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HERBAL DRUG STANDARDIZATION: AN OVERVIEW

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ABSTRACT
Standardization is an essential measurement for ensuring the quality control of the herbal drugs. Standardization of herbal drugs is the process involved in the physicochemical evaluation of crude drugs that covers various aspects of the herbal drug like selection and handling of crude material; safety, efficacy and stability assessment of the finished product; documentation of safety and risk based on experience,; alongwith the provision of product information to consumer and product promotion. The herbal drug standardization is essential in order to review the quality of drugs based on the concentration of their active principles alongwith the physical, chemical, phytochemical, standardization parameters. The review article critically reviews about the evaluation tools for standardization of herbal drugs.

KEYWORDS: Herbal Drugs, Standardization, Evaluation.

INTRODUCTION

There has been a tremendous increase in the herbal products worldwide both in developed and developing countries. According to one estimate, 80 % of the world population depends on herbal drug products for their primary healthcare needs.[1] The toxic side effects of the drugs of modern medicine and the lack of medicines for many chronic ailments have led to the recurrence of the herbal medicine. Therefore, it is essential to develop reliable, specific and sensitive quality control methods for developing the raw materials. Standardization of herbal drugs is considered to be an essential measurement for ensuring the quality control of the herbal drugs.[2] "Standardization" covers all the measures taken during the manufacturing process and quality control leading to a reproducible quality.[2-3] Herbal drugs standardization covers various parameters like botanical evaluation, physiochemical evaluation, pharmacological evaluation alongwith toxicological parameters associated with the herbal drug.[3,5] The present review article highlights about the pharmacopoeial and WHO guidelines for the standardization of herbal drugs. Moreover, various evaluation tools fort the hebal drug standardization have been discussed in the review.

PHARMACOPOEIAL GUIDELINES FOR STANDARDIZATION OF HERBAL DRUGS

The monographs and quality control tests for medicinal plants have been covered in several pharmacopoeias like Indian Pharmacopeia, The Ayurvedic Pharmacopeia of India, British Pharmacopeia, Chinese Herbal pharmacopoeia, British Herbal Pharmacopeia, Japanese pharmacopoeia, Japanese Standards for Herbal Medicine and United States Pharmacopoeia based on the medicinal plants used in their respective countries.[6-8] The monographs as compiled in the standard books like Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, Wealth of India and Ayurvedic formulary, provide all the necessary details for the various tests to be performed in order to determine the conformity of the crude or formulated herbal drug with the standards laid.[6-9] The monographs stating the quality parameters and standards of many herbs and their herbal products have been provided in several pharmacopeias internationally.

CLASSIFICATION OF HERBAL DRUGS

The herbal drugs can be defined as whole or plants parts, algae or fungi in unprocessed state usually in dried form but sometimes fresh. The herbal drugs can be classified as:

1. Ayurvedic herbalism

It is derived from the Sanskrit word "ayurveda" which means "the science of life". The ayurvedic hebalism originated in India more than 4000 years ago.[10-11]

2. Chinese herbalism

It was originated in China which formed an extremely sophisticated system of diagnosis, identification and treatment over the centuries. The Chinese herbalism has an element of traditional related medicine.[10-11]

3. Western herbalism

The western herbalism originated from Rome, Greece and then developed to North Europe and South America.

Western herbalism is considered primarily as a system of people's medicine in the existing world.[10-11]

WHO GUIDELINES FOR STANDARDIZED HERBAL DRUGS

It is accepted worldwide that the standardization of herbal drug is wide and deep. According to WHO, the herbal drug standardization is the process involved in the physicochemical evaluation of crude drugs that covers various aspects like selection and handling of crude drug material; safety, efficacy and stability assessment of finished products; documentation of safety and risk of the product formulation to consumer and product promotion. The guidelines set by WHO for herbal drug standardization[9] can be summarized as follows:

