PHARMACOGNOSTICAL TERMINOLOGIES

TRADITIONAL DRUGS (also known as Indigenous Medicine) comprises medical knowledge systems that developed over generations within various societies before the era of modern medicine.

It includes Ayurveda, Siddha, Unani, Iranian medicine, Islamic medicine, Traditional Korean Medicine, Acupuncture, Traditional African medicine, and other medical knowledge and practices all over the globe.

As per WHO traditional medicine means:

" The health practices, approaches, knowledge and beliefs incorporating plant, animal, and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illness or maintain well-being."

HERBAL DRUGS: The study or use of medicinal herbs to prevent and treat diseases and ailments or to promote health and healing.

HERBAL FORMULATIONS/MEDICINES: as per 'WHO'

"Finished, labelled medicinal products that contain as active ingredients aerial or underground parts of the plant or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, volatile oils and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined, isolated constituents of plants are not considered to be herbal medicines."

AYURVEDIC DRUGS: Medicines based on the principles of Ayurveda and designed to maintain or improve health through the use of dietary modification, massage, yoga, herbal preparations, and other measures.

AYURVEDIC FORMULATIONS: As per Drug & Cosmetic Act 1940,

All medicines intended for internal or external use, for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae

described in the authoritative books of Ayurvedic systems of medicine specified in the First Schedule of Act.

UNORGANIZED DRUGS: They are either mixtures of chemical substances or decomposition products of substances originally present in the biological source of the drug.

ORGANIZED DRUGS: They are the crude drugs of plant or natural origin and having cellular structure or define structure.

HERB: A flowering plant which stem does not produce woody tissue and generally dies back at the end of each growing season. Bothe grasses and forbs are herbs.

SHRUB: A woody plant of relatively low height, having several stems arising from the base and lacking a single trunk.

STEM: The main ascending axis of a plant, which bears the leaves, auxiliary buds, and flowers and contains a hollow cylinder of vascular tissue.

LEAF: A green, flattened, lateral structure attached to a stem directly or by a stalk and functioning as a principal organ of photosynthesis and transpiration in most plants.

FLOWER: The reproductive structure of angiosperm plants, consisting normally of stamens and carpels surrounded by petals and sepals all borne on the receptacle (one more or these structures may be absent).

ROOT: The descending axis of a plant that lack buds, leaves, or nodes and serves as support, draws minerals and water from surrounding soil and sometimes stores food.

SEED: A mature fertilized plant ovule, consisting of an embryo and its food store surrounded by a protective seed coat (testa).

Fruit: The ripened ovary or ovaries of a seed-bearing plant, together with accessory parts, containing the seeds and occurring in a wide variety of forms.

BARK: The tough outer covering of the woody stems and roots of trees, shrubs, and other woody plants. It includes all tissues outside the vascular cambium.

Quality control methods for medicinal plant materials, World Health Organization, Geneva

QUALITY CONTROL METHODS FOR MEDICINAL PLANT MATERIAL

1. Powder fineness and sieve size
2. General advice on sampling
3. Determination of foreign matter
4. Macroscopic and microscopic examination
5. Thin-layer chromatography
6. Determination of ash
7. Determination of extractable matter
8. Determination of water and volatile matter
9. Determination of volatile oils
10. Determination of bitterness value
11. Determination of haemolytic activity
12. Determination of tannins
13. Determination of swelling index
14. Determination of foaming index
15. Determination of pesticide residues
16. Determination of arsenic and heavy metals
17. Determination of microorganisms
18. Radioactive contamination

1. POWDER FINENESS AND SIEVE SIZE

Powders

The coarseness or fineness of a powder is classed according to the nominal aperture size expressed in terms of the mesh of the sieve through which the powder will pass, and is indicated as follows:

DESCRIPTIVE TERM	PARTICLE SIZE
Coarse (2000/355)	All the particles will pass through a No. 2000 sieve, and not more than 40% through a No. 355 sieve
Moderately coarse	All the particles will pass through a No. 710 sieve,

(710/250)	and not more than 40% through a No. 250 sieve
Moderately fine (355/180)	All the particles will pass through a No. 355 sieve, and not more than 40% through a No. 180 sieve
Fine (180)	All the particles will pass through a No. 180 sieve
Very fine (125)	All the particles will pass through a No. 125 sieve

2. GENERAL ADVICE ON SAMPLING

The reliability of any conclusions drawn from the analysis of a sample will depend upon how well the sample represents the whole batch. General recommendations for the sampling of pharmaceutical materials in connection with quality control are provided in the thirty-first report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Because of the specific characteristics of medicinal plant materials, in particular their lack of homogeneity, special handling procedures are required in relation to sampling. The following procedures should be observed when selecting and preparing an average sample from a batch of material.

