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STANDARDIZATION OF HERBAL DRUGS

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ABSTRACT

In recent years, there has been great demand for plant derived products in developed countries. These products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics. There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines. Due to lack of infrastructures, skilled manpower reliable methods and stringent regulatory laws most of these manufacturers produce their product on very tentative basis. 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. Standardization expression is used to describe all measures which are taken during the Manufacturing process and quality control leading to a reproducible quality. It's also involving the Study from birth of plant to its clinical application. It also means adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity respectively by adding recipients or by mixing herbal drugs or herbal drug preparations.

KEYWORD: In recent years, there has been great nutraceuticals and cosmetics.

INTRODUCTION

Standardization is a system that ensures a predefined Amount of quantity, quality & therapeutic effect of Ingredients in each dose. Herbal product cannot be considered scientifically valid if the drug tested has not been authenticated and characterized in order to ensure Reproducibility in the manufacturing of the product. Moreover, recently many dangerous and lethal side effects have been reported, including direct toxic effects, Allergic reactions, and effects from contaminants, and interactions with herbal drugs. Therapeutic activity of herbal formulation depends on its phytochemical Constituents. The development of authentic analytical Methods which can reliably profile the phytochemical Composition, including quantitative analyses of marker/ Bioactive compounds and other major constituents, is a Major challenge to scientists.

Standardization is an important step for the establishment of a consistent biological activity, a consistent chemical Profile or simply a quality assurance program for Production and manufacturing of an herbal drug. The Authentication of herbal drugs and identification of adulterants from genuine medicinal herbs are essential for both pharmaceutical companies as well as public health and to ensure reproducible quality of herbal medicine.

STANDARDIZATION OF HERBAL DRUGS

Defination

Standardization of drug means confirmation of its identity and determination of its quality and purity and detection of nature of adulterant by various parameters like morphological, microscopical, physical, chemical and biological observations.

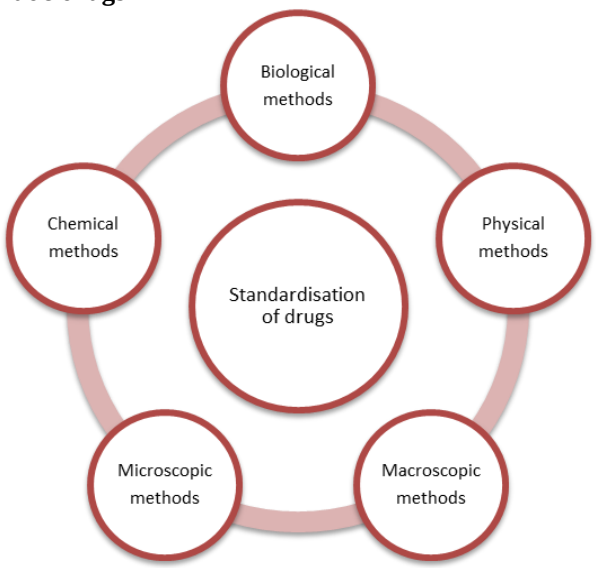
WHO Guidelines for herbal drugs standardization and Evaluation

The WHO Guidelines can be summarized as follows:

- **Identity of the drug:** Botanical evaluation- sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements etc.
- **Physicochemical character of the drug:** Physical and chemical identity, chromatographic fingerprints, ash values, extractive values, moisture content, volatile oil and alkaloidal assays, quantitative estimation protocols etc.
- **Pharmacological parameters**- biological activity profiles, bitterness values, hemolytic index, swelling factor, foaming index etc.
- **Toxicity details :-** pesticide residues, heavy metals, microbial contamination like total viable count, pathogens like *E.coli, Salmonalla, P. Aeroginosa* , , *S. Aureus, Enterobacteria* etc.

