Tantia University Journal of Homoeopathy and Medical Science
ReviewArticle
|Volume 3|Issue 4 |Oct.- Dec. 2020|
E-ISSN : 2581-8899, P-ISSN; 2581-978X

Need of Standardization of Herbal Drugs in Current Era

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Abstract

In recent years more people throughout world are turning to use medicinal plant products in healthcare system. Therefore evaluation of the parameters based upon chemical, physical, microbiological, therapeutics and toxicological studies can serve as an important tool in stability studies. Standardization of herbal drugs means confirmation of its identity, quality and purity. The present overview covers the standardization parameters with their standards value of the some herbal drugs.

Key word- Herbal, Drug, Standardization, Current Era, TLC, HPLC.

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Received – 10/09/2020 Revised- 25/11/2020 Accepted – 30/11/2020

INTRODUCTION

India is a mother hub for development of Ayurveda, Unani, Siddha; Homoeopathy and other natural herbs based health science (Ayush). Standardization of drug means confirmation of its identity, quality and purity throughout all phases of its cycle *i.e.* shelf life, storage, distribution and use by various parameters. As we all know in our Ayurvedic system of medicines drug standardisation of Ayurvedic formulation is a big challenge. So it is necessary to promote ISM manufacturing industry people for drug standardization work. Ministry of Ayush, Government of India recently established Pharmacopoeia Commission of Indian medicines and Homoeopathy (PCIM and H) for setting up drug standard of ASU and H Medicines.

How to Cite this Article- Sharma M., Choudhary P. Sharma O., Need of Standardization of Herbal Drugs In Current Era. TUJ.Homo & Medi.Sci. 2020; 3(4):64-70.

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

Methods of standardization should take into consideration all aspects 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. Of these, the phytochemical profile is of special significance since it has a direct bearing on the activity of the herbal drugs.

Hence, the phytochemical evaluation for standardization purpose includes the following:

1. Preliminary testing for the presence of different chemical groups.
2. Quantification of chemical groups of interest (*e.g.*, total alkaloids, total phenolics, total triterpenic acids, total tannins). Establishment of fingerprint profiles.
3. Multiple marker-based fingerprint profiles.
4. Quantification of important chemical constituents [4].

Methods of Standardization: Phytotherapeutic agents are normally marketed as standardized preparations in the form of liquid, solid (powdered extract), or viscous preparations.

1. **Morphological or Organoleptic Evaluation:** It includes the evaluation of herbal drugs by size, shape colour, odour, taste and particular characteristics like touch, texture *etc.* This is a technique of qualitative evaluation related to the study of morphological and sensory report of whole drugs. *eg*. Fractured surfaces in cascara, cinchona, and quillia bark and quassia wood are essential characteristics.
2. **Macroscopic and Microscopic Examination:** Medicinal plant materials are categorized according to sensory, macroscopic and microscopic characteristics. An examination to determine these characteristics is the first step towards establishing the identity and the degree of purity of such materials, and should be carried out before any further tests are undertaken.
3. **Physical Evaluation:** Each monograph contains detailed botanical, macroscopic and microscopic descriptions with detailed illustrations and photographic images which provide visual documentation of accurately identified material. A microscopic analysis assures the identity of the material and as an initial screening test for impurities**.**

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

a. **Determination of ash:** The ash remaining following ignition of medicinal plant materials is determined by three different methods which measure total ash, acid-insoluble ash and water soluble ash. Acid-insoluble ash is the residue obtained after boiling the total ash with dilute hydrochloric acid, and igniting the remaining insoluble matter. This measures the amount of silica present, especially as sand and siliceous earth. Water soluble ash is the difference in weight between the total ash and the residue after treatment of the total ash with water.

b. **Determination of extractable matter:** This method determines amount of active constituents extracted with solvents from a given amount of medicinal plant material.

   i. Water Soluble extractives
   ii. Alcohol Soluble extractives
   iii. Ether Soluble extractives

c. **Determination of Foreign Matter:** Herbal drugs should be prepared from the confirmed part of the plant. They should be totally free from insects or moulds, including visible and excreta contaminant such as stones, sand, harmful and poisonous foreign matter and chemical residues.. Macroscopic evaluation can easily used to determine the presence of foreign matter although microscopy is essential in certain special cases for example starch intentionally added to "dilute" the plant material

4. **Chemical Evaluation:** The most of drug contain definite chemical constituents to which their pharmacological and Biological activity depended. Qualitative chemical test used to identify drug quality and purity. The identification, isolation and purification of active chemical constituents depends chemical methods of evaluation. Preliminary phytochemical investigation is also a part of chemical evaluation. Some Qualitative chemical test for chemical evaluation crude drug is Saponification value and acid value *etc*

4.1 Chromatographic Fingerprinting and Marker Compound Analysis: A chromatographic fingerprint of an Herbal Medicine (HM) is a

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

chromatographic pattern of the extract of some common chemical components of pharmacologically active and or chemical characteristics.

4.1.1 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.

