WWW.IJRPR.COM

**International Journal of Research Publication and Reviews**

Journal homepage: www.ijrpr.com ISSN 2582-7421

# Standardization of Marketed Semisolid Herbal Formulation

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**ABSTRACT:**

The world is witnessing an unprecedented growth in the usage of herbal products. India is a mother hub for natural herbs based science. Herbal drug technology is used for converting botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important.

Global harmonization WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines are of utmost importance. Standardization of drug means confirmation of its identity, quality and purity throughout all phases of its cycle.

An overview covering the different techniques involved in standardization of crude/ finished compound drugs so far, e.g. macroscopic methods, microscopic methods, physical methods, chemical methods, biological methods.

The chromatographic methods and comprehensive methods, such as fingerprint and multi-component quantification; hyphenated techniques, like HPLC-MS, GC-MS.

**Keywords:** WHO, Herbal medicine, Standardization,

## INTRODUCTION:

Herbal formulations have reached extensive acceptability as therapeutic agents for several diseases. The extraction of high-valued herbal compounds using microwave–assisted extraction and supercritical phase extraction technology followed by the standardization utilizing various spectroscopic, chromatographic and thermogravimetric techniques individually and/or in combination has been discussed in relation to herbal drugs. Capillary electrophoresis and polarographic techniques contributions towards standardization of herbal drugs is also reported. The traditional medicines cater about 85%of the world population for their health needs. It is essential to maintain safety, quality and efficacy of the plant and their products to avoid and serious health problems. Indian healthcare consists of medical pluralism and Ayurveda still remains dominant compared to modern medicine particularly for treatment of a variety of chronic disease conditions. WHO has provided some terms related to herbal drugs, according to their definitions. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products. Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, esential oils, resins and dry powders of herbs. Herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials. [1]

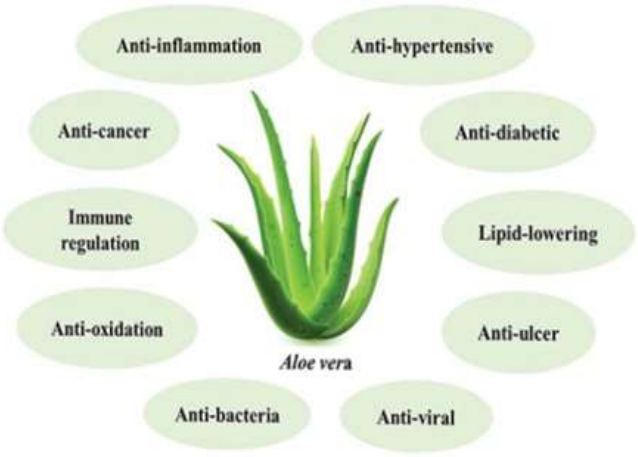
## Semisolid Herbal Formulations:

Herbal formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, meant for use to diagnose treat, mitigate diseases of human beings or animals and/or to alter the structure or physiology of human beings or animals.

Semisolid dosage forms are product's of semisolid consistency and applied to skin or mucous membranes for therapeutic or protective action or cosmetic function.[2]

***Examples of semisolid dosage form:***

1) Aloe Vera:




2) Kalka


3) Lepa kalpana:

4) Swarasa

5) Lepa kalpana

6) Ghrita

7) Kajjali

## Standardisation of Herbal Drugs:

In recent years, there has been great demand for plant derived products in developed countries. These productsare increasingly being sought out as medicinal products, nutraceuticals and cosmetics. In order to have a good coordination between the quality of raw materials, in process materials and the final products, it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis. Standardization is an essential measurement for ensuring the quality control of the herbal drugs. prescribing a set of standards or inherent characteristics, constant parameters, definitive qualitative and quantitative values, that carry an assurance of quality, efficacy, safety and reproducibility[3].

It is the process of developing and agreeing upon technical standards. Specific standards are worked out by experimentation and observations, which would lead to the process of prescribing a set of characteristics exhibited by the particular medicines. Hence standardization is a tool in the quality control process**..** American Herbal Product association defines: “Standardization refers to the body of information and control necessary to product material of reasonable consistency.

“Standardization” expression is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality.It also encompasses the entire field of study from birth of a plant to its clinical application. “Evaluation” of a drug means confirmation of its identity and determination of its quality and purity and detection of its nature of adulteration.[4]

Methods of standardization should take into consideration all aspect that contribute to the quality of the herbal drugs, namely correct identity of the sample, organoleptic evaluation, pharmacognostic evaluation, volatile matter, quantitative evaluation (ash values, extractive values), phytochemical evaluation, test for the presence of xenobiotics, microbial load testing, toxicity testing, and biological activity.[3,4]

## Need of Standardisation-

- Modern system of medicine is based on sound experimental data, toxicity studies and human clinical studies.[5]
- But, Pharmacopoeial standards on raw material, finished products are not available. cGMP for herbal industry are not well defined. [5]
- The lack of quality standards has resulted in mild to serious adverse effects ranging from hepato toxicity to death[5].
- Hence, herbal ingredients require tools for determining identity, purity and quality and tools have to be technically sufficient, rapid and cost effective with GMP equipment.[5]
- Standardization of herbal drug is not an easy task as numerous factors influence the bio efficacy, reproducible therapeutic effect.[5]

## Factors affecting safety and Quality: [6]

- Quality of starting materials
- Complexity of nomenclature of herbal ingredients
- Chemical contamination by heavy metals
- Choice of chemical markers
- Adulteration with synthetic chemical drugs[

## Who Guidelines for Quality Standardized Herbal Formulations:

1) Quality control of crude drugs material, plant preparations and finished products. [7,8]
2) Stability assessment and shelf life [7,8]
3) Safety assessment; documentation of safety based on experience or toxicological studies.[7,8]
4) Assessment of efficacy by ethno- medical information and biological activity evaluations.[7,8]

## Conclusion: -

India can emerge as the major country and play the lead role in production of standardized, therapeutically effective herbal formulation. India needs to explore the medicinally important plants.[9]

This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization such as UV-visible, TLC, HPLC, HPTLC, GC-MS, Spectrofluorimetric and other methods.[9]

The Indian herbal industry is growing in a tremendous rate. With the tremendous increase in traditional herbal therapy several concerns regarding the safety and quality of herbal medicines have also been observed[9].

There is need for more advanced techniques of standardization. The advancement of analytical techniques will serve as a rapid and specific tool in the herbal research, thereby, allowing the manufacturers to set quality standards and specifications.[9]

There is need for development of techniques which includes both traditional methods of evaluation and modern methods of evaluation[9]. This will improve the quality of the drug and also motivates the Practitioners to get more involved in the standardization process[9].

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