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## QUALITY STANDARDIZATION OF HERBAL AND HERBO-MINERAL MEDICINES, CURRENT CHALLENGE TO BE OVERCOME

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### Abstract

Herbal medicines are used globally for their efficacy and safety margins. However, quality control of these drugs is one of the challenges in current scenario. Herbal medicines facing issues including lack of authentication, non-availability, inadequate standardization methodologies and regulatory insufficiency. It is required to overcome these issues related to the standardization of herbal medicines. Similar consideration must be adopted for herbo-mineral preparations which mainly come under the umbrella of *Rasa Shastra* in Ayurveda. This involves uses of materials known as *Rasa dravyas* and these *Rasausadhis* are characterized by their specific properties and qualities. Ayurveda described particulars techniques for quality evaluation of *Rasa dravyas*. Additionally modern research suggested organoleptic tests and heavy metal analysis along with sophisticated techniques like High-Performance Thin Layer Chromatography (HPTLC), X-ray Analysis and Atomic Absorption Spectrometry, etc. The proper standardization of herbal and herbo-mineral formulations is essential to ensure their safety and efficacy. However there are some challenges in this area which are to be overcome in future to enhance acceptability of natural drugs amongst global population.

**Key-Words:** *Ayurveda, Standardization, Medicines, Herbal, Mineral, Rasa, Herbo-mineral*

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## **Introduction**

Herbal products are used for healthcare purpose from ancient time and their acceptance increases day by day due to their wide range of applicability and safety. However these products presently facing quality challenges and establishment of standardization protocol under the regulatory control. Standardization of herbal drugs includes physicochemical evaluation raw as well as final drugs, safety consideration, stability assessment, chemical analysis and purity tests, etc. The ancient science suggested many approaches for quality assessment of herbal products, moreover modern science presented various novel techniques for ensuring quality and safety of natural drugs [1-4].

Standardization of herbal medicines involves assessment of inherent characteristics, qualitative confirmation, quantitative analysis and reproducibility of constant parameters, etc. Standardization of herbal medicines faces many challenges since these are mixtures of many constituents, active principle often unknown, reference or standard compounds sometimes not available, chemical and natural variability in plant species and adulteration, etc. Quality of raw materials also affects quality of final products. Additionally quality of herbal medicines is also affected by harvesting methods, storage condition, drying method, transportation and seasonal variability, etc. Currently various microscopic, macroscopic, chromatographic and spectrophotometric methods are available along with physicochemical techniques for standardizing herbal products [3-5].

### **Need of Standardization:**

- ❖ To ensure safety, potency, efficacy and purity of drugs.
- ❖ To meet standards set by regulatory bodies and pharmacopoeias, etc.
- ❖ To gives reproducibility in quality manufacturing and testing
- ❖ To prevent any complication related with wrong or low quality products.
- ❖ Quality assessment and control are necessary to ensure consistent and reliable products [3-5].

### **Herbo-mineral formulations:**

The herbo-mineral formulations in Ayurveda mainly referred to *Rasa aushadhis* which are prepared by different procedures such as *Shodhana*, *Bhavana*, *Mardana* and *Marana*. These drugs are valued for their efficacy even in low doses, fast pharmacodynamic & pharmacokinetic properties and advantage of palatability. *Kupipakawa-Rasayana*, *Pottali-Rasayana* and *Parpati-Rasayana*, etc. are major types of formulations of herbo-mineral category. These drugs impart therapeutic effects against many diseases. Therefore evaluation of safety and efficacy of herbo-mineral formulations is very important to ensure their desired effect [5-7].

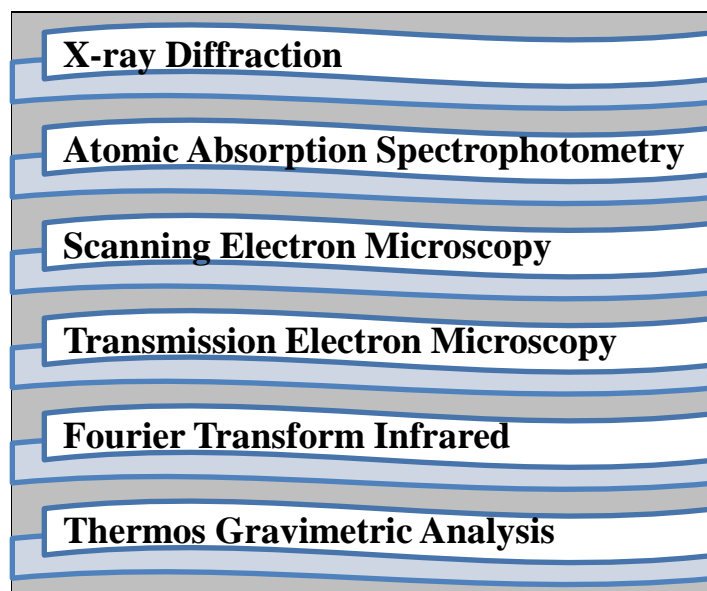
### **Quality Standardization of Herbo-Mineral Formulations:**

