

QUALITY CONTROL OF CRUDE DRUGS

Physical and Biological Evaluation



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PHYSICAL EVALUATION

Physical constants are sometimes taken into consideration to evaluate certain drugs. These include moisture content, specific gravity, optical rotation, refractive index, melting point, viscosity and solubility in different solvents.

○ **Moisture content**

Determined by heating the drug at 105 °C in an oven to constant weight.

- **Aloe:** NMT 10 %; **Ergot:** NMT 8 %
- **Digitalis:** NMT 5 %; **Acacia:** NMT 15 %



- **Viscosity**

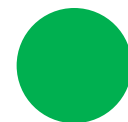
Viscosity of a liquid is constant at given temperature and is an index of composition. It can be used as a means of standardising liquid drugs.

- **Liquid paraffin:** Viscosity NLT 64 centistrokes at 37.8 °.

- **Melting Point**

It is one of the parameters to judge the **purity** of crude drugs. In case of pure chemicals, the melting point is very **sharp** and **constant**. Since the crude drugs from animal or plant origin contains mixed chemicals, they are prescribed in certain **range** of melting point.

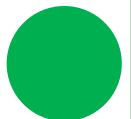
- **Colophony:** 75-85°C; **Kokum butter:** 39-42°C



○ **Solubility**

The presence of adulterant in a drug could be indicated by solubility studies.

- **Castor oil** is soluble only in **3** volumes of 90% alcohol while adulterated form may show good solubility in alcohol.
- **Balsam of Peru** is soluble in chloral hydrate solution.
- **Colophony** is freely soluble in light petroleum.
- **Asafoetida** is soluble in carbon disulphide.



- **Optical rotation**

Certain substances are found to have a property of **rotating** the plane of polarised light in pure state or in solution. Thus they are called as optically active and this property is called as optical rotation.

- **Right** side rotation known as **dextro** rotatory

- **Left** side rotation known as **laevo** rotatory

Clove oil : $+75^{\circ}$ to 80°

Castor oil: $+3.5^{\circ}$ to 6.0°

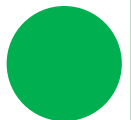
Eucalyptus oil: 0° to $+10^{\circ}$

Chenopodium oil: -30° to -8°



ASH VALUE

- Ash value is the criterion of **purity** or **identity** of the crude drugs.
- The **residue** remaining **after incineration** is the ash value of the drug, which simply represent inorganic salts, naturally occurring in drug or deliberately added to it as a form of adulteration.
- Many a times the crude drugs are admixed with sand, soil, calcium oxalate, chalk powder.
- Total ash usually consists of phosphate, carbonates, silicates and silica.
- **Cannabis:** Total ash-15.0 and acid-insoluble ash-5.0; **Clove:** 7.0 and 0.75; **Cardamom:** 6.0 and 3.5.



EXTRACTIVE VALUES

- Extracts obtained by exhausting crude drugs are indicative of approximate **measures of their chemical constituents.**
- Different solvents are used for the extraction because of the **diversity of chemical nature** and properties of content of drugs.

- **Water-soluble extractives**

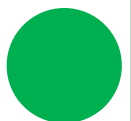
This method is applied for the drugs which contain water-soluble chemical constituents such as **tannins, sugars, glycosides.**

Senna leaves: NLT 30%; Aloe: NLT 25%;

Linseed: NLT 15%; Ginger: NLT 10%;



**Soxhlet
Extractor**



- **Alcohol-soluble extractives**

Alcohol is ideal solvents for extraction of various chemicals like **tannins, resins, flavonoids.**

Examples: Aloe: NLT 10%;

Myrrh: NLT 70%

Siam benzoin: NLT 90%;

Sumatra Benzoin NLT 75%

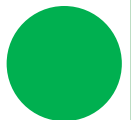
- **Ether-Soluble extractives**

Used for the evaluation of drugs containing volatile oil.

