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Review Paper

Review On Plant Drug Quality Control Review

K. Malleswari, Dr. D. Rama Brahma Reddy*, K. Venkata Sai

Nalanda institute of pharmaceutical sciences, siddhardh Nagar, Kantepudi (v), Sattenapalli(M), Guntur (DIST)-522438, AP, India.

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ABSTRACT

Comincreasing popularity globally as drugs, complementary and alternative medicines, food supplements, cosmetics and, more surprisingly, as medical devices. The complexity of herbs and extracts, supplied to such a wide range of markets and in different requlatory environments, raises major quality issues, increasing the need for appropriate analytical methods for their identification and standardization, but also for the detection of adulterants and contaminants. Customs laboratories are often confronted with herbal samples which pose a range of challenges, ranging from quality issues to safety and even legal issues. Selecting a relevant analytical method, from the many available (microscopy, spectrometry, spectroscopy, chromatography…), is a crucial point that mainly depends on the set analytical goals. This review aims to detail such analytical goals and their complexity to propose a selection of analytical methods likely fit for each purpose. Major limiting factors, such as herbal product naming, sampling and sample preparation are also discussed

INTRODUCTION

medical plants are a very important source for natural plants, which offer a chemical diversity important for the pharmaceutical industry and are the cornerstone for many complementary and alternative medicines food supplements, cosmetics and, more surprisingly, medical devices. The complexity of herbs and extracts, supplied to such a wide range of markets and in different requlatory environments, raises major classification and quality issues, increasing the need for appropriate analytical methods for their identification and standardization, but also for the detection of adulterants and contaminants.

Customs laboratories are often confronted with herbal samples (herbal medicines, food supplements, tobacco, cannabis, …), thus facing many different questions that range from identity confirmation to contamination assessment, risk

***Corresponding Author:** Dr. D. Rama Brahma Reddy
Address: *Department of phytochemistry, Nalanda institute of pharmaceutical sciences,Siddarth Nagar, Kantepudi(V), Sattenapalli(M),Guntur (DIST)-522438,AP,India.*
Email ✉: malleswarikunchala105@gmail.com

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identification, classification problematics or legal issues. Significant advances have been made in recent years in the processing and study of medicinal plants, including modern extraction methods and identification of key components. Many analytical methods, often hyphenated, including chromatography, microscopy, spectrometry, spectroscopy, DNS barcoding etc., have been applied to determining the identification and quality of herbal products, Moreover, modifications to published methods are continuously being added and improved yielding an even wider variety of possible analytical choices. But the selection of a given method should be carefully pondered, according to the set analytical objectives.

A general problem is the authentication of plant material. The application of analysis of the genetic profile of plants is gaining inclusion in state and commercial analytical laboratories. The authentication of medicinal plants through DNA barcoding is a gold standard that has been successfully applied to detect adulteration in several high-value species . However, there are limitations within genetic profiling, and also in the accessibility of such technology in basic laboratory settings. In many cases the identification of key chemical biomarkers, active or purely analytical, is often the main approach used; this can be done through direct comparison with chemical reference compounds or by hyphenated methods (GC- and HPLC-MS or MS/MS), referring to public or commercial libraries of compounds. However, many phytochemicals are not commercially available nor described in databases also, the phytochemistry of many herbal medicins can be quite complex and still relatively unknown, questioning the choice of such identification or standardization strategies. The concept of analytical profiling is then proposed, aiming to define a reference chromatographic, spectroscopic, or chromato-spectrometric profile or fingerprint, for a given plant or extract, including a documentation of its robustness and acceptable variations. This approach requires a considerable amount of work to establish an authenticated library of acceptable samples and likely adulterants or counterfeits.

The present review describes possible analytical goals that can be set for herbal samples and their complexity, to help in the selection of analytical methods appropriate for each purpose.