- **Botanical evaluation**- The botanical evaluation covers the sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements etc.
- **Physicochemical parameters**- Various physiochemical parameters include the physical and chemical identity, chromatographic fingerprints, ash values, extractive values, moisture content, volatile oil content, quantitative estimation protocols etc.
- **Pharmacological parameters**- The pharmacological parameters include various biological activity profiles, bitterness values, swelling factor, foaming index etc.
- **Toxicological parameters**- The toxicological parameters include pesticide residues, heavy metals etc.[9-14]

EVALUATION TOOLS FOR HERBAL DRUGS STANDARDIZATION

There have been a number of evaluation tools for the standardization of herbal drugs and their formulations.[9-10,15-18] The evaluation tools can be summarized as:

1. Authentication

The most important step in the development of standards for Herbal drug ia the authentication of a plant. Authentication of plant is done by evaluating different parameters like family, biological source, chemical constituents and the parts of plants collect like leaf, flower and root.[9-10,15-18]

2. Macroscopical Evaluation

The macroscopic evaluation of crude drugs refers to the evaluation of a drug by colour, odour, taste, size, shape, alongwith some special features like touch and texture, etc.

The macroscopic evaluation is also called morhological or organoleptic evaluation.

The morphological evaluation of the crude drugs is a technique of qualitative evaluation based on study of morphological and sensory profiles of whole drugs.[9-10,15-18] The parameters used for this type of evaluation include the following:

2.1. Colour: The colour is used to indicate the general origin of drug.

2.2. Size: The size of the particles of crude drug covers **t**he length, width and thickess of the crude material, which has great importance in the evaluation of a crude drug.

2.3. Odour and Taste: The odour and taste of the crude drug is a sensitive criteria based on individuals perception. The odour can be indistinct, distinct, aromatic, balsamic, spicy, fruity, mouldy, musty, rancid, weak or strong. The taste of a crude drug can be of two types, i.e. true tatse which can be acidic, saline, bitter, alkaline or metallic; and false taste which can be categorized as mucilaginous, astringent, pungent, acrid or nauseous.

3. Microscopic Evaluation

The microscopic evaluation of the herbal drugs is valuable for both powder and crude drugs.[9-10,15-18] The microscopic evaluation can be categorized as:

3.1. Qualitative Microscopy

This method is used to identify the organized drug by their known histological characters through transverse section (T.S.), longitudinal section (L.S.), radial longitudinal section (R.L.S.), or tangential longitudinal section (T.L.S.). Microscopic Evaluations also covers study of different constituents by using different staining reagents.

3.2. Quantitative Microscopy: The quantitative microscopy involves following different parameters like:

3.2.1 Palisade Ratio: It is defined as average number of palisade cells beneath each epidermal cell.

3.2.2. Stomatal No: It is defined as average number of stomata per square millimeter area of epidermis.

(a) Stomatal Index: It is the percentage which the number of stomata forms to the total number of epidermal cells.

(b) Vein Islet Number: It is defined as average number of vein islet per square millimeter of the leaf surface midway between midrib and the margin.

(c) Vein Termination Number: It is defined as average number of vein terminations per square millimeter of the leaf surface midway between midrib and the margin.

4. Chemical Evaluation

Chemical nature of the constituents can be used as tool to device a method for the analysis of the constituents.[9-10,15-18] It involves the following:

4.1. Chemical Assays: The chemical assays are considered to be the **s**pecific assays for different active principles e.g. total alkaloids, glycosides, resins, tannins, volatile oil, saponins etc. is carried out by different chemical tests.

4.2. Chemical Test: the chemical tests are used for the determination of specific chemical constituents which may be present in any drug to which its therapeutic activity is attributed.

4.3. Phytochemical Screening: Phytochemical screening can be defined as the extraction, screening and identification of the medicinally active substances found

in plants. Some of the bioactive substances that can be derived from plants are flavonoids, alkaloids, carotenoids, tannins, antioxidants and phenolic compounds.