Examples: Capsicum: NLT 12%;

Nutmeg: 25%

Linseed: 25%



VOLATILE OIL CONTENT

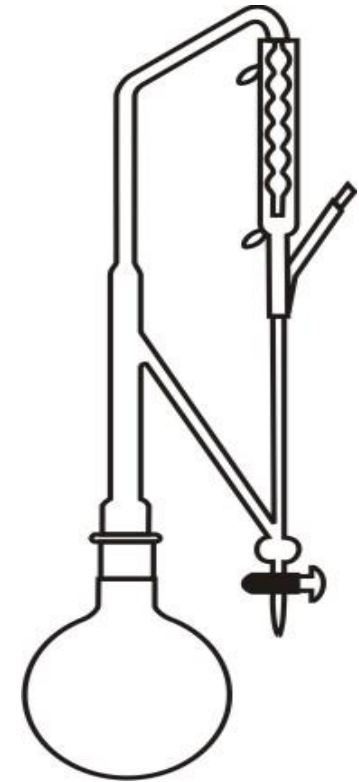
- Pharmaceutical significance of aromatic drugs are due to their odorous principles *i.e.* Volatile oil.
- These drugs are standardized on the basis of their volatile oil content.

Clove: NLT 15%;

Fennel: NLT 1.4%;

Cardamom seed: NLT 4%;

Fresh lemon peel: NLT 2.5%.

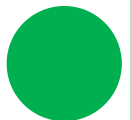


**Clevenger
Apparatus**



BIOLOGICAL EVALUATION

- Herbal drugs are accessed for their biological efficacy.
- **Hepatoprotective activity**
Many drugs, chemicals, industrial pollutants, hepatitis virus, ethyl alcohol are known to cause hepatitis, cirrhosis and **liver damage**.
- **Animal:** Male/ female albino rats
- **Induced by:** Carbon tetrachloride, alcohol, paracetamol, rifampicin (anti-TB drug).
- **Standard:** Silimarin (Obtained from Milk Thistle)
- **Parameters:** SGPT, SGOT, Alkalline phosphate
- Histopathological studies of liver.



- **Anti-diabetic activity**

Many drugs like **Karela** (*Momordica charantia*), **Jamun** (*Syzigium cumini*); **Methi** (*Trigonella foenu-graceum*); **Gudmar** (*Gymnema sylvestre*) have been used in traditional system of Medicine for the treatment of Diabetes mellitus (Type 2)

- **Animals:** Albino rats, mice, rabbits

- **Induction by:** Streptozotocin (**STZ**), Alloxan, *i.p*

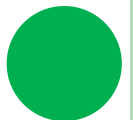
- **Standard:** metformin, glimeperide, glibenclamide, gliclazide

- **Parameters:** Blood sugar by **GOD-POD** method;

Insulin by ultra sensitive rat ELISA kit;

Lipid profile, TC, TGs, HDL, LDL, VLDL.

- Histopathology of pancreas



- **Anti-inflammatory activity**

Many plants are used for the treatment of inflammation in Rheumatoid arthritis, Gout.

- **Animals:** Mice, rats

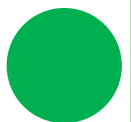
- **Induced by: Carragenan**, isolated from iris moss *Chondus crispus*, 0.1 ml 1 % w/v in saline in rat right hind-paw.

- Drug extract is given orally 1 hour or 30 minutes *i.p* **before test**.

- Volume of paw is measured just after injection then every after an hour subsequently for 5 times.

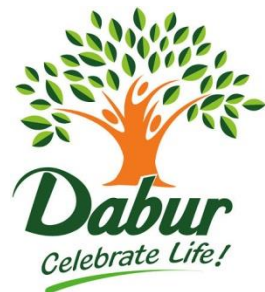
- Volume of paw is measured by volume displacement method using **Plethysmometer**

- Measurement: **0 = No activity; + = slight;**
+ = Pronounced



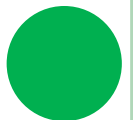
QUALITY CONTROL

- In short, **Quality** can be defined as
 - It is the character with respect to fineness.
 - It refers to the grade of excellence.
 - Meeting the requirement of customers.
- **Quality control** refers to processes involved in maintaining the quality and validity of a manufactured product.
- **In general**, all medicines, whether they are of synthetic or of plant origin, should fulfill the basic requirements of being efficacious and safe.

