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METHODS FOR STANDARDIZING HERBAL MEDICINES

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ABSTRACT
Herbs are plants or parts of plants valued for their medicinal, aromatic, or savory qualities. They can be consumed, inhaled, or applied topically. Herbal products often contain various naturally occurring biochemicals from plants, many of which contribute to their medicinal benefits. These medicinally beneficial chemicals are referred to as "active ingredients" or "active principles," and their presence depends on several factors, including the plant species, the time and season of harvest, the type of soil, and the method of preparation.

KEYWORDS: chromatography, crude drug, extraction, standardization, botanical product, pharmacogenetics, toxicology

INTRODUCTION
According to the World Health Organization (WHO), standardization and quality control of herbal products involve the physicochemical evaluation of crude drugs, covering aspects such as selection and handling of raw materials, safety, efficacy, and stability assessments of finished products, documentation of safety and risk based on experience, provision of product information to consumers, and product promotion. Herbal medicines, as primary remedies in traditional medicine systems, have been utilized in medical practices since ancient times[1].

Herbal Drugs
Herbal drugs are finished labelled products containing active ingredients derived from aerial and underground parts of plants or other plant materials. The term "herbal drugs" refers to plant parts converted into phytopharmaceuticals through processes involving collection, harvesting, drying, and storage[2].

Types of Herbal Drugs
1. **Single/Crude Drugs**:
    - These are primarily whole, fragmented, or cut plants or plant parts, usually in dried forms but sometimes fresh. This category may also include algae, fungi, and lichen.
2. **Multiple Herbal Formulations**:
    - Formulations obtained by subjecting herbal ingredients to various manufacturing processes such as extraction, distillation, expression, fractionation, chromatography, and formulation[3].

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A. Advantages of Herbal Medicines

a) Herbal medicines are significantly cheaper compared to conventional medications, making them affordable for everyone, unlike other forms of treatment that can be financially burdensome.

b) Herbal medicines can be consumed without a prescription and are readily available at local drug stores[4].

c) Herbal medicines are often more effective in treating certain conditions compared to other medications. They are typically natural and free from synthetic additives unless mixed with other chemical components.

d) One of the greatest benefits of herbal medicine is the absence of side effects. They also provide long-lasting benefits for overall wellness[5].

B. Disadvantages of Herbal Medicines

a) Herbal medications are not typically approved by government regulatory bodies. Their consumption is usually at the individual's own risk, and branded herbal supplements may lack quality assurance[6].

b) Despite their advantages and disadvantages, the benefits of herbal medicines generally outweigh the drawbacks. It's advisable to seek guidance from a qualified herbal practitioner to maximize their benefits.

c) Herbal medicines may not be effective against serious ailments. They cannot treat conditions like a broken bone or manage heart attack-related issues as effectively as conventional medical treatments[7].

Concept and Scope

All medicines, whether synthetic or of plant origin, should meet basic requirements of safety and efficacy (EMEA, 2005; WHO, 2002c, 1998c, 1996, 1991a,b, 1990, 1988). Standardization of herbal medicines involves establishing set standards, inherent characteristics, constant parameters, and definitive qualitative and quantitative values that ensure quality, efficacy, safety, and reproducibility. It's a process of developing and agreeing upon technical standards through experimentation and observation [8].

Currently, identifying all claimed ingredients in a herbal formulation is challenging. Therefore, the initial focus should be on developing parameters to identify the presence of all ingredients. Various chromatographic and spectrophotometric methods, along with evaluation

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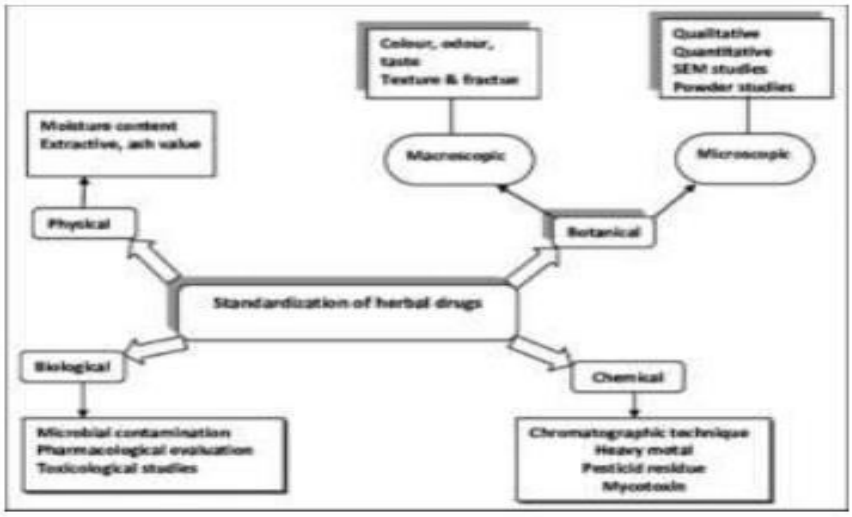
of physicochemical properties, can help establish patterns for identifying different ingredients [9].