- Organoleptic evaluation is performed for the assessment of odor, color and appearance of drugs.
- Physicochemical Parameters performed for extracts used in formulations, these includes assessment of pH, loss on drying, alcohol-soluble extractive and water-soluble extractive value, etc.
- Heavy metal analysis is performed to check presence of lead, arsenic and mercury, etc.
- Phytochemical screening of crude extracts is performed to assess chemical compositions which may include test for Alkaloids, Glycosides, Flavonoids, Saponins, Tannins and Steroids, etc.
- Modern technique utilizes Thin-Layer Chromatography (TLC) and High Performance Thin Layer Chromatography (HPTLC). These techniques used to detect the botanical materials and confirming the identity & purity of raw as well as finished products [4-6].

### **Specific Tests for *Rasa aushadhis* According to Ayurveda:**

Ayurveda science described specific tests for *Rasa aushadhis* which includes test for *Verna*, *Nisvadutam*, *Nishchandratvam*, *Varitara*, *Unama*, *Rekhapurnatvam* and *Slakshnatvam*, etc. These test performed to confirm specific color of *Bhasma*, to ensure tastelessness of *Bhasma*, to check presence of fineness and lightness. These formulations also checked for

their non-irritant nature and smoothness. *Apurnabhavta* is test which denotes the incapability of *Bhasma* to retain its metallic form while *Amla Pariksha* ensures the ability of *Bhasma* to maintain its color during the procedure [6-10]. Modern medical science presented several methods for quality evaluation of herbo-mineral formulations, some them are depicted in **Figure 1**.



**Figure 1: Modern Techniques for Quality Evaluation of Herbo-mineral Formulations**

#### **Challenges of herbal drug standardization:**

Standardizing herbal drugs poses numerous challenges which are to be overcome in future. Here are some of the key hurdles that need to be addressed:

- ✓ Herbal drugs comprise a vast array of active and inactive compounds, their composition varying widely based on factors like species, geography, harvest time and environmental factors, etc.
- ✓ Natural variations in raw materials lead to inconsistencies between different batches of the same herbal drug.
- ✓ Accurate identification of species and subspecies is crucial as different plants can have differing pharmacological effects.
- ✓ Adulteration or substitution with similar-looking but different plants is common.

- ✓ Herbal drugs may contain contaminants like heavy metals, microbes and pesticides, etc. these can impart health risks if consumed without testing or purification.
- ✓ Lack of standardized cultivation practices leads to variability in raw material quality.
- ✓ Variability in extraction and processing methods can impact the final product's consistency and potency.
- ✓ Herbal drugs are complex mixtures, complicating the isolation and quantification of individual components.
- ✓ Limited availability of reference standards for many herbal constituents hampers quality control.
- ✓ Lack of global standards makes it hard to ensure consistent quality across different markets.
- ✓ Ensuring consistent absorption of active compounds is challenging due to formulation variability.
- ✓ Integrating traditional knowledge with modern approaches requires careful documentation.
- ✓ Lack of rationale and experimental logic behind the folkloric use of many drugs [4-7, 11].

## **Conclusion**

Plant materials are utilized as home remedies, over-the-counter drugs, in the form of raw materials in pharmaceutical industry and as herbal or natural drugs. The traditional Ayurveda formulation also prepared from natural sources mainly from plants or plant based products. The establishment of recognized guidelines for evaluating their quality is very crucial. Emerging evidence highlights the risks associated with the indiscriminate use of herbs. The acceptance of herbal products as remedies for various conditions increases in recent time therefore their standardization has become paramount. Modern analytical tool can be used to test various quality parameters of natural drugs. The effective quality control of herbal formulations is essential to ensuring their safety and efficacy starting from selection of raw material to the final finished products. The uniform and harmonize

approaches of herbal drug standardization must be develop to overcome challenges related with the quality standardization of herbal and herbo-mineral medicines.

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