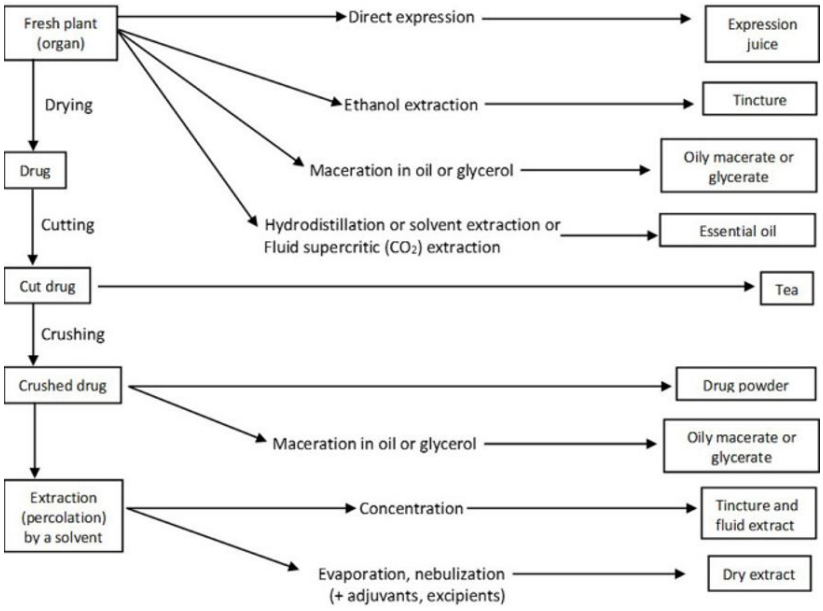

Figure 1 : The major types of standards

 GACP: GACP involves guidelines for the cultivation and harvesting of medicinal plats to ensure they are of the highest quality.

 Good Manufacturing Practices (GMP): GMP provides a framework for themanufacturing processes, ensuring cleanliness, proper storage, handling, and labeling of herbal products.

 Bioactive Compound Quantification: The concentration of bioactive compounds

 Stability Testing: Herbal products should undergo stability testing to assess their shelf life and how they might degrade over time.

2. Standardization of Herbals: Standardization is the process of ensuring uniformity and anunchanging level of competence and composition of natural medicines.

This involvesestablishing specific criteria for the concentration of active compounds or markers that determine the identity and potency of the herbal product.(Kunle, 2012) Futuristic Trends in Pharmacy & Nursing.

INTRODUCTION TO QUALITY CONTROL AND STANDARDIZATION OF HERBALS:

specific chemical compounds, known as marker compounds that are characteristic of the herb and responsible for its therapeutic effects.

 Active Ingredient Concentration: Standardization ensures that the herbal product contains a specific amount of the active ingredient(s) to ensure its potency and efficacy.

Batch-to-Batch Consistency: By standardizing herbal products, manufacturers aim toachieve consistent quality and therapeutic effects from one batch to another.

 Regulatory Compliance: Standardization helps herbal medicines meet the regulatoryrequirements of various health authorities, ensuring consumer safety and confidence.

In conclusion, quality control and standardization are crucial steps in the production of herbal medicines. They aim to ensure the safety, efficacy, and consistency of herbal products, thereby promoting their acceptance and integration into modern healthcare systems.

Ensuring Safety and Purity:

- **Detects Contaminants:** Screens for harmful heavy metals, pesticide residues, and microbial growth.
- **Identifies Adulterants:** Spots fake or substituted plant parts mixed into the raw materials.
- **Prevents Toxicity:** Ensures no dangerous natural toxins or spoiled matter are present.

Guaranteeing Consistency and Efficacy:

- **Standardizes Potency:** Measures exact amounts of active chemical markers so every dose works the same way.
- **Minimizes Natural Variation:** Accounts for differences caused by climate, soil, and harvest time.
- **Builds Trust:** Provides reliable products that medical professionals and consumers can safely use.

Quality Challenges in Herbal Drug Quality:

1. Verification and identification:

- Plant species are sometimes misidentified because they share similar physical traits.
- Using the incorrect plant material might result in toxicity rather than treatment.
- For instance, mistaking Aristolochia species for other herbs might result in nephrotoxicity.

2. Standardization:

- Herbal remedies include intricate combinations of phytochemicals that are influenced by the environment, soil, harvest date, and processing techniques.
- The dose-response is unclear due to the fluctuating concentration of the active component.

3. Contamination:

- Substitution with less costly herbs, addition of fillers, or mixing with synthetic medicines.
- Results in lower efficacy and significant safety hazards

4. **Contamination:**

- Herbal products may contain heavy metals (lead, mercury, arsenic), pesticide residues, microbes, or mycotoxins.
- Contaminants can cause liver, kidney, or neurological toxicity.

5. **Stability & Shelf Life:**

- Many phytochemicals degrade with light, heat, or moisture.
- Loss of potency and unpredictable therapeutic effect.

6.**Lack of Regulatory Uniformity:**

- Herbal medicines are classified differently across countries (drug, supplement, or food).
- No universal standard for quality testing, labeling, and safety evaluation.

