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Pharmacognacy I

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Standardization of herbal drugs (Quality Control)

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.

Different techniques involved in standardization of crude drugs

- Macroscopic methods
- Microscopic methods
- Physical methods
- Chemical methods
- Biological methods

1-Morphological or organoleptic evaluation (Macroscopic methods)

It refers to evaluation of drugs by color, odor, taste, size, shape, &special features like touch, texture, etc. It is a technique of qualitative evaluation based on the study of morphological &sensory profiles of whole drugs. Organoleptic evaluation means conclusions drawn from studies resulted due to impression on organs of senses.

The study of form of a crude drug is Morphology while description of the form is Morphography. The fractured surfaces in cinchona, quillaia &cascara barks& quassia wood are important characteristics .Aromatic odor of umbelliferous fruits &sweet taste of liquorice are example of this type of evaluation. The ovoid tears of gum acacia, ribbon shaped characteristic of tragacanth, disc-shaped structure of nux-vomica, conical shape of aconite, quills of cinnamon etc are important diagnostic characters.

The general appearance of the lot of a crude drug often indicate whether it is likely to comply with prescribed standards , such percentage of seed in colocynth , stalk in clove , etc .Over-drying, makes Leaf drugs & flowers brittle &cause to break in transit making the task of morphological evaluation difficult.

The wavy shape of rauwolfia , pungent taste of capsicum &ginger ,brown color of cinnamon , odor & taste of spice-drugs like , asafetida, black pepper , nutmeg , caraway , cumin , etc. are important diagnostic organoleptic characteristics.

2-Microscopic evaluation

This method allows more detailed examination of a drug &it can be used to identify the organized drugs by their known histological characters, it is mostly used for qualitative evaluation of organized crude drugs in entire &powdered forms.

By microscope, know the property, permits the minute structure under study to be enlarged & can be used to confirm the structural detail of the drugs from plant origin. For the effective results, various reagents or stains can be used to distinguish Cellular structure .Microscopic evaluation also covers study of the constituents by application of chemical methods to small quantities of drugs in powdered form or to histological section of drug (Microchemistry or chemo microscopy). A drop of phoroglucinol &concentrated HCl give red stain with lignin . Mucilage is stained pink with rhuthenium red & also, when treated with corallin soda & few drops of sodium carbonate solution, cellulose swells & dissolves in cuoxam, while N\50 iodine solution stains starch & hemicelluloses blue.

Histological studies are made from very thin sections of drugs .The characteristics of cell walls, cell contents, starch grains, calcium oxalate crystals, trichomes, fibers, vessels, ect. can be studied in details , e.g. lignified trichomes in nux-vomica , warty trichomes of senna ,wavy medullary rays of cascara bark, glandular trichomes of mint ect. The powdered cloves do not contain sclereids or calcium oxalate crystals ,but both of them are present in powdered clove stalks .Powdered clove fruit show presence of starch, while absent in cloves .Presence of non-lignified vessels in powders of rhubarb & ginger indicate adulteration .The presence or absence of crystals of aloin indicates different varieties of aloes.

Notes: trichomes are the tubular elongated or glandular outgrowth of the epidermal cell or (called plant hairs)

3-Chemical evaluation

It comprises of different chemical tests &chemical assays .The isolation , purification &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. Some of these tests are useful in evaluation:

Resin (sulphated ash, acid value,)

Balsams (acid, saponification &ester values)

Volatile oils (acetyl &ester values)

Gums (methoxy determination &volatile acidity).

The qualitative chemical tests are useful in detection of adulteration. The purity of crude drugs is ascertained by quantitative estimation of active chemical constituents present in them .The method may be useful in determining single active constituent or the group of related constituents present in the same drug.

4-Physical standardization of herbal drugs:

- Viscosity
- Melting point
- Solubility
- Moisture content and volatile matter
- Specific gravity
- Density
- Optical rotation
- Refractive index
- Bitterness value
- Hemolytic activity
- Swelling index
- Foaming index
- Ash value
- Astringency

❑ 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.

❑ 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

❑ Solubilty

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

❑ 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, toulene distillation method is used

e.g. Aloe should have moisture content not more than 10% w/w

❑ 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˚

❑ Refractive index

When a ray of light passes from one medium to another of different density, then the ratio of velocity of light in vaccum 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 pressure e.g. Castor oil has refractive index 1.4758-1.527

❑ 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
- Acid insoluble ash is the residue obtained after boiling the total ash with dil. HCl and igniting the remaining insoluble matter.
- Water soluble ash is the difference in weight between total ash and residue after treatment of total ash with water.

❑ Determination of extractable matter:

- 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.
- Readjust 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

❑ Cold marceration

- 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℃ for 6hrs, cool and weigh immediately.
- Calculated the content of extractable matter in mg per g of air dried material.

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 units 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

5-biological evaluation

When the estimation of potency of crude drug or its preparation is done by means of effect on living organisms like bacteria , fungal growth ,of animal tissue or entire animal ,it is known as bioassay. This method is generally called for ,when standardization is not adequately done by chemical or physical means & also for conformity of therapeutics activity of raw material & finished product. bioassay is the measure of sample being tested capable of producing biological effect as that of the parathion. Such activity is represented in units known as International Unit (I.U). example ,Vit. A ,Vit. D & Heparin.

Thanks