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# A Review on Standardisation of Traditional Herbal Formulations

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**ABSTRACT**
The standardization of traditional herbal formulations is crucial to ensuring their safety, efficacy, and consistency. Traditional herbal medicines, widely accepted due to their effectiveness, include various forms such as Asava, Arishta, Gutika, Bhasma, Lehya, and Churna. However, the variability in plant materials caused by factors like geographical location, harvesting time, and processing methods necessitates rigorous standardization processes. These processes involve multiple evaluation techniques, including physical, microscopic, biological, and chemical analyses. The standardization also includes determining moisture content, ash value, extractable matter, and shelf life, alongside advanced techniques like thin-layer chromatography (TLC). Despite the global popularity of herbal products, the absence of a standardized quality control profile poses a significant barrier to their widespread acceptance. Therefore, establishing robust standardization protocols aligned with international guidelines is essential for enhancing the credibility and therapeutic reliability of traditional herbal formulations.

**Keywords:**Standardization, Herbal formulations, Arista, Asava, Bhasma, Churna, Lehya, Ghutika.

## I. INTRODUCTION

Generally, any medicines, whether they are synthetic or of plant origin, for being safe and effective it should fulfill the basic requirements of (EMEA, 2005; WHO, $2002_C$, $1998_C$, 1996, 1991a, b,1990,1988). The term "Herbal drugs "means of plants or plant parts that are converted into phytopharmaceuticals using simple processes. The processes involve harvesting, drying and storage (EMEA,1998). Hence,they are capable of variations which may caused by difference in the plant growth, geographical locations, time of harvesting and other factors.(1)

Traditional Herbal Formulations are the dosage forms which are traditionally used Herbal Medicines Formulations. The world wide acceptance on these formulations is due to effectiveness of those formulations. Some of the common Traditional Herbal Formulations includes Asava (Liquid),Arishta (Liquid), Gutika (Solid), Bhasma (Powder), Lehya (Semisolid), Churna (Powder). As the formulations, there are several techniques and procedures for preparation and Standardization.

The preparations are initially starts on drying and powdering the crude drug. After the powdering of crude they are subjected to different techniques of preparations on varying the different formulations.

The need forStandardization are to ensure the purity, safety, quality, potency and efficacy of the formulation. for meets those perspectives, the regulatory authorities follows various standards of quality which are specifically prescribed for raw materials and finished products in pharmacopoeias, which could be effective in traditional herbal formulations.(1)

According to WHO (1996aab,1992), standardization of herbs is a process involving physico-chemical evaluation safety and risk documentation based on experience, providing information about the product to the consumer and its promotion. During the manufacture, formulation, storage, packaging, transport and distribution of a medicinal product, it may change the efficacy, safety, stability, and therefore the standardization of herbal medicinal products is a necessity of an era for the actual process, Phytochemical standardization consists of all possible information generated in relation to the

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chemical fractions present in the herbal medicinal product. (2)
standardizations are meant to be evaluate the formulation which should to meets the standards that are mentioned in international guidelines.

## CLASSIFICATION OF HERBAL MEDICINES

Based on their origin evolution and the forms of current usage:[6]

- Category 1: Indigenous herbal medicines.
- Category 2: Herbal medicines in systems
- Category 3: Modified herbal medicines
- Category 4: Imported products with a herbal medicine base

## ADVANTAGES OF HERBAL MEDICINES

Herbal medicines have following advantages:[7]

- They have large amount of use.
- They have better patient tolerance as well as acceptance.
- They are cheap
- They are not harmful
- The medicinal plants have renewable source of cheaper medicines.

## THE NEED FOR STANDARDIZATION

Despite the growing global popularity of herbal products, one significant barrier to their widespread acceptance is the absence of a standardized quality control profile. The quality of herbal medicine, specifically the composition of constituents in the final product, directly affects both its efficacy and safety. However, the complex nature and inherent variability of the constituents found in plant-based drugs pose challenges in establishing quality control parameters, although modern analytical techniques are anticipated to assist in addressing this issue. Additionally, the constituents that contribute to the purported therapeutic effects are often unknown or only partially understood. This situation is further complicated by the use of combinations of herbal ingredients, as is common in traditional practices, where a single product may contain as many as five different herbal components. Consequently, batch-to-batch variation begins with the collection of raw materials, particularly in the absence of any reference standards for identification.

## PHYSICAL EVALUATION

Parameters like colour, odour, texture was evaluated. Colour and texture were evaluated by visual inspection and touch sensation respectively. Odour was inspected by sensing inspection.