7. **Clinical Evidence & Pharmacovigilance:**

- Limited large-scale clinical trials to validate safety and efficacy.
- Weak adverse drug reaction (ADR) reporting systems for herbal medicines

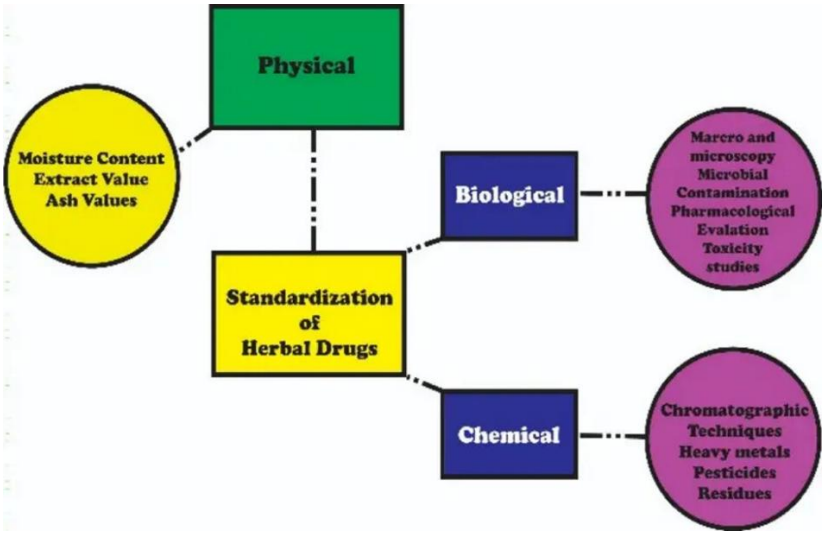

Figure 2: Standardization of Herbal drugs

Figure 3: Quality tansitivity and readability system

Table1:

The various parameters for identification, evaluation and standardization.

Sr. No	Methods	Evaluation parameters
1	Authentication	· Components of herbs · The Present Condition of the Regions · Family · A Supply Based on Organisms · constitution
2	Morphological and sensory evaluation	· Colour · Smell · Tastes · Size · Shape
3	Microscopical evaluation	· Palisade ratio · Stomatal Number · Stomatal index · Vein islet number · Veinlet termination number · Quantitative microscopy
4	Chemical evaluation	•Test •Assay
5	Biological evaluation	· Microbial contamination · Pesticides contamination · Pharmacological activity of drugs
		· Solubility

6	Physical evaluation	· Moisture content · Melting point · Optical rotation · Refractive index · Ash value · Extractive value · Volatile oil content · Foreign matters etc.

WHO's GMP guidelines:

The goal of the Good Manufacturing Practice (GMP) Guidelines for Herbal Medicinal Products is to guarantee that products are always produced in compliance with quality standards. The production and storage of Herbal Medicinal Products are covered by these standards.

(a) Premises:

The manufacturing site must be well chosen, designed, built, and maintained to ensure that the operations to be carried out are supported and that proper hygiene and sanitation are maintained. Effective steps should be taken to prevent any contamination from pests or the surrounding terrain.

(b) Areas for Storage:

Storage spaces should be large enough to accommodate the orderly placement of items like packaging and starting gear, bulk and finished goods, and items in. items that have been released, rejected, returned, or recalled due to a counter blockade.

(c) Outfit Construction:

The production outfit needs to be planned and built to support the manufacturing process. The dress should be made to facilitate efficient cleaning, aid in the collection of dust or debris, and reduce any adverse effects on the quality of the goods.

(d) Hygiene and Sanitation:

Hygiene and sanitation should be practiced in a manner that prevents product contamination. It should include cleaning and drying a gutted before packaging the products.[13]

(e) completed goods:

Finished goods, appropriately packaged after being moved from the product area, must be kept in the finished goods stores inside the area that has been declared under counter blockade. Nevertheless, the completed products store should provide the required environmental conditions.

(f) Packaging and Labelling:

Before being put into use, the packaging line should be checked for agreement. The attire should be practical and clean. All equipment and goods from the prior packing operation should have been taken out. During labelling and packaging, samples should be collected and inspected at random. Activities.

(g) Quality assurance:

Quality control is a crucial component of GMP since it ensures that products have a consistent quality that is appropriate for their intended application.

ADVANTAGES:

- Here are the major benefits of using herbal medicine.

- Cost effective and accessible. High quality herbs should always be taken in controlled dosages as prescribed by a qualified naturopath.
- Natural healing.
- Mitigated risk of side effects.
- You can safely test and try different herbs.

DISADVANTAGE:

The primary constraints are the absence of formulation for raw materials, processing techniques, and final goods, dose formulation, and the absence of quality control standards.