Method of Standardization

1. Authenticated raw material forms the fundamental starting point in developing a botanical product. Each stage—from harvest to storage, processing, and formulation—can significantly impact the quality and consistency of the final product. Therefore, implementing methods to ensure quality control during manufacturing and storage is essential to guarantee optimal efficacy and safety of these products. Such controls are also crucial for evaluating pharmacological, toxicological, or clinical studies involving botanical products. Authentication becomes particularly important for drugs that are often substituted or adulterated with morphologically and chemically similar varieties. Many herbal drugs on the market cannot be reliably identified or authenticated based on their morphological or histological characteristics, potentially leading to ineffective treatment or exacerbating the condition [10].
2. According to the World Health Organization (WHO) guidelines (1996a, b; 1992), standardization and quality control of herbal products involve the physicochemical evaluation of crude drugs. This process includes the selection and handling of raw materials, as well as safety, efficacy, and stability assessments of the finished product. It also encompasses documenting safety and risk based on experience, providing product information to consumers, and promoting the product.



Determination of Alcohol Soluble Extractive Value

1. Approximately 5 grams of air-dried coarse powdered drug were weighed and macerated with 100 ml of 90% alcohol in a closed flask for 24 hours. The mixture was shaken frequently during the first 6 hours and allowed to stand for an additional 18 hours.
2. After maceration, the mixture was rapidly filtered to prevent solvent loss.

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3. A 25 ml aliquot of the filtrate was evaporated to dryness in a tarred flat-bottomed shallow dish, dried at 105°C, and then weighed.
4. The percentage of alcohol-soluble extractive values was calculated relative to the weight of the air-dried drug.

Chemical test	Reagents used	Results
Alkaloids		
Mayer	Potassium mercuric iodide solution	Creamy precipitate
Wagner	Iodine potassium solution	Brown precipitate
Hager	Saturated solution of picric acid	Yellow color
Dragendroff	Potassium bismuth iodide solution	Reddish brown precipitate
Amino acid		
Millons test	Millions reagent	White precipitate

Determination of Water-Soluble Extractive Value

1. Approximately 5 grams of air-dried powdered drug was taken and macerated with 100 ml of chloroform water in a closed flask for 24 hours, shaking frequently during the first 6 hours and then allowing it to stand for 18 hours.
2. Subsequently, the mixture was filtered rapidly, taking precautions to prevent solvent loss.
3. A 25 ml portion of the filtrate was evaporated to dryness in a tarred flat-bottomed shallow dish, dried at 105°C, and then weighed.
4. The percentage of water-soluble extractive value was calculated relative to the air-dried drug.

Chemical Tests

Chemical tests serve the following purposes:

- Preliminary (primary) testing for various chemical functional groups.
- Quantification (percentage) of specific chemical groups of interest (e.g., total alkaloids, phenolics, triterpenes, tannins) or establishment of fingerprints.
- Creation of multiple marker-based fingerprint profiles using different marker compounds to indicate the percentage presence of multiple chemical groups.

Qualitative chemical tests include acid value, saponification value, etc. Some of these tests are particularly useful in evaluating:

- Resins (acid value, saponification value).
- Balsams (acid value, saponification value, ester value).
- Volatile oils (acetyl value, ester value).
- Gums (methoxy determination, volatile acidity).

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Table no.- 4 – chemical tests

Ninhydrin	Ninhydrin solution	Violet color
Folin	Folin phenol reagent	Blue color
Pauly	Sulphanillic acid, sodium nitrite and sodium carbonate	Cherry red color
Carbohydrates		
Molisch	Alcoholic alpha naphthol+ sulphuric acid	Purple to violet color changes
Barfoed	Barfoed reagent	Red color
Selivanoff	Selivanoffs reagent	Rose color
Tests for pentoses	Hydrochloric acids phloroglucinol	Red color
Anthraquinone glycosides		
Borntrager	Borntrager reagent	Pink ammonical layer

Some important preliminary tests with their obtaining results and regents used.