## MICROSCOPIC EVALUATION

A comprehensive and precise characterization of plant material necessitates an extensive physical examination. Microscopic analysis of plants is essential for confirming the identity of the material and serves as an initial screening method for detecting impurities.

## BIOLOGICAL EVALUATION

Pharmacological activity of certain drugs has been applied to evaluate and standardize them. The assays on living animal and on their intact or isolated organs can indicate the strength of the drug or their preparations.

## CHEMICAL EVALUATION

This encompasses the processes of screening, isolating, identifying, and purifying the chemical constituents. A chemical analysis of the drug is conducted to evaluate the efficacy of the plant material concerning its active ingredients. The chemical screening or tests may involve color reaction tests, which assist in establishing the identity of the drug substance and detecting potential adulteration.

## DETERMINATION OF ASH

The determination of ash content involves three distinct methods that assess total ash, acid-insoluble ashand water-soluble ash from ignited medicinal plant materials. The total ash method quantifies the overall residue left after ignition, which encompasses both "physiological ash" from the plant tissue and "non-physiological ash" from external contaminants on the plant's surface. Acid-insoluble ash is derived by boiling the total ash in dilute hydrochloric acid and then igniting the remaining insoluble residue, which primarily indicates the presence of silica, particularly in the form of sand and siliceous earth. Water-soluble ash is calculated by subtracting the weight of the residue left after treating the total ash with water from the total ash weight.

## DETERMINATION OF EXTRACTABLE MATTER

The method assesses the quantity of active compounds extracted from a specified quantity of medicinal plant material using various solvents.

1. Water-soluble extracts
2. Alcohol-soluble extracts
3. Ether-soluble extracts

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**SHELF-LIFE**

The assessment of shelf life for herbal medicinal drug products parallels that of chemically defined active pharmaceutical ingredients; however, the unique characteristics of herbal products must be taken into account.

**TLC**

Thin layer chromatography is simply known as TLC. It is one of the most popular and simple chromatographic technique used of separation of compounds. In the phytochemical evaluation of herbal drugs, TLC is being employed extensively for the following reasons:

1. It enables rapid analysis of herbal extracts with minimum sample clean-up requirement
2. It provides qualitative and semi quantitative information of the resolved compounds.
3. It enables the quantification of chemical constituents.

**MOISTURE CONTENT**

Low moisture content ensures the better stability.

**ASAVA & ARISHTA**

Asavas and arishta are therapeutic formulations created by immersing herbal substances, either in powdered form or as a decoction (kwatha), in a solution of sugar or jaggery for a designated duration. This process allows for fermentation, which produces alcohol and aids in the extraction of both alcohol-soluble and water-soluble active compounds present in the herbs.

STANDARDIZATION TECHNIQUES [3]

**Table 1**

| |
|---|
| 1.Organoleptic characters |
| • Colour |
| • Clarity |
| • Odour |
| • Taste |
| 2.Physical evaluation |
| • pH |
| • Density |
| • Specific gravity |
| • Viscosity |
| 3.Total solid content |
| 4.Alcohol content |
| 5.Test for methanol |
| 6.Test for reducing sugars |
| 7.Test for non-reducing sugars |
| 8.Microbial contamination |
| • Total microbial count |
| • Total fungal count |
| 9.Test for heavy metals |
| 10.Pesticidal residue |
| 11.Stability study |
| 12.Refractive index |

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**LEHYA**

Lehya or Avaleh is one of the several groups of Ayurvedic formulations. It arises from Sanskrit root word Lih Aswadane, the form of medicine which can be tasted with help of tongue. It is a semi-solid preparation of drugs, prepared with the addition of jaggery, sugar or sugar candy and boiled with prescribed drug juice or decoction [4].

STANDARDIZATION TECHNIQUES

**Table 2**

| |
|---|
| 1.Organoleptic characters |
| • Colour |
| • Odour |
| • Taste |
| 2.Physical evaluation |
| • pH |
| • Viscosity |
| 3.Total ash value |
| 4.Acid insoluble ash value |
| 5.Loss on drying |
| 6.Identification by tlc, hptlc |
| 7.Total solid reducing sugar |
| 8.Fat content |
| 9.Test for heavy metal |
| 10.Microbial contamination |
| • Total microbial count |
| • Total fungal count |
| 11.Pesticidal residue |
| 12.Test for aflatoxin |

**GUTIKA**

Gutika, an ancient and traditional dosage form in Ayurveda.Contemporary terminology designates gutika as tablets, while spheroids are identified as clusters of fine powders or granules that comprise bulk pharmaceuticals and excipients.

