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Official drug :mean natural or synthetic drug that organized and included in official pharmacopeia which is :

1-British pharmacopeia

2-United state pharmacopeia

3-European pharmacopeia

Example:-

a- Seed of the plant Vinca Rosa and their active constituent (Vincristin and vinblastin) which is used in the treatment of cancer disease.

b-Dried leaf of the plant digitalis and their active constituent (Digitoxin or Digoxin) these drugs are used for the treatment of some heart disease.

c- Extract of the unripe fruit of the plant pappaver somniferum and their constituent (Morphine) which is used as Narcotic.

Unofficial drug:- These drugs are natural or synthetic substances which are recognized and included in official pharmacopeia but after a period of time these drugs appear toxic effect ex:-

A-Khat used as narcotic.

B-Colchicum which used for the treatment of gout.

- **None official drug**:- these drugs are never appear in official pharmacopeia.

- Plants growing in their native countries are said to be:- (in digenous) to those regions such as pinus palustris in the southern united states.

- Plants are said to be (naturalized) when they grow in a foreign land or in a locality other their native homes such as Datura which was introduced into the united states from Europe.
- Cultivated medicinal plants have been propagated for centuries in china, India, Europe and many other lands.

Evaluation of drugs:

- To evaluate a drug means to identify it and to determine its quality and purity.

- The identity of a drug can be established by it's actual collection from a plant or animal that has been positively identified.
- another method of identification is the comparison of a representative unknown sample to a published description of the drug and to authentic drug samples.

- Quality refers to the intrinsic value of the drug (i.e the amount of medicinal principles or active constituents present.

The evaluation of a drug involves a number of methods:-

1-Organoleptic

2-Microscopic

3-Biologic

4-Chemical

5-Physical

1-Organoleptic refers to evaluation by means of the organs of sense and includes the macroscopic appearance of the drug, its odor, taste and color.

2-Microscopic is the study of specific charac. Feature in powdered plant drugs since powdered plant drugs possess few microscopic features of identification other than color, odor and taste.

3-The pharmacologic activity of certain drugs has been applied to their evaluation and standardization. Assays on living organisms as well as on it act organs indicate the strength of the drug and because living organisms are used, the assays are called biologic assays or bioassays.

4-Chemical methods because the active constituents of many natural drugs have been determined, chemical methods of evaluating crude drugs are useful, the chemical assay represents the best method of determining the official potency.

Standards applicable to crude drugs

There are a number of standards, which can be applied to the evaluation of crude drugs either in the whole or the powdered condition.

1-Sampling

Before a consignment of a drug can be evaluated, a sample must be drawn for analysis; considerable care must be exercised to ensure that this sample is truly representative

2-preliminary examination

In the case of whole drugs the macroscopical and sensory characters are usually sufficient to enable the drug to be identified. E.g. size , colour , odour , this is called organoleptic examination

3- Foreign matter

The difficulty of obtaining vegetable drugs in an entirely pure condition is fully recognized, and pharmacopoeias contain statements as to the percentage of other parts of the plant or of other organic matter which may be permitted.

Drugs containing appreciable quantities of potent foreign matter, animal excreta, insects or mould, should, however, be rejected even though the percentage of such substances be insufficient to cause the rejection of the drug on the percentage of foreign matter.

4-Moisture content

Not only is the purchase of drugs (e.g. aloes, gelatin, gums) which contain excess water, uneconomical, but also in conjunction with a suitable temperature moisture will lead to the activation of enzymes and, given suitable conditions, to the proliferation of living organisms.

A large number of methods are now available for moisture determination

e.g: Loss on drying, Separation and measurement of moisture , Chemical methods , Spectroscopic methods

5-extractive values

The determination of water-soluble or ethanol-soluble extractive is used as a means of evaluating drugs the constituents of which are not readily estimated by other means

6-ash values

When vegetable drugs are incinerated, they leave an inorganic ash which in the case of many drugs is of importance and indicates to some extent the amount of care taken in the preparation of the drug.

