UNIT - 1

CHAPTER - 1

HERBS AS RAW MATERIALS

1.1 Definition of herb

Herbs generally refers to the leafy green or flowering parts of a plant (either fresh or dried), while spices are usually dried and produced from other parts of the plant, including seeds, bark, roots and fruits. In botany, the word "herb" is used as a synonym for "herbaceous plant"

Herbs are the usable parts of herbaceous plants (plants that lack a woody stem). The word herb most often refers to those that have culinary, cosmetic, or medicinal uses.

The culinary uses of herbs are what differentiate them from spices. While herbs are referred to as leafy greens or flowering parts of a plant, fresh or dried, spices, on the other hand, are produced from the other parts of the plants, which are usually dried, including berries, roots, barks, seeds, and fruits. In general use, herbs are used for food, flavoring, medicine, or fragrances due to their savory and aromatic properties. Many people new to indoor gardening start by growing an herb garden because they are small and the plants are considered hardy, meaning they can withstand neglect, as well as useful.

Example of herbs

Basil, mint, fenugreek, chives, parsley, watercress, rosemary, sage, oregano, coriander/cilantro, dill, lavender, lemon balm, borage.

1.2 Herbal medicine

Herbal medicine is the oldest and still the most widely used system of medicine in the world today. It is medicine made exclusively from plants. It is used in all societies and is common to all cultures.

There are many different types of herbal medicine that spring from different cultures around the world. All these have the use of medicinal plants in common, but they vary in the plants they use, the way they prepare and use medicines from these plants, and the philosophy of their treatment approaches. Different cultures may also use the same plants but differ in how it is used, or the part they use.

In Australia the most commonly found cultural types of herbal medicine are Western, Aboriginal, Chinese and Ayurvedic (Indian), although there are also many other cultures represented in Australia that utilize their own unique and traditional herbal treatments.

The National Herbalists Association of Australia represents the practice of Western herbal medicine, which is based on European herbal medicine traditions. We also have an Aboriginal and Torres Strait Islander (ATSI) membership category. These members work in their local communities using traditional Aboriginal bush and Western herbal medicine.

Herbal medicine is increasingly being validated by scientific investigation which seeks to understand the active chemistry of the plant. Many modern pharmaceuticals have been modeled on, or derived from chemicals found in plants. An example is the heart medication digoxin derived from foxglove (*Digitalis purpurea*).

Using plants as medicine provides significant advantages for treating many conditions. The therapeutic activity of a plant is due to its complex chemical nature with different parts of the plant providing certain therapeutic effects.

1.3 Herbal medicinal product

Herbal medicinal products are medicinal products where the active ingredient consists exclusively of herbal substances or herbal preparations. Natural remedies are medicinal products where the active ingredient is of natural origin and consists of an animal part, a bacterial culture, a mineral or a salt.

Herbal drug is the part of the medicinal plant used for therapeutic purposes. According to the European Pharmacopoeia (EU) herbal drugs (substances) are mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichens in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs. Herbal drugs are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

From an herbal substance, different herbal preparations can be made. They can represent the active ingredient in an individual herbal medicinal product. Any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal throughout most of the history, plants have been a source of medicines for the treatment of a wide array of diseases. Plant parts and plant extracts have been traditionally used to prevent or cure diseases.

During the recent years there has been renewal in the use of herbal products, which may be due to growing consumer dissatisfaction with

conventional medicines, progress in chemical, pharmacological and clinical evaluations, development of newer dosage forms and increase in auto medication. Herbal Medicinal Products (HMP) is those medicinal products that contain exclusively as ingredients herbal drugs (e.g. parts of plants) or pharmaceutical preparations there of (e.g. extracts, essential oils, etc.).

The World Health Organization (W.H.O.) encourages, recommends and promotes traditional/herbal remedies in national health-care programs because these drugs are easily available at low cost, comparatively safe, and have increasing public faith inthem. Various monographs on the quality, safety, and efficacy of selected medicinal plants, as well as recommendations on the cultivation of medicinal plants, on the quality control, and safety and efficacy of herbal medicinal products are published.