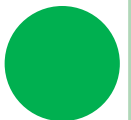


PROBLEMS IN QUALITY CONTROL OF HERBAL DRUGS

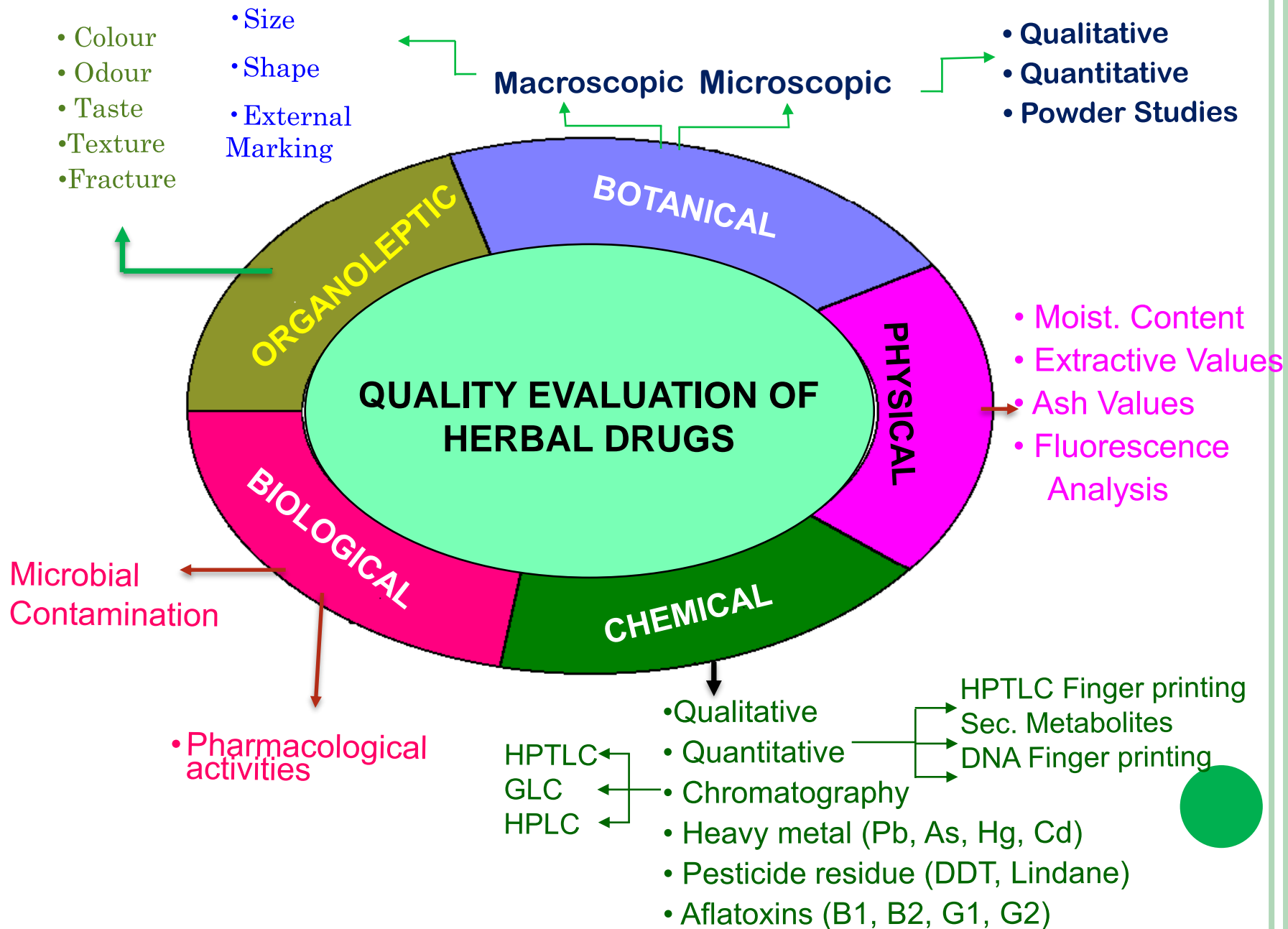
- Herbal drugs are usually **mixtures** of many constituents.
- The active principle(s) is (are), in most cases unknown.
- Selective analytical methods or **reference** compounds may not be **available** commercially.
- Plant materials are **chemically** and **naturally** variable.
- The source and quality of the raw material are variable.
- The methods of harvesting, drying, storage, transportation, and processing have an effect.



WHO GUIDELINES FOR QUALITY CONTROL OF HERBAL DRUGS



WHO guidelines for quality control of herbal drugs



THANK YOU