STANDARDIZATION TECHNIQUES [5]

**Table 3**

| |
|---|
| 1.Organoleptic characters |
| • Colour |
| • Odour |
| • Taste |
| 2.Test for heavy metal |
| 3.Microbial contamination |
| • Total microbial count |
| • Total fungal count |
| 4.Pesticidal residue |
| 5.Test for aflatoxins |
| 6.Tablet thickness |
| 7.Friability test |
| 8.Hardness test |
| 9.Weight variation test |
| 10.Disintegration study |

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| |
|---|
| 11.Dissolution time |
| 12.Identification by |
| • Tlc |
| • Hptlc |
| • Glc |

**CHURNA**

Churna refers to the powdered form of a single drug or a mixture of two or more drugs that has been powdered separately before being blended homogeneously. Churna is a fine powder of medication or drug mixture, according to the Indian Ayurvedic Formulary. According to Sharangadha, the synonyms for churna are raja or kshoda, and churna refers to a finely powdered dry medication that is administered in the dose of one karsha-parmana.

STANDARDIZATION TECHNIQUES

**Table 4**

| |
|---|
| 1.Organoleptic characters |
| • Colour |
| • Odour |
| • Taste |
| 2.Loss on drying |
| 3.Total ash |
| 4.Acid insoluble ash |
| 5.Test for heavy metal |
| 6.Microbial contamination |
| • Total microbial count |
| • Total fungal count |
| 7.Pesticidal residue |
| 8.Test for aflatoxin |
| 9.Particle size |
| 10.Water soluble extractive |
| 11.Alcohol soluble extractive |
| 12.Identification by hptlc |

**BHASMA**

Bhasma is an Ayurvedic preparation made from metals or minerals. This preparation undergoes treatment with herbal juices or decoctions and is subjected to specific amounts of heat according to the puta system of Ayurveda. This method has been recognized in the Indian subcontinent since the 7th century A.D. and is frequently recommended for the management of various health conditions. Bhasma is asserted to consist of biologically produced nanoparticles and is often prescribed alongside other Ayurvedic medicines. [7]

STANDARDIZATION TECHNIQUES

**Table 5**

| |
|---|
| 1.Organoleptic characters |
| • Colour |
| • Odour |
| • Taste |
| 2.Loss on drying |

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| |
|---|
| 3.Total ash |
| 4.Acid insoluble ash |

**TABLE 6**[7]

| Heavy Metal | Test | Observation | Inference |
|---|---|---|---|
| Cadmium | $NH_4$ OH added in the sample solution | White ppt. of cadmium hydroxide soluble in excess $NH_4$ OH | Presence of cadmium |
| Cadmium | Potassium ferrocyanide added | White ppt. of cadmium ferrocyanide | Presence of cadmium |
| Bismuth | $H_2$ S gas added in the sample solution | Dark brown ppt. soluble in hot dil. $HNO_3$ but insoluble in $NH_4$ S | Presence of bismuth |
| Bismuth | $NH_4$ OH | White ppt. insoluble in excess $NH_4$ OH dissolved in dil. HCl | Presence of bismuth |
| Lead | Dil. HCl added in the sample solution | White ppt. of $CaCl_2$ soluble in boiled water & conc. HCl | Presence of lead |
| Lead | KI is added in the sample solution | Yellow ppt. soluble in boiling water | Presence of lead |

**Table 7** [7]

Physical Properties

| Characteristic | Sample 1 | Sample 2 | Sample 3 |
|---|---|---|---|
| Bulk Density | 0.666 | 0.476 | 0.555 |
| Tap Density | 0.909 | 0.625 | 0.80 |
| Carr's index | 26.73 | 23.84 | 30.625 |
| Hausner's ratio | 1.36 | 1.31 | 1.44 |
| Angle of repose | 36.50 | 39.69 | 35.75 |
| pH | 5 (acidic) | 6 (acidic) | 6 (acidic) |
| Crude Fiber | 4.7 | 4.15 | 4.2 |

**Table 8**

Heavy Metal Tests (Triphala Churna of Patanjali, Shree Ayurveda and Laboratory made) [7]

| Test | Observation | Result |
|---|---|---|
| Cadmium ($NH_4$ OH added) | White ppt. is absent | Absence of cadmium |
| Cadmium (Potassium ferrocyanide added) | White ppt. is absent | Absence of cadmium |
| Bismuth ($H_2$ S gas added) | Dark brown ppt. is absent | Absence of bismuth |
| Bismuth ($NH_4$ OH) | White ppt. is absent | Absence of bismuth |
| Lead (Dil. HCl added) | White ppt. of $CaCl_2$ is absent | Absence of lead |
| Lead (KI added) | Yellow ppt. is absent | Absence of lead |

