Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

LESSON PLAN- THEORY
B.PHARM 6TH SEMESTER
Subject: Herbal drug technology

Sl. No	Topic	Reference Book	Teaching Aids
1	Herbs as raw materials	Reference 1	PPT
2	Biodynamic agriculture	Reference 3	PPT
3	Indian systems of medicine	Reference 5	PPT
4	Nutraceuticals	Reference 2	CHALK BOARD
5	Herbal drug and herbal food interactions	Reference 6	CHALK BOARD
6	Herbal cosmetics	Reference 4	CHALK BOARD
7	Herbal excipients	Reference 7	CHALK BOARD
8	Herbal formulations	Reference 1	CHALK BOARD
9	Evaluation of drugs	Reference 8	CHALK BOARD
10	Patent and regulatory requirements of natural products	Reference 9	CHALK BOARD
11	Regulatory Issues	Reference 2	CHALK BOARD
12	Herbal industry	Reference 7	CHALK
13	Schedule T	Reference 1	CHALK BOARD

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Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in
7. Indian Medicine & Homeopathy)
8. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of
9. Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

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Affiliated to the Tamilnadu Dr. M.G.R. Medical University, and
The Directorate of Medical Education, Chennai.

LESSON PLAN- PRACTICAL

B.PHARM 6TH SEMESTER

Subject-Herbal drug technology

S.NO	TOPICS
1.	To perform preliminary phytochemical screening of crude drugs.
2.	Determination of the alcohol content of Asava and Arista
3.	Evaluation of excipients of natural origin
4.	Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5.	Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6.	Monograph analysis of herbal drugs from recent Pharmacopoeias
7.	Determination of Aldehyde content
8.	Determination of Phenol content
9.	Determination of total alkaloids

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Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table.

Course study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

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HERBAL DRUG TECHNOLOGY

According to the syllabus based on 'Pharmacy Council of India'
Third year B.Pharmacy.,
Sixth semester

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

Objectives: Upon completion of this course the student should be able to:

1. Understand raw material as source of herbal drugs from cultivation to herbal drug product
2. Know the who and ich guidelines for evaluation of herbal drugs
3. Know the herbal cosmetics, natural sweeteners, nutraceuticals
4. Appreciate patenting of herbal drugs, GMP.

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

Definition of herb, Herbal medicine, Herbal medicinal product, Herbal drug preparation, Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material.

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/ Bioinsecticides.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-II **7 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III **10 Hours**

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:
Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations:
Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV **10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:
a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V **07 Hours**

General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

HERBS AS RAW MATERIALS

Introduction:

The interest of people in herbal medicines has increased significantly in both developing and developed countries. There is a great demand for these herbs, hence there is a need to adopt systemic scientific methods for selection, cultivation, collection, processing and ensure the quality, purity, safety, potency and develop modern methods for their quality control so maximum benefit is obtained from these herbal medicines

Herbs:

It consists of entire plant or any part of the plant

Herbal Drug:

- These consist of plants or any part of the plants, usually in unprocessed or crude forms (crude drugs) which have medicinal value.
- They include different parts of plants like entire aerial part, flowers, fruits, seeds, bark, leaves, roots, rhizomes etc.
- The constituents and their therapeutic activity may be known or unknown

Herbal drug preparation:

- They are processed form of herbs. They are derived from herbal drug by various techniques like extraction, fractionalization, purification, conc. fermentation and may be in the form of powders, extracts, tinctures, fixed oils, volatile oils, resins, gums, etc.
- They contain a mixture of various constituents. However pure isolated compounds do not come under this category
- Herbal Medicinal Products (Finished Herbal Products):
- These are the medicinal products which contain exclusive herbal drugs or herbal drug preparation which are made from one or more herbs
- They may contain excipients in addition to active ingredients

HERB:

It consists of any part of the plant like leaves, flowers, fruits, roots and rhizomes, bark, tubes, stems and branches

HERBAL MEDICINAL PRODUCTS:

It includes various herbal formulation like tablets, syrups, capsules, semisolid dosage forms etc.

FIXED COMBINATION:

It includes herbal medicinal products which contain more than one herbal drug preparations.

Source of herbs:

Herbs or medicinal plants can be obtained from two sources:

- Wild source
- Cultivated source

A. Wild Source:

- The plants are obtained from the wild sources such as forest, plains, river banks etc.
- Obtaining herbs from wild source is my economical, less time consuming, decreased cost of labour
- However it also offer various disadvantages such as quality of the plants cannot be predicted due to various environmental changes. The plants will not be uniform in their growth and yielding characteristics.
- Modern scientific techniques cannot be applied to increase the yield as well as quality
- If the plants are obtained continuously from wild source for prolonged periods a may lead to depletion of raw materials from the wild

B. Cultivated source

In recent times, medicinal plants have been systematically cultivated by applying modern scientific techniques.

Advantages:

- Quality and purity is ensured
- Better yield and more profit
- Ensures regular supply of raw materials

Application of modern scientific techniques is possible

Crop Planning: Means ensuring regular supply of raw material to the industry

Application of Scientific Techniques: It includes tissue culture genetic engineering, hybridization and germplasm

STEPS INVOLVED IN THE SELECTION IDENTIFICATION AND PROCESSING OF HERBAL RAW MATERIALS:

Steps Involved in processing of Herbal Drugs

↓

Selection of Herbs

↓

Identification & Authentication

↓

Cultivation of Herbs

↓

Collection of Herbs

↓

Processing of Herbal Raw Material

A. Selection of herbs:

- The species or botanical variety selected for cultivation should be the same as specified in the official Pharmacopoeia or national documents
- In case of newly introduced medicinal plants, the variety selected for cultivation should be identified and documented

B. Identification & authentication of herbal materials:

- **Botanical identity:** The species, subspecies, genus, variety etc. of the plant for cultivation should be verified from a qualified botanist/institute and recorded
- **Specimens:** In case of a new plant with medicinal properties whose identity is not known, a specimen of the plant should be submitted to a national herbarium for identification & documentation.
- **Seeds and other propagation materials:** The suppliers of seeds and other propagation materials should specify all the necessary information relating to the identity, quality as well as their breeding history. The seeds and propagation materials should be free from contamination and diseases in order to promote healthy plant growth

C. Cultivation of medicinal plants:

- Cultivation of medicinal plants requires intensive care and management as various factors such as environment, soil, irrigation, pests, etc. play a vital role. These factors vary from one plant to another
- Scientific documented methods should be followed, if nom data available, traditional methods should be adopted and a systemic method should be developed through research
- Good Agricultural Practices in Cultivation (GACP) and Conservation Agriculture (CA) which aims to improve, conserve & make more efficient use of natural resources.

D. Collection of herbs:

- For the collection of medicinal plants, a proper time should be selected. Herbs are selected for collection at a stage when they yield maximum amount of chemical constituents skilled labour should be employed as they are trained to identify and select the herbs at a proper stage
- The age of the plant also plays a vital factor for their selection. Diseased plants should be rejected, season of collection should be given due consideration while selecting the plant for collection

E. Processing of herbal raw materials:

- Processing of herbal raw materials involves various stages from which the crude drugs undergo after harvesting. It can be classified into primary and secondary processing
- Cultivation of medicinal plants is also drawn as propagation, which can be done by sexual and asexual methods.
- **Collection:** If mean harvesting of the plant material.

PROCESSING OF HERBAL RAW MATERIALS

PRIMARY PROCESSING	SECONDARY PROCESSING
Garbling	Cutting/sectioning
Washing	Aging/sweating
Parboiling	Baking/Roasting
Leaching	Boiling/Streaming
Drying	Stir frying Fumigation Extraction

PRIMARY PROCESSING: (It is the basic or initial processing)

It includes simple procedure by which the herbs are prepared like sorting of different parts, garbling, cleaning, drying etc.

Garbling (Sorting):

- This process helps in ensuring the purity and cleanliness of the harvest materials
- Dirt like soil, dust, impurities like insects, dead tissues and residual non medicinal plants are separated from the raw material
- The process depends on the part of the plant to be prepared. The process may involve procedures such as removing dirt, foreign substances, discarding damaged parts, peeling of barks, sieving, trimming, removal of hair from roots, removal of seeds from fruits, stripping of leaves from stems.
- This may be done by mechanical means but in some cases it is usually performed manually by hands

Washing:

- After garbing the herbal raw materials should be cleaned well to remove the traces of remaining soil, dirt and other impurities from the surface
- The roots, rhizomes and tubers are washes with clean water. During the washing process, scrapping and brushing may be necessary

Parboiling (Blanching):

- After washing, certain herbal raw materials need to undergo parboiling process in which they are put in boiling water for short period.
- This may help in improving the storage life of the raw materials and preventing insert/mould contamination.
- It may also facilitate in further processing such as removal of stubborn impurities as well as outer coats/covering of raw materials

Leaching:

- Some impurities can be removed by subjecting the plant material under running water known as leaching. However the duration of leaching should be controlled to prevent the loss of chemical constituents present in the drug

Drying:

- In some cases, the plant material should be thoroughly dried after washing in order to prevent the deterioration and degradation of active constituents. They must be dried as soon as possible to remove moisture and reduce damage due to microbial or mould infestation
- Drying also prevents the activation of certain enzymes which may otherwise degrade the active ingredients and also facilitate grinding and milling of the raw material.
- Depending on the drug and nature of ingredients, different drying methods can be used,

1. **Natural drying:**

   a) **Sun drying:**

      - Most herbal raw material can be dried in open air under direct sunshine provided the climate is suitable. The duration of drying process depends on the physical structure of the plant material and weather conditions.
      - The plant materials should be spread out in thin layers, care should be taken to prevent contamination by dirt impurities
      - While drying the plant material should also be protected from inserts, birds, rodents, pests and other domestics

   b) **Shade drying:**

      - Some medicinal plants cannot be directly exposed to sunlight, hence need to be dried under shade
      - This drying process is slow but helps in minimizing loss of color, volatile oils and aromatic compartments from being evaporated

2. **Artificial drying:**

   - Drying by artificial heat is more rapid than open air drying and is necessary in rainy seasons and regions where there is high humidity.
   - The temperature and equipment used for drying depends on the physical and chemical nature of the drug and its constituents. various equipment such as tray dryers, spray dryers, vacuum dryers are used
   - Overheating may lead to excessive loss of volatile components as well as decomposition of chemical constituents. The temperature should be kept maintained below 60°c wherever possible.

   a) **Tray dryers (Oven)**

      - The drugs which do not contain volatile oils and are quite stable to heat or which need deactivation of enzymes are dried in tray dryers

- In the process, hot air of the desired temperature is circulated through the dryers and this facilitates the removal of water content of the drug (belladonna roots, cinchona bark, tea and raspberry leaves and gums are dried by this method)

b) Vacuum dryers:

- The drugs which are sensitive to higher temperature are dried by this process.

E.g. Tannic acid and digitalis leaves

c) Spray dryers:

- Few drugs which are highly sensitive to atmospheric conditions and also to temperature of vacuum-drying are dried by spray-drying method. The technique is followed for quick drying of economically important plant or animal constituents, rather than the crude drugs.

E.g. Papaya latex, pectin, tannins etc.

SECONDARY PROCESSING: (It includes advanced techniques or done post primary processing)

The secondary processing differs from one herbs to another depending upon the nature of active ingredients as well as therapeutic properties

Secondary processing includes techniques such as removal of foreign substances, prevention of microbial/infestation, enhancing the efficacy of drugs, reducing the toxicity, extraction using suitable solvents, conc. & drying of extracts

These are further standardized by different methods.

Cutting, Sectioning and communition:

- After thoroughly drying, the herbal materials are processed by cutting and sectioning into smaller sizes which are convenient for storage as well as extraction
- Various sizes can be obtained depending on the part of herb and extraction methods used. It may be small particles, coarse powder or fine powder

Aging/Sweating:

- Aging refers to storing the raw material for a specified time after harvesting
- It is generally done under sun or in shade for up to a year
- During the process of aging excessive water is evaporated & enzymatic reactions may occur to alter the chemical composition of herbal materials
- **E.g.** Cascara bark should be aged for at least one year prior to use in medicinal preparations to reduce its irritant effects

- Sweating is done by subjecting the herbal materials at a temperature between 45 to 65°C with high humidity for a period ranging from one week to few months. The herbal materials are stacked between woolen blankets or other kind of cloth
- The sweating process is considered a hydrolytic and oxidative process in which some of the chemical ingredients of the herbs are hydrolyzed or oxidized

Baking/Roasting:

- It is a process of drug heating where the herbal materials is heated in ovens. The temperature of heating and duration of baking /roasting vary from one herbal material to another until the drug develops a specific color
- **E.g.** Nutmeg is roasted till they turn to yellowish brown color

Boiling/Streaming:

- In the boiling process the drug is cooked in water or any other liquid solvent such as vinegar, wine, milk or animal urine.
- **E.g.** Acorus calamus rhizome is boiled in cow's urine with stream using a streamer resulting in development of moist texture

Stir frying:

- In the process in which the herbal material are put in spot of frying pan and continuously stirring or tossed for a specific period under heat until the external color changes, charred or even carbonized. To facilitate uniform heating, the drug material can be admixed with sand, talc or clay
- **E.g.** Liquorice roots and rhizomes are stir fried with honey

Fumigation:

- Sometimes the harvesting raw materials are subjected to fumes. Fumigation with Sulphur-dioxide is commonly employed for some medicinal herbs for the purpose of preserving, color, improved appearance, bleaching and preventing the growth of inserts and moulds.

EXTRACTION OF HERBAL MATERIALS:

Extraction is a process of separation in which the chemical constituents present in plant and tissues are removed by using selective solvents which is called menstrum.

Herbal extracts includes infusion, decoctions, fluid extracts, tinctures and powder extract.

The herbal preparation so obtained may be ready for use as medicinal agent or it may be further processed to finished products such as tablets, capsules and pills.

I. Infusion

It is a liquid preparation obtained by extracting herbal materials with either cold or hot water without boiling. Other solvent may also be used

II. Decoction

It is a liquid preparation obtained by boiling the herbal material with water

III. Fluid extract

It is a liquid preparation obtained by maceration or percolation of herbal materials in alcohol. The ratio will be one part of liquid contain one part of herbs (1:1)

IV. Tinctures

It is dilute alcoholic extract of herbal materials typically made up of 1 part of herbal material with 5 to 10 parts of the solvent

V. Powdered extract

It is a form of herbal preparation which is processed into dried, granulated or powdered materials.

BIODYNAMIC AGRICULTURE

Introduction:

- Biodynamic agriculture is a form of organic farming which includes various concepts introduced by Rudolf steiver in 1924.
- Bio dynamics is a system of organic agriculture which recognizes the biological and chemical values of soil and treats soil fertility, plant growth and livestock care as ecologically interrelated tasks.
- Bio dynamic farming is an alternative where the chemical fertilizers are totally replaced by microbial (biological) nutrients derived from bacteria, algae, fungi and it emphasizes the use of manures and composts.
- Bio dynamic farming treats animal, crops and soil as single system and fertilizers the use of traditional systems and development of new local breed and varieties.
- It uses various herbal and mineral additives in the manufacture of composts and field sprays. Bio dynamic farming also emphasizes on the use of astronomical sowing and moon planting calendar.
- Bio dynamic farming promotes composting, green manuring, crop rotations, inter cropping, mixed cropping, etc. as well as employing predators, parasites, which are natural enemies of pests.

PRINCIPLES AND GUIDELINES FOR GOOD AGRICULTURE PRACTICE (GAP) OF MEDICINAL PLANTS:

- The guidelines described for GAP are intended to streamline the cultivation of medicinal plants as per the well regulated methods and follow a systematic way in cultivation process as it is important for the production of good quality plant material.
- The various stages of processing which are included in good agricultural practice (GAP) are described as follows.

1. Seeds and cm utilization material:

- The seeding materials are to be identified botanically, indicating plant variety, cultivar, chemo type and its origin.
- **Biodynamic agriculture**: it is also known as organic farming technique.
- The material used should be 100% traceable.
- The above same rule applies to vegetative materials as well.
- The parent material of vegetative part used in organic productions should be certified and authentically organic**.**

2. Cultivation:

- Depending on the method of cultivation (conventional or organic) growers should be allowed to follow different standards operating procedures (SOP) for cultivation.
- Care should be taken to avoid environmental disturbances.
- The principles of good crop husbandry must be followed including appropriate rotation of crops.

3. Soil and fertilization:

- Medicinal and aromatic plants should not be grown in soils that are contaminated by sludge.
- The soil should also not be contaminated by heavy metals, pesticidal residues and other unnatural chemicals.
- The use of fertilizers and other chemical products should be as minimum as possible and in accordance with the demands of the plant.

4. Irrigation:

- Irrigation should be minimized as much as possible and only applied as per the needs of the plant.
- Irrigation water should be free from contaminants such as faeces, heavy metals, pesticides, herbicides and other hazardous substances.

5. Crop maintenance:

- Tillage (Preparation of land for growing crops) should be adapted to enable good plant growth and must be carried out whenever required.
- Pesticides and herbicides should be avoided as far as possible.
- The use of pesticides and herbicides has to be documented.

6. Harvesting:

- Harvesting should be done when the plants are in their best quality and quantity.
- Harvesting should be done in optimum conditions as wet soil, dew, rain, high humidity can produce unfavorable effects.

7. Primary processing:

- It includes steps such as washing, drying, freezing etc,
- Processing equipment must be cleaned and regularly serviced.

- Buildings used for processing should be clean, aerated & provide protected for the harvested crop from birds, insects, rodents and animals.
- All the processed material should be inspected and substandard products must be discarded.

8. Packaging:

- The product should be packed in clean, dry preferably new sacs, bags or cases.
- The label must be clear, permanently fixed and made from non -toxic material.
- Re-usable packaging materials should be well cleaned and dried before use, care should be taken that they do not cause contamination.

9. Storage and transport:

- Packaged dried materials and essential oils should be stored in a dry, well aerated building in which temp. Fluctuations are controlled and good aeration is provided.
- Fresh products should be stored between 1 to 5 ‘C, while frozen products should be stored below -18’C or below -20’C for long term storage.
- Essential oils should be stored as per the chemical storage standards.
- During transportation, sufficiently aerated vehicles should be used.
- National regulations on transport have to be followed.

10. Staff requirements:

- Personnel involved in the good agricultural practice (GAP) should receive adequate training and education related to the nature of the work being carried out.
- The staffs who work with the plant material must have a high degree of personal hygiene.
- Staff with infectious diseases should not be allowed into the rooms in which they can come into contact with plant material.

11. Documentation:

- All the propagation material and steps in the production process must be documented.
- All the starting materials,
- Processing steps including location of cultivation have to be documented.
- All agreements between producer and buyer should be fixed in a written form.

12. Quality assurance:

- In order to ensure a good quality of the produced crude drug, it is extremely advisable to educate all personnel dealing with the crop at various stages.
- Consultation and feedback should be taken from buyers of medicinal and aromatic plants regarding the quality & other properties of plant material and an agreement have to be made.

PEST AND PEST MANAGEMENT IN MEDICINAL PLANTS:

- Pest is an undesired animal or plant which cause: loss of cultivated plants, the different types of pests infecting medicinal plants are as follows.

Types of pests:

- Fungi/Viruses
- Insects
- Weeds
- Non Insect Pest.

1. Fungi and Virus:

Examples: Ascochyta atropae causes necrosis of leaf. Cercospora atropae produces leaf spot disease.

2. Insects:

Insects such as flea beetle, flies, moth, cutworms, grass hoppers, spiders, termites, etc, also produces significant loss of cultivated plants.

3. Weeds:

A weed is an undesired plant, it can produce losses more than any other pests or diseases. They cause depletion and shortage of nutrients, waters, light, space to the cultivated plants. They also increase the cost of labour and equipment and reduce the quality of cultivated plant.

Example of weeds are Parthenium, Ragweed, Medican tea, Varnish tree, etc.

4. Non insect pests:

They are further sub classified as follows

Vertebrates: Animals like Monkeys, Rats, Rabbits, Squirrels, Birds, Pigs, etc.

Invertebrates: Animals like crabs snails, mites, nematodes, etc.

Fungi and Viruses: They also include various other microorganism which infect the growing medicinal plant and cause loss of quality as well as quantity.

Methods of pest control:

Different techniques are followed to achieve pest control effectively. These methods are discussed as follows:

- Mechanical
- Agricultural
- Biological
- Chemical

1.Mechanical method:

- It include simple techniques like hand picking, pruming, burning, using of pest traps, collection and destruction of eggs, larvae and insects. Construction of concrete ware houses to protect from rodents and animals. Rats and mouse traps are also used.

2.Agricultural method:

- It includes various methods such as crop rotation, inter cropping, integrated weed management methods, solarisation, etc. Production of pest and insect resistant plants through genetic engineering technique is another approach.

3.Biological method:

- This method involves combating of pests with other living organisms such as employment of cats to combat rats and squirrels, employment of birds to combat insects. Some chemical substances produced by female insets such as sex attractants, which can be used to lure male insects and prevent reproduction.

4.Chemical method:

- Pests are controlled using chemical pesticides which include insecticides, fungicides, herbicides, rodenticides. However these chemical substances are highly toxic to human beings. Improper use of these chemical pesticides may lead to toxic effects on human and animals.

  Examples:

  - **Rodenticides:** Arsenic trioxide.
  - **Insecticides:** Malathion, Parathion, Methoxychlor.
  - **Miticides:** Tetradifon, Chlorobenzolate.

- **Fungicides:** Chlorophenols, Quaternary ammonium compounds, etc.
- **Herbicides:** 2,4 Dichloro phenoxy acetic acid, calcium arsenate.

BIO-PESTICIDES/BIO-INSECTICIDES FOR PEST MANAGEMENT:

These are pesticides obtained from natural sources like microorganisms, plants, animals, insects & certain minerals.

Advantages of bio pesticide over chemical pesticides:

- They are non-toxic to plants as well as humans.
- They are biodegradable & do not leave any toxic residues.
- They are less expensive and can be grown along with the cultivated medicinal plants.
- They are ecofriendly and do not affect soil fertility.
- They are safe to handle and use.

Types of bio-pesticide:

- Microbial
- Biochemical
- Plant pesticides

1.Microbial pesticides:

- They consist of microorganisms, microbial pesticides can control different kinds of pests and are relatively specific for its target pests. It is reported that some fungi are used to control weeds and insects.

2.Biochemical pesticides:

- These are naturally occurring chemical substances which are obtained from insects and animals which have the ability to control the pests by non-toxic mechanism. These include substances like insect sex hormones.

3.Plant pesticides:

- Various plant are reported to poses pesticidal and insecticidal properties. They can be grown along with cultivated plants to combat insects and can be used in powdered form or the constituents can be extracted from them and used to spray on the crops.

  Examples: Neem, Tobacco, Pyrethrum, Derris, Ryania.

Bio-pesticides/Bio-insecticides: They include all the plants or substances which are derived from such plants that have the ability to kill or resist the various pests and protect the cultivating medicinal plant.

Introduction:

- Bio-pesticides are typically microbial biological pest control that are applied in a manner similar to chemical pesticides.
- Available in different formulations.
- Also used to control soil borne and seed borne fungal pathogens.
- Disadvantages of them are, high specificity slow speed of action and their requirement of suitable condition for their survival.
- Even though, biopesticides are best for controlling the pests of agriculture then the chemicals.
- Therefore, there should be more works on production on biopesticides and encourage people to use biopesticides to control the pests.
- Bio-pesticide is a formulation made from naturally occurring substances that controls pests by non-toxic mechanisms and in ecofriendly manner.
- Bio-pesticides may be derived from animals (e.g. nematodes), Plants (Chrysanthemum, Azadirachta) and micro-organisms (e.g. Bacillus thuringiensis, Trichoderma, nucleopolyhedrosis virus), and include living organisms (natural enemies) etc.
- However, bio-pesticides are generally less toxic to the user and are non-target organisms, making them desirable and sustainable tools for disease management.

Advantages of Bio-Pesticides:

- Inherently less harmful and less environmental load,
- Designed to affect only one specific pest or, in some cases, a few target organisms,
- Often effective in very small quantities and often decompose quickly thereby resulting in lower exposures and largely avoiding the pollution problems
- When used as a component of Integrated Pest Management (IPM) programs, bio-pesticides can contribute greatly.

Types of Bio-pesticides:

Microbial Pesticides

Plant- incorporated-protectants (PIPs)
Biochemical pesticides
Biotic agents (Parasitoids and Predators)

Some of the Important Microbial Pesticides

Bacillus thuringiensis:

- Discovered in Japan in early 20th century and first become a commercial product in France in 1938.
- Control lepidopterous pets like American bollworm in cotton and stem borers in rice.
- When ingested by pest larvae, but releases toxins which damage the mid gut of the pest, eventually killing it.
- Main sources for the production of but preparations are the strains of the subspecies kurstaki, galeriae and dendrolimus.

Agrobacterium Radiobacter (Agrocin):

- Agrobacterium radiobacter is used to treat roots during transplanting that checks crown gall.
- Crown gall is a disease in peaches, grapevine, roses and various plants caused by soil borne pathogen Agrobacterium tumefaciensm.
- The effective strains of A. radiobacter posses two important features:
- They bare able to colonize host roots to a higher population density.
- They produce an antibiotic, agrocin, that is toxic to A. tumefaciens

Pseudomous fluorescens (Phenazine):

- This bacteria is used to control damping of caused by Pythium sp., Rhizoctonia solani, Gaeumannomyces graminis.
- It has ability to grow quickly in the rhizosphere.

