagement, targeted training for regulators and manufacturers, and the expansion of testing infrastructure, existing capacity gaps could be addressed.

**Acknowledgement**

The authors would like to thank the Director General of Health Malaysia for his permission to publish this article. The authors would also like to thank NPRA's Research and Development Committee as well as Committee on Strengthening Quality Control Testing of Natural Products for their valuable input during the development of survey questionnaire.

**Conflict of interest statement**

The authors declare no conflict of interest. This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

**References**

1. Fortune Business Insights. Herbal medicine market size, share, growth | Forecast, 2024–2032 [Internet]. Pune (IN): Fortune Business Insights; 2025 Oct 27 [cited 2024 Nov 7]. Available from: https://www.fortunebusinessinsights.com/herbal-medicine-market-106320
2. World Health Organization. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues [Internet]. Geneva (CH): WHO; 2007 June 5 [cited 2024 Nov 7]. Available from: https://www.who.int/publications/i/item/9789241594448
3. World Health Organization. Quality control methods for herbal materials [Internet]. Geneva (CH): WHO; 2011 June 5; [cited 2024 Nov 7]. Available from: https://www.who.int/publications/i/item/9789241500739
4. World Health Organization. WHO global report on traditional and complementary medicine 2019 [Internet]. Geneva (CH): WHO; 2019 June 4 [cited 2024 Nov 7]. Available from: https://www.who.int/publications/i/item/978924151536
5. Therapeutic Goods Administration (AU). Identity testing for herbal materials: guidelines [Internet]. Canberra (AU): Australian Government Department of Health; 2004 [updated 2004 May 25; cited 2024 Nov 7]. Available from: https://www.tga.gov.au/identity-testing-herbal-materials
6. European Medicines Agency. Guideline on quality of herbal medicinal products/traditional herbal medicinal products Rev.3. Amsterdam: EMA; 2022 Jan 18 [cited 2024 Nov 7]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/final-guideline-quality-herbal-medicinal-productstraditional-herbal-medicinal-products-revision-3_en.pdf
7. Ahmed IA. Natural drugs from plants [Internet]. London (GB): IntechOpen Limited; 2022. Chapter 4, Ethnomedicinal uses of some common Malaysian medicinal plants. [cited 2024 Nov 7]. Available from: https://www.intechopen.com/books/11752
8. National Pharmaceutical Regulatory Agency. Drug Registration Guidance Document (DRGD) 3rd ed (8th rev) [Internet]. Putrajaya (MY): NPRA; 2024 [updated 2024 July; cited 2024 Nov 24]. Available from https://www.npra.gov.my/easyarticles/images/users/1153/DRGD%20July%202024/MAIN-BODY-Drug-Registration-Guidance-Document-DRGD-3rd-Edition-8th-Revision-July-2024.pdf
9. Government of Malaysia. Control of Drugs and Cosmetics Regulations 1984. Putrajaya (MY): Government of Malaysia; 1984. 19 p.
10. National Pharmaceutical Regulatory Agency. Guidelines on good manufacturing practice for traditional medicines and health supplements 1st ed [Internet]. Kuala Lumpur (MY): NPRA; 2008 [updated 2008 Jan 1; cited 2024 Nov 7]. Available from https://www.npra.gov.my/index.php/en/guidelines-for-compliance-licensing/1541-guidelines-on-good-manufacturing-practice-for-traditional-medicines-and-health-supplements.html
11. Pharmaceutical Services Programme. Pharmaceutical Services Programme strategic plan: 2021–2025 [Internet]. Putrajaya (MY): Ministry of Health; 2021 [updated 2021; cited 2024 Nov 7]. Available from: https://pharmacy.moh.gov.my/sites/default/files/document-upload/pharmaceutical-services-programme-strategic-plan-2021-2025.pdf
12. Grochau I, Caten CS, Forte MMC. Motivations, benefits, and challenges on ISO/IEC 17025 accreditation

of higher education institution laboratories. Accred Qual Assur. 2018 May;23(3):145–53.
13. Muyumba NW, Mutombo SC, Sheridan H, Nachtergael A, Duez P. Quality control of herbal drugs and preparations: The methods of analysis, their relevance and applications. Talanta Open. 2021 Dec; 4: 100070.
14. Fink A. How to conduct surveys: a step-by-step guide. 6th ed. Thousand Oaks (CA): Sage Publications; 2017. 224 p.

