Course Code: BP603T
Course Title: Herbal Drug Technology

Unit 1

1.1. **Herbs as raw material**

1.2. **Biodynamic agriculture**

1.3. **Indian systems of medicine**

Definitions :

Herb:

- ✓ Refers to plants used in various forms or preparations, valued for their therapeutic benefits, and sold as dietary supplements.
- ✓ A short lived plant or perennial, biennial or annual plant which does not have woody tissue.

Herbal drug preparation:

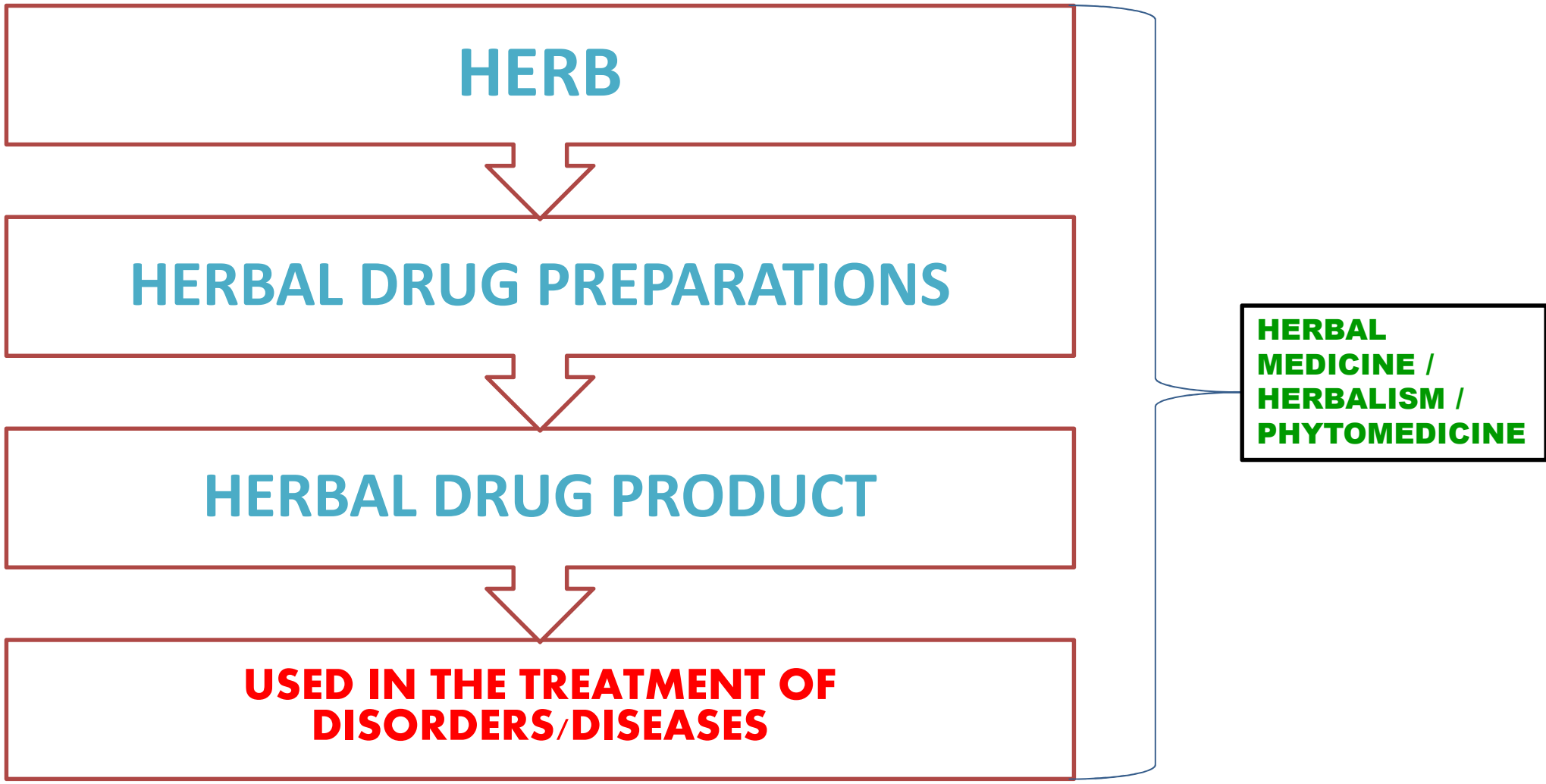
- ✓ The preparations obtained by subjecting herbal substances to treatment of such methods- extraction, distillation, fractionation, purification, concentration & fermentation

Herbal medicinal products:

- ✓ Any medicinal product, exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two.
- ✓ Finished labelled pharmaceutical preparation that contain one or more than one plant material

Herbal Medicine / Herbalism :

- ✓ An approach to wellness and healing which uses plant or plant-derived preparations to treat, prevent, or cure various health conditions and ailments.
- ✓ Re establish ***HEALTH & BALANCE.***
- ✓ Her medicine have the property to go deeper into body to treat the root cause of ***DISORDERS & DISEASES***


HERB
HERBAL DRUG PREPARATIONS
HERBAL DRUG PRODUCT
USED IN THE TREATMENT OF DISORDERS/DISEASES
HERBAL MEDICINE / HERBALISM / PHYTOMEDICINE

HERB

HERBAL MEDICINE

HERBAL MEDICINAL PRODUCT

HERBAL DRUG PREPARATIONS

1.1. Herbs as Raw Material

- Source of herbs
- Identification and authentication of herbs

Herbs as Raw Material

Herb:

- The word herb derived from the latin word herba – Grass/green stalks
- Herbs include any part of the plant like leaves, roots, stem, bark etc posses therapeutic activity

Herbal medicine:

- Branch of science deals with medicinal plants, it includes modern standards of testing of herbs and medicines derived from natural sources

Herbs as Raw Material

Herbal Medicinal product:

Defined as any medicinal product, exclusively containing one or more active ingredients of herbal origin

Herbal Drug Preparations

Preparations which are made from herbal drugs and are prepared by the help of different processes like infusion, decoction, maceration, distillation, fermentation etc. These include whole plant/parts, powdered herbal drugs, extracts, essential oil, processed exudates of herbal materials

SOURCE OF HERBS:

- Plants have ability to synthesize wide variety of chemical compounds that are used to perform important biological functions and to defend against attack from insects, fungi and herbivorous
- Many of these phytochemicals have beneficial effects on long term health when consumed by humans and can be used to treat diseases effectively
- Phytochemicals are divided into Primary metabolites and secondary metabolites

Herbs or medicinal plants can be obtained from three sources viz:

A.Wild source

B.Cultivated source

C.By using modern scientific techniques like tissue culture, polyploidy, mutation, hybridization, genetic engineering, germplasm etc. on cultivated plants

A. WILD SOURCE:

The plants are obtained from wild source and grow themselves without any type of care at unutilized land such as forests, plains, river banks, etc.

The wild plants also have reasonable active constituents and sometimes new variety is produced. These plants grow under favorable conditions in natural habitat.

Advantages:

- Economical; No cost of land, caring, fertilizers, irrigation etc.
- Less time consuming.

Disadvantages of wild plants:

- The quality of the plants cannot be predicted due to various environmental changes.
- The plants will not be uniform in their growth and yielding characteristics.
- The collection is uneconomical as these are widely distributed in different locations.
- They are sparsely distributed, so chances of adulteration and substitution are more.
- 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 period, may lead to depletion of raw material.
- They cannot fulfill the demand when required.
- Sometimes genetically different plants are developed.

B. CULTIVATED SOURCE

The plants are obtained from cultivated source.

These plants are grown with proper care by human. Care is taken toward soil, climate, rainfall, irrigation, time of sowing and collection, altitude, temperature, fertilizers, manures, pesticides, weeds etc.

Advantages of cultivated plants:

- The quality and purity of medicinal plants can be ensured.
- Better yield and therapeutic quality, and give more profit.
- It ensures regular supply of raw materials due to planned cultivation.
- Application of modern scientific techniques like tissue culture, geneti engineering, hybridization, germplasm, mutation, polyploidy etc. are possible.
- Cultivation of medicinal and aromatic plants leads to industrialization and has given rise to several cottage and small scale industries.

- Rapid growth of phytopharmaceuticals, perfumery and allied industries is possible due to cultivation of medicinal and aromatic

C. By using modern scientific techniques like

Tissue Culture,

Polyploidy,

Mutation,

Hybridization,

Genetic Engineering,

Germplasm Etc. On Cultivated Plants

- **Primary metabolites –** Carbohydrates, proteins and lipids found in all the plants
- **Secondary Metabolites:** Compounds which have therapeutic actions, do not have any role in the growth of plants

  Eg: Alkaloids, glycosides, tannins, resins, volatile oil, latex etc

  Quinine – Anti malarial

  Reserpine – Anti hypertensive

  Digitoxin – Cardiac stimulant

Identification and authentication of herbal materials:

- Herbal materials may vary in composition and properties unlike conventional pharmaceutical products, which are generally prepared from synthetic, chemically pure compounds by means of reproducible manufacturing techniques
- Correct identification and quality assurance of the starting material is essential for safety and efficacy of the drug
- Drugs of poor quality destroys the clinical efficacy