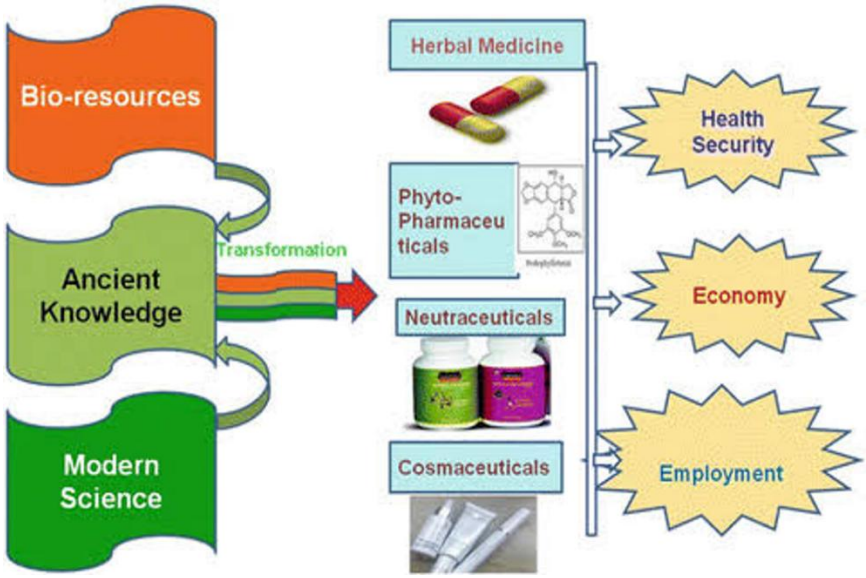

Figure 4: Quality Control of Herbal drugs Advantages and challenges

Application of Chromatography for the evaluation of Herbal drug and Formulation:

Withania somnifera, widely referred to as Ashwagandha, is a multifaceted herb that is integral to both traditional and contemporary herbal medicine. This plant, part of the Solanacee family, occupies an important role in the traditions of India and other regions. Ashwagandha is known for its possible therapeutic benefits, encompassing adaptogenic, anti-inflammatory, antioxidant, and stress relieving effects. Additionally, it has become noteworthy in the pharmaceutical and dietary supplement sectors because of its numerous health advantages. The quality and genuineness of Ashwagandha products can be affected by multiple factors, such as the cultivation source, processing techniques, and storage environments.

This precious herb is, nonetheless, susceptible to possible adulteration and contamination, which could jeopardize its effectiveness and safety. To maintain the purity and quality of Ashwagandha formulations, it is crucial to create analytical techniques that can identify adulteration in these products. HPTLC has become a useful resource in this context, providing an economical and effective method for separating and examining intricate combinations of chemical substances. HPTLC provides a quick, economical, and effective technique for dentifying pure Ashwagandha BRM from possible adulterants in Ashwagandha items present in the market, enhancing the overall integrity and trustworthiness of herbal products in the sector. This technique conserves time and resources by allowing the analysis of several samples at once on a single plate, reducing both solvent usage and waste

generation. It acts as an essential quality assurance method, confirming the authenticity and purity of Ashwagandha products, which in turn boosts consumer confidence and supports the reputation of the herbal sector.

CONCLUSION

When dealing with herbal products, intricate mixtures of compounds embedded in complex matrices, customs laboratories are faced with many different questions, that may involve multifarious and sometimes cumbersome analytical work. This paper aims at summarising the different challenges that can be encountered and the various analytical methods appropriate to answer a given question. It must be stated that, very often, no single analysis will solve a challenge so that a reasoned combination of methods and skills is required, and not all methods are necessarily applicable to all possible components of a mixture or type of matrix. In practice, the selection of an appropriate analysis method should also be based on the nature of the sample and the number of components to be analysed.

In an ideal world, a plant or an herbal product should always be unambiguously identified, with all possible adulterants, contaminants and impurities controlled for. This is hardly possible, technically and economically. And so, a trade-off is often necessary, challenging the whole concept of "proof of quality"; in fact, the intended use of a given material (combined with an accepted level of risk) will condition its more or less enacting quality requirements:

Registration as a drug

Marketing as a food, a cosmetic or a medical device

Use as a raw material for traditional medicine in a developed country

Use as a raw material for traditional medicine in a developing country

This means a delicate analytical balance between what is needed for safety and efficacy, what is desirable and what is locally feasible, the all depending on available technology, local regulations and acceptable costs. This balance can be determined in part from traditional knowledge (plausibility of safety) or by identification of known toxic markers (e.g. pyrrolizidine alkaloids,…), but also by serendipity, in deciphering causes of accidents (e.g. Illicium, Aristolochia,…). And the "proof of quality" certainly evolves with such knowledges.

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