Trichoderma:

- Trichoderma is a fungicide effective against soil born diseases such as root rot.
- This is also used against Necteia galligena, that causes silver leaf disease of fruit trees by entering through pruning wounds.

Metarizium anisopliae:

- It infects spittlegbugs, rhinoceros beetles.

Beauveria bassiana:

- Controls Colorado potato beetle.

Verticillum lecanii:

- Controls aphids and whiteflies

Nomuraea riley:

- Controls soybeans caterpillars

Baculoviruses (Bvs):

- Controls lepidopterous and hymenopterous pests.
- Rod shaped, circular double stranded super coiled DNA.
- Bathyplectes, trichrogramma, encarsia, muscidifurax etc.

Biotic agents / Natural enemies:

Predators:

They consume several to many prey over the course of their development, they are free living and they are usually as big as or bigger than their prey.

- Lady beetles, rove beetles, many ground beetles, lacewings, true bugs such as Podisus and Orius, syphid fly larvae, mantids, spiders, and mites such as Phytoseiulus an Amblyseius.

“

INDIAN SYSTEMS OF MEDICINES

A. BASIC PRINCIPLES OF AYURVEDA, SIDDHA, UNANI, HOMEOPATHY

INTRODUCTION:

Traditional system of medicine also known as indigenous/folk medicines/alternate medicine comprises of medicinal aspects of knowledge, skills, and practices based on different cultures and different people which are used to treat the diseases.

It includes various system being practiced throughout the world

"AYUSH"

A – Ayurveda

Y – Yoga

U – Unani

S – Siddha

H – Homeopathy

DEFINITION:

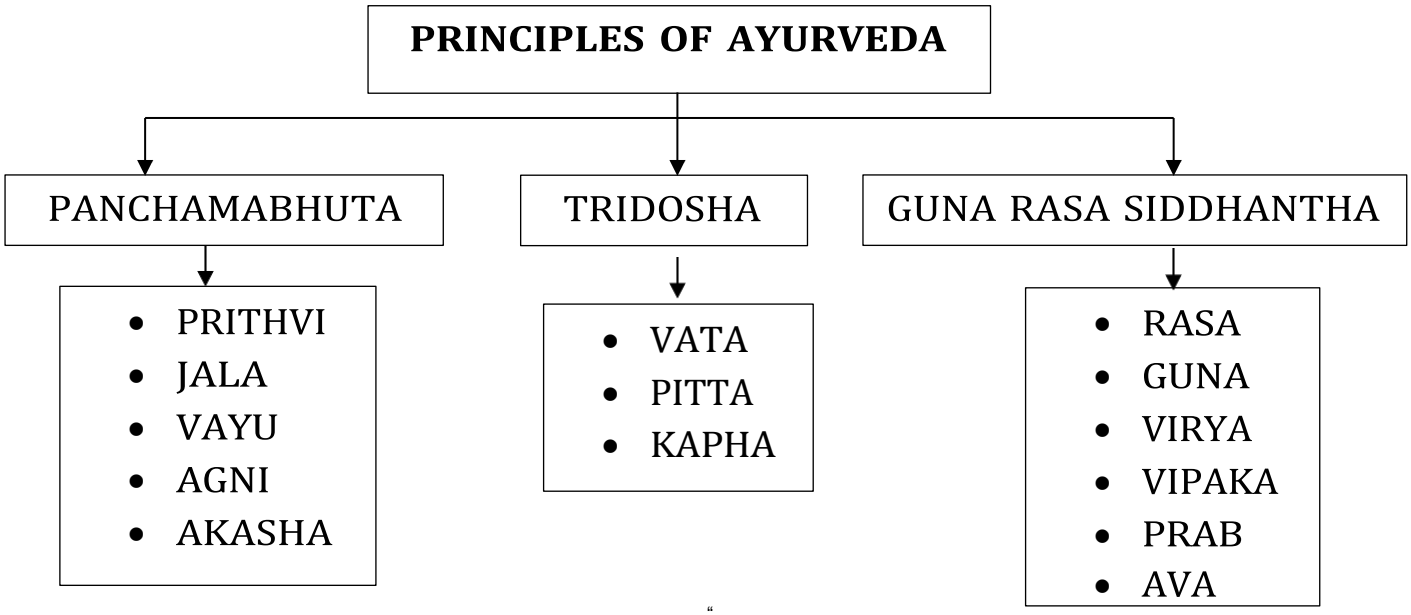
According to WHO,

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

AYURVEDA – INDIAN SYSTEM OF MEDICINE

- "Ayur" means life and "Veda" means science of life
- This system of medicine came into existence in about 900BC
- Ayurveda system of medicine is the oldest written medicine system and in certain cases, it is even assumed to be the most effective than modern medicines
- Charaka and Sushruta made significant contributions to Ayurveda
- The Book "Charak samhita" was written by charaka and he was known as father of Ayurveda
- Ayurveda system of medicine developed an extensive use of medicine from plant origin

BASIC PRICIPLES IN AYURVEDA



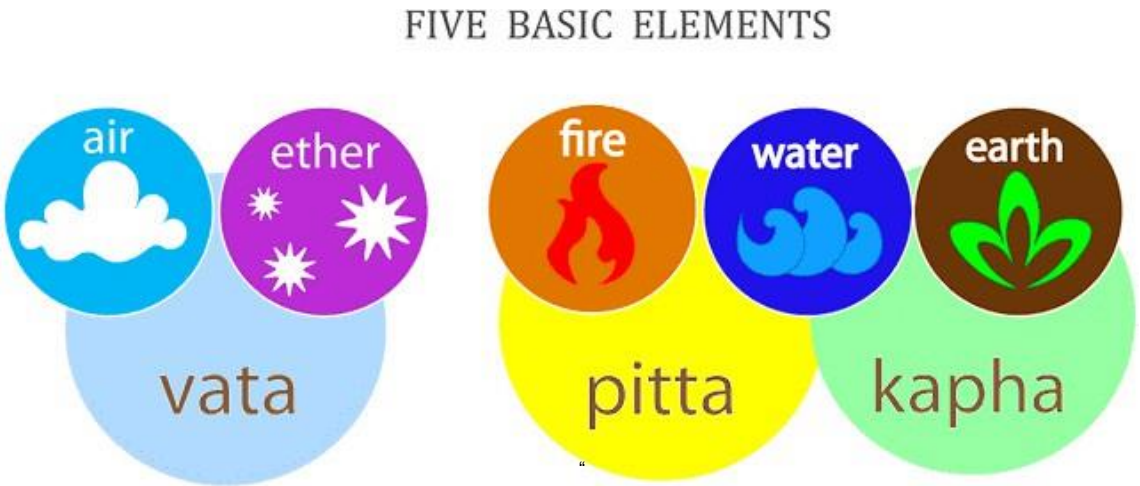
PANCHA BHUTA

According to this theory, universe are made up of five elements (Pancha Bhuta) and they are present in the human body,

- Earth (PRITHVI)
- Water (JALA)
- Fire (AGNI)
- Air (VAYU)
- Space/Ether (AKASHA)

TRIDOSHA

The five elements (Pancha Mahabhuta) exist in human body in three different forms, together known as “Tridosha”



- VATA (Air + Space/Ether)
- PITTA (Fire + Water)
- KAPHA (Water + Earth)

These tridoshas when present in balanced form in the body is considered as healthy condition, any imbalance in tridoshas is considered as diseased condition. Ayurveda tries to maintain the balance in these elements

DOSHAS	REPRESENTATIVES
Vata	• Factors responsible for movements and sensations (ANS, CNS). • It regulates the psychic and nervous system. • Imbalance of this leads to diseased of ENT, heart, urinary tract, skin etc.
Pitta	• Factors responsible for digestion, metabolism, heat production, blood pigmentation, endocrine function, energy • It regulates energy production, digestion, tissue building etc. • Imbalance of this leads to disease like acidity, indigestion, liver and skin diseases
Kappa	• Factors responsible for strengthening stomach, joints, limbs and refreshing sense organs • It regulates heat, formation of fluids, mucous etc. • Imbalance of this results in joints pain, brain disease, drowsiness etc.

SAPTA DAHU (Basic structures of body)

Combinations of these five elements (Pancha Mahabhutha) form seven basic tissues of the body which referred as "SAPTA DAHU"

1. Food juices (RASA)
2. Blood (RAKTA)
3. Muscle tissues (MAMSA)
4. Fat tissues (MEDA)
5. Bone marrow (MAJJA)
6. Bone tissues (ASTI)
7. Reproductive organs (SHUKRA)

These sapta dahu undergo wear and tear to form "MALA" (Excretory products)

GUNA-RASA-VIRYA-VIPAKA-PRABHAVA SIDDHANTHA:

These are considered as five pharmacological principles/properties of "Dravya" (drug substances),

RASA (TASTE – Therapeutically active agents)

GUNA (UNIVERSAL – Certain physical attribution of drug, which effect the tridosha)

VIRYA (TO PRODUCE ACTION – An active principle by which potency is characterised)

VIPAKA (DIGESTION & ASSIMILATION – End product of all digestive transformation of drugs)

KARMA/PRABHAVA (THERAPEUTIC ACTION – Actual therapeutic activity of the drug in individual)

MALAS (By-products of Dhatus)

1. Urine
2. Faeces/Stool
3. Sweat

The Doshas, Dhatus and Malas should be in equilibrium state to assure heath and any imbalance leads to disease

DIAGNOSIS:

1. Diagnosis was based on moment-to-movement monitoring of interaction between health and illness
2. Diagnosis includes investigation of
   i. Urine
   ii. Pulse
   iii. Nervous system
   iv. Mucous and mucous secretions
   v. Stool
   vi. Body sounds
   vii. Digestion fire
3. Observation of Doshas (Vatta, Pitta, Kapha)
4. Observation of Skin, Eyes, Hair, Nails and Tongue

TREATMENT

Treatment involved in different methods

- Elimination therapy
- Alleviation therapy
- Psychic therapy
- Surgical therapy

In addition to single drugs, compound formulations are generally used to treat diseases in the form of tablets, pills, powders and syrups

Treatment include use of,

- Herbs (Plant remedies)
- Metals (Gold, silver, copper, lead, tin and iron)
- Minerals
- Animal drugs

SOME AYURVEDIC DRUG AND USES:

DRUG	USES
Arjun-aristha	Heart disease
Khadir-aristha	Skin disease
Kumary-asava	Liver disease
Chirayantha arka	Fever

SIDDHA – TAMIL SYSTEM OF MEDICINE

- "Agastya" was believed to be the father of siddha medicine and he wrote a book known as "AGATTIYAR CHARKKU"
- To achieve mastery over nature and longevity, the ancient Tamils introduced two ways in their quest of knowledge
  - Yoga
  - Siddha medicine

- Person dedicated to the task of ailing the community were use to be yogis also known as Siddhars. Siddhars were men born with great talents who lived for thousands years and by their devotion, search of truth, attained perfection in their life

BASIC PRINCIPLES OF SIDDHA MEDICINE:

"Nature the best physician

Food itself is a medicine"

- According to siddha medical science, universe is composed of five elements
  - Earth
  - Water
  - Air
  - Fire
  - Ether

- Man consumes water and food, breathes the air, maintains heat in body and remains alive because of life force provided by ether
- Earth is the first element which provides fine shape to the body and includes bone, muscle, skin, hair, tissues etc.
- Water represents blood, glandular secretions, vital fluids etc.

- Fire is responsible for emotion, vigor and vitality and helps in digestion, circulation, respiration and nervous system activity.
- Ether represents man's mental and spiritual faculties
- Harmonization/equilibrium between these makes a person healthy

TRIGUNA – VATA, PITTA, KAPHA

VATA – People with predominant vata are characterized by stout, black, cold, inactive personalities. Increased vata develops flatulence, acidity, obesity, heart attacks etc.

PITTA – People with predominant pitta are characterized by lean, whitish complexioned hot personalities. Increased pitta shows early greying of hair, reddish eyes, burning chest, mental de-arrangement, anemia etc.

KAPHA - People with predominant kapha are characterized by well buid, good complexioned, well behaved personalities. Increased kapha leads to jaundice, heart attack, high fever, anemia etc.

DIAGNOSIS:

- Diagnosis involved examination of
  - Urine (MUTHRAM)
  - Pulse (NADI)
  - Eye (VIZHI)
  - Voice (DHWANI)
  - Body color (NERAM)
  - Tongue (TWAKA)
  - Body (DEHAM)
  - Faeces (MALAM)
- Diagnosis involved the study of person as well as disease. System emphasizes that the treatment must be based not only on disease but also patient characteristics (Age, Gender, Race, habits, Mental frame, Diet, Appetite, Physical condition, habitat etc.)

TREATMENT:

- The system made use of not only plant and animal drugs but also produced great treasure in treating diseases with metals and minerals

KASHAYAM (Decoction)
CHURNA (Powder)
TAILAM (Medicinal Oils)
CEULLIGAI (PILLS & TABLETS)
CHENDURUM (METAL COMPLEXES)
BHASMA (CALCINATED DRUGS)

- Metals were incinerated and used as medicine. Most commonly used metals includes gold, silver, tin, lead and iron in small quantities. They also used drugs that sublime on heating e.g. mercury and sulphur in small quantities
- Siddhas were aware of various pharmaceutical industrial process e.g. calcination, sublimation, distillation, fusion, separation, fermentation, congelation etc. and served as poly-pharmacists
- Some secret methods (especially fixing and consolidation of certain volatile substances e.g. mercury, sulphur, arsenic) are still a mystery
- Siddha treats all disease other than emergency conditions
- This system is effective in treating STD, UTI's, Liver and GIT diseases, general debility, post-partum anemia, fever, chronic diseases like arthritis, diarrhea and allergic disorders.

DIET IN SIDDHA:

Siddha system also gives importance to "Pathya" (restriction in diet)

RESTRICTED FOODS: Chicken, mangoes, coconut, fenugreek, mustard, sesame, almonds etc.

NON-RESTRICTED FOODS: wheat, milk, ghee, pulses, tender vegetables, goat meat, sugar etc.

UNANI SYSTEM OF MEDICINE:

Unani system of medicine has its roots in Greece. This system was introduced by "Hippocrates" who freed medicine from realm of superstitions and magic

This system was introduced in India by Abu Bakr Bin Ali Usman Kasahani, Sadruddin Damashiqui, Bahwabin Khawas Khan, Ali Geelani, Akabl Arzani and Mohammad Hoshim Alvi Khan

BASIC PRINCIPLES UNANI SYSTEM OF MEDICINE:

HIPPOCRATIC THEORY	PYTHOGORIAN THEORY
Blood (DUM)	Hot & Moist
Phlegm (BALGHAM)	Hot & Dry
Yellow Bile (SAFRA)	Cold & Moist
Black Bile (SAUDA)	Cold & Dry

- Unani system is based on Greece philosophy that considers the body to be made of four elements (Earth, Water, Air and Fire) which have four different temperaments (Cold, Hot, Wet, Dry)
- Interaction of these elements produces four temperatures;
  - Hot & Moist (Air)

- Hot & Dry (Fire)
- Cold & Moist (Water)
- Cold & Dry (Earth)

- The body consists of simple and compound organs which got their nourishment through four humors;
  - Blood
  - Phlegm
  - Yellow bile
  - Black bile
- It is believed that blood is hot and wet, phlegm is cold and hot, yellow bile is hot and dry and black bile is cold and dry
- Mijaz/Temperature/Humors of a person
  Mizaj-e-har (Hot)
  Mizaj-e-barid (Cold)
  Mizaj-e-yabis (Dry)
  Mizaj-e-rath (Moist)

Balance form of these 4 humors is called as healthy condition and imbalance form is known as pathological condition

DIAGNOSIS AND TREATMENT:

It is done by recording the parameters such as psychology, age, gender, habits, working condition, history etc.

- Pulse reading
- Examination of sputum, urine, stools
- Patient counseling

Diseases are detected with the help of pulse, urine and stool and treatment involves various strategies

TREATMENT METHODS	STRATEGIES
Ilaj bil tadbeer	Drugless regiments e.g. exercise, massage, hamam (Turkish bath), douches (Cold and hot) etc.
Ilaj bil ghiza	Diet therapy
Ilaj bil dawa	Correction of cause 1. Ilaj bil zid 2. Ilaj bil misl Drugs are given as crude or as compound drugs (mostly plant origin, some minerals and animal drugs)
Ilaj bil yad	Surgical procedures

UNANI MEDICINE:

- The material medica describes drugs obtained from herbs, animals, and mineral source
- Herbal drugs include various parts of plants and their products
- Animal drug includes organs, flesh, hair, bones etc.
- Mineral drug includes metal like gold, silver, lead, arsenic, etc. Precious stones like emerald, sapphire are also used

HOMEOPATHY SYSTEM OF MEDICINE:

- It is a specialized forms of therapeutics developed by a German physician, chemist and pharmacist "Dr. Samuel Christian Friedrich Hahnemann" in 1810
- So, the system treats the diseases or sufferings by the drugs that possess power of producing similar sufferings
- In the quest of reducing the damaging side-effects of drugs with medical treatments, Dr. Hahnemann began experimenting on himself and a group of health volunteers.
- He started giving smaller and smaller medicinal doses of drugs and found that as well as reducing toxicity, the medicines actually appears to be more effective at the lower the dose
- He also observed that symptoms caused by toxics "medicines" such as mercury, were similar to those of the diseases they were being used to treat e.g. syphilis, which lead to the principle he describes as "like cures like"

FUNDAMENTALS IN HOMEOPATHY:

LAWS	BASIS
Law of similia	Let likes be cured by likes
Law of simplex	Simple and single drug be prescribed at time
Law of minimum	Drugs are used in minimum quantities i.e. just to arise the reaction in a body
Drug providing	Drugs of known curative power should be known. Curative power is the ability of drug to produce disease symptoms when employed in healthy Individuals
Drug potentisation	Process of dynamization of the drug in such a way that it produce the curative effect
Vital force	Disease is noting but disharmonious flow of vital force that gives rise to abnormal sensation and functions. To achieve health, this force needed to be restored
Acute and chronic diseases	Characterization of disease on the basis of onset, nature of progress and termination
Individualization	No two individuals are alike in the world, so are the disease and medicine can't be prescribed on the basis of name of the disease
Direction of cure	Cure takes place within outward from above to downward and symptoms disappear in the reverse of their appearance

DIAGNOSIS:

- Collection of detailed case history and medicinal history
- Investigation of symptoms, location, sensation etc.
- Build up a symptoms picture of the patient

TREATMENT:

- Used drug in the form of mother tincture, small pills and powders
- Preparation of doses involved three processes, they are trituration, succession and serial dilution
- Potentiation is a physical process denotes by “C” three scales are used, they are decimal, centesimal and millesimal.

SOURCES OF MEDICINE:

- PLANTS: Various plants, fungi, etc.
- ANIMALS: Secretions, saliva, etc.
- MINERALS AND CHEMICALS: Toxic metals, inorganic salts etc.
- SERUM: Protoplasm of animals, hormones, etc.
- VACCINES: Bacterial and Viral products etc.

DISADVANTAGES OF HOMEOPATHY:

- Selection of correct drug is difficult
- It takes long periods of time to cure in chronic cases.

B. PREPARATION AND STANDARDIZATON OF AYURVEDIC FORMULATIONS VIZ ARITAS AND ASWAS, GHUTIKA, CHURNA, LEHYA AND BHASMA

DEFINITION:

Ayuvedic medicines are all the medicines intended for internal and external use, for or in the diagnosis treatment, or prevention of disease or disorder in human beings or animal and manufactured exclusively in accordance with the formulae described in the authorative books of ayurvedic systems of medicine specified in the first schedule of the Drug and Cosmetic act 1940.

AYURVEDIC DOSAGE FORMS

SOLID	SEMI SOLID	LIQUID
VATIKA	AVALEHA	ASAVA
GUTIKA	LEPA	ARISHTA
CHURNA	MATRAS	ARKA
BHASMA	KALKA	KWAHA
KSHARAS	SWARASA	TAILA
NASYAS	KAJJALI	DRAVAKA
SATTVA	PRAASH	NETRABINDU

VATIKA:

- Medicaments are in tablet form
- Prepared by compression

PREPARATION:

Plant Drug material dried

↓

Cleaned

↓

Finely powdered separately

↓

Minerals made to Bhasma + Additives (Mixed uniformly)

↓

Moistened with Syrup, Extracted, binder if required

↓

Make uniform tablets by direct compression on tablet compression machine

GUTIKA:

- Medicament is in the pills form

PREPARATION:

Plant Drug material dried

↓

Cleaned

↓

Finely powdered separately

↓

Minerals made to Bhasma + Additives (Mixed uniformly)

↓

Moistened with Syrup, Extracts

↓

Make uniform pencil cylinders

↓

Cut into same sizes & rolled in between fingers

↓

Dried in shade or sun

STORAGE:

- Air tight container
- Preparation containing vegetable drugs can be used for 2 years
- Pills and vatis should not lose their original color, smell, taste and form
- Preparations containing minerals or metals can be used for infinite period
- When sugar, salt is an ingredient, the pills should be kept away from moisture

PACKING:

- Bottles, Strip packing, Blister packing

MARKETED FORMULATIONS:

- Marikadi Gutika
- Khadiradi Vati
- Sanjivini vati
- Lakshmivilasrasa vati

CHURNA:

It is fine powder of drug or drugs

TYPES:

- Simple, Compound, Ash containing

PREPARATION:

Plant drug material dried

↓

Cleaned & Dries

↓

Finely powdered separately

↓

Sieved through 80# separately

↓

Pulverised together

↓

Filled in containers

MARKETED FORMULATIONS:

- Ashwagandhadi Churna
- Triphala Churna
- Trikatu Churna

- Sudarshan Churna
- Drakshadi Churna

BHASMA:

These are the preparation containing ash which are obtained through the process of incineration of crude drug treated with metallic or non-metallic minerals (gold, silver, zinc, copper) reagents or extract or plant juice or animal derived substances like shells & horns in closed crucibles or in pits with cow dung cakes

PREPARATION:

SODHANA

Cleaning, detoxification, purification process

↓

Reduce to fine powder

↓

React with mineral Herbal extract or minerals solution to form wet mass

↓

Convert into pellets or sludge

↓

INCINERATION

↓

White, gray, black colored ash collected

1. SHODHANA is a process of purification and detoxification by which physical and chemical blemishes and toxic materials are eliminated substances are subjected for further processing
   Remove harmful substances and impurities present in drugs

2. MARNA is a process in which metals and minerals are made into paste with various drugs and juices. Objective to make bhasma and this drugs are reduced to finest particles
3. JARANA is a process of decomposing the particles by subjected to fire treatment in a measured manner for reducing them to ashes. To make it absorbable

KSHARAS

- Alkaline basic substance obtain by dissolving ash in water
- It is hygroscopic, deliquescent in nature
- Salty
- Stable for long period

PREPARATION:

Ash
↓
Dissolved in water
↓
Extract dissolved matter
↓
Water removed by evaporation
↓
Salty solid residue collected

SATTVA

- Dried water extract of plant material

PREPARATION:

Crude drug cut into pieces
↓
Socked in water keep over night
↓
Strained
↓
Settle solid & Decant liquid
↓
Dry by evaporation of water

NASSAS

- Fine powdered dried blown into nostril or by aqueous or oily preparation by dropper it is instilled

AVALEHA

- It is sugar based semi solid preparation for oral use

PREPARATION:

Decoction (Kwatha) mixed with sugar, jiggery, sugar candy, honey

↓

Boil with continuous stirring

↓

Homogenous mass is prepared

LEPA

- Lepa are semi solid preparation for external application in the form of paste
- Vegetable powders are stable for 1 month but with mineral stable long last

PREPARATION:

Fine powdered drug + mineral mixed

↓

Add cows urine, water, oil ghee

↓

Make soft paste

MATRAS

It is highly potent, sticky preparation applied to tongue where from drug is absorbed

PREPARATION:

Drug is rubbed over sand stone in honey or milk like vehicle

↓

Collect on finger tips

↓

Applied to tongue

KALKA

Fresh or dried crude drug is powdered poured in hot or cool water to get vary fine paste is called is kalka

SWARASA

Kalka is expressed through the layers of cloths to produce thick juice generally crushed leaves or root of herbs are used

PRAASH

It is highly palatable preparation used for refreshing or rejuvenation of the body. Like jams

ARISHTA

These are liquid ayurvedic preparation prepared by process of fermentation (sandana process)

PREPARATION:

Decoction of Drug is prepared and placed in fermentation vessel

↓

Sugar, jiggery or honey is added

↓

Closed with earthen lid sealed edges with clay & cloth

↓

Fermented at constant temperature

↓

Set aside to settle down particle matter

↓

Fluid decanted & filtered

↓

Boil to avoid further fermentation

↓

Filled in bottle & sealed

ASAVA

These are liquid ayurvedic preparation prepared by process of fermentation (sandana process

PREPARATION

Water + sugar, jiggery, honey & Boiled

↓

Cooled

↓

Poured in fermentation of vessels

↓

Fine powder of drug is added to it

↓

Sealed

↓

Keep for fermentation

↓

Set aside to settle down particulate matter

↓

Fluid decanted & filtered

↓

Boil to avoid further fermentation

PROPERTIES:

- Should be clean
- No foam should be produced
- Should not become sour on standing
- It has characteristic, aromatic & alcoholic odour
- During fermentation, alcohol is produced which facilitates extraction of active constituents contained in the drug
- Alcohol also serve as preservative in the product
- Earlier, the wooden pots are fumigated with pippali powder and also smeared with ghee before the fermentation liquids are pour into them

MARKETED PREPARTIONS:

Asavas	Arishtas
Kumarisava	Dashmularishta
Madhukasava	Draksharista
Punarnavasava	Vidangarista
Chandanasava	Asokarishta

ARKA

- It is liquid formulation obtained by distillation of drug having characteristic odour

PREPARATION:

Fresh flowers or soft part containing volatile principle

↓

If hard part than powdered & moistened with water for softening for overnight

↓

Place in distillation unit (ARKAYANTRA) water is filled

↓

Heated & vapors are condensed to distillate is collected in receiver

TAILA (Medicated oil)

- It is lipophilic liquid prepared by dissolving or extraction medicinal substance with oils

PREPARATION:

Drug + oil paste cooked with stirring

↓

When medicated taila is cooked properly large amount of foam come at top

↓

Cooled

↓

Oil separated

MARKETED FORMULATION:

- Bhringa-raja Taila
- Maha Narayan Taila
- Laghu Visagarbha Taila
- Anu Taila
- Dhanvantara Taila

NETRABINDU

- It is prepared by dissolving specified crude drug in water, honey & used as eye drop

STANDARDIZATION OF AYURVEDIC DOSAGE FORMS: PARAMETERS OF EVALUATION

1. **Taxonomical Estimation**
   - Authentication of drug material
2. **Organoleptic/sensory Evaluation**
   - Color
   - Odour
   - Appearance
   - Powder particle size Distribution
   - Powder flow
   - Clarity
3. **Foreign Matter**
   - Foreign Plant
   - Own Plant
   - Other Plant
   - Mineral
4. **Microscopic Evaluation**

   QUALITATIVE
   - Palisade ratio
   - Vein Islet
   - Vein termination
   - Stomatal Intex
   - Stomatal Number

   QUANTITAIVE
   - Lycopodium Spore count method
   - Starch Grain
   - Calcium Oxalate Crystals

5. **Physicochemical Evaluation**
    - pH
    - Disintegration time
    - Friability
    - Hardness
    - Sedimentation Rate
    - Solubility
    - Viscosity

Ash value

- Total Ash
- Acid insoluble Ash
- Water soluble
- Sulphated Ash

Extractive values

- Water soluble
- Ethanol soluble
- Ether soluble

Oil related values

- Saponification matter
- Acid value
- Ester value
- Swelling Index
- Foaming Index
- Melting Range
- Optical Rotation

6. **Chromatographic & other Methods**
    - TLC & HPTLC
    - HPLC
    - UV Spectroscopy
    - GC-MS

7. **Pharmacological Parameters**
   (Bioassay to estimate potency)
    - Bitterness
    - Astringent Activity
    - Antimicrobial Activity
    - Hemolytic Activity
    - Antioxidant activity
    - Nitric oxide Scavenging Activity

8. Toxicological
(Establishment of Safety)

- Limit Tests
- Pesticide contain
- Heavy metals contain
- Aflotoxin
- Radio-active contamination
- Bio-burdan
- Pathogenic and Non-pathogenic

“

NUTRACEUTICALS

INTRODUCTION:

- The term was coined in 1989 by Dr. Stephen De Felice (Chairman of the Foundation for Innovation in Medicine)
- The term is intended for a nutritional supplement that is sold with the intent to treat or prevent disease and does not have any regulatory definition. Hence a "Nutraceutical" is any substance that may be considered a food or part of a food which provides medical or health benefits, encompassing, prevention and treatment of diseases.