Identification and authentication of herbal materials:

1) Taxonomic method
2) Herbarium sample
3) Macroscopic method
4) Microscopic method
5) Physico chemical method
6) Spectroscopic method
7) Chromatographic method

Identification and authentication of herbal materials:

1. *Taxonomic method:*

- Involves classical botanical methodologies for collection and documentation of the plant at its source
- Botanical origin of the drug is identified and its scientific binomial, that is genus, species is determined based on this method
- Information such as vernacular names, site of collection, detail of collector, season of collection, part collected etc are essential fundamentals even before authentication

2. *Herbarium coupon sample:*

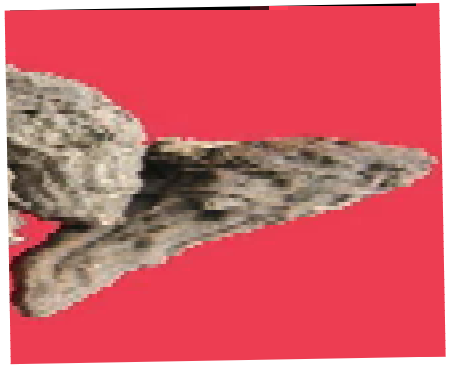
- Sample of collected material should be kept as a coupon sample in a herbarium or in a research institute for future reference
- Specimens collected from field were dried using blotting paper and uniform pressure was exerted on blotting papers by placing them in a plant press
- Blotting paper was changed every day (15 days), so that moisture from the specimen is removed completely
- After demoisturing, specimens were treated with a solution of $HgCl_2$ in formalin for about 2 min. They were again dried in dryers and mounted on herbarium sheet using fevicol

3. *Morphological method:*

- Refers to shape, size, colour, odour, taste and special features like texture and fracture

Shape: Nuxvomica seed – *disc*

Aconite root– *conical*



Colour: Fennel fruit – *greenish yellow*

Senna leaves- *greenish*

Odour: Umbelliferous fruits - *aromatic*

Asafoetida - *alliaceous*

Taste: Licorice root & rhizome – Sweet

Kalmegh root – Bitter

Fracture: Kurchi stem bark– granular

Picrorrhiza root- tough

4. *Microscopical method:*

- To identify organized crude drugs by their known histological characters
- Microscope, by virtue of its property to magnify, permits the minute structure under study to be enlarged
- Stains can be used to distinguish cellular structure

  - Phloroglucinol and con HCl - Lignin (Pink)
  - Ruthenium red – mucilage (Pink)

Histological studies – thin section of drugs

- Cell wall, cell contents, stomata, trichomes, fibres, vessels etc

Eg: Senna leaf – Paracytic stomata

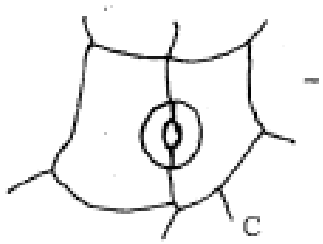
Nuxvomica seed – lignified unicellular trichomes

Senna leaf– Warty unicellular trichomes

Datura leaf– multicellular unbranched trichome

Vasaka – Diacytic stomata,

unicellular glandular trichome



Paracytic

Trichome

- Microscopic linear measurements and quantitative microscopy

Stomatal number: Average number of stomata per sq mm of epidermis of the leaf

Stomatal index : Percentage which the number of stomata form to the total number of epidermal cells; each stoma being counted as one cell

S.I = S/E+S

S.I = Stomatal index

S = No of stomata

E = No of epidermal cells in the same unit area

Palisade ratio : Average number of palisade cells beneath each epidermal cells

Vein-islet number : The number of vein islets per sq mm of the leaf surface midway between the midrib and margin

5. Physico chemical method:

- Moisture content
- Melting point
- Optical rotation
- Refractive index
- Ash content
- Extractive value
- ***Volatile oil content***
- ***Viscocity***
- ***Solubility***

6. Spectroscopic method:

- Infrared spectroscopy
- Electron spectroscopy for chemical analysis
- Atomic absorption Spectroscopy
- X Ray diffraction analysis
- X-Ray fluorescence analysis

7. Chromatographic method:

- PAPER CHROMATOGRAPHY
- TLC
- COLUMN CHROMATOGRAPHY
- HPLC
- HPTLC
- Gas Chromatography

Lecture No 10
Processing of Herbal raw material

At the end of this lecture, student will be able to

- Discuss the processing of herbal raw material

Content
Processing of Herbal raw material

- Primary processing
- Secondary Processing

Processing of Herbal as raw material

Primary processing:

Harvested/collected medicinal plants and/or their parts undergo a series of good practice post-harvest(and post-collection) processing procedures

- Garbling
- Washing
- Blanching
- Drying

Processing of Herbal as raw material

Garbling

- Garbling serves as the first step to ensure the purity and cleanness of the medicinal plant materials.
- All extraneous and unwanted matters including dirt (e.g. soil, dust, mud,), impurities (e.g. insects, rotten tissues), and residual non-medicinal parts must be separated from the medicinal part(s).