- **Microbial contamination.**

Different techniques involved in standardization of crude drugs



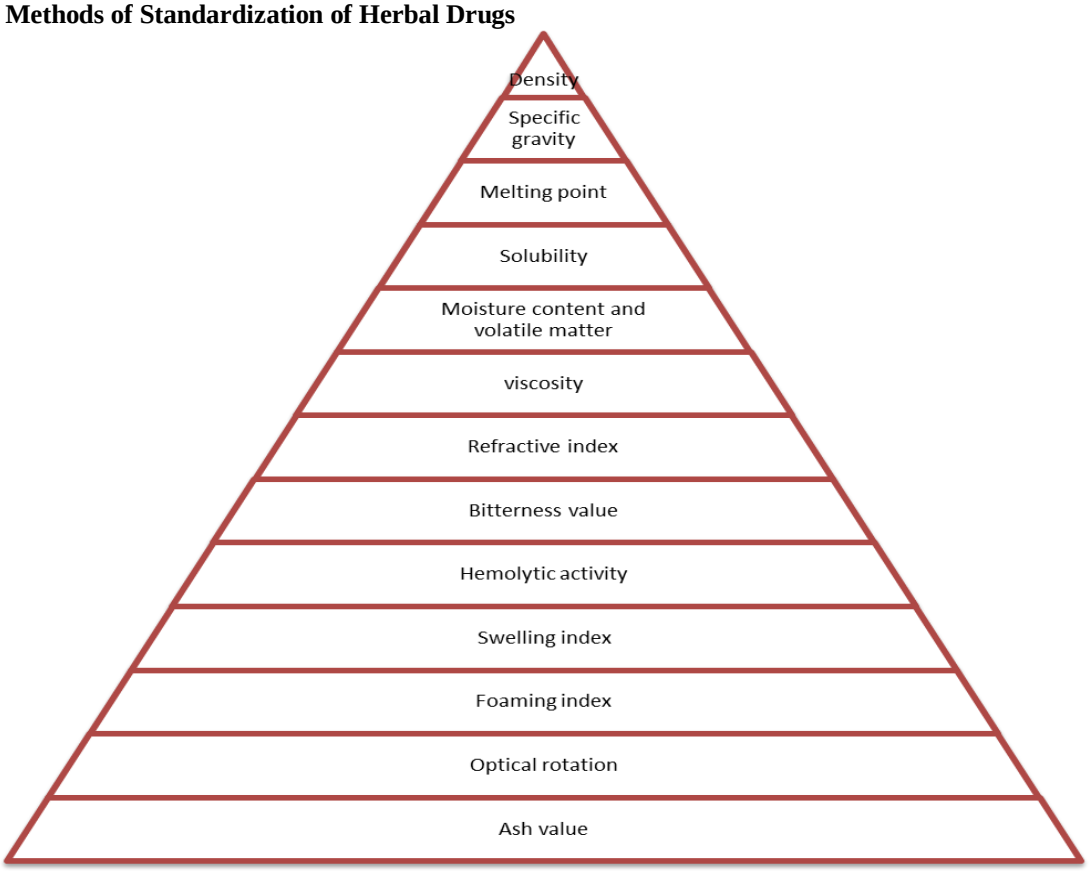
Macroscopic Methods of Standardization of Herbal Drugs

Visual inspection provides the simplest and quickest means by which to establish identity, purity and quality. Macroscopic identity of medicinal plant materials is based on shape, size, colour, surface characteristics, texture, fracture characteristics and appearance of the cut surface.

Microscopic Methods of Standardization of Herbal Drugs

Detail of cell structure and arrangement of the cells is useful for differentiating similar species. Select a representative sample of the material & If it is dried parts of a plant than it may require softening before preparation for microscopy, preferably by being placed in a moist atmosphere, or by soaking in water.

Physical Methods of Standardization of Herbal Drugs



1. Viscosity

Viscosity of a liquid is constant at a given temperature and is an index of its composition. Hence, it can be used as a means of standardizing liquid drugs.

2. Melting Point

In case of pure photochemical, melting points are very sharp and constant. The crude drugs from plant or animal origin, containing the mixed chemicals, are described with certain range of melting point. Their purity can be ascertained by determining their melting points in that range for E.g. Colophony- 75-80˚c Cocoa butter- 30-33˚c.

3. Solubility

The presence of adulterant could be indicated by solubility studies E.g. Pure Asafoetida is soluble in carbon disulphide.

4. Moisture Content And Volatile Matter

The moisture content of the drug should be minimized in order to prevent decomposition of crude drug either due to chemical change or microbial contamination. The moisture content is determined by heating a drug at 105˚c in an oven to a constant weight. For the drugs containing volatile constituents, toluene distillation method is used E.g. – Aloe should have moisture content not more than 10% w/w.

5. Optical Rotation

Optically active compounds have the property of rotating the plane of polarized light. This property is known as optical rotation. Normally, the optical rotation is determined at 25˚c using sodium lamp as the source of light. E.g. Castor oil has optical rotation from +3.5˚to +6˚.