DEFINITION:

- A nutraceuticals is a substance that is food or a part of food treatment of diseases
- Nutraceutical can be defined as a food or a part of food or a nutrient, which in addition to its nutrient values provides health benefits including promotion of health and prevention of disease

Nutrition + Pharma → NUTRACEUTICALS

"Food as Medicine"

- Most of the diseases such as Diabetes, cardiovascular, obesity, etc. occur due to incorrect diet and life style. Hence nutraceuticals play an important role in disease prevention as well as promoting health.

Objects:

- To increase Nutritional factor of food
- Activates immunity
- Increase feed consumption
- Induce maturation
- Anti- microbial capability
- No negative environment impact or Hazardous problems

Nutraceuticals also known as:

- Phytoceuticals
- Phytochemicals
- Phytonutrients
- Phytofoods
- Functional foods

GLOBAL MARKET OVERVIEW AND GROWTH OF NUTRACEUTICAL SEGMENT

- The nutraceutical market is predicted to record a revenue of USD 671.30 billion by 2024
- Developing countries have a high prevalence of non-communicable diseases like cancer, diabetes, cardiovascular ailments, etc. Therefore, the demand for nutraceuticals is expected to rise in these nation

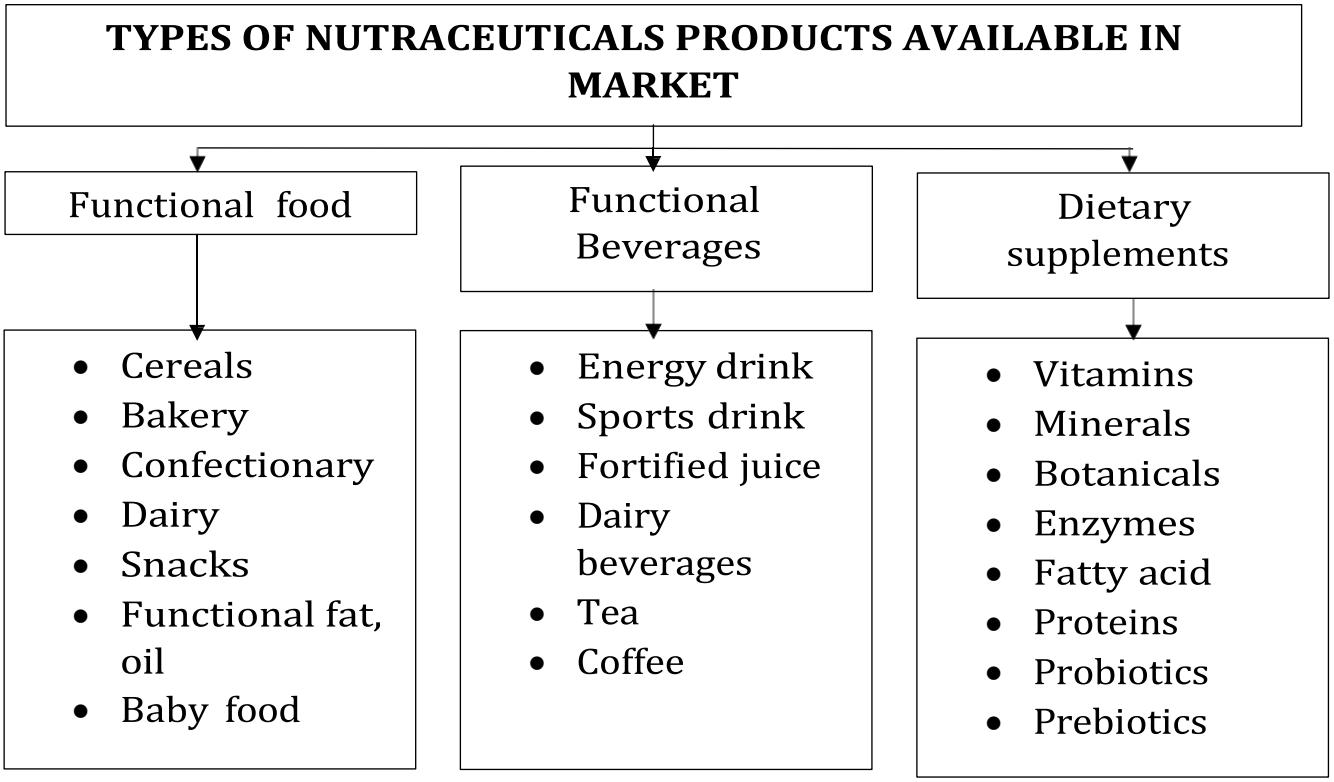
- Nutraceuticals are also gaining global importance and have become a part of daily diet due to increased risk of diseases due to improper life style and people continuously adapting preventive healthcare measures
- The gradually increasing healthcare expenses are also stimulating the demand for nutraceuticals
- Developed countries like united states and Europe have seen a fast emerging segment of customized products especially functional foods and beverages.
- Nutraceuticals have become an opportunity for economic growth of many developing countries which have a rich source of medicinal herbs and traditional knowledge of such plants, especially India, china and south American countries
- Nutraceuticals strengthens the body defence mechanism and improves the body's immunity towards the disease

TOP GLOBAL COMPANIES DOMINATING THE NUTRACEUTICAL MARKET:

- Top global companies dominating the global market include, pepsico, Kellogs, Herblife, Suntory, Nestle, Amway, Coca cola, Quest nutrition, Natures bountry inc, Post holdings inc and clif bar are the major manufacturers in functional beverages and protein industry

SCOPE OF NUTRACEUTICALS:

- Nutraceuticals are expected to deliver promising outcomes in the prevention and occurrence of various diseases resulting due to improper lifestyle and food habits.
- Various constituent of plant like catechins, carotenoids, lycopene, polyphenols, PUFA, etc., have been very effective in the prevention and occurrence of various diseases like cardiovascular, arthritis, cancer, Gastrointestinal disorder etc.



CLASSIFICATION:

It may classified based on:

1. Natural source
2. Pharmacological condition
3. Chemical constituents

Classification: Based on their source

1. PLANT**:** Tomato, garlic, Momordica
2. ANIMAL**:** Shark liver oil, cod liver oil
3. MINERALS**:** calcium, Magnesium, Phosphorous
4. MICROORGANISM**:** Bifidobacterium, Lactobacilli

Classification based on their chemical groupings

1. INORGANIC MINERAL SUPPLEMENTS: Minerals
2. DIGESTIVE ENZYMES: Enzymes
3. PROBIOTICS: Helpful bacteria
4. PREBIOTICS: Digestive enzymes
5. DIETARY FIBRES: Fibres
6. ANTIOXIDANTS: Natural antioxidants
7. PHYTOCHEMICALS:

a)	Fatty acids	omega 3 fatty acid
b)	Isoprenoids	Carotenoids
c)	Lipids	Spingolipids

Inorganic Mineral Supplements:

Calcium, Magnesium, manganese, boron, Copper, Zinc

Probiotics:

Live active microorganisms which when administered in adequate amount acquires health on the host

e.g. E.Coli, Bacillus species, species of Lactobacillus

Probiotics:

Non digestible substance provide beneficial physiological effect for host by stimulating the flavorable growth of limited number of indigenous bacteria

e.g. Inulin, Oligofructose

Dietary Fibers:

Structural carbohydrate of plants

Neither digested nor absorbed

Insoluble fibers:

- Absorption of water in GIT
- Speeds up digestion and elimination time
- Increased stool weight
- Promotes regular eliminates
- **e.g.** cereals, wheat product, Brown rice, Fruits & veg with peels

Soluble fibers:

- Lowers serum cholesterol
- Regulates blood sugar level
- **e.g.** Oats, Dried beans, Legumes, Fruits, Vegetables

Antioxidants:

Anti-oxidants are in 3 categories:

- True anti- oxidant
- Reducing agents
- Anti- oxidant synergists

Antioxidants deficiency cause disease like cancer, Rheumatoid arthritis, cardiovascular system, Alzheimer disease.

True anti-oxidants: React with free radical and block chain reaction

Reducing: It have low redox potential, readily get oxidized and effective against oxidizing agents

Synergistics: It enhance the effect of other antioxidants

Use in disease:

CONDITION	NUTRACEUTICALS
Allergy relief	Ginkgo biloba
Arthritis support	Glucosamine
Cancer preservation	Flax seed, Green tea
Cholesterol lowering	Garlic
Digestive support	Digestive enzyme
Diabetic	Garlic, Momordica
Female hormone support	Black cohosh, flash unicorn
Immunomodulator	Ginseng
Prostate	Tomato lycopenes

ALFALFA

FAMILY: *Fabaceae* / *Leguminosae*

SPECIES: *medicago sativa*

ACTIVE CONSTITUENTS: carotenoids, Triterpenoid saponin, Isoflavonoid

PART USED: Herb

HERBAL USES: Arthritis, high cholesterol, diabetic, Peptic ulcer and it has diuretic and emetic

CHICORY

SYNONYM: kaasani

BIOLOGICAL SOURCE: Dried leaves and roots of *Cichorium intybus*

FAMILY: Compositae

ACTIVE CONSTITUENTS: Flavonoids, tannin, triterpenoids, umbeliferon, scopoletin

HERBAL USES: Jaundice, liver problem, Diabetes, intestinal worms

GINGER

BIOLOGICAL SOURCE: ***Zingibar officinalis***

FAMILY: Zingiberaceae

ACTIVE CONSTITUENTS: Gingerol, shagol, Zingiberin, Starch, Zingeberol

HERBAL USES: Boost digestion, control Nausea, Reduce arthritis, Increase blood flow, prevent cancer, Decrease cholesterol

FENUGREEK

SYNONYM: Medhika, Methi

BIOLOGICAL SOURCE: Dried ripe seeds of ***Trigonella Foenum***

FAMILY: Leguminoseae

ACTIVE CONSTITUENTS: Fenugreekine, trigonellin, Diosgenin

HERBAL USES: Diabetes, Hyperlipidemia, Hypercholesterol, ulcer, upper respiratory tract infection, Arthritis

GARLIC

SYNONYM: Lasun

BIOLOGICAL SOURCE: Dried bulbs of ***Allium sativum***

FAMILY: Liliaceae

ACTIVE CONSTITUENTS: Allicin, Allyl propyl disulphide, selenium, scordinins

HERBAL USES: Hypertension, Diabetes, Hypercholesterol, Hyperlipidaemia, Flatulence, spasm

HONEY

SYNONYM: Madhu

BIOLOGICAL SOURCE: Sugar secretion deposited in honey comb by bees ***Apis mellifera, Apis dorsata***

FAMILY: Apidae

ACTIVE CONSTITUENTS: Glucose, Fructose, Dextrin, Maltose, Formic acid, Acetic acid

HERBAL USES: Nutritive and in cough

AMLA

SYNONYM: Amalaki, Indian Gooseberry

BIOLOGICAL SOURCE: Dried ripe fruits of ***Phyllanthus emblica***

FAMILY: Euphorbiaceae

ACTIVE CONSTITUENTS: Gallic acid, Ellagic acid, vit C, Amino acid, Phyllembin

HERBAL USES: Powerful antioxidant, accelerates the cell regeneration, Building the body's immune system

GINSENG

SYNONYM: Ninjin

BIOLOGICAL SOURCE: Dried roots of ***Panax ginseng (Korea) Panax quinquefolium***

FAMILY: Araliaceae

ACTIVE CONSTITUENTS: Oleanic acid, Panaxodiol, Panaxotriol**,** Dammarol

HERBAL USES: Stress, Fatigue, Erectile dysfunction, Hyperglycemia, Aging, cvs, Menopausal symptoms

ASHWAGANDHA

SYNONYM: Withania

BIOLOGICAL SOURCE: Dried roots of ***Withania somnifera***

FAMILY: solanaceae

ACTIVE CONSTITUENTS: Triacontane, Dihydroxystigmasterol, Withamine, Somnine, Amino acid, Withanolides, withaferine A

HERBAL USES: Sedative, Diuretics, Emetic, Dyspepsia, Flatulence, Asthma, Nervic tonic, Liver complains

SPIRULINA

BIOLOGICAL SOURCE: Blue-green algae**, *Spirulina platensis* & *Spirulina maxima***

FAMILY: Oscillatoriaceae

ACTIVE CONSTITUENTS: Beta carotene, protenous nitrogen,lipid, vitamin F , Fatty acid, Phycobiliprotein, glycogen, rhamnose

HERBAL USES: Immunostimulatory, Hypolipidemic antiviral, Anti-inflammatory and anti-cancer effects

NUTRACEUTICALS IN DIABETES:

- Diabetes mellitus is characterized by abnormal high level of blood glucose or either due to insufficient insulin production
- Common form-
  1. Type I (5%) autoimmune disorder
  2. Type II (95%) obesity

Role of Nutraceuticals:

- ✓ **Lipolic acid –** Universal anti-oxidant for treatment of Neuropathy. It is a possible at more effective as a long term dietary supplement
- ✓ **Dietary fibres** used for both pharmacological and food supplements, possess reduction in weight by glucose and lipid control
  They are two types in fruits, viz. water soluble fiber and water insoluble fiber. They are present in fruits, vegetable, grains, legumes etc. They are used to correct constipation, bowel irregularities, Haemorrhoids

NUTRACEUTICALS IN CARDIO VASCULAR SYSTEM:

- **CVS** disorder is a disorder of heart and blood vessels and Hypertension, Congestive Heart Failure, Stroke, Peripheral vascular disease and etc.
- Majority CVS disorder are preventable

Role of Nutraceuticals:

- ✓ Nutraceuticals in form of antioxidant, dietary fibers, vitamin, minerals are used with physical exercise for prevention and treatment of CVS disorder
- ✓ Polyphenol present in grape wine reduce arterial disease
- ✓ Flavonoids are widely distributed in onion, black grapes, red wine, apple, cherries
- ✓ Flavonoids are available as flavones (Chamomile) flavonones (Citrus fruit) for curing cvs disorder
- ✓ Flavonoids protect vascular and capillaries that supply oxygen and nutrients

NUTRACEUTICALS IN CANCER

- A disease caused by uncontrolled division of abnormal cells in the part of body
- They may be malignant or Benign

Role of Nutraceuticals:

Nutraceuticals have ability to control and regulate the DNA damaging factor in cancer cells

- ✓ It posses therapeutic benefits like Anti-obesity, immunity enhancement, cardiovascular, Anti-diabetic effects
- ✓ It has proven to be potential to interfere even at late stage cancer and alter the metastatic spread of cancer by increasing the phytochemicals
- ✓ By utilizing daily diet of nutraceuticals specific sides to entire gene combination found in particular form of cancer

NUTRACEUTICAL IN IRRITABLE BOWEL DISEASES:

- Irritable Bowel syndrome is a chronic gastrointestinal that are characterized by abdominal pain or discomfort at least 3 days and change is frequency and form of stool

Role of Nutraceuticals:

- ✓ Nutraceuticals such as bioactive peptides, phytochemicals, omega-3-poly unsaturated fatty acids
- ✓ Dietary supplements such as fish oil, curcumin, aloe vera treat bowel syndrome
- ✓ Curcumin and green tea supplemation cause reduction in IBD
- ✓ Bifidobacterium infantis over Lactobacillus and placebo treat abdominal pain or discomfort and bowel movement difficulty

NEUTRACEUTICALS IN GIT;

- The GIT disorder is refer to any condition or disease within the GI tract (from mouth to Anus). This also includes liver, Pancreas, Gall bladder

HERB DRUG AND HERB FOOD INTERACTION

Definition:

It is defined as an ***"alteration in the duration or magnitude of pharmacological effect of one drug produced by another Herb food or other substance".***

Drug interaction is a reaction between two or more drugs or between a drug and a food, beverage or supplement inside the body.

A drug interaction can make the drug less effective, Increased activity or cause unwanted side effects.

Types of Drug Interaction:

- Drug- Drug interaction
- Drug- food interaction
- Drug-Disease interaction

DRUG-DRUG INTERACTION**:**

Most common type of drug interaction. More the medications administered, greater is the chance of drugs interacting with each other. One drug may potentiate the activity of another or inhibit its activity or serious unexpected side effects may occur.

E.g. Vicodin a pain killer when taken along with sedating antihistamine drug that produce additive effect of drowsiness.

DRUG-FOOD INTERACTION**:**

This is another type of drug interaction where drugs interact with food/ Beverage and can produce various side effects.

E.g. Grape juice reduces the enzyme activity in liver which are responsible for metabolizing drug thus resulting in increased blood levels of certain drugs such as cholesterol lowering drugs (Statins), this leads to toxic effects of the drug such as muscle pain and muscle injury.

DRUG-DISEASE INTERACTION

Sometimes drugs also interact with certain diseases where the disease alter the way a drug works.

E.g. Oral decongestants like pseudoephedrine, Phenylephrine may increase the Blood Pressure and can be dangerous in patients having hypertension.

MECHANISM OF DRUG INTERACTIONS:

PHARMACODYNAMIC	PHARMACOKINETIC
	• Absorption • Distribution • Metabolism • Excretion

PHARMACODYNAMIC INTERACTION:

This occurs when two or more drugs administered together act at the similar receptor sites leading to enhancement (additive or synergistic) effects or decreased (antagonistic) effects.

E.g. Chlorpromazine given to prevent nausea and vomiting interacts with antipsychotic medications like haloperidol and produce serious and possible fatal irregular cardiac rhythm.

PHARMACOKINETIC INTERACTION:

This occurs when drugs interact during the process of Absorption, Distribution, Metabolism and/or Excretion.

ABSORPTION INTERACTIONS:

Some drugs can alter the absorption of another drug

E.g. calcium can bind with some drugs like tetracycline and HIV drug dolutegravir and block its absorption, Hence such drug should not be taken along with milk and antacids.

** ***Pharmacodynamic interactions occur due to the Pharmacological effects of drugs*** **

DISTRIBUTION INTERACTIONS:

One or more drugs can compete with each other for plasma protein binding sites resulting in displacement of one drug thereby increasing its blood levels and toxicity.

E.g. Fenofibric acid (cholesterol lowering agent) and warfarin (blood thinner) when administered together, compete for the protein binding sites leading to displacement and increased blood levels of warfarin thus resulting in bleeding.

METABOLISM INTERACTIONS:

Enzymes in the liver such as cytochromes are responsible for metabolizing drugs and eliminating them from the body. Some drugs may alter the enzyme levels or its activity resulting in fast or slow metabolism of drugs.

E.g. DILTIAZEM (Anti-hypertensive) inhibit the cytochrome enzyme responsible for metabolizing SAMVASTATIN (Hypo-cholestremic) and elevates its blood levels resulting in serious liver and muscle side effects.

EXCRETION INTERACTIONS:

Some Non-steroidal Anti-Inflammatory Drugs (NSAID's) like indomethacin may lower the kidney function and reduce the excretion of lithium, a drug used for bipolar disorders. In such cases dose adjustment is required.

HERB-DRUG / FOOD INTERACTIONS:

- Even though herbal medicines are obtained from natural sources, their active ingredients are potent chemicals which can give rise to herb-drug or herb-food interactions.

- Herbal supplements and nutraceuticals are been purchased over the counter (OTC) and may be labelled as "All Natural" but that does not mean they are always safe.
- Herbal supplements are not subject to review by the FDA and their use can often be risky when taken along with other drugs or foods.

MINIMIZING HERB-DRUG / HERB-FOOD INTERACTIONS:

- Avoid taking mucilage containing herbs like ISPHAGULA, flax with other drugs, as mucilage can inhibit the absorption of many drugs. Even mucilage containing drugs can alter the blood sugar levels which have to be considered in case of diabetic patients. Spicy substances such as ginger, capsicum, etc can enhance the absorption rate of some drugs, Hence they need to be taken one hour after drug administration.
- Heart tonic herbs such as hawthorn/ digitalis/ cactus, should be avoided when taking heart medications.
- Caffeine containing herbs like green tea, kola nut, coffee and herbal stimulants like ephedra should be avoided when taking heart medications or mood altering drugs or antidepressants.
- Avoid herbs or formulations containing liquorice when using diuretics like furosemide because liquorice can cause potassium depletion from the body.
- While taking anti-depressants like mono amino oxidase (MAO) inhibitors, avoid African aphrodisiac herbs containing YOHIMBINE.
- Green vegetables like broccoli, spinach, cabbage, etc which have high vitamin-k content are reported to interact with anticoagulant drugs as vitamin-K has coagulation promoting effects.
- Grape fruit juice interacts with calcium channel blockers (antihypertensive), lipid lowering drugs, psychiatric medications, oral contraceptives and antiallergic medication. Grape juice modified the metabolism pattern of these drugs in the liver.

a) HYPERCIUM

Hypercium is a flowering plant in hypericaceae family. It is most commonly used for depression, Anxiety, Menopause

INTERACTION:

- Hypercium + Anti-biotic, Anti- depressant, oral contraceptives, immune suppressants, sedatives
- Hypercium + Anti-depressants: Increase 5HT may cause some problems such as Hallucination, confusion, fever, sweating

SIDE EFFECTS:

- Dizziness
- Anxiety
- Restlessness
- Diarrhea
- Tiredness

USES:

- Depression
- Menopause

- Somatization disorder
- Wound healing
- Irritant bowel disease

HYPERICUM PERFORATION (St. John, s Wort)

- It is a popular herb used to treat mild depression.
- The active constituent of this herb is known as "hypericin" which has similar effects on the brain as that of mono amino oxidase (MAO) inhibitors (antidepressant)
- If taken together, it may produce dangerous drug interactions resulting in rapid rise in blood pressure, severe head ache, collapse and death.
- Foods such as cheese, chicken liver, fish, legumes, soya sauce should be avoided with this drug.
- Hypericin has also reported to produce interactions with immune suppressant drug cyclosporine, anti viral drug indinavir, oral contraceptives, digoxin
- Benzodiazepines are resulting in increased sensitivity to light, anxiety, dizziness, dry mouth, fatigue and sexual dysfunctions.

b) **KAVA-KAVA** (Piper methysticum)

- It is a root found on south-pacific Island. It has calming effect, producing in brain similar to the drug Diazepam
- It can also prevent convulsion and relax muscle
- But it Is not on additive
- It is available as dietary supplement in powder and Tincture form

INTERACTION:

- It should not be taken with drugs which act on nervous system such as barbiturates, antidepressants, antipsychotics and alcohol.
- Because psychotropic medicines are used to treat psychiatric disorder, Anti-depressant and alcohol has sedating effect
- It is reported that concomitant use of kava with central nervous system depressant can increase the risk of drowsiness and motor reflex depression.
- Kava has also reported to produce hepatotoxic effects when taken with some drugs.