Recommended procedures

- Sampling of material in bulk
- Sampling of material in retail packages

3. DETERMINATION OF FOREIGN MATTER

Medicinal plant materials should be entirely free from visible signs of contamination by moulds or insects, and other animal contamination, including animal excreta. No abnormal odour, discoloration, slime or signs of deterioration should be detected. It is seldom possible to obtain marketed plant materials that are entirely free from some form of innocuous foreign matter. However, no poisonous, dangerous or otherwise harmful foreign matter or residue should be allowed.

During storage, products should be kept in a clean and hygienic place, so that no contamination occurs. Special care should be taken to avoid formation of moulds, since they may produce aflatoxins.

Macroscopic examination can conveniently be employed for determining the presence of foreign matter in whole or cut plant materials. However, microscopy is indispensable for powdered materials.

Any soil, stones, sand, dust and other foreign inorganic matter must be removed before medicinal plant materials are cut or ground for testing.

Definition: Foreign matter is material consisting of any or all of the following:
- Parts of the medicinal plant material or materials other than those named with the limits specified for the plant material concerned;
- Any organism, part or product of an organism, other than that named in the specification and description of the plant material concerned;
- Mineral admixtures not adhering to the medicinal plant materials, such as soil, stones, sand, and dust.

Sample size

It is difficult to prepare a pooled sample of foreign matter since most of it adheres to the medicinal plant materials which are intrinsically non-uniform. Special procedures requiring considerable practice are therefore necessary. The problem is especially difficult when the samples of unbroken crude medicinal plant materials selected are small; they should be sufficiently large to be representative.

The following quantities constitute a sample, unless otherwise specified in the test procedure for the plant material concerned.

Plant material Sample size

- Roots, rhizomes and bark 500 g
- Leaves, flowers, seeds and fruit 250 g
- Cut medicinal plant materials
- (Average weight of each fragment less than 0.5 g) 50g

Recommended procedures

Foreign matter in whole or cut medicinal plant materials

Weigh a sample of plant material, taking the quantity indicated above unless otherwise specified in the test procedures for the plant material concerned. Spread it in a thin layer and sort the foreign matter into groups either by visual inspection, using a magnifying lens (6x or 10x), or with the help of a suitable sieve, according to the requirements for the specific plant material. Sift the remainder of the sample through a No. 250 sieve; dust is regarded as mineral admixture. Weigh the portions of this sorted foreign matter to within 0.05g. Calculate the content of each group in grams per 100g of air-dried sample.

For some medicinal plant materials where the foreign matter may closely resemble the material itself, it may be necessary to take a pooled sample of the plant material and apply a critical test, either chemical, physical or by microscopy. The proportion of foreign matter is calculated from the sum of the portions that fail to respond to the test.

4. DETERMINATION OF ASH

The ash remaining following ignition of medicinal plant materials is determined by three different methods which measure total ash, acid-insoluble ash and water-soluble ash.

The *total ash* method is designed to measure the total amount of material remaining after ignition. This includes both "physiological ash", which is derived from the plant tissue itself, and "non-physiological" ash, which is the residue of the extraneous matter (e.g. sand and soil) adhering to the plant surface.

Acid-insoluble ash is the residue obtained after boiling the total ash with dilute hydrochloric acid, and igniting the remaining insoluble matter. This measures the amount of silica present, especially as sand and siliceous earth.

Water-soluble ash is the difference in weight between the total ash and the residue after treatment of the total ash with water.

Recommended procedures

Total ash

Place about 2-4g of the ground air-dried material, accurately weighed, in a previously ignited and tared crucible (usually of platinum or silica). Spread the material in an even layer and ignite it by gradually increasing the heat to 500-600°C until it is white, indicating the absence of carbon. Cool in a desiccator and weigh. If carbon-free ash cannot be obtained in this manner, cool the crucible and moisten the residue with about 2 ml of water or a saturated solution of ammonium nitrate R. Dry on a water-bath, then on a hot-plate and ignite to constant weight. Allow the residue to cool in a suitable desiccator for 30 minutes, and then weigh without delay. Calculate the content of total ash in mg per g of air-dried material.

Acid-insoluble ash

To the crucible containing the total ash, add 25 ml of hydrochloric acid (~70g/l) TS, cover with a watch-glass and boil gently for 5 minutes. Rinse the watch-glass with 5 ml of hot water and add this liquid to the crucible. Collect the insoluble matter on an ashless filter-paper and wash with hot water until the filtrate is neutral. Transfer the

filter-paper containing the insoluble matter to the original crucible, dry on a hot-plate and ignite to constant weight. Allow the residue to cool in a suitable desiccator for 30 minutes, and then weigh without delay. Calculate the content of acid-insoluble ash in mg per g of air-dried material.

Water-soluble ash

To the crucible containing the total ash, add 25 ml of water and boil for 5 minutes. Collect the insoluble matter in a sintered-glass crucible or on an ash less filter-paper. Wash with hot water and ignite in a crucible for 15 minutes at a temperature not exceeding 450°C. Subtract the weight of this residue in mg from the weight of total ash. Calculate the content of water-soluble ash in mg per g of air-dried material.