It is important to define various terms used for herbal medicinal products. In the United States, these products are called "Botanical Products", and are defined as finished, labeled products that contain vegetable matter as ingredient which may include plant materials (A plant or plant part as well as exudates thereof), algae, macroscopic fungi or combination of these. A botanical product depending on its labeling and intended use may be a food, dietary supplement, a drug, a medical device (e.g. gutta-percha), or a cosmetic under the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Food and Drug Administration(FDA) has issued a "Guidance for Industry: Botanical Drug Products" For this Guidance document, the term botanicals include plant materials, algae, microscopic fungi and combination thereof. It does not include: materials derived from genetically modified botanical species (i.e. by recombinant DNA technology or cloning, fermentation products, and highly purified substances (e.g. paclitaxel) or chemically modified substances (e.g. estrogens synthesized from sweet potatoes extracts) derived from botanical sources.

Botanical Drug Product Botanical Drug is a botanical product that is intended for use as a drug that is prepared from a botanical drug substance (FDA). They are available in a variety of dosage forms such as solutions (e.g. teas), powders, tablets, capsules, elixirs and topical .Botanical Drug Substance is derived from one or more plants, algae, or macroscopic fungi. It is prepared from botanical raw materials by one or more of the following processes: Pulverization, decoction, expression, aqueous extraction, ethanol extraction or other similar process (FDA). Botanical Ingredient is a component of a botanical drug substance or product that originates from a botanical raw material. Botanical Raw Material is a fresh or processed (e.g. cleaned, frozen dried or sliced) part of a single species of a plant or a fresh or processed alga or microscopic fungus.

Quality of herbal medicinal products

Quality is a key issue in the development of safe and efficacious herbal medicinal products. Quality according to ICH guidelines can be defined as a degree to which a set of inherent properties of a product, system or process fulfills requirements. This term includes such attributes as the identity, strength, and purity. Quality cannot be tested into products, i.e., quality should be built in by design.

Quality does not happen by accident, it must be planned. In these trials, for 5 top selling single-herb preparations, 49% listed Latin binomial of the plant, 10% identified plant part used, 65% identified manufacturer, 28% reported processing or extraction method, and 51% reported at least one expected constituent and amount. Lack of appropriate standards is one of the key factors that limits wider acceptance of herbal drugs.

The main reason advanced for the difficulty in developing quality control standards is that most of these products use whole herbs, or parts of plants or their total extracts, and in many cases a mixture of number of plants. These drugs often contain a varied number and quantity of chemical constituents. It is challenging to develop suitable standards because a plant drug or its preparation is regarded asone active entity in its entirety, whether or not the active constituents with therapeutic activity are known.

Standardization of an herbal drug is not just an analytical operation ending with the identification and assay of an active principle rather it entails total information and controls necessary to guarantee composition consistency. Directives on the analytical control of a plant drug must take into account the fact that the plant material has a complex composition. Therefore, the analytical limits cannot be set as precisely as for the pure chemical compound. Plant drugs are naturally inconsistent and their composition is influenced by several factors suchas age of the plant, geographical source and climate, harvesting period, method of drying, storage period and conditions.

To eliminate some of the causes of inconsistency, use should be made of cultivated rather than wild plants which are often heterogeneous with respect for above factors and consequently in their content of active principles. All these factors make standardization of herbal medicinal products a difficult task, requiring innovation while applying modern techniques to develop standards for medicinal plants and their products.

In many cases, the active principles in herbal medicinal products have yet to be identified. Guidelines for the characterization and standardization of herbal preparations have been proposed to ensure the reproducibility of quality and, thus suitability of the product for pharmacological, clinical and toxicological studies. Key quality issues in the development of herbal medicinal products may be-

- Influence of the collection and post-harvesting process (drying, storage, etc.)
- Variability of the biological materials (biodiversity, chemo types, etc.)
- Complexity of the composition of herbal drugs and herbal drug preparations
- Active principles are sometimes not identified or only partially known influence of the extraction process

Possible contaminants (adulterations, heavy metals, radioactivity, pesticides, etc.)