Tannis		
Ferric chloride	Ferric chloride	Blue color
Flavonoids		
Alkaline reagent	10%sodium hydroxide solution	Intense yellow color
Ammonium hydroxide	10% ammonium hydro oxide	Yellow fluorescence
zinc	Zinc dust and conc. HCl	Red color

RESULTS AND DISCUSSION

In the field of drug research, there is a significant scope for Ayurvedic researchers, especially in India, which plays a major role in producing standardized and therapeutically effective Ayurvedic formulations. It is crucial for India to explore medicinally important plants, a task achievable through the evaluation and analysis of herbal products using advanced modern techniques.

These guidelines for assessing herbal medicines aim to facilitate the efforts of regulatory authorities, scientific bodies, and industry in developing, evaluating, and registering such products. The advancement of analytical techniques serves as a rapid and specific tool in herbal research, enabling manufacturers to establish quality standards and specifications. This, in turn, supports the process of seeking marketing approval from regulatory authorities based on considerations of therapeutic efficacy, safety, and shelf-life of herbal drugs.

Effective regulation and control of herbal medicines in international commerce necessitates close collaboration between national institutions capable of conducting regular reviews and maintaining oversight.

CONCLUSION

Plant materials are extensively utilized worldwide as home remedies, in over-the-counter drug products, and as raw materials for the pharmaceutical industry, representing a significant

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portion of the global drug market. The quality of herbal drugs encompasses all factors that directly or indirectly contribute to their safety, effectiveness, and acceptability. The field of herbal drugs and formulations is rapidly advancing, with much yet to be explored in terms of their standardization. Therefore, when developing herbal formulations, comprehensive knowledge of the specific drug is essential, encompassing its organoleptic characteristics, phytoconstituents, pharmacological actions, and standardization across various parameters using diverse techniques. The Indian medicinal industry is undergoing profound changes with the increasing adoption of traditional herbal treatments. Many companies are emphasizing the safety, quality, and efficacy of herbal drugs, highlighting the need for more advanced standardization techniques. Advanced analytical methods serve as crucial tools in herbal medicine research, enabling manufacturers to establish quality standards and specifications essential for obtaining marketing approval from regulatory authorities. National health organizations should ensure comprehensive oversight of all herbal pharmaceutical products under their control. Quality control of herbal products must establish robust analytical methods not only for active ingredients but also for factors such as pesticide residues, toxin levels, heavy metal contamination, adherence to good agricultural practices (GAP), and good manufacturing practices (GMP). There is a pressing need for the development of techniques that integrate traditional methods of evaluation and modern standards to meet the evolving demands of herbal medicine quality assurance and regulatory compliance.

REFERENCE

1. K. Kulkarni, G. Jagtap —A Comprehensive Review on Herbal Drug —. American Journal of pharmtech research, 98-101, 2019.
2. Bhusnure Omprakash G, Suryawanshi Shivraj, Vijayendra Swamy S.M, Gholve Sachin B, —Standardization and quality evaluation of herbal drugs‖, 9(3), 1058-1061, 2019.
3. Anupam KR Sachhan, Garima Bishnoi, RupakKumar,‖ Need of Standardization of herbal drug in modern era‖, International Journal of phytomedicine, 8, 300-307, 2016
4. Nikam PH, Kareparamban J, Jadhav A, Kadam V. Future Trends in Standardization of Herbal Drugs. J Appl Pharm Sci, 2012.
5. Ekka NR, Namdeo KP, Samal PK. Standardization strategies for herbal drugsan overview. Res J Pharm &Technol, 2008
6. Mehta SJ, Shah DP, Mehta TJ, Patel PM, Patel NM. Compendial testing method on erbal crude drug- a review. Asian J Pharm Res, 2011
7. Bele AA, KhaleA. Standardization of herbal drugs: an overview. Int Res J Pharm, 011
8. SahilK, Sudeep B, Akanksha M. Standardization of medicinal plant materials. Int J Res Ayur& Pharm, 2011
9. Chanda S. Importance of pharmacogenetic study of medicinal plants: An overview. J Pharmakon & Phytochemical, 2014
10. Revathy SS, Rathinamala R, Murugesan M. Authentication methods for drugs used in Ayurveda, Siddha and Unani systems of medicine: an overview. Int J Pharm Sci& Res, 2012