Processing of Herbal as raw material

- The process may involve, depending on the plant material, procedures such as removing dirt and foreign substances, discarding damaged parts, peeling(to separate unwanted plant parts from the medicinal plant parts such as removing unwanted root bark from the roots or collecting stem bark from the stem)

Processing of Herbal as raw material

Washing

- After sorting, the medicinal plant materials should be cleaned well to remove remaining soil, dirt, dust, and other unwanted matters from the surface, especially roots, rhizomes and tubers, are commonly washed with clean water, dried soon after harvest/collection
- During the washing process, scraping and brushing may be necessary. It is generally recommended not to soak the medicinal plant materials in water for an unnecessarily long period of time
- Change water frequently as required

Processing of Herbal as raw material

Blanching

- Blanching process in which they are put into boiling water for a brief period of time without being fully cooked
- Which improves storage life of the processed materials by gelatinizing the starch and preventing mould/insect contamination, and facilitating further processing

Processing of Herbal as raw material

Drying:

- Unless used in the fresh state, the raw medicinal plant materials are to be dried after being sorted and washed
- In general, they must be dried as soon as possible to remove as much moisture as possible in order to ensure good keeping qualities and to reduce damage from mould and other microbial infestation
- Drying will also avoid tissue deterioration and phytochemical alteration caused by the actions of enzymes and microbial organisms; and will also facilitate grinding and milling

Processing of Herbal as raw material

Sun-drying:

- Most medicinal plant materials can be dried in open-air under direct sunshine, provided the climate is suitable for such a practice
- The duration of the drying process depends largely on the physical structure of the medicinal plant material and the weather condition
- In the case of natural drying in the open air, medicinal plant materials should be spread out in thin layers on drying frames and kept away from possible contaminations such as vehicle exhaust, heavy dusts, and rain, as well as protected from insects, rodents, birds and other pests

Processing of Herbal as raw material

Shade Drying:

- Some medicinal plant materials can be dried in the shade with or without artificial air flow to avoid direct exposure to strong sunlight
- Drying process is slow, but it is preferred to maintain (or minimize loss of) colour of leaves and flowers
- Low temperatures will also preserve most of the volatile and aromatic components from being evaporated

Processing of Herbal as raw material

Artificial Drying:

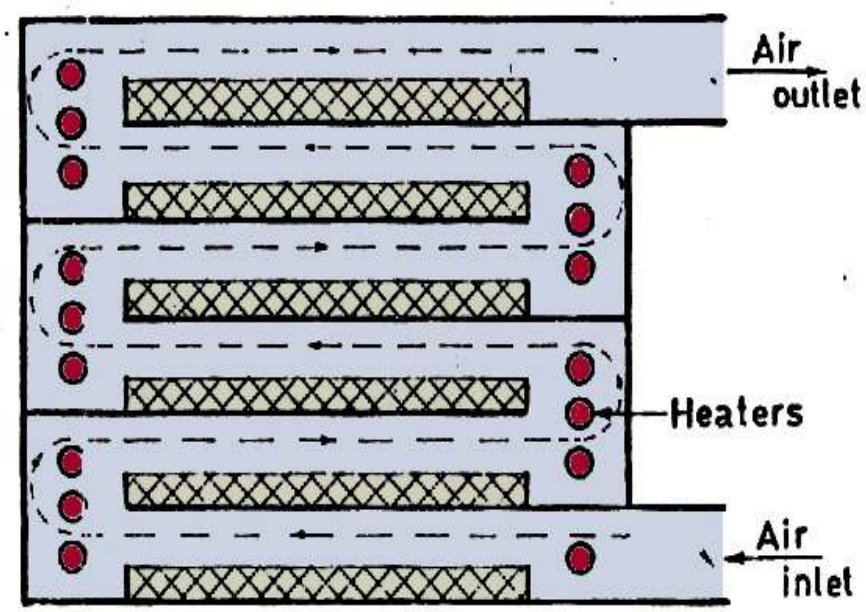
- Drying by artificial heat is more rapid than open-air drying and is often necessary on rainy days or in regions where the humidity is high.
- For artificial-heat drying, the temperature, humidity and other conditions should be governed by the physical nature of the drug and the physical/chemical properties of its active ingredients.
- Over-heating may lead to an excessive loss of the volatile components and/or decomposition of chemical ingredients. As much as possible, the temperature should be kept below 60°C.