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**Table 9**
Fluorescence Analysis [7]

| Solvent added | Sample | Daylight | Short UV wavelength (256 nm) | Long UV wavelength (365 nm) |
|---|---|---|---|---|
| 1N Sulphuric acid | 1, 2, 3 | Light brown | Light green | Dark green (1, 2), Dark Green (3) |
| 1N Nitric acid | 1, 2, 3 | Light brown | Light green | Dark green (1, 2), Dark Green (3) |
| 1N Hydrochloric acid | 1, 2, 3 | Light brown | Light green | Dark green (1, 2), Dark Green (3) |
| Iodine | 1, 2, 3 | Greenish brown | Dark green | Dark blue (1, 2), Dark bluish (3) |
| Potassium hydroxide | 1, 2 | Brown | Green | Dark blue |
| Potassium hydroxide | 3 | Light Brown | Green | Light bluish |
| Ammonia | 1, 2 | Brown | Green | Dark blue |
| Ammonia | 3 | Light Brown | Green | Light bluish |
| 1N Sodium hydroxide | 1, 2 | Dark brown | Dark green | Dark blue |
| 1N Sodium hydroxide | 3 | Brown | Dark green | Dark bluish |

## II. CONCLUSION

The growing global interest in traditional herbal formulations highlights the need for stringent standardization processes to ensure their safety, efficacy, and consistency. Despite their widespread use and acceptance, the inherent variability of herbal ingredients poses significant challenges in maintaining quality control. By implementing comprehensive standardization techniques, including physical, chemical, and biological evaluations, it is possible to overcome these challenges and establish reliable quality profiles for these products. Adherence to international guidelines and the adoption of advanced analytical methods will enhance the credibility of traditional herbal medicines, fostering greater confidence among consumers and healthcare providers. Ultimately, robust standardization practices are essential for integrating these time-honored remedies into modern healthcare systems while ensuring their therapeutic benefits remain consistent and reliable.

## III. DISCUSSION

Standardizing traditional herbal formulations is crucial to ensure their safety, efficacy, and consistency, especially as these remedies gain global recognition. Herbal products like Asava, Arishta, Gutika, Bhasma, Lehya, and Churna are prone to variability due to factors such as plant origin, harvesting time, and processing methods. This variability demands rigorous evaluation through physical, microscopic, biological, and chemical analyses to ensure consistent quality.

Advanced techniques like Thin Layer Chromatography (TLC) are vital in detecting adulteration and verifying the presence of active compounds. Despite the challenges posed by the inherent complexity of herbal ingredients, modern analytical methods and adherence to international guidelines can establish reliable quality control parameters.

In summary, robust standardization practices are essential for integrating traditional herbal formulations into modern healthcare, ensuring their therapeutic reliability, and gaining wider acceptance in the global market.

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## REFERENCES:

[1]. Kunle OF, Egharevba HO, Ochogu PA. Standardization of herbal medicine: A review. Int J Biodivers Conserv. 2012 Mar;4(3):101-112. doi: 10.5897/IJBC11.163.

[2]. Tambare P, Tamboli FA, More HN. Standardization of herbal drugs: An overview. Int J Pharmacogn Pharm Sci. 2021;3(1):09-12.

[3]. Patwardhan B, Vaidya ADB, Chorghade M. Ayurveda and natural products drug discovery. Curr Sci. 2004 Sep;86(6):789-799.

[4]. Gokhale SB, Kokate CK, Purohit AP. A Textbook of Pharmacognosy. 34th ed. Pune: Nirali Prakashan; 2008. p. 165-169.

[5]. Mukherjee PK. Quality control of herbal drugs: An approach to evaluation of botanicals. 1st ed. New Delhi: Business Horizons; 2002. p. 187-199.

[6]. Gulzar Alam, Arun K Mishra. Traditional and modern approaches for standardization of herbal drugs: A review. ActaBiomedicaScientia.2017;4(1):40-55

[7]. D.K. Kadam, P.D. Ahire, J.v.Bhoye, A.R.Patil , D.K. Yadav.Comparatative standardization study of three triphala churna formulation: Kadam et al.IJP,2016;Vol.3(11):482-490.