SIDE EFFECT:

- May cause Liver failure and should not use longer 3months
- Rashes
- Shortness of breath
- Swelling

USES:

- Anxiety, restlessness
- Insomnia, relieve pain
- Anti-depressant
- Anticonvulsant effect
- Muscle relaxing

c) **GINKGO BILOBA** (Maiden hair tree)

- It is a fan shaped leaves tree. It is taken by mouth for memory disorder including Alzhemer's disease
- It is also used for condition due to reduce blood flow in brain. This leads to memory loss, Headache, Dizziness

INTERACTION:

- Ginkgo + Ibuprofen: Both drugs can slow blood clotting. On combination, there is too much of slow blood clotting, It may chance of bleeding and bruising
- Ginkgo+ Anti-coagulant: It may also have chance of bleeding and bruising
- Ginkgo + warfarin: Both drugs can slow blood clotting. It may also chance of bleeding and bruising

SIDE EFFECTS:

Their seeds may contain toxin and cause effects like

- Seizure
- Loss of consciousness

USES:

- Glaucoma
- Heart disease
- High cholesterol
- Schizophrenia
- Control blood pressure
- It has been used to treat symptoms of Alzheimer, Dementia, Parkinson's disease and to enhance the memory capabilities.

d) GINSENG (Panax ginseng)

- American Ginseng (Panax quinquefolis) is on herb used for fight infection such as cold and flu and makes symptoms milder when infection occurs
- Ginseng is used to improve the body's resistance to stress, boost the immune system and improve the sense of wellbeing and stamina

INTERACTION:

- Ginseng + Anti-depressant: Stimulate the body
- Ginseng + Anti-diabetes: Both drugs lower blood sugars. On combination, it may cause too low level of blood glucose

SIDE EFFECTS:

- Headache
- Restlessness
- Insomnia

USES:

- Improves digestion
- Treat infection of intestine
- Treat vomiting, inflammation of colon
- Anemia treatment

e) **GARLIC** (Allium sativum)

- Garlic is a plant in the Allium (onion) family. It can relieve sickness including common cold. Improve the function of immune system. Also reduces cholesterol

INTERACTION:

- Garlic + Warfarin: Garlic increases warfarin effect. It may chance of bruising and bleeding
- Garlic + Isoniazid, saquinavir, cyclosporine: Do not take in combination because Garlic, may quickly breakdown the Isoniazid, saquinavir and decreases their effect

SIDE EFFECTS:

- Bleeding disorder
- Digestion problem
- Low Blood Pressure
- Burn sensation in mouth and stomach

USES:

- Atherosclerosis
- Diabetes
- Hyperlipidemia
- High Blood Pressure
- Ring warm
- Some cancer

***** Grape juice decreases the activity of cytochrome P450 3A4 enzyme that are responsible for breaking down many drugs and toxins. *****

***** Grape juice contain compounds known as Furanocoumarins, that Block the CYP 3A4 enzymes *****

f) PEPPER (Piper Nigrum)

- Most commonly used species of dried unripe fruit.
- It is taken by mouth for arthritis, Asthma, Stomach upset, Headache, Sinus infection

INTERACTION:

- Pepper + cyclosporine: Increase their effect and increase in interaction
- Pepper + Lithium: Diuretic effect decreases the level of lithium
- Pepper + Anti diabetic: Leads to decreases the blood sugar level
- Pepper + Anti-coagulant: Shows the blood clotting and increase the chances of bruising and bleeding

SIDE EFFECTS:

- Allergic reactions in some patient
- Burning
- Nausea
- Sneezing

USES:

- Diarrhoea
- Cancer
- Pain
- Stomach upset

g) EPHEDRA (Ephedra gerardiana)

- It is an herbal for asthma, bronchitis, allergies, cold, flu symptoms.
- Also for weight loss

INTERACTION:

- Ephedra + Theophyllin: Asthma, Chronic bronchitis
- Ephedra+ MAO, Nardil: Risk of increase blood pressure
- Ephedra should not combine with stimulant drugs (Caffeine).It may cause additive effect

SIDE EFFECTS:

- Nausea
- Headache
- Dry mouth

- Dizziness
- Anxiety

USES:

- Heart disease
- High blood pressure
- Thyroid disorder
- Glaucoma

HERBAL COSMETICS

- The word cosmetic was derived from the Greek word “kosm tikos” meaning having the power, arrange, skill in decorating.
- Using various permissible cosmetic ingredients to form the base in which one or more herbal ingredients are used to provide defined cosmetic benefits only, shall be called as “herbal cosmetics”

DRUG AND COSMETIC ACT 1940:

Any Article or preparation intended to rubbed, poured, sprinkled or sprayed on or introduced to or applied to any part of human body for cleaning, perfuming, beautifying, promoting, attractiveness or altering the appearance and includes any article intended for use as component of cosmetics.

Cosmetic used to perform the following actions:

- To clean
- To perfume
- To change the appearance
- To protect
- To keep in good condition
- To correct the body odor etc.,
  and field of application of cosmetic remains to the epidermis, hair system, nails, lips, teeth & mucous membrane of oral cavity.

Natural and Synthetic:

- The use of natural ingredients in personal and health care product has been practiced since time immemorial leading to increased use of herb with a curative value.
- Modern research proves that herbs while being effective are also mild and soothing.
- Potent synthetic preparation and chemicals, though effective, constitute a toxic burden to human body.
- "As the science advances, man made his life easy. Despite its harmful effect on long term usage. As he started realizing serious effect of these he looked back into the olden life style.so the ultimate example for this is Ayurveda/Herbal Usage”

COSMECEUTICALS:

- Cosmeceuticals is the fastest growing segment of the personal care products these are cosmetic products which contain biologically active principles or ingredients of plant origin.
- There is an increased demand for the use of natural substances in cosmetics in recent years due to their mild action and non-toxic in nature in many cases they are found to be quite effective.

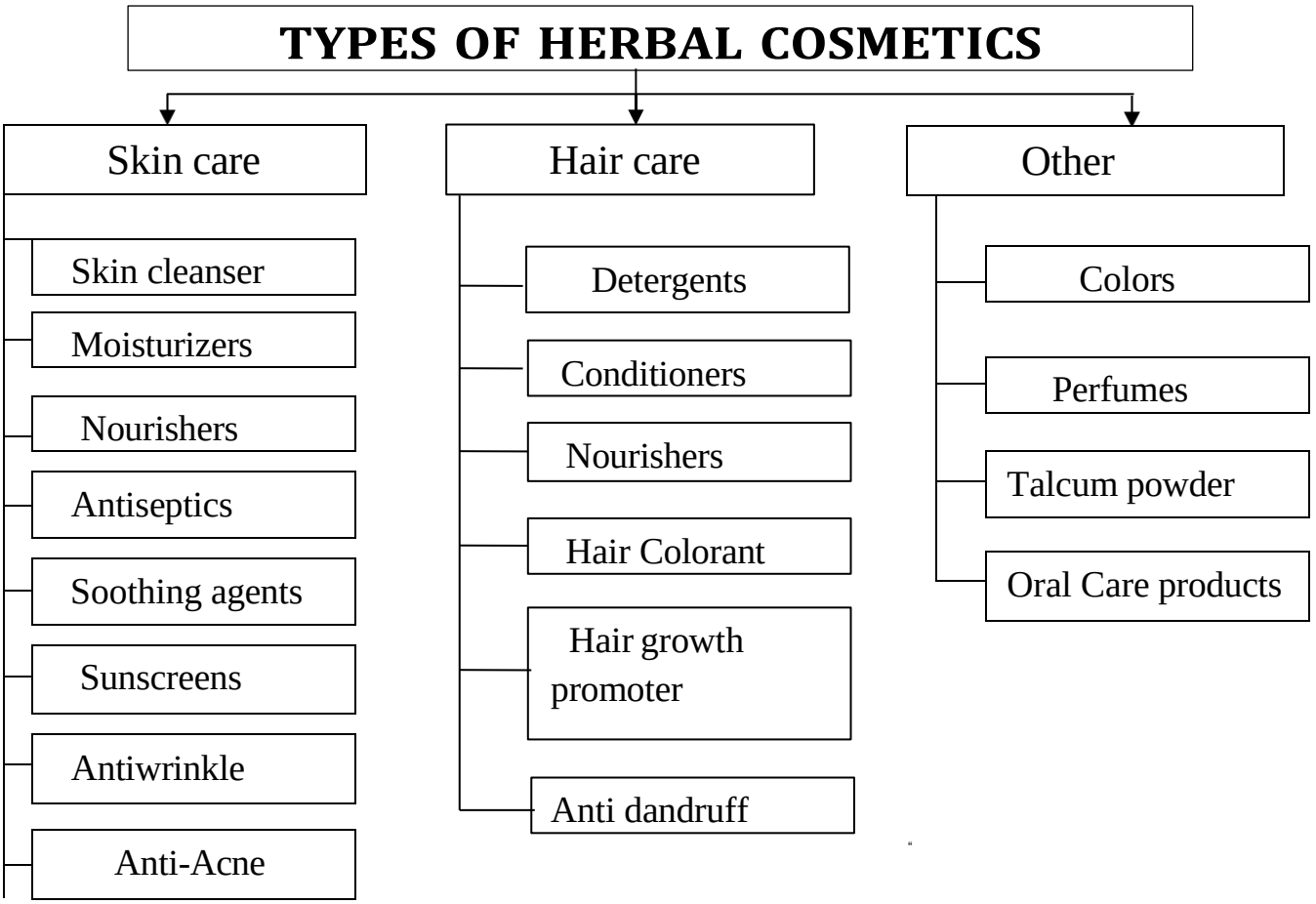
COSMETIC-PHYTOGNOSY:

- Which deals with biochemical and physicochemical properties of plant derived ingredients to be used in cosmetics.
- Basically, six different types of plant derived ingredients are used in herbal cosmetics.

Type of plants derived ingredients are used in herbal cosmetics

- Fresh materials
- Dried materials
- Acellular product (oils, resins, gums)
- Galenical preparation (infusions, decoctions, extracts)
- Processed extracts
- Pure isolated compounds

Cosmetic Phytognosy is a new terminology for the science of functional plant derived cosmetic ingredients.



1. Skin Care Products

- Skin is constantly exposed to dirt, microbes, irritants, radiation and toxins which can affect the skin in many ways.
- Hence to protect the skin cleanse it and restore the tone, soothen it and prevent tanning, wrinkle and scar formation, various preparations are used which are enlisted

EXAMPLE

- **Skin cleansers :**
  - ✓ **Eg:** Milk, cucumber, citrus peels, aloe.

- **Moisturizers:**
  - ✓ **Eg :**Aloe-vera, almond oil ,rose
- **Nourishers:**
  - ✓ **Eg:** Honey, carrot peach wheat germ oil.
- **Antiseptics:**
  - ✓ **Eg :** Neem, turmeric, tulsi, lavender oil.
- **Soothing agents (Emollients):**
  - ✓ **Eg:** Sesame oil, almond oil, aloe-vera
- **Sunscreens:**
  - ✓ **Eg:** Aloe-vera, chamomile, calendula, cucumber
- **Anti-Wrinkle & anti-Aging:**
  - ✓ **Eg:** peach, liquorice, papaya, aloe-vera, apricot, turmeric
- **Anti-acne :**
  - ✓ **Eg:** cucumber gel, vetiver.

2. Hair care product:

- Hair complexion, color and style play an important role in people's physical appearance.
- Hair care preparations are applied topically to the scalp and hair.
- These contain ingredients which either clean, condition or nourish the hair or prevent dandruff formation.
- The following are the various hair care preparations.

EXAMPLE:

- **Detergents:**
  - ✓ **Eg:** Soap nut, shikekai, reetha.
- **Conditioners:**
  - ✓ **Eg:** Henna, amla , hibiscus, rosemary, tea
- **Nourishers:**
  - ✓ **Eg:** brahmi, bringraj, eggs, coconut oil, sesame oil
- **Hair colorants:**
  - ✓ **Eg:** Henna
- **Hair growth promoters:**
  - ✓ **Eg:** Brahmi, hibiscus, coconut oil, amla, sesame oil
- **Anti dandruff:**
  - ✓ **Eg:** Soap nut , shikekai, lemon, thyme, Aloe-vera

3. Other cosmetic

These are used to prepare various cosmetic products like lipstick, nail polishes, eye products.

Eg: Anthocyanins, saffron, turmeric, carotenoids, indigo, capsicum, chlorophyll.

✓ **Perfumes:**

Eg: Volatile oils of plants like rose , lavender, jasmine, sandalwood

✓ **Talcum powders:**

It contains talc with added plant extracts to impart the desired flavour and odours.

Eg: sandalwood, rose, jasmine, lavender, etc..

Oral care (Hygiene) products:

- Oral care products like tooth pastes, powder, mouth wash, mouth freshners etc.
- Various herbs and their extracts are incorporated into these preparations in order to achieve antimicrobial, antiseptic, anti-plaque, anti- inflammatory and mouth freshening properties.

Eg: Neem, mentha, chamomile, sage, myrrh, nutmeg, chitosan, calendula, rosemary, etc.

STUDY OF DRUGS USED IN COSMETICS:

1) Soapnut (Ruth)

It consists of pods of *Sapindus trifoliatus, Sapindus mukorassi.*

- **Family:** Sapindaceae.
- **Description:**
  - It is a shrub with linear pods, the dried powder of the pods is brown in color and have soap like properties.
- **Chemical constituents:**
  - It contains saponins (10-11.5), mucilage, gums, proteins.
  - Saponins contain sapindosides A, B, C and D, diosgenin, gitogenin, chlorogenin and rusogenin.
- **Uses:**
  - It is used as detergent, hair cleanser, hair growth promoter and antidandruff agent.

2) Amla (Indian gooseberry)

It consists of dried and fresh fruits of *Phyllanthus emblica.*

- **Family:** Phyllanthaceae
- **Description:**
  - It is a small tree with a number of globular fruits which are yellowish green in color
  - They have a sour and astringent taste.
- **Chemical constituents:**
  - It is a rich source of ascorbic acid (Vitamin C), other constituents include tannins, minerals such as iron, calcium, phosphorous.
  - It is also rich in pectin.
- **Uses:**
  - Amla is used as a hair growth promoter, hair nourisher hair conditioner and colorant

3) Henna (Mehendi)

It consists of fresh and dried leaves of *Lawsonia inermis*

- **Family:** Lythraceae.
- **Description:**
  - It is a flowering plant and its leaves are used to color and decorate the skin and hair
- **Chemical constituents:**
  - Henna contains a soluble component known as lawsone

- It is responsible for the colour.
- It also contains xanthones, tannins, flavonoids and coumarins

- **Uses:**
  - Henna is used as hair colorant, hair dye, hair conditioner and nourisher.
  - It produces a cooling effect on the skin.
  - It is also used to treat burns and wounds

4) Hibiscus (Jaswand)

It consists of dried flowers and leaves of *Hibiscus rosa sinensis*,

- **Family:**Malvaceae.
- **Description :**
  - Red and white varieties are generally used in hair care preparations.

- **Chemical constituents:**
  - It contains Vitamins, flavonoids, anthocyanins, quercetin, mucilage and albumin.
- **Uses :**
  - It is used as hair growth promoter, anti greying agent, hair conditioner, hair rinser.
  - It gives smoothness and shine to the hair.

5) Tea (Chai)

It consists of dried leaves of Thea sinensis and Camellia sinensis,

- **Family:**
  - Theaceae
- **Description:**
  - The leaves are collected, dried and made into the form of tea dust
- **Chemical constituents:**
  - Tea contains polyphenols, catechin epicatechin, caffeine, theophylline, theobromine
- **Uses:**
  - It is used as hair conditioner, colorant.
  - If gives Smoothness and shihe to hair

6) Aloe (Kumari)

It consists of dried or fresh mucilage of Aloe vera

- **Family:** Liliaceae,
- **Chemical constituents:**
  - It contains anthraquinones like rhein, aloin, emodin, minerals and mucilage.
  - Chemically mucilage is a polysaccharide consisting of salts of poly uronic acids.
- **Uses:**
  - Aloe has good wound healing properties.
  - It is used in skin care and hair care cosmetics,
  - It is used to treat radiation burns,
  - It is also used as a hair conditioner and nourisher.
  - Aloe is used as an ingredient in various sunscreen c and skin moisturizer creams

7) Liquorice (Glycyrrhiza)

It consists of dried roots and stolons of Glycyrrhiza glabra,

- **Family:** Leguminosae.
- **Chemical constituents:**
  - Liquorice contains saponin glycosides, glycyrrhizin.
  - It also contains flavonoids, liquiritin and isoliquiritin
- **Uses:**
  - The ammonium and sodium salts of glycyrrhizinic acid are widely used in cosmetics.
  - It has skin improving properties hence used in skin care cosmetics.

8) Turmeric (Curcuma)

It consists of dried and frsh rhizomes of Curcuma longa,

- **Family:** Zingiberaceae.
- **Chemical constituents:**
  - It contains volatile oils, resins,curcuminoids like curcumins
- **Uses:**
  - Antiseptic and anti-inflammatory, skin conditioning and antioxidant properties
  - It is used in skin care cosmetics.
  - It is also used as a colouring agent, antimicrobial and wound healing agent.
  - It is incorporated in ointments & creams.

9) Bhringraj

It consists of the entire herb of Eclipta alba,

- **Family:** Asteraceae.
- **Chemical constituents:**
  - It contains alkaloid ellipticine, amyrin, wedelolactone, wedelic acid and luteolin.
- **Uses:**
  - Anti-inflammatory.
  - It improves the skin complexion.
  - It is also used as a dentifrice

10) Sandalwood

It consists of heart wood of Santalum album,

- **Family:** Santalaceae.
- **Description:**
  - The wood is obtained from main stem and branches.
  - It is collected from adult 25 years old trees.
- **Chemical constituents:**
  - It contains volatile oils, which contain 95% of two isomeric sesquiterpene alcohols namely a alpha and beta santalol.
  - It also contains santalal, santene, santanone,santalone and santalene
- **Uses :**
  - Sandalwood is used in perfumery, as skin conditioner, in creams, lotions soaps and powders.

11) Sesame oil

It is a fixed oil obtained from Sesamum indicum,

- **Family:** Pedaliaceae.
- **Chemical constituents:**
  - It contains glycerides of fatty acids, mainly oleic, linoleic, palmitic, stearic and arachidic acids. It also contains phenol, sesamol.
- **Uses:**
  - It is used as nutritive softening agent (emollient),
  - Used in manufacture of soaps,ointments and pastes

12) Bees wax

It is the purified wax obtained from honeycomb of bees *Apis mellifera.*

- **Family:** Apidae.
- **Chemical constituents:**
  - It contains esters monohydric alcohols, myricin, myricyl palmitate, cerotic acid, mellisic acid and an aromatic substance cerolein
- **Uses:**
  - It is used in the preparation of ointments,plasters, cosmetic, creams.

HERBAL EXCIPIENTS

INTRODUCTION:

- Excipients/ Pharmaceutical aids are the substances which are inert and have little or no therapeutic value, but are essential in the manufacture of various pharmaceutical dosage forms such as tablets, capsules, syrups, etc…
- Excipients are mixed with the active ingredients to make up the volume or improve the stability or mask the bitter taste or improve the appearance, odour and other characteristics of the dosage forms.
- Binding agents, suspending agents, viscosity builders, disintegrating agents, etc also constitute pharmaceutical excipients/ aids

Advantages/ significance of herbal excipients

1. **Biodegradable**
   - Naturally occurring substances show no adverse effects on the environment or other living beings and they are easily biodegradable.

2. **Biocompatible and nontoxic**
   - Most of the herbal excipients are carbohydrates in nature.
   - They are compatible and non toxic with most of the ingredients.

3. **Economic**
   - Herbal excipients are cheaper and their cost of production is comparatively lesser.

4. **Safe and free from side effects**
   - Naturally occurring excipients are safer and without any side effects.

5. **Easily available**
   - Natural excipients are produced in most of the countries, hence easily available

Note: Biodegradable are the substances which can be easily taken back into the earth naturally without causing any harm to the environment.

Disadvantages of herbal excipients

1) **Microbial contamination:** During production, herbs are exposed to external environment hence there are Chances of microbial contamination.

2) **Biochemical variation:** Variation in the quality of product may occur due to various environmental factors.

3) **Uncontrolled rate of hydration:** This occurs due to biochemical variation and difference in the quality of materials from one batch to another.

4) **Heavy metal contamination**: Herbs are always associated with the rick of heavy metal contamination

CLASSIFICATION OF HERBAL EXCIPIENTS

- Colorants
- Sweeteners
- Binding agents
- Diluents
- Viscosity builders
- Ointment bases
- Disintegrating agents
- Flavoring agents
- Emulsifying agents

Note: Microbial contamination occurs due to improper processing as well as presence of excessive amounts of moisture in the raw material.

EXAMPLE:

- **Colorants:**
  - ✓ **E g:** henna, chlorophyll, caramel, amaranth, indigo.
- **Sweeteners:**
  - ✓ **E g:** glycyrrhiza, honey, stevia.
- **Binding agents:**
  - ✓ **E g:** acacia, gelain, tragacanth, starch.
- **Diluent:**
  - ✓ **E g:** lactose, starch mannitol, sucrose.
- **Viscosity builders:**
  - ✓ **E g:** pectin, tragacanth, cellulose, guar gum, gelatin
- **Disintegrating agents:**
  - ✓ **E g.** Starch, isapgol husk, carboxy methyl cellulose.
- **Ointment bases:**
  - ✓ **E g:** lanolin, bees wax.
- **Emulsifying: agents:**
  - ✓ **E g**: acacia agar, guar gum, methyl cellulose.
- **Flavouring agents:**
  - ✓ **E g:** cardamom vanilla, lemon oil, orange oil.
- **Perfumes:**
  - ✓ **E g:** rose, lavender, sandalwood

STUDY OF HERBS USED AS EXCIPIENTS:

1) Henna

It consists of dried leaves of *Lawsonia inermis*

- **Family:** Lythraceae.
- **Chemical constituents:**
  - Henna contains lawsone as its chief constituent, Other constituents include phenols, coumarins, flavonoids and tannins.
- **Uses:**
  - Colouring agent.

2) Amaranth

It consists of flowers of Amaranthus hypochondriacus and other species of Amaranthus

- **Family:** Amaranthaceae
- **Chemical constituents:**
  - It contains polyphenols, vitamins and flavonoids.
- **Uses:**
  - Dyeing agent

3) Madder

It consists of dried root of Rubia tinctorum

- **Family:** Rubiaceae,
- **Chemical Constituents:**
  - Anthraquinone alizarin, the hydrolysis product of ruberythric acid, is the main dye component of Rubia tinctorum.
  - It contains several anthraquinone glycosides.
- **Uses:**
  - Madder root contains the anthraquinone pigment alizarin and has been since ancient times a popular fine red dye plant.

4) Liquorice

It consists of dried roots and stolons of Glycyrrhiza glabra,

- **Family:** Leguminosae.
- **Chemical constituents:**
  - It contains glycyrrhizinic acid, liquiritin, isoliquiritin.
- **Uses:**
  - Sweetening agent

5) Stevia:

It consists of the plant Stevia rebaudiana

- **Family:** Compositae.
- **Chemical constituents:**
  - It contains stevioside, rebaudioside, steviol
- **Uses:**
  - Sweetening agent

6) Acacia

It is the dried gummy exudation obtained from the stems and branches of Acacia Arabica

- **Family:** Leguminosae.
- **Chemical constituents:**
  - It contains sugars like arabinose, galactose, rhamnose and glyceronic acid.
- **Uses:**
  - Acacia is used as binding agent, suspending agent, emulsifying agent and Viscosity builder

7) Saffron

Saffron is the dried stigma and style tops of Crocus sativus Linn.

- **Family:** Iridaceae.
- **Chemical constituents:**
  - The Saffron contains volatile oil (1.3%), fixed oil, and wax.
  - Crocin is the chief colouring principle in Saffron.
  - crocetin (an aromatic compound), gentiobiose, α and γ-carotenes, lycopene, zeaxanthin, β-sitosterol, palmitoleic, oleic, linoleic & linolenic acids.
- **Uses:**
  - Saffron is used fever, cold, as colouring and flavouring agent, cosmetic pharmaceutical preparations, and as spice

8) Gelatin

It is a protein obtained by partial hydrolysis of animal connective tissue like bone skin, tendons and ligaments.