6. Refractive Index

When a ray of light passes from one medium to another of different density, then the ratio of velocity of light in vacuum to its velocity in substance is termed as refractive index of second medium. It is constant for a pure drug and varied with wavelength of incident light, temperature and pressuring. Castor oil has refractive index 1.4758-1.527

7. Ash Values And Extractives

The residue remaining after incineration is the ash content of drug Total ash method is used to measure the total amount of material remaining after incineration

Ash value

It involves non-volatile inorganic components.

High ash value is the indicative of contamination, substitution, adulteration or Care lessness in preparing the crude drugs.

I) Total ash

Total ash is designed to measure the total amount of material produced after complete incineration of the drug material at as low temperature as possible (about 450°C) to remove all the carbons. Total ash usually consists of carbonates, phosphates, silicates and silica.

ii) Acid insoluble ash

Ash insoluble in HCl is the residue obtained after extracting the total ash with HCl. It gives idea about the earthy matter.

iii) Water soluble ash

Is the difference in weight between total ash and residue after treatment of total ash with water.

iv) Carbonated ash- Ash is treated with ammonium carbonate.

v) Nitrated ash- Ash is treated with dilute nitric acid.

8. DETERMINATION OF EXTRACTABLE MATTER

1. Hot Extraction

Place 4 Gms powdered material in a conical flask. Add water and weigh to obtain total weight. Shake and allowed to stand for 1hr. attach the reflux condenser and boil for 1hr. Adjust to the original weight with solvent. Shake and filter. Transfer the filter to a flat bottomed disk and evaporate to dryness on a water bath. Dry at 105˚ c for 6hrs, cool and weigh immediately. Calculate the content of extractable matter in mg per g of air dried material.

2. Cold Maceration

Place the powdered material in a conical flask. Macerate with 100ml of solvent specified for 6hrs, shake then allowed to stand for 18hrs. Filter and transfer the filtrate to flat bottomed disk and evaporate to dryness on a water bath. Dry at 105˚c for 6hrs, cool and weigh immediately. Calculated the content of extractable matter in mg per g of air dried material.

9 . Bitterness Value

Medicinal plants having strong bitter taste are therapeutically used as appetizing agents. The bitterness is determined by comparing the threshold bitter concentration of an extract material with that of quinine hydrochloride the bitterness value is expressed as unit's equivalent to the bitterness of a solution containing 1gm of quinine hydrochloride in 2000ml. 0.1gm of quinine hydrochloride is dissolved in 100ml drinking water and the stock solution is prepared. Then it is diluted and tested and compared with drug.

Bitterness value in unit per gm = 2000*cA*B

Where,

A = concentration of stock solution

B = volume of test solution in tube with threshold bitter concentration

C = quantity of quinine hydrochloride in the tube with threshold bitter concentration

10. Hemolytic Activity

Many medicinal plant materials, of the families Caryophyllaceae, Araliaceae, Sapindaceae, Primulaceae, and Dioscoreaceae contain saponins. The most characteristic property of saponins is their ability to cause haemolysis; when added to a suspension of blood, saponins produce changes in erythrocyte membranes, causing haemoglobin to diffuse into the surrounding medium. The haemolytic activity of plant materials, or a preparation containing saponins, is determined by comparison with that of a reference material, saponin R, which has a haemolytic activity of 1000 units per gm.

11. Swelling Index

The swelling index is the volume in ml taken up by the swelling of 1gm of plant material under specified conditions. Its determination is based on addition of water or a swelling agent as described in test procedure for each individual plant material.

12. Foaming Index

The foaming ability of an aqueous decoction of plant material and their extracts is measured in terms of foaming index. Many medicinal plant materials contain saponins that can cause a 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.

13. Moisture Content And Volatile Matter

Azeotropic method is used to directly measure the water present in a material. Loss on drying In order to measure volatile matter, plant is diluted with water and distillate is collected in a graduated tube. The aqueous portion separates and returns to distillation flask. A solvent of low mass density with a suitable boiling point may be added to measuring tube to easily separate the volatile oil.

CHEMICAL METHODS OF STANDARDIZATION OF HERBAL DRUGS

It comprises of different chemical tests and assays. The isolation, purification and identification of active constituents are chemical methods of evaluation. Quantitative chemical tests such as acid value, saponification value etc., are also covered under this technique. Qualitative chemical tests are used in detection of adulteration.