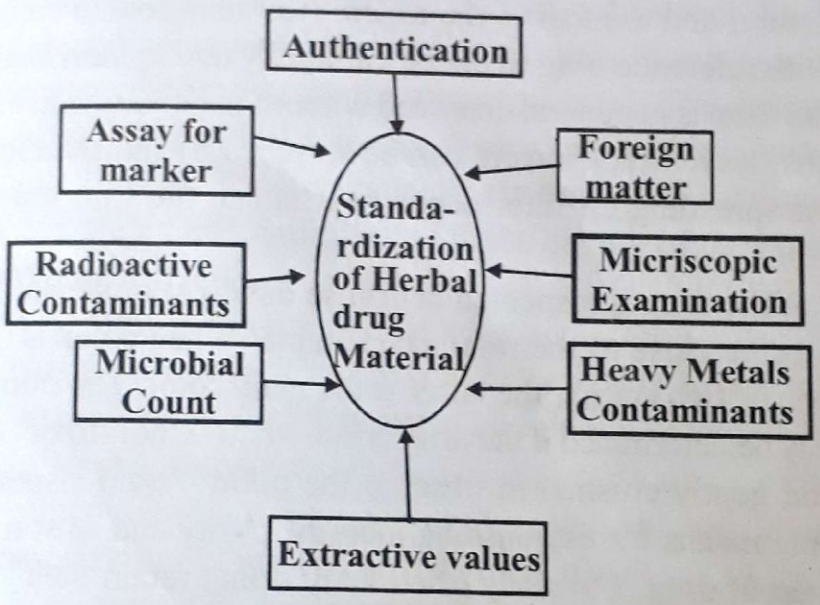

Fig- Authentication and standardization of herbal raw material

Quality control of raw material

Consistent quality of herbal medicinal products can only be assured if the starting materials are defined in an explicit and rigorous manner. Each plant used for processing should be taxonomically identified and checked using its Pharmacognostic and chemotaxonomic characteristics. Comparison of a sample from raw material with herbarium specimens maintained in a manufacturing house repository can prove useful. The geographical source, season of collection, method of drying, parts of the plant used, whether fresh or dried, should be recorded.

Authentication

The plant material is collected from an appropriate geographical source at an appropriate stage of its growth and under conditions to ensure consistency of material and hence quality. It is authenticated by detailed taxonomical study and the correct botanical identity is established so that chances of intentionally or unintentional adulteration or substitution are avoided.

Foreign matter

Plant parts other than those constituting the drug are considered as foreign matter. This also includes any other matter of plant or mineral origin present in the drug sample. The medicinal plant material should be entirely free from soil, stones, dust, insects and other animal contamination including animal excreta.

Organoleptic evaluation

Organoleptic examination refers to evaluation of the material by means of organs of sense and includes the macroscopic appearance of the drug including its form, surface and size; odor; taste; occasionally the sound or snap of its fracture; and the feel to the touch. It is advisable to compare the drug sample with reference drug to check variability due to individual human perception. The form is in general observed without pre-treatment. However, drugs like herbs, leaves and flowers can be softened by moistening them in water and then spreading on filter paper to examine the true shape of the drug.

The color of the drug is inspected in diffuse day light or similar light and should match, or be close to the reference sample. When color is described in a combination of two colors, the latter is the main color. The odor and the taste should only be determined if the drug is known to be non-toxic. Aromatic drugs should be gently crushed to observe the odor. Visual inspection is a quick and simple means for establishing identify, purity and to some degree quality of an herbal drug. Carefully dried leafy drugs retain their color and freshness and over-drying makes them brittle: this can easily be detected by visual examination.

Microscopic examination

Microscopic examination of the plant drug is not only essential for the study of adulterants but also in correct identification. The technique is used to determine characters of tissues, cells and cell content in sections, powders or surfaces of herbal drugs. Diagnostic microscopic features like type of stomata, trichomes, fibers, vessel thickenings and ergastic cell content are of immense value in plant drug standardization.

Quantitative microscopy of drugs, which contain a constant number of some parameters like stomatal number, stomatal index and palisade ratio, is of help in differentiating closely allied species.

Volatile matter

For volatile-oil-containing drugs such as mint, oregano and basil, the volatile-oil content is determined by water distillation using standardized-apparatus designed for this purpose. This constitutes an important quality control parameter and the percent range content of volatile oil is specified for such aromatic drugs in their official monographs.