7-determination of volatile oil

Minimum standards for the percentage of volatile oil present in a number of drugs are prescribed by many pharmacopoeias.

8- tannin content

The method refers to those polyphenols adsorbed by hide powder and giving a colour reaction with sodium phosphomolybdo-tungstate reagent.

9-bitterness value

This standard is relevant to Bogbean leaf, Centaury, Gentian and Wormwood of the BP. These drugs are used for their bitter effect and specific directions for the determination of the standard are given under each monograph. The bitterness value is determined organoleptically by comparison with a quinine hydrochloride solution which acts as the standard.

10- Swelling index

This is defined in the BP as the volume in millilitres occupied by 1 g of a drug, after it has swollen in an aqueous liquid for 4 h. In some instances, as with linseed and psyllium seed where the mucilage is in a layer near the surface of the drug, the standard can be determined on the whole drug; in other cases such as marshmallow root where the mucilage is distributed throughout the tissues, the powdered drug is used

11-RF values

Pharmacopoeias are increasingly employing thin-layer chromatography as a means for assessing quality and purity. It suffices to mention here that the RF value (rate of flow, i.e., distance moved by solute divided by distance moved by solvent front) of a compound, determined under specific conditions, is characteristic and can be used as an aid to identity. RF values vary from 0.0 to 1.00.

12- **Microbial contamination**

Generally , manufacturers should ensure that , for crude drugs to be taken internally , the limits for bacterial & mould contamination as applied to foodstuffs . Considerable quantities of drugs are sterilized in special equipments by treatment with ethylene oxide .

13-toxic residues

These may arise in crude drugs as a result of pesticide application during cultivation of the drug and at a later stage from fumigation of the stored product.

Thin-layer chromatography (TLC) and gas chromatographic methods are available for the determination of organochlorine and urea derivatives, enzymatic methods for organophosphorus compounds, colorimetric methods for urea derivatives, and spectroscopic techniques for paraquat, triazines and heavy metals

14-Heavy metal accumulation

under certain circumstances the levels of some metals, particularly those of lead, cadmium, copper and mercury, can increase to unacceptable concentrations. This may arise either by the deliberate inclusion of, for example, mercury compounds in a particular herbal formulation or by the natural accumulation of heavy metals in herbs growing under particular environmental conditions.

In the second instance, increased levels of heavy metals can arise from the nature of the soil and via atmospheric pollution Determination is by atomic adsorption spectroscopy after acid digestion of the sample with concentrated nitric, hydrochloric and sulphuric acids

Break

Assays

A crude drug may be assayed for a particular group of constituents for example, the total alkaloids in belladonna or the total glycosides of digitalis.

Alternatively, it may be necessary to evaluate specific components—for example, the reserpine content, as distinct from the total alkaloid content, of Rauwolfia spp

Spectroscopic analysis

In spectroscopic analysis we are concerned with the capacity of certain molecules to absorb vibrations at specific wavelengths . E.g UV and IR

Fluorescence analysis

Many substances—for example, quinine in solution in dilute sulphuric acid—when suitably illuminated, emit light of a different wavelength or colour from that which falls on them. This emitted light (fluorescence) ceases when the exciting light is removed.

nMr spectroscopy

Although this technique is usually associated with structure-determinations of organic compounds the use of 1H-NMR spectroscopy has been described for the assay of atropine and hyoscine in extracts of Belladonna.

Immunoassays

Such assays are highly sensitive and usually very specific and have been developed as a powerful analytical tool for the quantitative determination of many compounds in biological fluids.

Radioimmunoassays (RIA). The assay depends on the highly specific reaction of antibodies to certain antigens. There are various modifications of the technique and it is the saturation method that has been developed for phytoanalysis.

tandem mass spectroscopy (MS–MS)

In phytochemistry to date, mass spectroscopy is usually associated with the structure elucidation of compounds rather than with their assay. However, by the simultaneous use of two mass spectrometers in series it is possible to determine quantitatively the amount of a particular targeted compound in complex mixtures, plant extracts or even in dried plant material.