## Appendix

*Complete responses for Domain 2 and Domain 3 of the questionnaire*

Domain 2: Manufacturers' awareness on QC testing of raw material

| Awareness on QC testing of raw materials | n (%) |
|---|---|
| 1. Is it important to test the raw materials? (n=72) | |
| Yes, it is important as to ….. (n=47)* | 47 (65.3) |
| ensure the supply of correct raw materials. | 38 (80.9) |
| adhere to regulatory requirement. | 31 (66.0) |
| ensure no adulterant. | 28 (59.6) |
| ascertain the content of raw materials. | 27 (57.4) |
| ensure free from contamination by heavy metals, microbes, or chemicals. | 2 (4.3) |
| No, it is not important because ….. (n=18)* | 18 (25.0) |
| it incurs cost. | 17 (94.4) |
| suppliers have provided sufficient documentation. | 13 (72.2) |
| it will delay manufacturing plan. | 12 (66.7) |
| wastage of raw materials. | 6 (33.3) |
| finished product will be tested. | 5 (27.8) |
| it is not a regulatory requirement. | 4 (22.2) |
| Unsure | 7 (9.7) |
| 2. Do the suppliers of raw materials provide CoA? (n=72) | |
| Yes | 55 (76.4) |
| No | 12 (16.7) |
| Occasionally | 5 (6.9) |
| For responders who answered "No" and "Occasionally", what documents are received? (n=17) | |
| Delivery order, receipt and/or invoice | 8 (44.4) |
| No document | 6 (33.3) |
| Safety data | 1 (5.6) |
| Raw material specification | 1 (5.6) |
| In-house QC testing | 1 (5.6) |
| 3. Details included in the CoA of raw materials provided by suppliers: (n=66)* | |
| Organoleptic test | 55 (83.3) |
| Heavy metal test | 52 (78.8) |
| Raw materials details | 51 (77.3) |
| Microbial limit test | 45 (68.2) |
| Moisture content | 44 (66.7) |
| Extraction ratio | 31 (47.0) |
| Extraction solvent | 28 (42.4) |
| Test for identification and comparison to standard reference | 26 (39.4) |
| Assay of standardised compound | 23 (34.8) |
| Ash content | 21 (31.8) |
| Not applicable because not receiving CoA | 10 (15.2) |
| Pesticide and herbicide residue | 9 (13.6) |
| Aflatoxin | 5 (7.6) |

| Awareness on QC testing of raw materials | n (%) |
|---|---|
| 4. If no CoA is provided by the supplier, do respondents conduct QC testing on the raw materials? (n=72)* | |
| Yes | 54 (75.0) |
| No, QC testing is not conducted because … (n=18)* | 18 (25.0) |
| Costly | 13 (72.2) |
| Limited quantity of raw materials | 8 (44.4) |
| Not a regulatory requirement | 7 (38.9) |
| Unable to find a suitable lab for testing | 5 (27.8) |
| Others: Unaware of the specific tests required for raw materials | 1 (5.6) |
| Others: Wastage of raw materials | 1 (5.6) |
| Others: Refrain from procuring from suppliers who do not provide CoA | 1 (5.6) |
| Others: Testing on finish products are more important | 1 (5.6) |
| Others: Time consuming | 1 (5.6) |
| 5. Are the respondents aware of the standard methods available for identifying herb? (n=72) | |
| Yes | 53 (73.6) |
| No | 19 (26.4) |