CHEMICAL EXAMINATION

- Detection of alkaloids
- Detection of carbohydrates and glycosides
- Detection of phytosterols
- Detection of fixed oils and fats
- Detection of saponins
- Detection of phenolic compounds and tannins
- Detection of protein and free amino acids
- Detection of gums and mucilage
- Detection of volatile oils

TEST	REAGENTS USED	COLOUR FORMED
1. Test for alkaloids		
a) Mayer's test	Potassium mercuric iodide solution	Cream ppt
b) Wagner's test	Iodine potassium solution	Brown ppt
c) Hager's test	Saturated solution of picric acid	Yellow colour
d) Dragendroff's test	Potassium bismuth iodide solution	Reddish brown ppt
2. Test for amino acids		
a) Millon's test	Millon Reagent	White ppt
b) Ninhydrine test	Ninhydrine solution	Violet colour
3. Test for carbohydrates		
a) Molish test	Alcoholic α Naphthol+ Sulphuric acid	Purple to violet colour ring
b) Barfoed's test	Barfoed's regents	Red colour
c) Seliwanoff's test	Seliwanoff's reagent	Rose colour
d) Test for Pentoses	HCL+ Phloroglucinol	Red colour

The chemical evaluation also includes CHROMATOGRAPHY OF HERBAL DRUG i.e. Seperation, identification, impurity detection and assay of herbal drug in the formulation or in the extract are carried out by following methods:

a) TLC b) HPTLC c) HPLC d) GLC

Pharmacological Methods Of Standardization of Herbal Drugs

Drugs which cannot be assayed by chemical or physical means are evaluated by biological methods.

BIOLOGICAL STANDARDISATION

This is true for the substances having Interfering obstacles when quantity is too small. No specific chemical test is available when the action of drug is due to a mixture of substance; Purification of drug is not possible.

BIOASSAY

When the estimation of crude drug or its preparation is done by means of its effect on living organism like bacteria, fungi, or animal tissue or entire animal it is known as bioassay.

TOXICOLOGICAL STANDARDIZATION

1. Determination of pesticides.
2. Determination of arsenic and heavy metals
3. Determination radioactive contamination
4. Determination of aflatoxins.

- **Determination of pesticides**

WHO and FAO (food & agricultural Organisation) set limits of pesticides, which are usually present in the herbs. These are mixed with the herbs during the time of cultivation. Mainly pesticides like DDT, BHC, toxaphene, aldrin cause serious side effectsin human beings.

- **Determination of arsenic and heavy metals**

Arsenic and heavy metals are even in trace amounts but they are dangerous removed from herbal drugs. Amount is estimated by matching the depth of colour with of standard stains.

- **Radioactive contamination**

The exposure cannot be avoided because of many naturally occurring sources including radio nucleotides occurring in ground and atmosphere.

- **Determination of Aflatoxins**

Aflatoxins are naturally occurring mycotoxins produced mainly by Aspergillus flavus and Aspergillus parasiticus. The toxin is known to produce cancer in human beings.

MICROBIAL CONTAMINATION

Tests are designed to minimize the accidental contamination of micro organisms.

CONCLUSION

The field of the herbal drugs and formulations is very vast and there is still lot to explore on the subject of standardization of these. So, while developing an herbal drug formulation it is must to have all the related knowledge of that particular drug including all its organoleptic characters to phytoconstituents to pharmacological action to its standardization in respect to various parameters via various techniques.

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 so as to seek marketing approval from regulatory authorities for therapeutic efficacy, safety and shelf life of herbal drugs.

REFERENCES

1. Scholars Research library Der pharmacia lettre, 2010; 2(6): 302-315.
2. J Pharm Educ Res., December 2011; 2: 2. (Neeraj choudhary & bhupinder singh sechon) 55 to 59.
3. Tandardisation and Evaluation of Herbal Drug Formulations- Sunita Panchawat, Kamal Singh Rathore, Dr. S.S. Sisodia, Dr. R.K. Nema.
4. Standerdisation of Herbal drugs- Priyanka m. Yadav M.Pharm guided by: mrs. Nisha h. Parikh, department of quality assuarance Arihant School Of Pharmacy & BRI.
5. ADVANCE TECHNIQUES IN STANDARDIZATION OF HERBAL DRUGS & FORMULATIONS Dr. Satish Nayak Principal Bansal College of Pharmacy Bhopal.