5. Physical Evaluation

In this Method Herbal dugs are evaluated on the basis of some important physical properties of active constituents.[9-10,15-18]

6. Biological Evaluation

It includes determination of therapeutic activity of herbal drugs by using biological models of intact animals, animal preparation, isolated living tissue or micro-organisms.[9-10,15-18] The biological evaluation of the crude drugs can be done by:

6.1. Bioassay

It can be defined as the assay of pharmacologically active substance by using biological animal models.

6.2. Microbial Assay

Microbial assays refer to the biological assays specially performed with micro-organism like bacteria and fungi for determination of potency of antibiotics, antimicrobial and antifungal drugs.

CONCLUSION

Standardization of herbal drugs is essential in order to assess the quality of drugs, based on the concentration of their active principles. It is required to have all the crucial knowledge of the particular drug about its organoleptic characters, phytoconstituents alongwith the pharmacological action to its standardization in respect to various parameters while developing an herbal drug formulation. The field of the herbal drugs formulations is vast and deep. Although there are a number of standardization techniques available till date but there is still lot to explore on the subject of standardization of the herbal drugs and hence new approaches are demanded in order to completely explore the standardization of herbal drugs.

REFERENCES

1. Ekor M. The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. Front Pharmacol, 2013; 4: 177.
2. Sasidharan S, Chen Y, Saravanan D, Sundram KM, Yoga Latha L. Extraction, isolation and characterization of bioactive compounds from plants' extracts. Afr J Tradit Complement Altern Med, 2011; 8: 1-10.
3. Garg V1, Dhar VJ, Sharma A, Dutt R. Facts about standardization of herbal medicine: a review. Zhong Xi Yi Jie He Xue Bao, 2012; 10: 1077-83.
4. Boyle SP, Doolan PJ, Andrews CE, Reid RG. Evaluation of quality control strategies in Scutellaria herbal medicines. J Pharm Biomed Anal, 2011; 54: 951-7.
5. Ong ES. Extraction methods and chemical standardization of botanicals and herbal preparations. J Chromatogr B Analyt Technol Biomed Life Sci, 2004; 812: 23-33.
6. Anonymous. 'Indian Pharmacopoeia' Controller of Publication, Delhi, Vol. II, 1996; A53-A54.
7. Anonymous. The International Pharmacopeia, General Methods of Analysis, 3rd edn. World Health Organization, Geneva. 1, 1979.
8. Anonymous. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. World Health Organization, Geneva, 2000.
9. Kumar T. Standardization of Herbal Drugs – A Review. Int J Uni Pharm Bio Sci, 2013; 2: 13.
10. Patwekar SL, Suryawanshi AB, Gaikwad MS, Pedewad SR, Potulwar AP. Standardization of herbal drugs: An overview. The Pharm Innovation J, 2015; 4: 100-4.
11. Vickers A, Zollman C. Herbal medicine. West J Med, 2001; 175: 125-8.
12. Sahoo N. Herbal drugs: standards and regulation. Fitoterapia, 2010; 81: 462-71.
13. Zhang J, Wider B, Shang H, Li X, Ernst E. Quality of herbal medicines: challenges and solutions. Complement Ther Med, 2012; 20: 100-6.
14. Calixto JB. Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents). Braz J Med Biol Res, 2000; 33: 179-89.
15. Swapnil GP, Anita SW, Ramesh CP, Sandeep MA. Standard Tools for Evaluation of Herbal Drugs: An Overview. The Pharma Innovation, 2013; 2: 60-5.
16. Evans WC. 'Trease and Evans Pharmacognosy' W.B. Saunders, Edinburg, London, 15th Edn, 2002; 74-81.
17. Handa SS, Rakesh DD, Vasisht K. 'Compendium of Medicinal and Aromatic Plants' Asia, ICS UNIDO, Ist Edn, 2006; 133-42.
18. Ansari S.H. 'Essentials of Pharmacognosy' Birla Publishing Pvt. Ltd., New Delhi, 2nd Edn., 2007; 9-11.