- **Chemical constituents:**
  - Gelatin chemically contains amino acids like glycine, alanine, glutamic acid, proline, argginine, aspartic acid, leucine, isoleucine.
- **Uses:**
  - Binding agent, thickening agent, emulsifying agent, in the manufacture of capsules.

9) Tragacanth

It is the dried exudation obtained from the stem and branches of *Astragalus gummifer*

- **Family:** Leguminosae.
- **Chemical constituents:**
  - It contains gums, tragacanthin and bassorin.
- **Uses:**
  - Binding agent and Viscosity builder

10) Lactose

It is a natural disaccharide obtained from milk.

- **Chemical constituents:**
  - It contains sugars galactose and glucose.
- **Uses:**
  - Diluent in tablets and capsules.

11) Mannitol

It is a saccharine exudation from the stems of Fraxinus ornus,

- **Family:** Oleaceae.
- **Chemical constituents:**
  - It is a white, crystalline, odourless, non hygroscopic sweet powder.
  - It is freely soluble in water and insoluble in alcohol
- **Used:**
  - Sweetening anger and diluents.

12) Guar gum

It is the ground endosperm of seeds of Cyamopsis tetragonlobus,

- **Family:** Leguminosae
- **Chemical constituents:**
  - It contains 85% guran, galactose, mannose .
- **Uses:**
  - Binding agent, disintegrating agent, suspending agent and emulsifying agent

13) Starch

It consists of polysaccharide granules obtained from the grains of maize, rice, wheat potatoes.

- **Chemical constituents**:
  - It contains water soluble amylase and water Insoluble amylopectin, which swells and is responsible for gelatinizing properly of starch.
- **Uses:**
  - It is used as binding agent, disintegrating agent and diluent

14) Sandalwood oil

It is the volatile oil obtained by steam distillation of heart Wood of Santalum album,

- **Family:** Santalaceae.
- **Chemical constituents:**
  - It contains sesquiterpene alcohol namely alpha and beta-santalol.
- **Uses:**
  - Used in perfumery industry.

15) Rose oil

It is a volatile oil distilled from fresh flowers of Rosa gallica and other rose species

- **Family:** Rosaceae.
- **Chemical constituents:**
  - Rose oil contains linalool, nerol, citronellal and geraniol
- **Uses:**
  - Used in perfumes and flavouring agent.

16) Cardamom oil

It is a volatile oil distilled from the seeds of Elettaria cardamomum,

- **Family:** Zingiberaceae.
- **Chemical constituents:**
  - It contains cineol, alpha terpinyl acetate, terpeneol, borneol and sabinene.
- **Uses:**
  - Used as a flavoring agent.

17) Orange oil

It is a volatile oil obtained by expression from fresh peels of the ripe fruits of Citrus limonis,

- **Family:** Rutaceae.
- **Chemical constituents:**
  - Orange oil contains limonene, citral, citronellal.
- **Uses:**
  - Used as a flavouring agent

HERBAL FORMULATION

- Herbs have been used in a wide variety of dosage forms, large number of herbal formulations containing the plants or their extracts with proven medicinal activity are being used.
- With the advances of pharmaceutical technology, modern dosage forms have evolved.
- Herbal formulations/ dosage forms can be broadly

Classified into three categories via:

1. TRADITIONAL DOSAGE FORMS
2. MODERN HERBAL DOSAGE FORM
3. NOVEL DOSAGE FORM

1. TRADITIONAL DOSAGE FORMS

These are derived from various traditional systems of medicines like Ayurveda, Unani, Homeopathy, etc…

Example: pills, powders, semi fluid extracts, pellets, tinctures, etc...

Note: Herbal formulations may contain a single herb or combinations of different herbs.

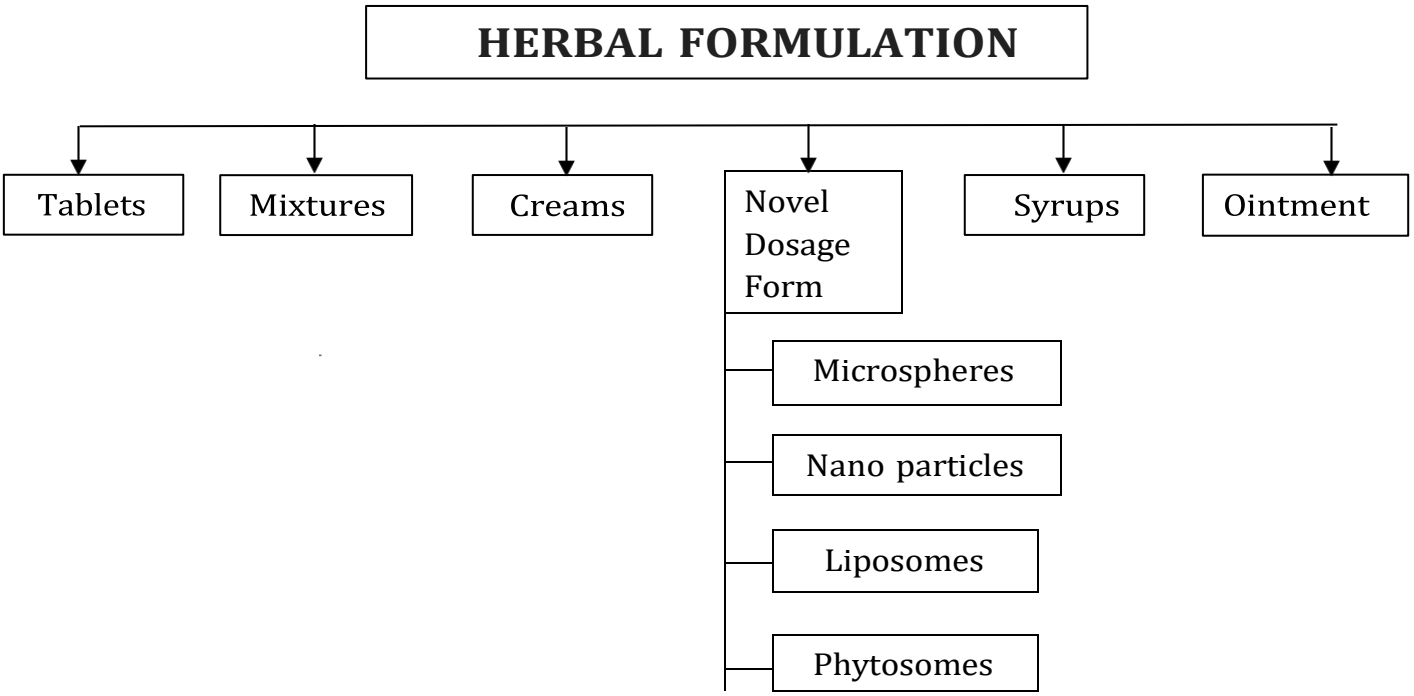
2. MODERN HERBAL DOSAGE FORM

- These formulations are developed from modern technological processes
- Modern herbal formulations offer small dosage size, they are user friendly.
- Convenient and have good absorption characteristics.

Example: tablets, capsules, syrups, solutions, suppositories, injections.

3. NOVEL DRUG DELIVERY STEMS (NDDS) NOVAL DOSAGE FORM:

- With the advancement in different scientific techniques of preparing formulations, novel dosage forms are being developed to overcome the limitations of conventional dosage forms such as tablets, syrups, solutions, etc….
- Many novel dosage forms have been developed successfully which have offered better acceptance by the health system.
- A few novel dosage forms available in the market are transdermal patches, implants, nasal systems, microcapsules microspheres, liposomes, phytosomes, etc,



HERBAL CREAM

These are viscous, semisolid preparations which may be oil in water type (aqueous) creams or water in oil type (oily) creams.

HERBAL MIXTURE

- These are the preparations containing combination of two or more herbal ingredients which are formulated into various formulations like tablets, capsules, ointments, creams, etc…
- These mixtures or combinations of herbal ingredients may have more than one activity and can be used to treat multiple ailments on they may produce additive or synergistic effects for a single disease.

HERBAL SYRUPS

- These are preparations formulated by incorporating sugar solution with plant extracts such as infusions, decoctions, juice, fermented products or simple solutions.
- Honey or unrefined sugar is used to prepare syrups as they act as good preservatives.
- Herbal syrups are made with equal proportions of herbal extracts with honey or sugar solution of known concentration.
- Various flavours like orange, raspberry, menthe can also be added to mask the bitter taste as well as improve the palatability of the formulation.

HERBAL OINTMENTS

- These are semisolid dosage forms meant for external application to the skin or mucous membrane.

- Ointments perform softening (emollient) and protective action.
- Waxes like bees wax, paraffin wax are used as base or carrier.
- Various active herbal ingredients in the form of powders, dried extracts can be incorporated in the bases which provide therapeutic benefits.

HERBAL TABLETS

- These are solid dosage forms of powdered herbs, herbal extracts or their constituents prepared by moulding or compression.
- In addition to the active ingredients, these contain diluents like binding agents which provide strength to withstand normal handling while transportation and storage, colouring agents to improve the appearance, sweetening and flavouring agents to mask the bitter taste, disintegrating agents to facilitate the breakdown and absorption in the gastrointestinal tract are added.

NOVEL DRUG DELIVERY SYSTEMS (NDDS)/ NOVEL DOSAGE FORMS

PHYTOSOMES

- The concept of Phytosomes is another breakthrough for the development in herbal drug technology.
- Phytosomes contain active herbal ingredients surrounded and bonded by phospholipids.
- They are produced by bonding phosphatidyl choline with the ingredients thereby producing a complex.
- The phospholipids structure has a water soluble choline head and fat soluble body and tail (phosphatidyl portion).

Novel dosage forms usually contain pure isolated compounds.

- Herbal nano particles are colloidal system with particle size of about 1 to 1000 nm.
- The choline head (water soluble) binds with the active compounds (herbal ingredients), while the phosphatidyl portion (fat soluble) comprising of body and tail envelops the choline bound materials (ie, active ingredients) as a result microspheres or vesicles are produced whereby the valuable components of the herbs are protected.
- Phytosomes enhance the absorption and improve the bioavailability of herbal ingredients by enhancing their delivery to the tissues thereby lowering its dose and reducing the side effects,

- They also protect the active herbal ingredients from destruction by the digestive juices and gut bacteria.
- Several studies have shown that the body uses phytosome molecules more effectively than that of non phytosome molecules.

LIPOSOMES

- These are prepared by incorporating the active ingredients inside the microscopic double layered membranes which are made of phospholipids (known as phospholipids vesicles).
- These vesicles are suspended in an aqueous solvent uniformly.
- Drugs incorporated in the liposomes can be delivered to the desired site in desired concentration.
- This novel drug delivery system is especially targeted to liposomal delivery of drugs in cancer chemotherapy, arthritis, haemophilia and diseases of the immune system.

NANO PARTICLES

- These are colloidal particles of the submicron size which act as carriers for drug molecules
- These are used to target various sites in the treatment of cancer, disease of the reticulo endothelial system and enzyme replacement therapy in liver.

MICROSPHERES

- These are small, solid particulate carriers containing the dispersed drug particles either in solution or crystalline form.
- Microspheres are used as carriers for drugs and therapeutic agents especially in cancer treatment and hormonal disorders.

EVALUATION OF DRUGS

WHO & ICH GUDELINES FOR THE ASSESSMENT OF HERBAL DRUGS

Assessment/Evaluation/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, Microscopic, Physical, Chemical and Biological observations. The Evaluation of herbal drugs is necessary because of three main reason.

1. Biochemical variation in drug.
2. Deterioration due to improper processing and storage.
3. Adulteration and Substitution.

Crude Drugs

Crude drugs are plant, animal or their parts which after collection are subjected to only drying or making them into transverse/ longitudinal slice piece or peeling them in some cases.

Crude Drug Occurrence

Crude drug are generally obtained by plant, animal and mineral origin.

1. Plant Origin: Whole plant or part of plant like leaves flowers, seed and barks or vegetable saps, extracts and secretions.
2. Animal Origin: Whole animals, glands or organs, extracts and secretions
3. Mineral Origin: Ferrous sulfate, Magnesium, Zinc, Gold etc.,

Herbal Drug/Formulation

According to WHO, a herbal drug or formulation is regarded as finished labelled products that contain active ingredients such as aerial or underground parts of plant or other plant material or combinations thereof, whether in the crude state or as plant preparations.

Guidelines for Quality Control of Herbal formulations

WHO (World Health Organization) has given certain guidelines for assessment of herbal drugs and most of the countries have adopted these guidelines. The following are the aims and objectives of WHO guidelines in standardizing the herbal drugs.

- Quality Control of crude drugs material, plant preparations and finished products.
- Stability assessment and shelf life.
- Safety assessment; documentation of safety based on experience or toxicological studies
- Assessment of efficacy and evaluating their biological activity.

Definition of Drug Evaluation

Drug Evaluation may be defined as the determination of identity, purity and quality of a drug.

- **Identity:** Identification of biological Source of the drug

- **Quality:** The Quantity of the active constituent present.
- **Purity:** The extent of foreign organic material present in a crude drug.

Importance of Evaluation of Crude Drugs

Determination of biochemical variation in the drugs. Identification of deterioration due treatment and Storage.

Reporting substitution and adulteration, as result of carelessness, ignorance and fraud.

METHODS OF STANDARDIZATION AND HERBAL DRUG EVALUATION

The evaluation of a drug is done by following methods

1. Organoleptic evaluation
2. Morphological evaluation
3. Microscopic evaluation
4. Physical evaluation
5. Chemical evaluation
6. Biological evaluation

AUTHENTICATION OF HERBAL DRUGS

The existence of numerous plant species and subspecies make it difficult to properly identify them, hence it is essential that before starting any processes on herbs, they need to be properly identified and authenticated from a reputed institution or organization. The following institutes are involved in the authentication of herbs.

NAME OF INSTITUTES

- Central Council for Research in Ayurveda and Siddha (CCRAS)
- Central Council for Research in Unani Medicine (CCRUM)
- Central Council for Research in Homeopathy (CCRH)
- Central Council for Research in Yoga and Naturopathy (CCRYN)
- Central Council for Indian Medicine (CCIM)
- Central Council for Homeopathy (CCH)

LABORATORIES

- Pharmacopoeial Laboratory for Indian Medicine (PLIM)
- Homeopathy Pharmacopoeia laboratory (HPL)

NATIONAL INSTITUTES

- National Institute of Homeopathy (NIH)
- National Institute of Ayurveda (NIA)
- National Institute of Unani Medicine (NIUM)
- National Institute of Naturopathy (NIN)
- National Institute of Siddha (NIS)
- Institute of Post-Graduate Training and Research in Ayurveda (IPGTRA)

- Rashtriya ayurved Vidyapeeth (RAV)
- Morarji Desai National Institute Of Yoga (MDNIY)

1. ORGANOLEPTIC EVALUATION

This refers to drug evaluation by means of organs of sense and includes other sensory organs like color, odor, taste, size, shape and texture.

It includes the study of morphology and other sensory characters

A. Odour

- Distinct
- Indistinct
- Aromatic

B. Taste

- Acidic (sour)
- Saccharine(sweet) indicates sugar or sugar like substance **e.g** liquorice
- Saline (salty)
- Alkaline
- Bitter: indicates presence of substance such as bitter principle **e.g** alkaloids, glycosides
- Tasteless
- Distinctive sensation to the tongue
  - Mucilaginous and Oily (soft feeling) **e.g** linseed
  - Astringent indicates presence of tannin
  - Pungent (warm biting sensation) **e.g** Ginger
  - Acrid (irritant sensation) **e.g** Aconite, coca
  - Nauseous (tending to excite vomiting) **e.g** Ipecac

C. Colour

- White: **e.g** Starch
- Pale yellow: **e.g** Ginger, quill, White Pepper
- Deep yellow: **e.g** Peeled Liquorice
- Light pale brown: **e.g** Nux-vomica, Fennel
- Dark brown: **e.g** Cloves bud
- Dark reddish brown: **e.g** Cinchona
- Red (brick red): **e.g** Cinnamon bark inner portion
- Pale green: **e.g** Lobelia
- Greenish brown: most of the leaves herb

2.MORPHOLOGICAL EVALUATION

Study of morphology includes visual examination of drug like study of shape & size of various parts of crude drug.

A. Flower

- Floral parts, corollas, anther, Ovary and receptable

B. Leaves and leaflet

- Length, width, apex, margin, venation, the texture of the leaf and the hairs in upper and lower surface
- The feel of the surface described as soft, hairy smooth etc.,

C. Bark

The barks occur in three shapes

- Flat or curved pieces
- Single quill
- Double quills

Barks have two surfaces, an outer and an inner. The inner surface is usually lighter in color, than the outer surface.

D. Roots and Rhizome

A general scheme of examination of subterranean parts includes the size, shape, colour, surface, direction of growth, fracture, transverse surface, fractured surface, odour and taste, food reserves, chemical tests and special features etc.,

E. Fruit

A general method of macroscopical examination of fruit drug includes

- Exocarp
- Mesocarp
- Endocarp
- Seed

3.MICROSCOPICAL EVALUATION

Helps in the study of the presence of adulterants & correct identification of the medicinal plants. Drug is soaked in water if it is not fresh, then fine T.S is taken and stained for study of the arrangement of the cells important staining liquids used are **phloroglucinol** and **HCl** for lignified tissues, **Chlor-zinc iodide** for cellulose tissues, **Ruthenium Red** for gums & mucilage containing cells.

The slides of this test drug are compared with the slides of the authentic crude drugs. This helps in the study of substances like starch, fixed oils, aleurone grains, calcium oxalate, mucilage etc., **e.g.** P-amarous shows wavy walled epidermal parenchyma whereas P-madraspatensis shows straight walled epidermal parenchyma.

A. Palisade Ratio

It represents the average number of palisade cells beneath one epidermal cell, using four continuous epidermal cells for the count.

It is determined from powdered drug with the help of camera lucida

Examples

- Adhatoda vasica:5.5-6.5
- Cassia angustifolia:5.5-10.0

B. Stomata

A minute epidermal opening present on arial parts of plants, stomata consists of central pore, two kidney shaped similar cells(guard cells) and varying number of subsidiary cells.

Epidermal of leaf shows different characteristics **e.g.** Cuticle, stomata, trichome

Types of Stomata- 4 types

- Moss type
- Gymnospermous type
- Gramineous type
- Dicotyledonous → It is having diagnostic significance and classified based on form of arrangement of subsidiary cells.

Dicotyledons types →5 types

1. Paracytic or rubiaceous or parallel stomata: In these stomata two guard cells covered by two subsidiary cells **e.g.** Senna
2. Diacytic or caryophyllaceous or cross celled stomata: In these stomata the guard cells are covered by two subsidiary cells on right angle to that of stomata. **e.g.** Peppermint
3. Anisocytic or cruciferous or unequal celled stomata: In these stomata number of guard cells is two but covered by three subsidiary cells and in that one is small in size with other two **e.g.** Datura
4. Anomocytic or ranunculaceous or irregular celled stomata: In these type stoma is surrounded by varying number of subsidiary cells **e.g.** Digitalis
5. Actinocytic or radiate celled stomata: Two guard cells are surrounded by radiating subsidiary cells.

C. Stomatal number

The average number of stomata present per square per square millimeter of the epidermis is known as stomatal number.

D. Stomatal index

- It is the percentage proportion of the number of stomata to the total number of epidermal cells.
- Stomatal number varies considerably with the age of the leaf but stomatal index is relatively constant for a given species.

Stomatal index calculated by:

$$S.I = S/E+S$$

Where,

S.I →Stomatal index
S→ Number of Stomata per unit area
E→ Number of epidermal cells in the same unit area

E. Vein-islet Number

Vein-islet number is defined as the number of vein-islets per sq.mm of leaf surface.

F. Vein-termination Number

It is defined as the number of veinlet termination per sq.mm of the leaf surface between midrib and margin.

G. Trichomes or plant hairs

- These may be referred to as plant hairs. These are warty outgrowth of epidermal cells. A trichome consists of two parts, root which is based in the epidermal lining and body which is outside the epidermal lining.
- Trichomes are of three types
  - Covering Trichomes
  - Glandular trichomes
  - Hydatodes

They may be unicellular or multicellular

H. Calcium oxalate Crystals

Several cells contents present in vegetable drugs. The inorganic crystalline compound by virtue of their specific shapes can be utilized for the identification of herbal drugs. Due to this reason they are called Diagnostic Characters of Plants

I. Cubical (cube shape) **e.g.** Senna, Glycyrrhiza
II. Rhombic (diamond shape)
III. Tetragonal **e.g.** Onion
IV. Mono Clinic (all three axes are unequal) **e.g.** Gall
V. Acicular (long Slender, pointed, bundles) **e.g.** Squill, Cinnamon
VI. Rosettes Clusters (aggregation of Crystals) **e.g.** Clove, Arjuna
VII. Microsphenoidal (minute in structure) **e.g.** Henbane

I. Quantitative Microscopy:

Lycopodium spore method: It is used especially chemical and other methods of evaluation of drugs fail to determine quality.

Lycopodium spores are much characterized in shape and appearance and uniform in size (25pm) on average, 94000 spores present/mg of Lycopodium powder.

It consist of

- Well defined particles which may be counted.
- Single layered cells or tissues the area of which may be traced under suitable magnification and actual area calculated.
- The objects of uniform thickness, the length of which can be measured and actual area calculated.

4.PHYSICAL EVALUATION

A. Determination of foreign Organic matter

Drugs should be free from moulds, insects, animal, faecal matter and other contamination such as earth stones and extraneous matters. Foreign organic matter should be not more than 2% W/W.

B. Determination of Ash value

- Total Ash

  Total Ash is designed to measure the amount of inorganic impurities present in the crude drug. The drug material is subjected to incineration at a temperature of about 500-600^{0}C to remove all the carbons. Total ash usually consist of carbonates, phosphates, silicates and silica.

- Acid Soluble Ash

  Acid insoluble Ash is the residue obtained after extracting the total ash with HCl. It gives an idea about the earthy matter present in the drug.

- Water Soluble Ash

  The total ash content which is soluble in water is known as water soluble ash. It gives an idea about the presence of water-soluble salts present in the drug.

C. Determination of Extractive value

It gives an idea about the amount of chemical constituents present in the drug. Extractive value are again sub classified based on the nature of constituents present in the drug as water soluble extractive, alcohol soluble extractive and non-volatile ether soluble extractive value.

D. Determination of Moisture content

10gm of drug is taken in an evaporating dish. Then it is dried at 105^{0}C for 3 hours and weighed again. Drying and weighing is continued for an hour interval until difference between two successive weighing corresponds to not more than 0.25 percent. The reading is taken after a constant weight is reached and the moisture content is determined.

E. Refractive Index

When a ray passes from one medium to another of different density, it is bent from original path. Thus,the ratio of velocity of light in vacuum to its velocity in a substance is termed as refractive index of the second medium. Depending upon purity, it is constant for a liquid and can be consider as one of its standardization.

5.CHEMICAL EVALUATION

It consists of Qualitative and Quantitative methods.

A. QUALITATIVE CHEMICAL EVALUATION

Qualitative tests comprise of various chemical tests to identify the nature of compounds present in the crude drugs.

- Test for Alkaloids: Mayer’s test, Dragendroff’s test, Hager’s test, Wagner’s test
- Test for Glycosides and sugars: Borntrager’s test, Molisch’s test, killer killiani test, legal test etc.,
- Test for Phytosterols: Liebermann’s and Burchard tests.
- Test for Tannins and Phenols: Ferric chloride test.

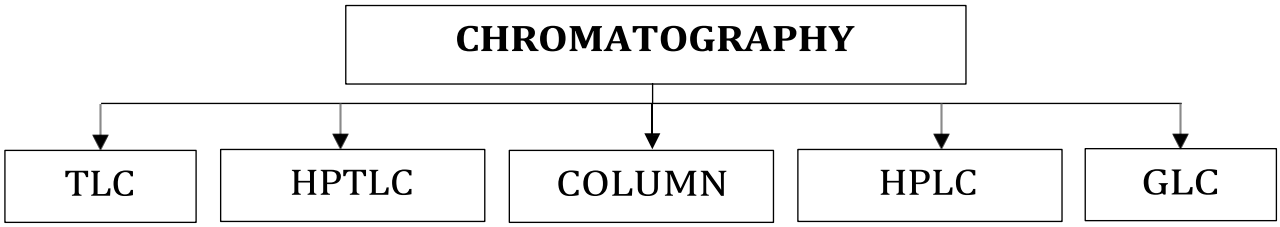
- Test for Proteins and Amino acids: Millen's test, Ninhydrin test, Biurett's test etc.,
- Test for Gums and Mucilage: Swelling Index

B. QUANTITATIVE CHEMICAL EVALUATION

It includes chemical assays and chromatographic methods which are used to quantify the chemical compounds present in the crude drug.

Chromatographic Techniques

The Chromatographic techniques are the new and most common methods used to separate, identify and quantify the plant constituents. It consists of various methods which are as follows



Thin Layer Chromatography (TLC)

TLC technique has become a most important analytical tool for separation and determination of natural products. It is simple, economical and rapid method to analyse plant extracts and carryout the fingerprinting of samples by using the standard or marker compounds.