Chemistry of drugs

Chemical compounds that give plants their therapeutic properties called constituents of plants because the plant is composed of many chemical compounds called (active constituents). These active constituents are differentiated from (Inert constituents) which also occur in plant and animal drugs but have no definite pharmacologic activity like cellulose, lignin, starch, coloring matters and others.

- **Active constituents may be divided in to 2 classes:**

1-Pharmaceutically active.

2-Pharmacologically active

1-Pharmaceutically active constituent, may cause precipitation or other chemical changes in the medicinal preparation (ex. Cinchona bark or it's extract could not be used in formulating preparation containing iron salts because the cinchotannic acid would combine with these salts and cause precipitation: cinchotannic acid is pharmaceutically active constituents.

2-Pharmacologically active constituents are responsible for the therapeutic activity of the drug that may be either single chemical substances (like: alkaloids, glycoside, hormones, enzyme, steroids).

Or mixtures of principle (like fixed oils, fats, waxes, volatile oils, resins, oleoresins).

- All these constituents have been referred to as (Secondary) plant substances [differ from primary plant substances which include (carbohydrates protein and fatty acid).

❖The secondary constituents of drug plants are influenced by 3 factors:-

- Heredity (genetic composition)
- Ontogeny (stage of development)
- Environment

❖Genetic effect induce both quantitative and qualitative changes but those caused by environment influences are primarily quantitative.

(ex. Plants of the same species have the same form and structure "phenotypically" may differ in genetic composition "genotypically" this may results in distinct difference in chemical composition such plants are said to belong to different chemical races.

- Ontogeny also plays a significant role in the nature of the active constituents found in medicinal plants, usually the concentration of secondary metabolites would increase with the age of the plant but it may also range according to the stage of development (ex. In the opium poppy (Papaver somniferum. F. Papaveranceae).
- The morphine content is highest 2-3 weeks after flowering, if the plant is harvested earlier, other compounds like thebaine predominate, on the other hand if harvesting is delayed too long, the morphine decomposes.

- Environmental factors that can produce variation in secondary plant constituents include:

*Soil, *Climate, *associated flora and *Methods of cultivation.

- Because all these factors are more or less related, they are difficult to evaluate individually, for example: Many alkaloid-containing plants accumulate higher concentrations of secondary constituents in moist regions than in dried land, this may be related to the soil which is usually poor in nitrogen in dried region and rich nitrogen sources are usually required for good yield of alkaloids, this is not necessarily in case of volatile oils which doesn't required excess of nitrogen to increased their yielding.

- On the earth the green plant are the main source for many organic substances. Some of those natural substances have economically useful for various scientific and commercial application. These organic substances are synthesize and degraded to form another organic substances by series of chemical reactions these chemical reactions are named as "Metabolism" therefore these organic substances are classified as primary and secondary metabolize.

• Primary metabolite: which formed by biosynthesis (by anabolism)

- Secondary metabolite: which formed by the degredation of the primary metabolize (by catabolism).

- **Primary metabolite properties by comparison with secondary metabolite:-**

1-These substances are formed by photosynthesis.

2-They found in high concentration in the plant (cells).

3-They have high molecular weight.

4-They are sources for energy.

5-They have structural and functional roles in the plant.

- Structural: means it found in cell wall constituents.
- Functional: means it has a role in some plant's functions.
- Ex: Different sugars like glucose, sucrose, amino acids, fatty acids DNA, RNA and protein.

- **Secondary metabolite properties:-**

1-These substances biosynthetically derived from primary metabolite by three main pathway:

a. Shikimic acid pathway

b. Acetate malonate pathway

c. Acetate mevalonate pathway.

2- They have small molecular weight.

3- They found in small concentration in the cells of plant.

4- They are not sources of energy.

5- They have no apparent or clear function in the plant but often they have ecological roles. Ex:- volatile oil have pollinate attractant useful for human because they are used as drug.

- THE END