4.1.2 HPTLC: HPTLC technique is widely employed in pharmaceutical industry in process development, identification and detection of adulterants in herbal product and helps in identification of pesticide content, mycotoxins and in quality control of herbs and health foods. It has been well reported that several samples can be run simultaneously by use of a smaller quantity of mobile phase than in HPLC. It has also been reported that mobile phases of pH 8 and above can be used for HPTLC.

4.1.3 HPLC: Preparative and analytical HPLC are widely used in pharmaceutical industry for isolating and purification of herbal compounds.

4.1.4 Liquid Chromatography - Mass Spectroscopy: (LC-MS) LC-MS has become method of choice in many stages of drug development. Recent advances includes electrospray, thermospray, and ionspray ionization techniques which offer unique advantages of high detection sensitivity and specificity, liquid secondary ion mass spectroscopy, later laser mass spectroscopy with 600 MHz offers accurate determination of molecular weight proteins, peptides. Isotopes pattern can be detected by this technique.

4.1.5 Liquid Chromatography-Nuclear Magnetic Resonance (LCNMR): LC-NMR improves speed and sensitivity of detection and found useful in the areas of pharmacokinetics, toxicity studies, drug metabolism and drug discovery process... These new hyphenated techniques are useful in the areas of pharmacokinetics, toxicity studies, drug metabolism and drug discovery process.

4.1.6 Gas Chromatography (GC-MS): GC equipment can be directly

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

interfaced with rapid scan mass spectrometer of various types. GC and GC-MS are unanimously accepted methods for the analysis of volatile constituents of herbal medicines, due to their sensitivity, stability and high efficiency. Especially, the hyphenation with MS provides reliable information for the qualitative analysis of the complex constituent.

4.1.7 GC-FID: A number of detectors are used in gas chromatography. The most common are the flame ionization detector (FID) and the thermal conductivity detector (TCD).

4.1.8 Supercritical Fluid Chromatography (SFC): Supercritical fluid chromatography is a hybrid of gas and liquid chromatography that combines some of the best features of each. SFC permits the separation and determination of a group of compounds that are not conveniently handled by either gas or liquid chromatography.

4.2 DNA Fingerprinting: DNA analysis has been proved as an important tool in herbal drug standardization. This technique is useful for the identification of phytochemically indistinguishable genuine drug from substituted or adulterated drug. It has been reported that DNA fingerprint genome remain the same irrespective of the plant part used while the phytochemical content will vary with the plant part used, physiology and environment.

4.2.1 Genetic Marker: A genetic marker is a gene or DNA sequence with a known location on a chromosome and associated with a particular gene or trait. It can be described as a variation, which may arise due to mutation or alteration in the genomic loci that can be observed.

4.3 Radioactive Contamination: The microbial growth in herbal drugs is usually avoided by irradiation. Dangerous contamination may be the consequence of a nuclear accident. The WHO, in close cooperation with several other international organizations, has developed guidelines in the event of a wide spread contamination by radio nuclides resulting from major nuclear accidents.

5. Biological Evaluation:

5.1 Determination of Bitterness Value: Medicinal plant materials that have a strong bitter taste are employed therapeutically, mostly as appetizing agents. Their bitterness stimulates secretions in the gastrointestinal tract,

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

especially of gastric juice. Bitter substances can be determined by taste

5.2 Determination of Haemolytic Activity: Many medicinal plant materials, especially those derived from the families Caryophyllaceae, Araliaceae, Sapinaceae, Primulaceae, and Dioscoreaceae contain saponins..

5.3 Determination of Foaming Index: Many medicinal plant materials contain saponins that can cause persistent foam when an aqueous decoction is shaken. The foaming ability of an aqueous decoction of plant materials and their extracts is measured in terms of a foaming index.

5.4 Determination of Pesticide Residues: Limits for pesticide residues should be established following the recommendations of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) which have already been established for food and animal feed. These recommendations include the analytical methodology for the assessment of specific pesticide residues .

5.5 Determination of Arsenic and Heavy Metals: Contamination of medicinal plant materials with arsenic and heavy metals can be mattributed to many causes including environment pollution and traces of pesticides.

6. Stability testing of herbal products:

6.1 Analytical Methods for Herbal Products: The analysis of herbal preparations is mostly done by running high performance liquid chromatography (HPLC) or gas chromatography (GC) and thin layer chromatography (TLC) methods, quantitative determinations by UV visible spectroscopy or combinations of these. HPLC and GC methods can be used for identification and purity testing, as well as the detection of single compounds for assay, is possible during one analysis. LC and GC mass coupling [55] are the also tools for determination but, they are highly sophisticated and expensive methods.

CONCLUSION

The Indian herbal industry is growing in a tremendous rate. More number of herbal products is arrived in the market. The safety and efficacy of herbal products are dependent upon the standardization of these herbal drugs. The traditional approach towards standardization is insufficient for current herbal market and hence there is need for more advanced techniques for standardization. The quality of herbal drugs is the sum of all factors which contribute directly or indirectly to the

 E-ISSN : 2581-8899
P-ISSN: 2581-978X

safety, effectiveness and acceptability of the product.

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Conflict of Interest:None **Source of Support: Nil**