High Performance Thin Layer Chromatography (HPTLC)

It is one of the very useful methods for the qualitative and quantitative analysis of plant extracts. It is advanced form of TLC with shorter time and precise results.

Column Chromatography

Basically, it is a liquid chromatography in which mobile phase in the form of liquid phases over the stationary phase packed in a column. The column is made of either glass or metal. It is the oldest method and most commonly practiced method for the isolation of pure compounds.

High Performance Liquid Chromatography (HPLC)

It is one of the most versatile, safest, dependable, fastest and sensitive chromatographic techniques for the quality control of drugs. The term liquid chromatography refers to those methods where separation takes place in a packed column which act as stationary phase. A mobile phase is used as eluent. In HPLC, the mobile phase is forced through the column under high pressure.

Gas Liquid Chromatography (GLC): It is the most selective and versatile form of gas chromatography. Commonly it is used in the assay and analysis of starting materials and drug substances, quantification of drug substances in formulations and assay of impurities and solvents in the drug substances.

6.BIOLOGICAL EVALUATION

It consist of following evaluation methods

- Bitterness value
- Haemolytic activity
- Swelling Index

- Foaming Index
- Pesticide Residues
- Heavy Metals
- Micro-organism
- Aflatoxins
- Radioactive Substances

STABILITY TESTING OF HERBAL DRUGS

Stability testing is required to determine the shelf life and assign expiry dates to medicines

Herbal drugs may be single active constituent or entire herb r combination of herbs consisting of mixture of constituents. Most of herbal drug products used are group of constituents.

Stability testing of herbal products is a complicated issue because the entire herbal product is regarded as the active substance, regardless of whether constituents with defined therapeutic activity are known.

Trace metals contamination leaching from the container, etc., and also provides statistics for determination of shelf life.

The stability testing of herbal products includes checking the quality which varies with the time under the influence of environmental factors, such as temperature, humidity, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial contamination.

Therefore evaluation of the parameters based upon chemical, physical, microbiological, therapeutic and toxicological studies can serve as an important tool in stability studies.

PROBLEMS RELATED TO THE HERBAL PRODUCT STABILITY

PHYSICAL INSTABILITY

Natural medicines are usually prone to physical instability due to presence of impurities and reaction with the container. Conditions like growth of the micro-organisms and insect feeding affect the secondary metabolites and chemical composition of plants.

Volatile active components of natural medicine have the problem of volatility and decreasing activity during storage for a long tim

ENVIRONMENTAL CONDITIONS

Environmental conditions such as rainfall, altitude, temperature, soil, storage conditions as well as different harvesting procedures, time and method of collection, manufacturing processes such as selecting, drying, purifying, extracting and genetic variability can create substantial variability in the product quality, stability and in the concentration of plant constituents.

Light is also an important factor affecting phytomedicines by generating free radicals.

CHEMICAL INSTABILITY

Herbal drugs are subjected to degradation during storage by oxidation, hydrolysis, crystallization, emulsion breakdown, enzymatic deterioration and chemical reactions with the additives & excipients. Temperature & Moisture are the two major factors that affect quality & stability of a herbal product.

A chemical reaction increases by 2 to 3 fold for every 10^0C rise in temperature. Moisture absorbed on to the surface of solid drug often increases the rate of decomposition if it is susceptible to hydrolysis. Presence of enzymes in the product also increases the rate of chemical degradation.

COMPLEX MIXTURE VARIABILITY AND INCONSISTENCY

Herbal formulation are complex mixtures of different components obtained during extraction process. Each component has variable shelf life, activity, concentration and consistency

It creates a problem during storage condition determination as it is not easy to determine the stability of final herbal preparation based on the activity and stability profile of a single component.

DRUG INTERACTION DETERIORATION DECOMPOSITION AND STORAGE

Moisture content above the critical value and mould growth in natural products can cause the interactions of the active components with the packaging materials

Also interactions of active components with the other ingredients of formulations used such as additives cause alterations in the novel drug activity.

Stability studies should be performed on at least three production batches of the herbal products for the proposed shelf life, which is normally denoted as long term stability and is performed under natural atmospheric conditions.

With the help of modern analytical techniques like spectrophotometry, HPLC, HPTLC and by employing proper guidelines it is possible to generate a sound stability data of herbal products and predict their shelf life, which will help in improving global acceptability of herbal products.

ROLE OF MARKERS IN DETERMINING THE STABILITY OF HERBAL DRUGS

Markers are chemically known compounds, which may or may not have the therapeutic effect, they are used to calculate the quantity of herbal medicinal ingredients in herbal medicinal products.

It is important to isolate and structurally elucidate chemically defined substances in plants, drug and / or drug preparations so that they can be used as markers that not only help to better understand the active principles of herbal drugs but also can enhance analytical quality control.

ANALYTICAL METHODS TO DETERMINE STABILITY OF HERBAL DRUGS

The analysis of herbal preparations is mostly done by modern chromatographic or spectroscopic methods like HPLC, gas Chromatography (GC), TLC, Quantitative determinations by UV visible spectroscopy or combinations of these.

HPLC and GC methods can be used for identification and purity testing, as well as the detection of single compounds for assay is possible during one analysis. LC and GC mass coupling are also the tools for determinations.

METHODS TO DEAL WITH HERBAL DRUG INSTABILITY

Determination of the Physical Parameter

Depending on type of preparation, sensory properties, physical constants, moisture, ash content, solvent residues & adulteration have to be checked to prove identity and purity microbiological contamination and foreign materials such as heavy metals, pesticides residues, alfatoxins & radioactivity also need to be tested.

To prove the constant composition of herbal preparations, appropriate analytical methods have to be applied and different concepts have to be used in order to establish relevant criteria for uniformity.

Determination of the impurity profile

This technique helps in the identification of impurities that result from degradation of active constituents. The active constituents are subjected to a known degradation process and the degradation products are identified.

Degradation may be due to oxidation, reduction or hydrolysis hence we can have an idea of what could be the degradation products.

These can be listed and kept as a reference library of degradation products. For routinely doing an impurity profile, this library can be referred and the nature and structure of the impurity can be traced.

Since impurities decreases the stability of the natural medicines, it is important to note the type of impurities.

It can be done by the analytical methods as HPLC, TLC, capillary electrophoresis, spectrophotometry, GC, MS etc.,

Identification and quantification of all metabolites

Nonbiased identification and quantification of all metabolites in herbal or other natural products is vital to determine the status and stability of the complex mixtures.

IR spectroscopy in combination with chemometric data processing could provide total metabolic fingerprint profile of phyto formulations.

Controlled storage conditions:

Control measure to protect against deterioration includes the use of airtight container made of materials that will not interact physically or chemically with the material being stored

Storage in ventilated cool, dry area and periodic spraying of the stored area with insecticide will help to prevent the spread of infestation.

Influence of environmental factors such temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form particle size of drug, microbial contamination, trace metal contamination, leaching from the container etc., should be established to recommend proper storage conditions.

PATENTING AND REGULATORY REQUIREMENTS OF NATURAL PRODUCTS

PATENT

An exclusive and absolute right granted to the owner or inventor of an invention to create, utilize produce and market the invention is termed a **Patent**.

Such rights are awarded by the country of a limited time period, presuming that the invention fulfil all the conditions specified in the law.

These rights are said to be 'exclusive' because no other person can create, utilize, produce or market the invention in the absence of proper approval of the patent holder. The right of granting a patent is territorial in nature.

For all the types of products, the validity of patent is 20 years from the date on which the patent application is filed.

IPR

Intellectual property rights refers to the general term for the assignment of property rights through patents, copyrights and trademarks. These property rights allow the holder to exercise a monopoly on the use of the item for a specified period.

Intellectual property protection isn't as simple as declaring ownership of a particular product or asset. In most countries, there are four primary types of intellectual property (IP) that can be legally protected: **patents**, **trademarks**, **copyrights**, and **trade secrets**

The Patent **Act**, 1970 (Patents | **Intellectual Property India**) For protection of Inventions. The Trademark **Act**, 1999 (Trade Marks | **Intellectual Property India**) for protection of a word, phrase, symbol, and/or design that identifies and distinguishes the source of the goods of one party from those of others.

The regulatory authority for patents is the Patent Registrar under the office of the Controller General of Patents, Designs and Trade Marks, which is part of **India's** Ministry of Commerce and Industry. Patents are valid for 20 years from the date of filing an application, subject to an annual renewal fee.

FARMERS RIGHT

Farmers' Rights are critical to ensuring the conservation and sustainable use of plant genetic resources for food and agriculture and consequently for food security – today and in the future.

It gives governments the responsibility for implementing Farmers' Rights, and lists measures that could be taken to protect, promote and realize these rights:

- The protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- The right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;

- The right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture; and
- The right that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

BREEDER'S RIGHT

Plant breeders' rights (**PBR**), also known as **plant variety rights** (**PVR**)

These are rights granted to the breeder of a new variety of plant that give the breeder exclusive control over the propagating material (including seed, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of a new variety for a number of years.

With these rights, the breeder can choose to become the exclusive marketer of the variety, or to license the variety to others. In order to qualify for these exclusive rights, a variety must be new, distinct, uniform and stable.

A variety is:

- new if it has not been commercialized for more than one year in the country of protection;
- distinct if it differs from all other known varieties by one or more important botanical characteristics, such as height, maturity, colour, etc.;
- uniform if the plant characteristics are consistent from plant to plant within the variety;
- stable if the plant characteristics are genetically fixed and therefore remain the same from generation to generation, or after a cycle of reproduction in the case of hybrid varieties.

The breeder must also give the variety an acceptable "denomination", which becomes its generic name and must be used by anyone who markets the variety

BIOPROSPECTING

Bioprospecting is the process of discovery and commercialization of new products based on biological resources. These resources or compounds can be important for and useful in many fields, including pharmaceuticals, agriculture, bioremediation, and nanotechnology, among others.

Bioprospecting can be also defined as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature. It entails the search for economically valuable genetic and biochemical resources from nature.

Bioprospecting has only recently begun to incorporate such knowledge in focusing screening efforts for bioactive compounds.

BIOPIRACY

Biopiracy means the patenting of life

Biopiracy is defined as 'the illegal appropriation of life micro-organism, plants and animals including humans and the traditional knowledge that accompanies it".

Biopiracy is the situation where the indigenous knowledge of nature, originating with indigenous people, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves.

PATENTING ASPECTS OF NATURAL PRODUCTS

Patentable Natural Products

The following are the list of natural products which can be patentable

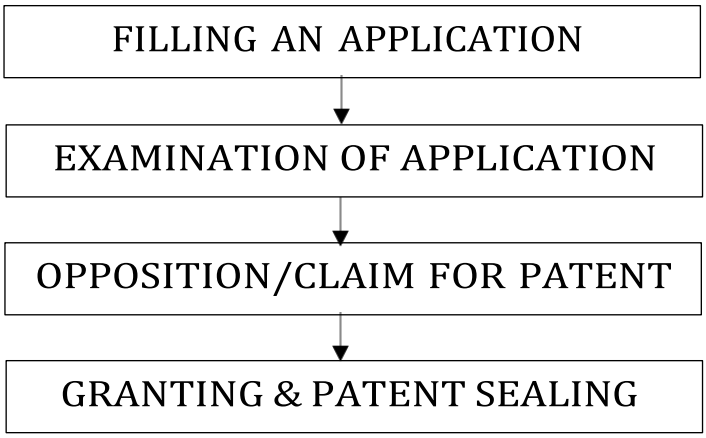
1. Novel isolation process of natural products from its surroundings. Example an Indian patent for process of isolation of azadirachtin from the seeds of neem plant.
2. Characterization of new product either by its structure or by other physical parameters.
3. A new application of isolated product provided unless such knowledge or invention do not exist anywhere. Example a Japanese patent for the use of turmeric as a stabilizer for an anti-fungal agent.
4. Invention and Novelties. For Example products like biopesticides.
5. Patenting in relation to biotechnology.
6. Patenting for Biological matter. For Example micro organism like *E.coli* in which human genes are introduced for the production of human insulin, HGH, Human Tissue, plasminogen activators are patented. Patentable microbial inventions include the following.
    - Processed products
    - Methods for producing new organism
    - Reducing pathogenicity
    - Increasing biological activity.
    - Invention of new organism and their composition.
7. Transgenic plants: plants can be altered genetically to obtain transgenic plants of desired characters. Example herbicide resistant cotton plant, insecticidal resistant tobacco plant. Such techniques are patentable.
8. Patenting of secondary metabolites by cell culture which include sophisticated and specific methods can be patented. Example production of taxol by cell culturing of taxus species.

Non-Patentable Natural Products

1. Plants grown in wild
2. Plants adopted for cultivation.
3. Hybrids or other cultural varieties which have been tried for particular use.

PROCEDURE FOR OBTAINING PATENT

It involves the following steps



a) Filling an application for patent

A patent application can be made on prescribed application form. This can be obtained from patent office, the applicant have to furnish the following information.

- Title, name, address and nationality of inventor.
- Specification: Giving the details of invention.
- Claims: Definition and Scope of invention.

b) Examination of application

Patent office examines patent applications with respect to usefulness, nature of claim and weather the patent has been filed earlier.

c) Opposition/claim for patent

A three month time is given for any application before granting and sealing of the patent.

d) Granting & patent sealing

Incase of no opposition or clearly satisfaction of all the objections by the applicant, the pantent is granted by the patent office and published in the official gazette. A patent can be kept alive by paying an annual fee within date which increases the age of the patent. It can be renewed after its expiry.

Advantage of Patenting

- A patent gives the right to stop others from copying, manufacturing, selling or importing the invention without the permission of inventor.
- A protection is provided for a predetermined period keeping the competitors at bay.
- The inventor has the authority to license his invention to others to use or sell it.

CASE STUDY OF NEEM

- the neem tree *Azadirachta indica* is a tropical evergreen tree native to India and is also found in other south east countries.
- The seeds, bark and leaves contain compounds with proven antiseptic, antiviral, antipyretic, anti-inflammatory, anti-ulcer and anti-fungal properties.
- In 1971, US timber importer “Robert Harson” observed that the trees usefulness in India and began importing neem seeds to his company head-quarters.

- He conducted safety and performance test of neem.
- Three years later he sold his invention to the US Department of agricultural and Multinational chemical corporation WR Grace and co.
- In 1992 the WR Grace and co secured its right to the formula that used the emulsion from the neem trees, seeds to make a powerful fungicide.
- In applying for the patient, the company had argued that it had used an extract of the trees, seed to make a new fungicide but the Indians claim that its patent was not sufficiently novel as Indian farmers have used this fungicide for decade.
- The Indians and members of the green party in the European union opposed the patent because they believed that the rights of the poor farmers in developing countries will be harmed.
- The neem patent became the first to challenge European and US patents on grounds of biopiracy.
- The Indian scientists argued that the Indians have known the medicinal properties of neem long back.
- The European Patent Office EPO accepted the arguments offered by Indian scientists and rejected the order of the US patent office to award the patent to WR Grace and co.
- The victory is a result of four year long effort by the research foundations for science technology and environment.

CASE STUDY OF CURCUMA

- Turmeric is a tropical herb grown in east India. Turmeric powder has a deep distinct color and bitter taste.
- It is used as dye, cooking, ingredient, litmus in chemical tests and for medicinal purposes.
- A United States patent on turmeric was awarded to the university of Mississippi medical centre in may 1995, specifically for the use of turmeric in wound healing.
- Two years later, a complaint was filed by India's Council of Scientific and Industrial Research (CSIR).
- CSIR argued that turmeric has been used in India for thousands of years for healing wounds and rashes and therefore the patent on its medical use was not a novel invention.
- The CSIR claim was supported by documentary evidence of traditional knowledge including ancient Sanskrit text and paper published in 1953 in the journals of Indian Medical Association.
- United states patent and trade mark office (USPTO) investigated the validity of the patent.
- In 1997 despite an appeal made by the patent holders, the USPTO upheld the CSIR objection and cancelled the patent due to lack of novelty

REGULATORY ISSUES

HERBAL DRUG REGULATIONS IN INDIA

Provisions relating to the manufacture and control of Ayurvedic, Siddha and Unani (ASU) drugs have been prescribed in the Drugs and Cosmetics act.

This acts describes the formation of Drugs Technical Advisory Board (DTAB), Which consists of various nominated members and the Drugs Consultative Committees (DCC).

The Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASU-DTAB)

The central government shall constitute a board by notifying in the official gazette. The board shall advice the central as well as state governments on technical matters arising out of the section 33-C of the Drugs and Cosmetics act and carry other functions assigned.

A) Constitution of the board

The board shall consist of the following members.

1. The Director general of Health services, Ex officio
2. The Drugs controller, Ex officio
3. The Director of Central Drugs laboratory, Calcutta, Ex officio
4. One Government analyst nominated by the central board.
5. One Pharmacognocist nominated by the Central Government.
6. One Phytochemist nominated by the Central Government.
7. Four persons nominated by the central Government, among which two from the members of Ayurvedic pharmacopeia committee and one each from Unani and Siddha pharmacopeia committee.
8. One teacher in Dravyaguna and Bhaishajya Kalpana to be nominated by the Central Government.
9. One teacher from Ilmul-Advia and taklis-wa-Dawasai to be nominated by the Central Government.
10. One teacher in Gunapadam to be nominated by the Central Government.
11. Three persons, one each represent the Ayurvedic, Siddha and Unani drug industry to be nominated by the Central Government.
12. Three persons, one each from amogst the practitioner of Ayurvedic, Siddha and Unani, Tibb systems of medicine to be nominated by the Central Government.

B) Functioning of the board

- The Central Government shall appoint a chairman from amongst its members
- The nominated members of the board shall hold office for three years but shall be eligible for renomination.
- The board may make bye laws to regulate its functioning and conduct of all activities.
- The central government shall appoint a secretary of the board and shall provide the board with such clerical and other staff.

The Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASU-DCC)

The Central Government may constitute an advisory committee as mentioned in the section 33-D of the Drugs and Cosmetics Act. This committee may advise the central and state governments and the Ayurvedic, Siddha and Unani drugs technical advisory board (ASU-DTAB) on any matter for the purpose of securing uniformity in the administration of this act (section 33-D) throughout India.

Constitution and Functioning of ASU-DCC

- The ASU-DCC shall consist of two persons nominated by central government and one person from the state government eho act as representative of the respective governments.
- The ASU-DCC shall meet when required to do so by the central government and shall regulate its own activities as per their requirements.

REGULATIONS FOR THE MANUFACTURE OF AYURVEDIC, SIDDHA AND UNANI (ASU) DRUGS

The section 33-EEB of the Drugs and Cosmetics act describes the regulation for the manufacture and sale of ASU drugs. The Act has set some standards related to the hygienic conditions, factory premises, prohibition of manufacture and sale of certain drugs and penalties for contravention of this act. The following requirements are taken into account.

A. Requirements of factory premises and hygiene Conditions

As per the act, it is mandatory to maintain proper hygienic conditions in the factory premises along with the following requirements.

- Factory or industry involved in the manufacture of ASU drugs should not be situated adjacent to open sewage, drain, public lavatory or any other factory which produces obnoxious odour, large quantities of waste, dust or smokw
- The premises of manufacturing unit shall be clean, hygienic and free from insects, rodents and other contamination.

Note: All the sections fall under the Schedule Z of the Drugs & Cosmetics Act

- The walls and floor of manufacturing rooms should be smooth, easily cleanable with water and should not accumulate dust or waste products
- The water used in the manufacture shall be pure and drining quality. It should be free from pathogenic organisms. Adequate facility should be provided to processes the containers and closures for washing, cleaning, drying, etc., and it should be separated from the manufacturing unit.
- Suitable arrangements shall be provided for disposing waste water and other materials in a manner that it does not affect the health of people in the surrounding area.
- Personnel working in the factory should be free from contagious diseases.

- Appropriate dress should be provided to the workers based on the nature of their work.
- Adequate facilities for personal cleanliness such as soap, towel, and antiseptics should be provided.
- Facilities for drinking water and separate wash rooms should be provided for men and women

B. Prohibition of manufacture and sale of certain ASU drugs

The act prescribes some criteria to prohibit the manufacture and sale of certain ASU drugs which are not manufactured or sold in accordance of the rules.

The following categories of ASU drugs can be prohibited from manufacture and sale.

- Any misbranded, adulterated or spurious ASU drugs.
- Any proprietary or patented medicine which does not display the list of all ingredients on the label of the container.
- The selling, stocking and distribution of any ASU drug which has been manufactured in contravention of the provision of this act.
- The manufacture, sale and distribution of any ASU drugs for which license has not been issued by the prescribed authority.

The above rules do not apply to Vaidyas and Hakims who prepared ASU drugs for the use of their own patients.

The above rules do not apply to ASU drugs which are manufactured in small quantities for the purpose of examination, test or analysis.

C. Power of central Government to prohibit the Manufacture, sale & distribution of ASU drugs in public interest

- The Section 33-EED of the Drugs and Cosmetics act prescribes certain powers of the central Government based on which the government can prohibit the manufacture, sale and distribution of ASU drugs which involve any risk to humans or animals or such drug does not have therapeutic value as claimed by the manufacturer or any misbranded and spurious drugs.
- Hence in such circumstance, the government may prohibit the manufacture, sale & distribution of drugs in public interest.

D. Penalty for the manufacture, sale and distribution of prohibited ASU drugs

As prescribed under the section 33-1 of the Drugs and Cosmetics act, any person himself on his behalf is engaged in the manufacture, sale and distribution of prohibited ASU drugs, penalty has been fixed as per the following guidelines

1. Any ASU drug which is deemed to be adulterated or manufactured without a valid license shall be punishable up to one-year imprisonment and with fine up to 2000 rupees.
2. Any ASU drug which is deemed to be spurious shall be punishable with imprisonment up to 1-3 years and with fine up to 5000 rupees.
3. Any ASU drug which contravenes any other provision of the act shall be punishable with imprisonment up to 3 months and with fine up to 500 rupees.

E. Manufacture on more than one set of premises

It ASU drugs are manufactured on more than one set of premises, a separate application shall be made and a separate license shall be obtained for each premises.

GENERAL INTRODUCTION TO HERBAL INDUSTRY

PRESENT SCOPE OF HERBAL DRUG INDUSTRY:

- Herbs have been known since the era of civilization and are highly esteemed all over the world as a rich source of medicinal agent.
- The popularity of natural products is increasing day by day due to the fact that they are comparatively safe, less toxic, less side effects, easily available and affordable prices when compared to synthetic drugs
- The herbal drug industry is a very fast growing sector in the international market. In India, various system of medicine like Ayurveda, Siddha, Unani, Homeopathy, Yoga, & Naturopathy are being utilized for the health care of people

SCOPE OF HERBAL DRUG MEDICINE AND INDUSTRY:

Indian Herbal Market:

- Herbal drugs constitute a major share of all the officially recognized system of health in India viz. like Ayurveda, Siddha, Unani, Homeopathy, Yoga, & Naturopathy, expect Allopathy
- More than 70% of India's 1.1 billion populations still use these non-allopathic systems of medicine. Currently, there is no separate category of herbal drugs or dietary supplements, as per the Indian Drugs Act.
- In India, raw drugs obtained from around 2,400 plant species. It is the fastest growing market & may attain to 14,500 crore & export to 9000 crore with a CAGR (Compound Annual Growth Rate) of 20% to 25% respectively, according to associated chambers of Commerce & Industry of India (Assocham)
- The "Herbal Industry Biz" has revealed that currently, the Indian herbal market size is estimated at 7000 crores & over 3600 crores of herbal raw materials & medicine are exported by India.
- In India, there are about 8000 medicinal plants are used. Out of which 25 manufacturers are large scale manufacturers. The annual turnover in India was around US $ 300 million for Ayurvedic & US $ 27.7 million for Unani

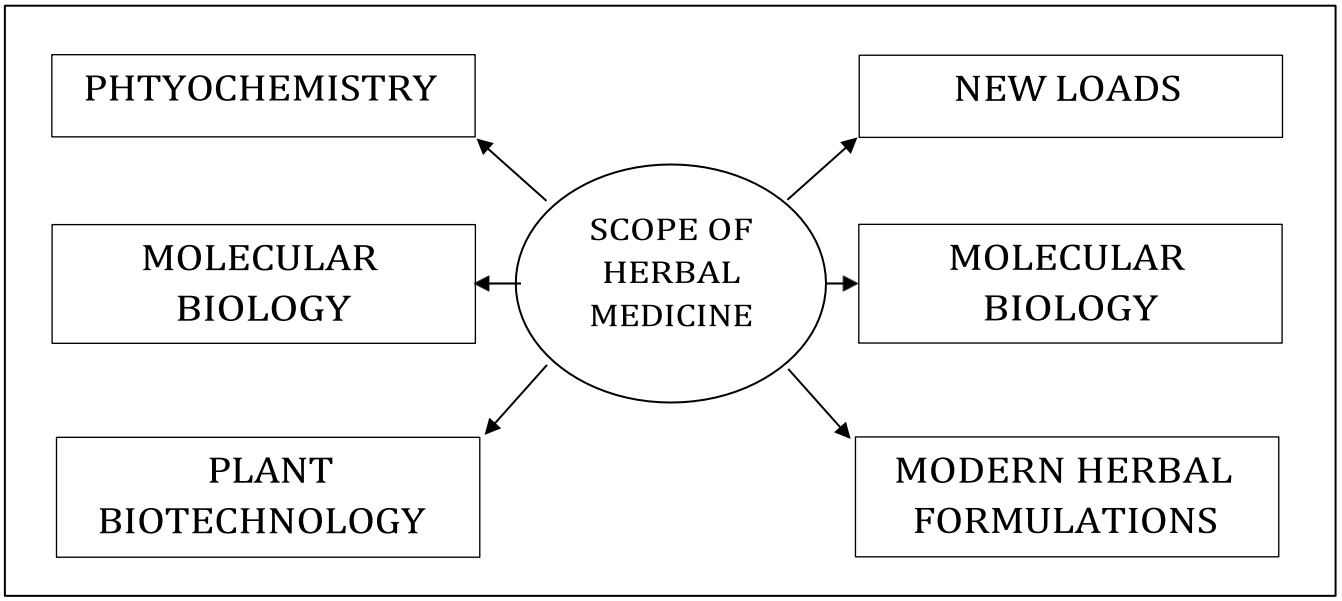
INTERNATIONAL SCOPE OF HERBAL MEDICINES:

According to the World Health Organization (WHO), approximately 25 per cent of modern drugs used in the United States have been derived from plants

- More than 120 active compounds isolated from higher plants are widely used in modern allopathic medicines today and 80% of them show a positive co-relation between their modern therapeutic use and the traditional use of the plants from which they are derived
- At least 7000 medicinal compounds derived plants, the ingredients of herbal medicine, are included in the modern pharmacopeia of drugs

- WHO estimates that 80 per cent of the world's population currently use herbal medicines for some aspects of primary health care
- They are also highly lucrative in the international market, generating billions of dollars in revenue.
- To cite few examples, annual revenue from herbal medicines and herbal products in Western Europe reached US $ 5 billion in 2003-2004 In china, sales of herbal products totaled US $ 14 billion in 2005
- Herbal medicine revenue in Brazil was USS 160 million in 2007

FUTURE PROSPECTS OF HERBAL MEDICINE/INDUSTRY:



- Herbal medicine based Traditional Medical system of treatment is a rapidly growing healthcare system of economic importance and is now widely used in many countries of the world. The following leads and development are the future prospects in the herbal drug industry
- Plant products can also be useful as starting material for the semi synthetic preparation of other drugs. Examples: Plant steroids (Diosgenin): Oral contraceptives, hormones. Microorganisms (Streptomyces genus): Antibiotics (Streptomycin, neomycin, tetracycline, chloramphenicol)
- The interest in natural products as a source of new biologically active compounds has expanded due to increasing research and development in phytochemistry

SOURCE OF DATA: As Per Association Chamber of Commerce & Industry (ASSOCHAM)

- It has been estimated that 56% of the lead compounds for medicine in British National Formulary are natural products or are derived from them
- With the development in the techniques of molecular biology, there has been an increase of interest in the use of naturally occurring proteins as potential therapeutic agents.