Domain 3: Feasibility for conducting QC testing on raw material

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| **A) Technical Aspect** | |
| 1. Are tests for raw material available in the respondents' setting? (n=72) | |
| Yes | 46 (63.9) |
| No | 26 (36.1) |
| 2. Are the respondents' QC testing facilities accredited? (n=41) | |
| Yes | 8 (19.5) |
| Name of the accreditation body (open ended response) (n=6) | |
| MS ISO/IEC 17025 | 2 (33.3) |
| Standard Malaysia | 2 (33.3) |
| Name of laboratory | 2 (33.3) |
| No | 33 (80.5) |
| 3. Type of QC testing available in the manufacturing plant? (n=39)* | |
| Organoleptic testing | 38 (97.4) |
| Moisture content | 21 (53.8) |
| Microbial limit test | 12 (30.8) |
| Heavy metal test | 9 (23.1) |
| Identification testing | 6 (15.4) |
| Assay of standardised compound | 2 (5.1) |
| Ash content | 2 (5.1) |
| Pesticide and herbicide residue | 1 (2.6) |
| Aflatoxin | 1 (2.6) |
| 4. Do respondents outsource the QC testing of raw materials? (n=72) | |
| Yes | 48 (66.7) |
| No | 24 (33.3) |
| 5. Is the outsourced lab accredited? (n=48) | |
| Yes | 45 (93.8) |
| It is accredited by … (open ended response) (n=43)* | |
| Department of Standard Malaysia, SAMM | 31 (72.1) |
| ISO 17025 | 8 (18.6) |
| NPRA | 4 (9.3) |
| Name of the outsourced laboratory | 1 (2.3) |
| Malaysian Institute of Chemistry | 1 (2.3) |
| Malaysian Palm Oil Board | 1 (2.3) |
| No | 3 (6.3) |

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| 6. Types of testing available in the respondents' facilities to identify raw material? (n=72)* | |
| Physical or macroscopic examination | 49 (68.1) |
| Chemical testing | 6 (8.3) |
| Thin layer chromatography | 3 (4.2) |
| High performance layer chromatography | 3 (4.2) |
| Chemical profiling | 2 (2.8) |
| Others: Fourier-transform infrared spectroscopy | 2 (2.8) |
| Others: Moisture test | 1 (1.4) |
| Others: Identified by expert and/or according to encyclopaedia | 1 (1.4) |
| Not applicable as the manufacturer doesn't have a laboratory | 25 (34.7) |
| 7. Does the identification test methods follow a standard reference procedure (n=72)? | |
| Yes | 23 (31.9) |
| No | 2 (2.8) |
| Unsure | 14 (19.4) |
| Not applicable as the manufacturer doesn't have a laboratory | 33 (45.8) |
| 8. What is the standard reference used in the respondents' setting? (n=28)* | |
| British Pharmacopoeia | 15 (53.6) |
| In-house standard | 13 (46.4) |
| US Pharmacopoeia | 7 (25.0) |
| The Pharmacopoeia of the People's Republic of China | 7 (25.0) |
| Malaysian Herbal Monograph | 5 (17.9) |
| Ayurvedic Pharmacopoeia | 1 (3.6) |
| 9. What is the reason for not having access to the available standard references for identification testing? (n=8) | |
| High cost of the reference materials | 2 (25.0) |
| Never conducted identification tests | 1 (12.5) |
| Lack access to the appropriate standard reference | 1 (12.5) |
| Manufacturing small quantities of products | 1 (12.5) |
| Unable to perform it; only perform organoleptic tests | 1 (12.5) |
| Not familiar with it | 1 (12.5) |
| Lack lab facilities and expertise | 1 (12.5) |
| 10. Can the respondents follow the methods specified in the standard reference for identification testing? (n=72) | |
| Yes | 23 (31.9) |
| No | 11 (15.3) |
| Not applicable as the manufacturer doesn't have a laboratory | 38 (52.8) |
| 11. What are the reasons of unable to follow methods specified in the standard reference? (n=21)* | |
| Lack of equipment | 16 (76.2) |
| Lack of personnel | 15 (71.4) |
| Expensive | 14 (66.7) |
| Lack of chemical substance needed | 13 (61.9) |
| Lack of competency | 13 (61.9) |
| Unfamiliar with the identification tests | 1 (4.8) |
| **B) Personnel Competency** | |
| 12. What is the minimum qualification level required for personnel conducting QC testing? (n=49) | |
| Bachelor degree | 17 (34.7) |
| Diploma | 17 (34.7) |
| SPM level or equivalent | 14 (28.6) |
| Below high school | 1 (2.0) |
| 13. What is the minimum qualification level needed for personnel to analyse/verify QC test results? (n=49) | |
| Bachelor or Degree | 32 (65.3) |
| Diploma | 12 (24.5) |
| SPM level or equivalent | 5 (10.2) |
| Below high school | 1 (2.0) |
| 14. How are QC results analysed? (n=42) | |
| Manually by human analysts | 28 (66.7) |
| Both manually and through computerisation | 12 (28.6) |