Quality control methods for medicinal plant materials

5. DETERMINATION OF EXTRACTABLE MATTER

This method determines the amount of active constituents extracted with solvents from a given amount of medicinal plant material. It is employed for materials for which as yet no suitable chemical or biological assay exists.

Recommended procedures

Method 1. Hot extraction

Place about 4.0g of coarsely powdered air-dried material, accurately weighed, in a glass-stoppered conical flask. Add 100ml of water and weigh to obtain the total weight including the flask. Shake well and allow to stand for 1 hour. Attach a reflux condenser to the flask and boil gently for 1 hour; cool and weigh. Readjust to the original total weight with the solvent specified in the test procedure for the plant material concerned. Shake well and filter rapidly through a dry filter. Transfer 25 ml of the filtrate to a tared flat-bottomed dish and evaporate to dryness on a water-bath. Dry at 105°C for 6 hours, cool in a desiccator for 30 minutes, then weigh without delay. Calculate the content of extractable matter in mg per g of air-dried material.

Method 2. Cold maceration

Place about 4.0g of coarsely powdered air-dried material, accurately weighed, in a glass-stoppered conical flask. Macerate with 100ml of the solvent specified for the plant material concerned for 6 hours, shaking frequently, then allow to stand for 18 hours. Filter rapidly taking care not to lose any solvent, transfer 25 ml of the filtrate to a tared flat-bottomed dish and evaporate to dryness on a water-bath. Dry at 105°C

for 6 hours, cool in a desiccator for 30 minutes and weigh without delay. Calculate the content of extractable matter in mg per g of air-dried material.
For ethanol-soluble extractable matter, use the concentration of solvent specified in the test procedure for the plant material concerned; for water-soluble extractable matter, use water as the solvent. Use other solvents as specified in the test procedure. *Quality control methods for medicinal plant materials*

6. DETERMINATION OF WATER AND VOLATILE MATTER

An excess of water in medicinal plant materials will encourage microbial growth, the presence of fungi or insects, and deterioration following hydrolysis. Limits for water content should therefore be set for every given plant material. This is especially important for materials that absorb moisture easily or deteriorate quickly in the presence of water.
The *azeotropic* method gives a direct measurement of the water present in the material being examined. When the sample is distilled together with an immiscible solvent, such as toluene R or xylene R, the water present in the sample is absorbed by the solvent. The water and the solvent are distilled together and separated in the receiving tube on cooling. If the solvent is anhydrous, water may remain absorbed in it leading to false results. It is therefore advisable to saturate the solvent with water before use.
The test for *loss on drying* determines both water and volatile matter. Drying can be carried out either by heating to 100-105 °C or in a desiccator over phosphorus pentoxide R under atmospheric or reduced pressure at room temperature for a specified period of time. The desiccation method is especially useful for materials that melt to a sticky mass at elevated temperatures.

Recommended procedures

Preparation of material

Prepare a suitable quantity of the sample by cutting, granulating or shredding the unground or unpowdered material, so that the thickness of the parts does not exceed 3 mm. Seeds or fruits smaller than 3 mm should be cracked. Avoid the use of high-speed mills in preparing the sample, and take care that no appreciable amount of moisture is lost during preparation. It is important that the portion is large enough to be a representative sample.

Loss on drying (gravimetric determination)

Place about 2-5g of the prepared air-dried material, or the quantity specified in the test procedure for the plant material concerned, accurately weighed, in a previously dried and tared flat weighing bottle. Dry the sample by one of the following techniques:

- In an oven at 100-105°C;
- In a desiccator over phosphorus pentoxide R under atmospheric pressure or reduced pressure and at room temperature.

Dry until two consecutive weighing do not differ by more than 5mg, unless otherwise specified in the test procedure. Calculate the loss of weight in mg per g of air-dried material.

7. DETERMINATION OF VOLATILE OILS

Volatile oils are characterized by their odour, oil-like appearance and ability to volatilize at room temperature. Chemically, they are usually composed of mixtures of, for example, monoterpenes, sesquiterpenes and their oxygenated derivatives. Aromatic compounds predominate in certain volatile oils.

Because they are considered to be the "essence" of the plant material, and are often biologically active, they are also known as "essential oils". The term "volatile oil" is preferred because it is more specific and describes the physical properties.

In order to determine the volume of oil, the plant material is distilled with water and the distillate is collected in a graduated tube. The aqueous portion separates automatically and is returned to the distillation flask. If the volatile oils possess a mass density higher than or near to that of water, or are difficult to separate from the aqueous phase owing to the formation of emulsions, a solvent with a low mass density and a suitable boiling-point may be added to the measuring tube. The dissolved volatile oils will then float on top of the aqueous phase.

Recommended procedure

Carry out the determination by steam distillation. Collect the distillate in a graduated tube, using xylene R or the solvent specified for the plant material concerned, and allow the aqueous phase to recirculate into the distillation flask. For all determinations read the rate of distillation from the marks engraved on the apparatus.