- Several genetically engineered natural products have had a significant impact and more than 20 biotechnology derived products are now in the market

  Example: tissue plasminogen activator is used as a thrombolytic after myocardial infractions Erythropoietin is used to treat anaemia associated with renal failure
- Several colony stimulating factors are used for cancer treatment

Natural products will continue to be important in the following three areas drug discovery

- As target for production by biotechnology
- As a source of new lead compounds of novel chemical structure
- As the active ingredients for useful treatments derived from traditional system of medicine

In the face of the increasing use and fast growing market of herbal medicines and other herbal healthcare products, in both developing and developed countries of the world, policy-makers, health professionals and the public are increasingly expressing concerns about the safety, efficacy, quality, availability, preservation, and further development problem of these herbal products. Public demand has also grown for evidence on the safety, efficacy and quality of the herbal products and traditional medicine (TM) and complimentary alternative medicine (CAM) practices

However, in order to ensure quality and safety of herbal medicines, their production, sale and use should be officially and legally controlled by established rules and regulations so that herbal medicinal can be used safety for medical and therapeutic purposes and efforts should be made to raise public awareness about the risks and benefits of using herbal medicines.

Overview on Plant Based Industries and Research Institutions in India

List of research institutions and centers in India

- Government of India also has expressed support and encouragement for the Traditional Indian Medicine (TIM).
- A Separate department for Indian System of Medicine and Homeopathy now known as AYUSH (Ayurveda, Yoga, Unani, Siddha, Homeopathy) was established in March 1995 to promote indigenous systems.
- Priority includes education standardization of drugs, enhancement of availability of raw materials, research and development, information, communication and larger involvement in the national system of delivering heath care
- In the year 1969, the Indian government established a central council for research in Indian medicine and Homeopathy (CCRIMH) to develop scientific research in different systems of medicine.

- As the research in herbal products expanded various government and private research centers developed which are actively engaged in the research and development of herbal medicines

The following are the list of few research institutions engaged in research in medicinal and aromatic plants in India

Herbal research institutions/ Centers in India

Name of Institute	City
CCRAS (Central Council for Research in Ayurvedic and Siddha)	New Delhi
RRL (Regional Research Laboratory) (CSIR)	Jammu-Tawi
NBRI (National Botanical Research Institute)(CSIR)	Lucknow
Gujarat Ayurveda University	Jamnagar
Bhavan's SPARC	Mumbai
National Institute of Ayurveda	Jaipur
Arya Vaidya Shala	Kottakal
Interdisciplinary School of Health Sciences	Pune
Banaras Hindu University	Vanarasi
CIMAP (Central Institute for Medicinal and Aromatic Plants)	Lucknow
ICMR (Indian Council for Medical Research)	New Delhi
National Medicinal Plants Board	New Delhi
Regional Medical Research Centre (ICMR)	Belgaum
PERD Centre (Pharmaceutical Education and Research Development)	Ahmedabad
CCRUM (Central Council of Research in Unani Medicine)	New Delhi
NISCOM (National Institute of Science Communication)	New Delhi
IMPCOPS (Indian Medical Practitoners Co-operative Pharmacy & stores Ltd.)	Chennai
IHMMR (Indian Institute of History of Medicine and Medical Research)	New Delhi
Zandu Foundation	Mumbai
CDRI (Central Drug Research Institute) (CSIR)	Lucknow
IMPLANT Centre (Inter-University Medicinal Plant Laboratory for Analysis, Nurture and Therapeutics)	Rajkot

LIST OF FEW HERBAL DRUG INDUSTRIES IN INDIA

NAME	CITY
Ansar Drugs Laboratories	Surat (Gujarat)
Acis Laboratories	Kanpur (UP)
Allen Laboratories Pvt. Ltd.	Kolkata
Basic Ayurveda	Ghaziabad
Dabur India Ltd.	Ghaziabad
Herbals (APS) Pvt. Ltd.	Patna
Herbo-Med (Pvt. Ltd.)	Kolkata
The Himalaya Drug Co.	Mumbai
Shipachem	Indore
Hamdard (Wakf) Laboratories	Delhi
Zandu Pharmaceutical works Ltd.	Mumbai
Shhri Baidyanath Ayurved Bhavan	Patna
Charak Pharmaceuticals	Mumbai
Biocon India Pvt. Ltd.	Bengaluru
Cipla Research Centre & Factory	Bengaluru
Government Quinine Factory	Mungpoo
Vicco Laboratories	Nagpur
Nagarjuna Herbal Concentrates	Kerala
Shree Dhootapapeshwar Ltd.	Mumbai
Sandu Pharmaceuticals Ltd.	Goa
Patanjali Ayurved	Uttarkhand
Sri Sri Ayurveda	Bengalore

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SCHEDULE T – GOOD MANUFACTURING PRACTICE OF INDIAN SYSTEMS OF MEDICINE

COMPONENTS OF GMP (SCHEDULE - T) AND IT'S OBJECTIVES:

GMP:

- Good Manufacturing Practice (GMP) is a production and testing practice that helps to ensure a quality product.
- GMP guidelines are not prescriptive instructions on how to manufacture products.
- These are a series of general principles that must be observed during manufacturing.
- When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements.
- It is the company's responsibility to determine the most effective and efficient quality process.

OBJECTIVES:

The Good Manufacturing Practices for ASU Drugs as described in Rule 157 of Drugs & Cosmetics Rules1945 with conditions as specified in Schedule T/GMP are to ensure that:

- Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination
- The manufacturing process is as has been prescribed to maintain the standards
- Adequate quality control measures are adopted
- The manufactured drug which is released for sale is of acceptable quality
- To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection.
- However, under IMCC Act, 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of Good manufacturing Practice (GMP)

BASIC PRINCIPLES OF GMP:

Many countries have created their own GMP guidelines & procedure. These GMP guidelines remain more or less similar to the ultimate goals of safeguarding the health of the patient as well as producing good quality medicine.

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language.

- Operators are trained to carry out and document procedures.
- Records are made manually or by instruments during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- A system is available for recalling any batch of drug from sale or supply.
- Complaints about marketed drugs are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective drugs and to prevent recurrence.

SCHEDULE T:

Requirements (GMP) of factory premises for Ayurvedic, Siddha, Unai drugs

For getting a certificate of "Good Manufacturing Practices" of Ayurveda, Siddha-Unani drugs, the applicant shall made application on plain paper, providing the information on existing infrastructure of manufacturing unit, and the licensing authority shall after verification of the requirement as per Schedule "T" issue the certificate within a period of 3 months in form of 26-E

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

COMPONENTS OF GMP:

GMP schedule for ISM manufacturing units is quite elaborate and broadly covers each and every component of manufacturing process. Different components of GMP are given below in order of appearance in Schedule – T.

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II.

PART-I

Factory Premises:

The manufacturing plant should have adequate space for:

- Receiving and storing raw material
- Manufacturing process areas
- Quality control section
- Finished goods store
- Office
- Rejected goods/drugs store.

GENERAL REQUIREMENTS:

Factory Premises:

I. Location and surroundings
II. Buildings
III. Water Supply
IV. Disposal of Waste
V. Containers Cleaning
VI. Stores (Raw materials, packing materials, Finished goods stores)
VII. Working Space
VIII. Health, Clothing, Sanitation and Hygiene of Workers
IX. Medical Services
X. Machinery and Equipment
XI. Batch Manufacturing Records
XII. Distribution records
XIII. Record of Market Complaints
XIV. Quality control

REQUIREMENTS FOR STERILE PRODUCT:

A. Manufacturing area
B. Precautions against contaminations and mix

FACTORY PREMISES:

Location and surroundings:

Location and surroundings of the pharmacy should be situated where there is:

- No open sewage
- No drainage coming from public areas & pubic lavatory
- No factory fume
- No excessive soot and smoke and dust

Buildings:

- Hygienic condition is needed.

- No cobwebs/insects/rodents.
- Adequate light & ventilation.
- No dampness or Moisture on floor and walls.
- Wall & floors should be even.
- Premises used for manufacturing, processing, packaging and labeling should be in conformity with the provisions of Factory Act.
- Compatible with manufacturing Operations.

- Logical placement of equipment to avoid risk of mixing, cross contamination and risk of omission of a control step. Designed, constructed and maintained well to prevent entry of insects/rodents.
- Interior surface should be smooth, easy for cleaning and disinfection.
- Mooring should be smooth and even so as not to permit retention or accumulation of dust or waste products.

Water Supply:

The water used in manufacturing should be pure and of potable quality. Adequate supply of water is required for washing the premises and containers.

Disposal of Waste:

In the manufacturing section and laboratories the waste water and residues which might the prejudicial to the work as well as public health shall be disposed of after suitable treatment as per guideline of pollution control to be followed.

Containers Cleaning:

In factories where operation involving the use of containers such as glass bottles, vials and jars are conducted. Adequate arrangement for washing, cleaning & drying of containers.

Stores:

It should provide adequate space for stores of different type of material such as raw material, packing material and finished products. Store should have proper ventilation and should be free from dampness

Raw Materials:

- Raw material store should have appropriate containers which would protect the quality of raw materials and prevent from contamination or rodents and Insect infestation.
- Suitable cabins for raw material of
    - Mineral origin
    - Metallic origin
    - Animal origin
    - Fresh herbs
    - Dry herbs or plant parts
    - Excipients, Volatile oils/perfumes and Flavors
    - Plants extracts, Exudates/Resins etc.
- Each container used for raw material storage should be properly identified with the label which indicates name of the raw material, source of supply and will also clearly state the status of raw material such as UNDER TEST or APPROVED or REJECTED.
- Label of raw material should clearly indicate Batch No or Lot No, and date at receipt of the consignment.

- All raw materials shall be sampled and got tested either by the in-house quality control technical person or by laboratories approved by the Government and should be used only on approval after verifying.
- Records of the receipt, testing and approval or rejection should be maintained.

Packing Materials: All packing materials such as bottles, Jars, capsules etc. should be stored properly. All Container and Closure lids should be properly cleaned and Dried before packing the products.

Finished Goods Stores:

- The finished goods transferred from the production area after proper packaging should be stored in proper shelves within an area marked **Quarantine**.
- After the quality control laboratory: and the experts have checked the correctness of finished goods with reference to its packing/labeling as well as the finished product quality described, then it will be Moved to **Approved Finished Goods Stock** area.
- Only approved finished goods should be dispatched as per marketing requirements. Distribution records should be maintained as required. Specific storage conditions should be provided for special drugs.

Working Space:

- The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of the operations.
- Facilities for easy and safe working, facilities to minimize or eliminate mixing up of the drugs should be provided. To prevent cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

Health, Clothing, Sanitation and Hygiene of Workers:

- Workers should be free from contagious diseases.
- Workers should use proper uniform suitable to work.
- Hands should be covered with cloth or synthetic covering.
- Personal cleanliness, clean towel, soap, scrubbing brushes, separate lavatories for men and women and facility for changing of clothes and cupboards to keep clothes/belongings should be maintained.

Medical Services:

- Annual medical check-up of all employees should be done to ensure freedom from Infectious diseases.
- First-Aid facility should be available.
- Health record of all the employees should be maintained

Machinery and Equipment:

- Equipment should be according to the size of operation, nature of product manufactured.
- Suitable Machinery manually operated; semi- automatic or automatic should be available in the manufacturing unit.
- These may include machines for use in the process of manufacture such as crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labeling and packing etc.
- To ensure ease in movement of workers and orderliness in operations a suitably adequate space will be ensured between two machines or rows of machines.
- These Equipment have to be properly installed and maintained with proper cleaning.
- Proper standard operational procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

Batch Manufacturing Records:

- Ayurvedic, Siddha, Unani drug manufacturer should maintain batch manufacturing record of every manufacturing.
- List of raw materials used, Quantity obtained from the store, tests conducted during the various stages of manufacture like taste, color, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurvedic, Siddha and Unnai.
- These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product.
- Details of transfer of manufactured drug to the finished product store along with record of the finished product, packaging etc. should be maintained.
- All manufacturing records should be duly signed by Production and Quality Control Personnel respectively.
- It should be essential to maintain the record of date, manpower, machine, equipment used along with in process record of various shodhana (purificatory procedures of poisonous drugs), Bhavana (trituration) in terms of internal use.

Distribution Records:

Records of sale and distribution of each batch of Ayurveda, Siddha and Unani Drugs should be maintained in order to facilitate prompt and complete recall of the batch, if necessary.

Record of Market Complaints:

- Manufacturers should maintain a register to record of the complaints as well as corrective action initiated to prevent recurrence regarding the products.

- Once in a period of six months, the complaint records have to be sent to the licensing authority.
- Register should be available for inspection during any inspection of the premises.
- Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha, Unani drugs should be maintained in separate register.

Quality Control:

- Every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory.
- The test shall be as per the Ayurveda, Siddha and Unani pharmacopoeia standard.
- There should be 150 sq. feet area for quality control section.
- For identification of raw drugs, reference books and reference samples should be maintained. Manufacturing record should be maintained for the various processes. To verify the finished products, controlled samples of finished products of each batch will be kept for 3 years.
- To supervise and monitor adequacy of conditions under which raw materials, semi-finished products and finished products are stored.
- Keep record in establishing shelf life and storage requirements for the drugs.
- Manufacturers who are manufacturing patent proprietary Ayuveda, Siddha, and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.
- The record of specific method and procedure of preparation, that is, Bhavana, Mardana and Puta (earthen pits) and the record of every process carried out by the manufacturer shall be maintained.
- The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurveda, Siddha and Unani systems of medicines published by Government of India shall be complied with.
- All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.
- Quality control section will have a minimum at one person with Degree qualification in Ayurveda/Siddha/Unani (A.S.U.) as per Schedule II of Indian Medicine Central Council Act, 1970 (84 of 1970) of a recognized university or Board.
- Provided that Bachelor of Pharmacy, Pharmacognosy and Chemistry may be associated with the quality control section.

REQUIREMENT OF STERILE PRODUCT

Manufacturing Areas:

Manufacturing area for the production of sterile of Ayurvedic, Siddha, Unani product, separate enclosed area should be provided. This area should be aseptic, dust-free, moisture less and should have bacteria free air supply

Precautions against contamination and mix:

a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building,

(b) Using appropriate pressure differential in the process area.

(c) Providing a suitable exhaust system.

(d) Designing laminar flow sterile air system for sterile products.

(e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.

(f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.

(g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature, relative humidity, volume filled, leakage and clarity shall be checked and recorded

PART – II

A. List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of ayurvedic, siddha system of medicines

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing areas like powdering, furnace, packing of liquids and Avaleha, Paks, could also be shared for these items.

S. NO	CATEGORY OF MEDICINE	MINIMUM MANUFACTURING SPACE REQUIRED	MACHINERY/ EQUIPMENT RECOMMENDED
1200 Square feet covered area with separate cabins or partitions for each activity. If Unani medicines are manufactured in same premises an additional area of 400 sq. feet will be required.			
1	Anjana/Pisti	100 sq. feet	Kharal/mechanized/motorizedKharal, End runner/Ball–mill,Sieves/Shifter.
2	Churna/Nasya/Manjan/Lepa/Kwath Chur	200 sq. feet	Grinder/Disintegrator/Pulveriser/Powdermixer/Sieves/Shifter.
3	Pills/Vati/ Gutika Matirai and tablets	100 sq. feet	Ball Mill, Mass mixer/powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, stainless steel trays / container for storage and sugar coating, polishing pan in case of sugar-coated tablets, mechanized chattoo (for mixing guggulu) where required
4	Kupi pakava / Ksara/ Parpati/ Lavana Bhasma Satva/Sindura Karpu/ Uppu/ Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/ Patila, Flask, Multani Matti/Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Mufflefurnace(Electrically operated), End/Edge Runner, Exhaust Fan, Wooden/ S.S.Spatula.

5	Kajal	100 sq. feet	Earthen lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, S.S.Patila, Filling/ packing and manufacturing room should be provided with exhaust fan and ultra violet lamps
6	Capsules	100 sq. feet	Air Conditioner, De-humidifier, hygrometer, thermometer, Capsule filling machine and balance.
7	Ointment /Marham Pasai	100 sq. feet	Tube filling machine, Crimping Machine, Ointment Mixer, End Runner/ Mill (Where required), S.S. Storage Container S.S.Patila.
8	Pak/Avaleh /Khand/ Modak/Lakaya	100 sq, feet	Bhatti section fitted with exhaust fan and should be fly proof, Iron Kadahi/S.S. Patila and S.S. Storage container
9	Panak, Syrup / Pravahi Kwath Manapaku	150 sq, feet	Tincture press, exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, filter press/Gravity filter, liquid filling machine, P.P.Capping Machine
10	Asava/Arishta	200 sq. ft.	Same as mentioned above. Fermentation tanks, containers and distillation plant where necessary, Filter Press.
11	Sura	100 sq. ft.	Same as mentioned above plus Distillation plant and Transfer pump
12	Ark Tinir	100 sq. ft.	Maceration tank, Distillation plant, Liquid filling tank with tap /Gravity filter/Filter press, Visual inspection box.
13	Tail / Ghrit Ney	100 sq. ft.	Bhatti, Kadahi/S.S. Patila, S.S.Storage containers, Filtration equipment, filling tank with tap/Liquid filling machine
14	Aschyotan / Netra Malham Panir/Karn Bindu/Nasa- bindu	100 sq. ft.	Hot air oven electrically heated with thermostatic control, kettle gas or electrically heated with suitable mixing arrangements, collation mill, or ointment mill, tube filling

B. List of machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of unani system of medicines

One machine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. similarly some of the manufacturing areas like powdering, furnace, packing of liquids could also be shared for these items.

S. No	CATEGORY OF MEDICINE	Minimum manufacturing space required	Machinery/equipment recommended
1200 square feet covered area with separate cabins, partitions for each activity. If Ayurveda/Siddha Medicines are also manufactured in same premises an additional area of 400 square feet will be required.			
1	Itrifal Tirya/majoon/ Laooq/Jawarish Khamiras	100 sq. feet	Grinder/Pulveriser, Sieves, powder mixer (if required), S.S. Patilas, Bhatti and other accessories, plant mixer for Khamiras.
2	Arq.	100 sq. feet	Distillation Plant (garembic), S.S. storage tank, Boiling Vessel, Gravity filter, Bottle filling machine, Bottle washing machine, Bottle drier.
3	Habb (Pills) and tablets.	100 sq. feet	Ball Mill, Mass Mixer/Powder mixer, Granulator drier, tablet compressing machine, pill/vati cutting machine, stainless steel trays/ container for storage and sugar coating, polishing
4	Sufoof (Powder)	200 sq. feet	Grinder /pulveriser, Sieves, Trays, Scoops, Powder mixer (where required).

5	Raughan (oils) (Crushing and boiling)	100 sq. feet	Oil Expeller, S.S. Patilas, Oil filter bottle, Filling machine, Bottle drier, Bhatti
6	Shiyaf, Surma, Kajal	100 sq. feet	End runner, mixing S.S. Vessel.
7	Marham, Zimad (Ointment)	100 sq. feet	Kharal, Bhatti, End runner, Grinder, Pulveriser, Triple Roller Mill (if required).
8	Qurs (Tab.)	100 sq. feet	Grinder/Pulveriser, Sieves, Powder mixer (where needed), Granulator, Drier, Tablet Compressing Machine, Die punches Trays, O.T. Apparatus, Balance with weights, Scoops, Sugar Coating Pan, polishing pan, Heater
9	Kushta	100 sq. feet	Bhatti, Kharal, Sil Batta, Earthen pots.
10	Murabba	100 sq. feet	Aluminium Vessels 50-100 kgs. Capacity, Gendna, Bhatti
11	Capsule	100 sq. feet	Pulveriser, Powder mixer (where needed), capsule filling machine, Air conditioner, De-humidifier, Balance with weights, storage containers, glass
12	Sharbat and Joshanda	100 sq. feet	Tinctum Press, exhaust fan fitted, Bhatti section, Bottle washing machine, Filter Press Gravity filter, Liquid filling tank with tap/liquid filling machine, hot air oven electrically heated with thermostatic control, kettle
13	Qutoor-e-Chashm and Marham (Eye drops, eye ointment)	100 sq. feet	Hot air oven electrically heated with thermostatic control, kettle.

C. List of equipment recommended for in-house quality control section

(Alternatively, unit can get testing done from the Government approved laboratory)

A	CHEMISTRY SECTION	B	PHARMACOGNOSY SECTION
1	Alcohol Determination Apparatus (complete set)	1	Microscopic Binocular
2	Volatile Oil Determination Apparatus.	2	Dissecting Microscope
3	Boiling Point Determination Apparatus	3	Microtome
4	Melting Point Determination Apparatus	4	Physical Balance
5	Refractometer	5	Aluminium Slide trays
6	Polarimeter	6	Stage microscope
7	Viscometer	7	Camera Lucida (Prism and Mirror type)
8	Tablet disintegration apparatus	8	Chemicals, Glass-ware etc.
9	Moisture meter		
10	Muffle Furnace		
11	Electronic Balance		
12	Magnetic stirrer		
13	Hot air oven		
14	Refrigerator		
15	Glass/Steel Distillation Apparatus		
16	LPG Gas Cylinders with Burners		
17	Water Bath (Temperature controller)		
18	Heating Mantles/Hot plates		
19	TLC Apparatus with all accessories (Manual)		
20	Paper chromatography apparatus with accessories		
21	Sieve size 10 to 120 with sieve shaker		
22	Centrifuge Machine		
23	Dehumidifier		
24	pH Meter		
25	Limit Test Apparatus		

THE END

Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

By Abinaya

lecturer

Introduction

- The modern allopathic system **(sometimes called as English medicine by common people**)has been globally acclaimed as the principal system of medicine, and so all the other systems prevalent and practised in various parts of the world are supposed to be **alternative system or TRADITIONAL SYSTEM or indigenous system of medicine**
- The philosophy and the basic principles of these so-called alternative systems might differ significantly from each other, but the fact cannot be denied that these systems have served the humanity for the treatment and management of diseases and also for maintenance of good health.
- About 80 percent of the world population still rely and use the medicines of these traditional systems.