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| Computerised through applications or tools | 1 (2.4) |
| Based on the CoA from Allied Chemists Laboratory | 1 (2.4) |
| 15. How frequently are personnel involved in QC testing provided with continuous training? (n=62) | |
| Never | 11 (17.7) |
| 1 – 2 times yearly | 47 (75.8) |
| 3 – 6 times yearly | 4 (6.5) |
| **C) Market Demand** | |
| 16. Is it necessary to conduct identification testing for raw materials used in natural products? (n=72) | |
| Yes | 52 (72.2) |
| No | 20 (27.8) |
| 17. The reasons for above responses are ….. (n=72)* | |
| Positive reasons | |
| To ensure the product safety (e.g. adulteration can be avoided) | 28 (38.9) |
| To increase the quality of finished products | 16 (22.2) |
| To prevent use of raw material contaminated by heavy metal | 1 (1.4) |
| Required for finished product testing | 1 (1.4) |
| Neutral or negatives reasons | |
| Important for quality, but lack of resource to enforce it | 1 (1.4) |
| Identification test is crucial, but unwilling to conduct it | 19 (26.4) |
| Delay production and increase cost | 4 (5.6) |
| Important for quality, but lack of resource to enforce it | 1 (1.4) |
| Use natural materials | 1 (1.4) |
| No benefit of testing raw materials as the testing of the finished product is the conclusion. | 1 (1.4) |
| 18. What is the estimated duration to complete an identification test of a raw material? (n=35) | |
| ⩽1 day | 3 (8.6) |
| 1 – 2 days | 2 (5.7) |
| 3 – 7 days | 6 (17.1) |
| 5 – 7 working days | 4 (11.4) |
| 10 – 20 working days | 5 (14.3) |
| 1 – 3 weeks | 9 (25.7) |
| 1 month | 2 (5.7) |
| Based on form of raw materials | 1 (2.9) |
| Unsure | 1 (8.6) |
| 19. What is the current cost for conducting an identification test on a raw material? (n=59) | |
| < RM 100 | 5 (8.5) |
| RM 101 – RM 200 | 7 (11.9) |
| RM 201 – RM 500 | 24 (40.7) |
| RM 501 – RM 1,000 | 12 (20.3) |
| >RM 1,000 | 11 (18.6) |
| 20. Are the time and cost required for raw material identification testing justified to ensure safety and quality of natural products? (n=72) | |
| Yes | 19 (26.4) |
| No | 21 (29.2) |
| Maybe | 32 (44.4) |
| 21. The reasons for Question 20 reply. It is … (n=33) | |
| Justified because…. | |
| To ensure the manufactured finished products are safe and high quality for consumers to use | 2 (6.1) |
| To ensure the quality and safety of raw materials | 2 (6.1) |
| Purchase from reliable source that save cost and waiting-time | 1 (3.0) |
| Not justified because ….. | |
| High testing costs raise product prices, risking market loss | 9 (27.3) |
| Testing raw materials is unnecessary because the conclusion is drawn from testing the finished product, which has a Certificate of | 3 (9.1) |

| Aspects considered for conducting QC testing on raw materials | n (%) |
|---|---|
| Analysis (CoA) | |
| Too many raw materials used in 1 finished products | 3 (9.1) |
| The raw materials are limited, in crude form, have a CoA, lack identification testing for local herbs | 5 (15.2) |
| Technical constraints such as insufficient technology, manufacturing delays, unavailability of external labs covering all compounds, and the requirement to comply only with GMP and DRGD | 4 (12.1) |
| Unsure | 2 (6.1) |
| Depending on the dosage form, may not be necessary for oil-based products | 1 (3.0) |