Ash value

On incineration, plant drugs leave an inorganic ash. The percentage of ash produced is an indicator of care taken during the processing plant material, especially for under-ground parts. The total ash, acid-insoluble ash, water-soluble ash and sulphate dash are determined using standard procedure described in official documents. A high acid-insoluble ash (consisting of silica) in many drugs such as senna, clove, liquorices, valerian and tragacanth indicates contamination with earthy material.

Extractive values

The determination of extractable matter refers to the percentage of matter extracted from the drug using specified quantity of solvent. Such extractive values provide an indication of the extent of polar, non-polar and medium polarity components present in the plant material. The determination of extractive values is today less relevant since more sophisticated methods of assaying active constituents are available. However, the extractive values in some instances are a quick indicator of gross quality of the plant material.

Pesticide residues

The use of biocidal agricultural chemicals, collectively known as pesticides, has greatly helped to reduce the presence of insects, fungi and molds in food. However, their excessive and unreasonable use has resulted in contamination of soil and waterlines. The toxic residues in medicinal plants can result from soil or water line pollution in an area, agricultural practices of using pesticides in cultivation of medicinal plants, or fumigation during storage. Soil or water line pollution in an area can also result in pesticide residues in wild-collected plants, which otherwise are free from them.

Since many herbal preparations are taken over long periods of time, limits for pesticide residues should be established following the recommendations of the Food and Agriculture Organization of the United Nations (FAO) and WHO. These recommended guidelines also give the analytical methodology of determining pesticide residues. Special emphasis is paid to checking the presence of Persistent Organic Pollutants (POPs) like DDT, aldrin, dieldrin and toxaphene congeners, which are not allowed in medicinal plants.

Heavy metal contamination

Contamination of medicinal plant materials with metals like arsenic, cadmium, lead, mercury and nickel can be attributed to many causes especially to environment pollution from industrial activity. The limits in parts per million of such heavy metals in medicinal plants should remain within specifications.

Microbial contamination

Medicinal plant materials normally carry a high number of bacteria and molds, often of soil origin. While a large range of bacteria and fungi forms the naturally occurring micro flora of herbs there may be a need to specify

the total count of aerobic microorganisms, yeast, molds and the absence of specifically objectionable microorganisms. Current practice of harvesting, handling and production often causes additional contamination and microbial growth. The determination of Escherichia E.coli and mold may reflect care taken in production and harvesting.

In addition, mycotoxin contamination should be fully considered. The presence of aflatoxins in plant material can cause health hazards if absorbed even in very small amounts. Their presence should be therefore ruled out after using a suitable cleanup procedure. Microbial count should be determined using pharmacopoeia or other validated procedure.

Radioactive contamination

Radioactive contamination should be tested for if there are reasons for concern. Irradiation may have been used as procedure for microbial decontamination and sterilization of plant materials after harvest. Effluent from adjoining industrial area can contain radioactive contaminants and flow into an area where the plant material is collected. Dangerous contamination may equally result from a nuclear accident. Under all such circumstances strict WHO and EU guidelines should be followed.

Assay for active constituents or markers

The quality of a drug depends on the content of its active constituents, the amount of which depends upon a number of factors that affect the quality of crude drugs. In drugs where the active constituents are known with certainty, the amount should be analyzed to assure the quality of the plant material. However, in a number of cases, either the information on active constituents is incomplete or they are not known.

Under these circumstances, any one of the chemically characterized components of the plant (called marker) is used as a reference for evaluating the quality of the plant material. Thus, the marker is a constituent of a medicinal plant material that is chemically defined and of interest for quality control purposes. Under most appropriate conditions, the marker should be one responsible for the biological activity of the drug or one of the constituents responsible for the activity. However, when an in active or inert chemical constituent is used for quality assessment, its choice should be justified.

When only inert chemical components are known from the plant, a judicious selection of one of them for marker purposes should be made giving priority to a component specific to the plant under consideration and its stability. The correlation of inactive marker to quality is indirect on the assumption that since the marker content is appropriate, the unknown active components will also be present in the desired amount. With advances in isolation and identification techniques, this difficulty will be overcome in the future with the isolation of active constituents of drugs.