Ayurveda

- Ayurveda originates from Sanskrit, composed of "ayus" and "veda". "Ayus"or "Ayur " stands for life and "Veda" is knowledge of science. Ayurveda is in combination, the knowledge of life or the science of life.
- According to Charaka (the ancient Ayurvedic scholar) "Ayu" means mind, body, senses and the soul. Ayurveda is an intricate medical system which is one of the oldest forms of healthcare system, originated in India thousands of years ago.
- The fundamentals of Ayurveda are found in the Vedas (Hindu scriptures) the ancient Indian books of wisdom. The Rig Veda (written over 6,000 years ago), contains a series of prescriptions to overcome various ailments of human body.
- The aim is to prevent illness, heal the sick and preserve the life as follows:
- "Swasthyas swasthya rakshanam"- indicates prolong life with health protection.
- "Aturasya vikar prashamanamcha"- indicates elimination of diseases and dysfunctions of the body.

Principle

- The Universe is made up of five elements: air, fire, water, earth and ether as per Ayurveda. these together are known as "Panchabhuta".
- These elements are interconnected with the human body by three "doshas" namely Vata, Pitta and Kapha.
- Any of the doshas accumulate beyond the desirable limit in the body; the body loses its balance. Every individual depends on getting a right balance of these three doshas ("tridoshas").
- Ayurveda suggests healthy lifestyle and nutritional guidelines to help the body to reduce the excess doshas.
- Sushrut Samhita says a healthy person is one who works on Ayurveda, with the balance of doshas, appetite is good, all tissues of the body and all natural urges are properly functioning whose mind, body and spirit are cheerful.

Principle

Tridosha or the Theory of Bio-energies:

- Vata pertains to air and ether elements that act as the force. It directs nerve impulses, circulation, respiration, and elimination.
- Kapha pertains to water and earth elements. Kapha is responsible for growth and protection. Eg: The mucosal lining of the stomach, the cerebral-spinal fluid etc.
- Pitta pertains to fire and water elements and deals with metabolism, Eg: The transformation of foods into nutrients. It helps in metabolism in the organ and tissue systems.

Treatment in Ayurveda

- Ayurveda has eight different techniques to diagnose illness, namely Nadi (pulse), Mootra (urine), Mala (stool), Jihva (tongue), Shabda (speech), Sparsha (touch), Druk (vision) and Aakruti (appearance). The treatments are carried out using plant based products procured from roots, leaves, fruits, bark, or seeds.

Ayurvedic Dosage Forms: Four types depending on their physical nature.

- Solid dosage forms like Vatika, Gutika
- Semisolid dosage forms like Aveleha,
- Liquid dosage forms like Arista, Asava, Taila,
- Powder dosage forms like Churna

Treatment in Ayurveda

- All the Ayurvedic preparations is named in two words.
- The first word may indicate either the disease for which the preparation is used (Jwarantaka Vati) or the property of the preparation (Kaameshwara-Modaka) or the drug contained (Arjuna Aristha) or the name of Saint (Narayana Taila) and the second word always indicates type of preparations (Aristha, Vati, Taila etc.).

Role of Pharmacognosy in Ayurveda Medicine System:

- Herbal drugs play a major role in formulation of Ayurvedic medicines.
- Many medicinal plants that are used in Ayurveda are selected based on abundant availability, low cost, less side effects, effective therapeutic efficacy and low toxicity.
- Ayurvedic formulations that are available in market are composed of more than 5 to 10 medicinal plants either from leaves or roots or bark or flower parts as sources.
- A vast number of crude drugs that are used in Ayurvedic preparations, procured from the plant sources
- Thereafter Pharmacognosy helps in identification of drugs through morphology and microscopy examinations that further helps in detection of adulterants as well as substituents.

Role of Pharmacognosy in Ayurveda Medicine System:

- Hence authenticated drugs are used for the formulations which give proper therapeutic actions with less side effects.
-
- Pharmacognosy helps identification, detection and isolation of the phytochemicals which gives idea for root level curing of the diseases.

- There are more than 5000 plants which are used in Ayurveda among that some of major plants are Ashwagandha, Ashoka, Amla, Arjuna, Turmeric, Tulsi, Haridra, Neem, Rauwolfia, Gymnema, Pudina, Hibiscus, Lemon grass, Black pepper, Clove, Cinnamon, Ginger etc.

Siddha

- Siddha medicine is one of the oldest traditional medicines.
- This healing system originated in South India.
- This system is based on ancient medicinal practices as well as disciplines.
- It also includes alchemy and mysticism.
- This system is thought to have developed between 2500 -1700 BC.
- Siddha medicine originated in Tamil Nadu, India as evident in the earliest Tamil writings (Tamil is one of the principal Dravidian languages). Agastyar or Agasthya, is believed to be the founding father of Siddha Medicine. Eighteen Siddhars are considered to be pillars of Siddha Medicine.
- There are references in literature of Tamil sangam, in the Tolkappiyam (Ancient Tamil Literature), , and in Thirukkural (Couplets), a work attributed to the Tamil saint Thiruvalluvar about this system.

- Medical information in Sangam age and Siddha Medicine
- The Sangam age is considered to be primitive and relics of ancient Tamil culture are being excavated from it.
- The Antiquity of Siddha Medicine system lies in the Dravidianculture and has its deep roots in Sangam literature.
- Tolkappiyam, Ettuthogai, Pathinen keelkanakku, Pathu Pattu, twin epics (Silambu/Manimekalai), Asarakovai, (Elathy, Siru panchamoolam, Thiri kadugam- Publications of Kadai sangam), Agananuru, Purananuru are some of the Sangam texts which describe about the plants which are used medicinally in Siddha medicine.

Principle

- The concepts of the Siddha medicine system are also allied to the Ayurveda system.
- The only difference is that the siddha medicine based on the concept of Vaadham, Pitham and Kabam in childhood, adulthood and old age, respectively, whereas in Ayurveda, it is totally reversed, as said Kabam is dominant in childhood, Vaatham in old age and Pitham in adults.
- According to the Siddha medicine, various psychological and physiological functions of the body are made up of the combination of seven elements namely:
  - ✓ Ooneer (plasma) is responsible for growth, development and nourishment;
  - ✓ Ischeneer (blood) is responsible for nourishing muscles, imparting colour - improving intellect;
  - ✓ Oon (muscle) is responsible for shape of the body;
  - ✓ Koluppu/kozhuppu (fatty tissue) is responsible for lubricating joints as well as : balance;
  - ✓ Elumbu (bone) is responsible for body structure and posture and movement;
  - ✓ Elumbu majjai (bone marrow) is responsible for formation of blood corpuscles;
  - ✓ Sukkilam (semen) which is responsible for human reproduction.

Principle

- In this medicine system, the physiological components of the humans are classified as Vaadham (air), Pitham (fire) and Kabam (earth and water) as like as Ayurveda system.
- According to this medicine system, the five elements that exist in nature are earth, water, fire, air, and ether, all of which form the original basis of all corporeal things.
- Traditions believed that there is an intimate connection between the macrocosm of the external world and the microcosm of the corporeal being.
- As per the system the element of earth is present in the human bone, flesh, nerves, skin and hair; water as element, is present in bile ,semen, glandular secretions, and sweat; the fire element is present in hunger, thirst, sleep and indolence; the air is present in contraction, expansion, and motion; and the ether is present in stomach, heart, neck and head.

Treatment

- The treatments for the imbalance of the *Tridoshas* are made up of the five elements. The drugs are made up of the five elements. By substituting a drug of the same constituents (*guna*), the equilibrium is restored.
- The correction of the imbalance is made by substituting the drug, which is predominately of the opposite nature.
- An example of *vatham* imbalance is cold and dry thus, the treatment will be oily and warmth.
- For inactivity of limbs, massage and activity are prescribed.
- If *pitham dosha* is increased, warmth is produced; to decrease *pitham*, sandalwood is administered, internally or externally because of its cold characteristics.
- The common preparations of Siddha medicines are:

1.Bhasma (Calcined metals and minerals), 2. Churna (powders), 3. Kashaya (decoctions).

4. Lehya (confections), 5. Ghrita (ghee preparations) and taila (oil prepara-tions).

6. Chunna (metallic preparations which become alka-line), 7. Mezhugu (waxy preparations).

8. Kattu (preparation that are impervious to water and flames.

Role of Pharmacognosy in Siddha System:

- Siddha medicine gives importance to the multiple uses of plants and minerals.
- For simple ailments, herbs are used as preliminary treatment in this system. According to Siddha theory it is believed that mercury preparations provided immunity to the body from decay, enabling it to conquer disease.
- Mercury and sulfur are used as supreme curatives even though those are extremely toxic to the human body.
- Siddha medicines are used for the management of chronic diseases and degenerative conditions, such as autoimmune conditions, rheumatoid arthritis, collagen disorders, and conditions of the central nervous system but the effectiveness are varied as per the situations.
- Leaf extract of *Adhatoda vasica* & roots of *Boerhavia diffusa* - to cure bronchial asthma, eosinophilia, seeds and leaves of *Apium graveolens* - in the treatment of asthma and bronchitis as well as liver and spleen diseases.
- *Alpinia galanga*- Root powder is used for treatment of arthritis

Unani

- Unani medicine system is also known as Unani Tibb, Arabian medicine or Islamic medicine.
- This system is a traditional system of healing and health maintenance.
- It is believed that the system originated in South Asia which is found in the doctrines of the ancient Greek physicians Hippocrates and Galen (460-377 BC).
- As per their literature, this medicinal system originated in Greece and Aesculapius (Roman god of medicine) is credited as originator of this Unani system.Buqrat also known as HIPPOCRATES is the father of unani medicine
- Unani system is written in Unan or Yunan in Arabic language. Hence, Unani medicine is also known as Arabian or Islamic medicine.

Principle

- This medicine system is based on two theories namely Hippocrates theory (Humour theory) and Pythogoras theory (Four Proximate qualities).
- The four humours namely Phlegm, Blood, Yellow bile and Black bile. Phlegm means Balgham, Blood is Dam, Yellow bile is Safra and Black bile is Sauda. The proximate qualities are like Hot, Cold, Moist and Dry.
- All the homours enter into the body and due to their balance or imbalance, health and illness occur respectively.
- It believes that the medicine system has originated at Circa 1025 A.D and the evidence is given in the book
- "The Canon of Medicine" in Persia, written by Avicenna (physician and muslim philosopher), after getting influenced by Greek, Islamic medicine and Indian medical teaching of Sushruta and Charaka.

Treatment

Diseases are treated in the following ways:

- *Ilajbil Tadbeer* (Regimental Therapy): Some drugless regimens are advised for the treatment of certain ailments, i.e. exercise, massage, hamam (Turkish bath), Douches (Cold and Hot) and the Regimen for Geriatrics.
- *Ilajbil Ghiza* (Dietotherapy): Different diets are recom-mended for the patients of different diseases.
- *Ilajbil Dava* (Pharmaco therapy): The basic concept of treatment is to correct the cause of the disease that may be abnormal temperament due to environmental factors and abnormal humours either due to internal causes or external causes which may be pathogenic microorganism, through (a) drugs of opposite temperament to the temperament of the disease that is called *Ilaj-bil-zid* or (b) drugs of similar temperament as of the temperament of the disease that is called as *Ilaj-bil-misl*
- *d) Ilajbil Yad* (Surgery)

Treatment

- The drugs used are mostly of the plant origin. Some drugs of animal and mineral origin are also used.
- Patients are treated either by single drug (crude drugs) or by compound drugs (formulations of single drugs).
- There are two types of compound drugs used in the treatment of the diseases, i.e. classical compound drugs which are in use for the hundreds and thousand years and patent/proprietary compound drugs which have been formulated by the individuals or institutions as per their research and experiences.
- *Unani* system of medicine is one of the oldest systems of medicine in the world; it is still popular and practiced in Indian subcontinent and other parts of the world.

Role of Pharmacognosy in Unani System of Medicine:

- Medicinal plants are rich resources of ingredients which are used in drug development are either pharmacopoeial, non-pharmacopoeial or synthetic drugs.
- It cures very critical diseases like Bars (Vitiligo), Dau sadaf (Psoriasis), Iltehab-e-kabid (Infective Hepatitis),
- Hasat-ul-kulya wa masana (Renal and Bladder calculus) etc. with the help of medicinal plants.
- Some medicinal plants that are abundantly used in Unani system,
- *Momordica charantia* are used for diabetes, abortifacient and emmenogogues; Berberis aristata, Butea monosperma, Hibiscus rosa-sinensis and Saraca used for emmenagogues (stimulates or increases menstrual flow) and have depressant action on uterine muscles; *Punica granatum*- for abortifacient, *Rauwolfia serpentina* for hypertension.

Homeopathy

- Homeopathic medicine system works on the principle of 'like cures like' (Similia Similibus Curanter).
- This medicine system of healing was coined by Dr. Samuel Hahnemann, a German physician.
- After that he named his new healing science by combining the two Greek words homeo, meaning "same," and pathy, meaning "disease."
- While translating William Cullen's Lectures on the Materia medica into German, Hahnemann was struck by the fact that the symptoms produced by quinine on the healthy body were similar to those of the disordered states that quinine was used to cure. This observation led him to assert the theory that "likes are cured by likes," similia similibus curantur; i.e., diseases are cured (or should be treated) by those drugs that produce in healthy persons symptoms similar to the diseases.

Principle

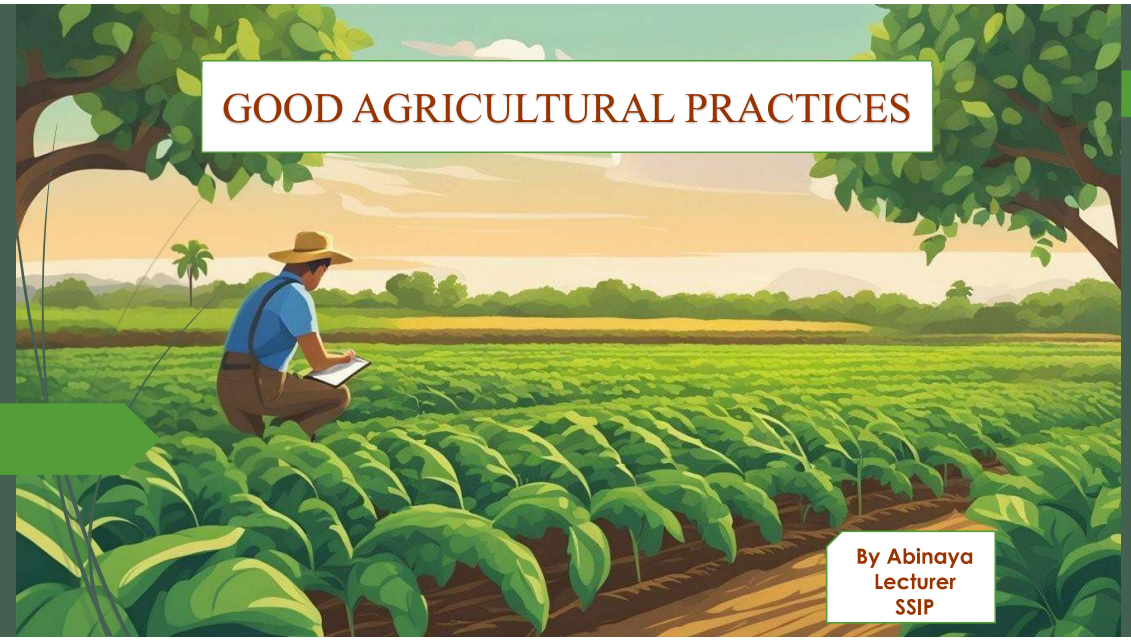
- Homeopathy is based on the principle of "like with like", that is a substance which causes symptoms when taken in large doses, can be used in small amount to treat those same symptoms.
- The treatment is based on the concept of proving and prover.
- Prover is the person whereas proving is the symptoms that are caused in prover by the various potencies of medicines.
- Like, drinking too much coffee can cause sleeplessness and agitation, so according to this principle, it could be used to treat people with these symptoms.
- Homeopathic medicines are prepared by specialist pharmacies using a careful process of and a specific form of vigorous shaking.

Theory

- Homeopathic medicine believes, various materials found in nature contain an energy field that can exert a healing effect on the body.
- This energy field is amplified or Potentiated by a series of dilutions. It is noticed that dilution enhanced the medicinal power of the drugs.
- The more the "mother tincture" is diluted, the healing effect will be stronger.
- It is based on the Dynamization theory by which the quality of the medicines is improved by vigorous shaking.
- This method also helps to remove the poisonous properties of the drugs.
- The materials used in homeopathic formulations can come from natural herbs, minerals, or from animal parts.
- Homeopathic preparations are written as 2X, 4X, 6X etc. and X indicates potency and the number of times the mother tincture is diluted and potentiated. The higher number indicates more dilute with stronger healing effect.

Role of Pharmacognosy in Homeopathy Medicine System:

- Homeopathy uses animal, plant, mineral, and synthetic substances in its remedies. Arsenic album (Arsenic oxide), Natrum muriaticum (Sodium chloride), opium (plant), and Thyroidinum (Thyroid hormone) are some of the homoeopathic medicines extracted from different sources.
- Some important medicinal plants used in Homeopathic medicine systems are:
- Rhus toxicodendron, used in treating paralysis of the lower extremities,
- Aconite napellus and Gelsemium sempervirens are used in treatment of paralysis.
- Arnica Montana, Nux-vomica are another well-known plant source used in pain relief as well as antacid respectively in homeopathy medicine.
- Belladona liquid from Atropa belladonna is used for running nose and any cold conditions in Homeopathic medicine.



GOOD AGRICULTURAL PRACTICES

- GAP are "a collection of principles to apply for on-farm production and post production process, resulting in safe and healthy food and non-food agricultural products, while taking into account economic, social and environmental sustainability"

Principles

- Safe, nutritious and economically sufficient food
- Maintain and improve natural resources
- Meet the demands of the society both socially and culturally
- Maintain the livelihood of people

GAP related to medicinal plants

- ✓ While cultivating medicinal plants both environmental as well as ecological conditions should be considered, to avoid any variations in physiological processes and in chemical constitution.
- ✓ No other plant species should be present in the plot to be used for cultivation of medicinal plant to avoid any genetic diversity.
- ✓ Contamination by chemicals or pollution of soil, water or air must be avoided.
- ✓ Cultivation of non-indigenous medicinal plants should be prohibited as it leads to biological and ecological imbalances.
- ✓ Appropriate amount of nutrients, essential elements and organic matter should be present, only then optimum growth and quality of medicinal plants can be assured.

- Animal manure at safe sanitary level and within acceptable microbial limits as well as pesticides and herbicides within minimum effective concentration should only be used.
- Harvesting should be done in an appropriate period after ensuring that production of materials in the medicinal plants is completed.
- Packing of the medicinal plant material should be done in inert boxes and must be stored and transported under clean and dry conditions.
- Climatic factors such as day length, rainfall, temperature, and temperature differences between day and night impact the physical, chemical, and biological qualities of medicinal plants.
- Understanding these parameters is essential as they influence plant physiology and biochemical activities.

Seeds and propagation material

- ✓ Identity and Quality: Suppliers must provide clear details on the identity, quality, and performance of seeds or propagation materials.
- ✓ Disease-Free and Resistant Materials: Materials should be free from diseases and contamination, and be resistant or tolerant to biotic and abiotic factors.
- ✓ Organic Certification: Propagation materials for organic production must be certified organic.
- ✓ Compliance with Regulations: Materials, including GMOs, should comply with regional and national regulations, with proper labeling and documentation.
- ✓ Exclusion of Undesirable Species: Avoid counterfeit, substandard, or adulterated materials, and exclude unsuitable species or varieties.

SOIL HEALTH MANAGEMENT

- Well drained Soil
- Green Manure:
  - Maintaining the organic content in the soil by adding animal manure and practicing crop rotation.
  - Use green manure like pulse crops (e.g., horse gram, sun hemp, cow pea) for food crops.
  - Apply animal manure in spring, two weeks before planting, but never during food crop cultivation.
  - A gap of 120 days should be maintained between the addition of manure and harvesting of fruits and vegetable crops.

- Soil Conservation: Implement practices like streamside buffer zones, planting cover crops (e.g., alfalfa), **Ditching** and hedging to reduce erosion and maintain soil composition.
- Soil Compaction: Avoid heavy machinery that may compact the soil.
- Deforestation Impact: Prevent deforestation to protect the nitrogen cycle and maintain beneficial soil bacteria.
- Fertilizer Use:
  - Apply the correct type and amount of fertilizers for optimal medicinal plant growth, avoiding overuse.
  - Organic and chemical fertilizers should be approved and used carefully to prevent soil leaching.

IRRIGATION MANAGEMENT

- Irrigation should comply to local, regional and international standards.
- Irrigate crops as needed and recycle water to prevent salinization.
- Avoid crops with high water requirements in a low availability region
- Ensure crops receive adequate water by creating channels to prevent stagnation.
- Prevent water seepage by controlling deforestation.
- Maintain the groundwater table by avoiding excessive water usage.
- Irrigate immediately after planting.
- Replace sprinklers with drip irrigation to reduce soil splash contamination.
- Choose irrigation methods based on plant needs and growth stages, considering potential health risks from vector-borne diseases.
- Ensure plants are neither overwatered nor underwatered.

HARVESTING

Optimal Harvesting Conditions:

- ✓ Harvest medicinal plants at the peak time for quality, considering plant growth stage and active constituents.
- ✓ Avoid harvesting in wet conditions to prevent microbial fermentation and mold.
- ✓ Clean, well-maintained tools and containers should be used, and materials should be transported in clean, dry conditions to prevent contamination.

Storage and Containers:

- ✓ Store harvested crops in thoroughly cleaned, sanitized containers to prevent microbial growth.
- ✓ Containers should be covered to block dust, insects, and pests, and food grains should be kept at optimal temperature and humidity.

Equipment and Worker Hygiene:

- ✓ **Clean harvesting equipment daily with potable water, and ensure machinery is in good working condition.**
- ✓ **Workers should follow hygienic practices to prevent contamination, and farm animals must be kept away from fields to avoid tampering.**

Post-Harvest Handling:

- ✓ **Prevent mechanical damage or compacting during storage to maintain quality.**
- ✓ **Identify and discard decomposed materials to avoid contamination.**
- ✓ **Ensure proper packing to meet the nutritional needs of food crops.**

GAP Related to Other Practices During Farming

- **Machinery tools should be used to progress the work at a faster rate on the farms.**
- **Organic wastes should be recycled.**
- **Safety precautions should be taken while handling the equipment and machines to prevent any accidents.**
- **Manure should be properly used to avoid food-borne illnesses.**

GAP Related to Animals

- **Ensure animals have sufficient space, ventilation, feed, and water for proper well-being.**
- **Avoid debeaking and tail docking unless absolutely necessary and done with care. Keep health records for all animals.**
- **Do not feed animals with their own waste, and ensure the feed supplier has quality assurance approval.**
- **Minimize animal transportation to prevent disease spread, and only purchase healthy animals.**
- **Use animal feces to nourish soil and consult a veterinarian if animals fall ill. Quarantine sick animals and provide appropriate care.**

Packaging

- **The product should be packed in clean, dry preferably new sacs, bags or cases**
- **The label must be clear, permanently fixed and made from non toxic material.**
- **Reusable packaging materials should be well cleaned and dried before use, care should be taken that they do not cause contamination.**

Storage and transport

- **Packaged dried materials and essential oils should be stored in a dry, well aerated building in which temperature fluctuations are controlled and good aeration is provided.**
- **Fresh products should be stored between 1 to 5°C, while frozen products should be stored below-18°C or below -20°C for long term storage.**
- **Essential oils should be stored as per the chemical storage standards.**
- **During transportation, sufficiently aerated vehicles should be used.**
- **National regulations on transport have to be followed**

Practices for Biodynamic Production for Vegetables

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Lecturer

NUTRIENT MANAGEMENT

- Green Manuring: Use sunhemp/sesbania to improve soil fertility.
- Soil Preparation: Apply 5-10 tonnes of organic manures (NADEP, Vermi, BD compost) in the descending moon phase.
- Cow Horn Manure: Spray before sowing/transplanting in the descending moon.
- Sowing: Plant 48 hours before the full moon (ascending phase).
- Transplanting: Done in the descending moon to strengthen roots.
- Seed Soak: Use cow pat pit solution (1:7) before sowing.
- Biodynamic Spray: Apply liquid manure (cow dung, urine, leguminous leaves, Vermi-wash) for growth and fruiting.
- Weed Management: Use mulching and aeration for root development.

DISEASE MANAGEMENT

1. Spraying twice cow horn silica (BD -501) at two leaf stage and fruit development stage
2. Base spraying horsetail (Equisetum arvensis)/casuarina extract for controlling fungal diseases.
3. Spraying fresh cow dung/biodynamic liquid manures prepared from cow urine, neem an d karanj a (Pongamia glabra) for controlling bacterial diseases.

TREATMENT OF PESTS AND WEEDS

- Pest and Disease Management: Biodynamic agriculture focuses on creating a balanced farm ecosystem to manage pests and diseases.
- Soil Imbalance: Weeds and plants are seen as vulnerable to pests due to soil imbalance.
- Control Methods: Ashes from pests or weeds are used for control after they are burned.
- For field mice, ashes from their skin are prepared when Venus is in the Scorpius constellation.
- Weed Control: Weed seeds are collected, burned, and the ashes spread on fields to block full moon influences and render the weeds infertile.
- Biodynamic Sprays: Liquid pesticides are made from cow urine, neem, karanja, calotropis, datura, castor, Thevetia, Vitex spp. leaves, etc.
- Nettle leaf extract is also used to control pests.