Processing of Herbal as raw material

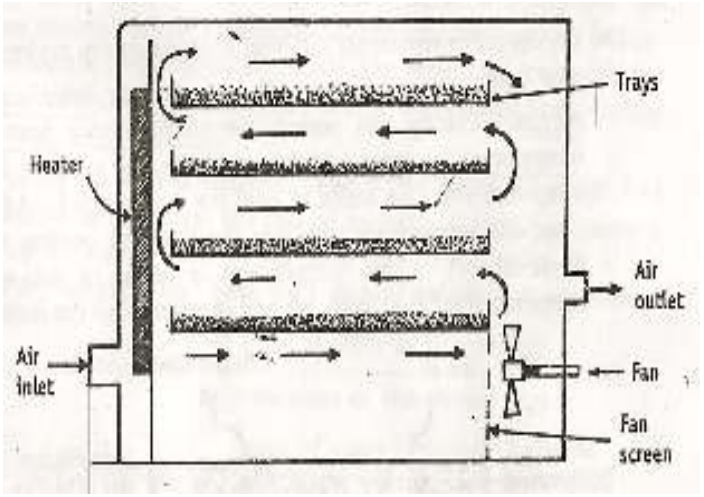
Tray dryer

- Shelf dryer/cabinet or compartment dryer
- Essentially hot air oven
- Material spread in thin layer in trays
- Number of trays depends on the size of the oven
- Hot air of desired temperature is circulated
- Dried material is taken out, cooled and pulverized

Tray dryer



Directed-circulation tray drier



Processing of Herbal as raw material

Secondary Processing

Cutting, sectioning, and communition: When thoroughly dried, the herbal materials are processed by cutting and sectioning into convenient sizes and shapes for storage,

- Where applicable, the herbal materials should be cut or sectioned into specific shapes or forms, or comminuted/pulverized into powder form according to common practice found in herbal medicines

Processing of Herbal as raw material

Ageing/Sweating: The aging process refers to storing the herbal materials for a period of time after being harvested or collected from the field prior to use.

- It is generally done under the sun or in the shade for up to a year, depending on the specific herbal material. During the process of aging, excessive water is evaporated and enzymatic reactions may occur to alter the chemical composition of the herbal material.
- For example, cascara sagrada bark should be aged for at least one year prior to use

Processing of Herbal as raw material

- A similar process known as sweating involves keeping the herbal materials at a temperature of 45-65°C with high humidity for an extended period of time, from one week to a couple of months, depending on the plant species

Baking/Roasting : It is a dry-heating procedure using indirect, diffused heat, where the herbal materials are put in a heating device, often embedded in bran or magnesium silicate (talc) powder to ensure even heating on the entire surface at an elevated temperature for a period of time.

Processing of Herbal as raw material

- Some herbal materials are wrapped in moistened papers during the roasting process. The exact temperature used and duration of baking/roasting vary from one herbal material to another.
- Some are baked or roasted until the surface colour turns yellowish brown; some may be further heated until charred.

Processing of Herbal as raw material

Fumigation

➢Fumigation by sulphur dioxide has been employed in post-harvest handling of some medicinal herbs for the purpose of preserving colour, improving fresh-looking appearance, bleaching, preventing the growth of insect and overcoming decays caused by moulds

Summary

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Content

Current Good Cultivation Practices

Current Good Cultivation Practices

✓ Cultivation of medicinal plants requires intensive care and management

✓ The conditions and duration of cultivation required vary depending on the quality of medicinal plant materials required

✓ If no scientific published or documented cultivation data are available, traditional methods of cultivation should be followed, where feasible. Otherwise a method should be developed through research

Current Good Cultivation Practices

Site selection

✓ Medicinal plant materials derived from the same species can show significant differences in quality when cultivated at different sites, owing to the influence of soil, climate and other factors

✓ These differences may relate to physical appearance or to variations in their constituents, the biosynthesis of which may be affected by extrinsic environmental conditions

✓ Risks of contamination as a result of pollution of the soil, air or water by hazardous chemicals should be avoided

Current Good Cultivation Practices

✓ The impact of past land uses on the cultivation site, including the planting of previous crops and any applications of plant protection products, should be evaluated

Ecological environment and social impact

✓Cultivation of medicinal plants may affect the ecological balance and, in particular, the genetic diversity of the flora and fauna in surrounding habitat

✓The quality and growth of medicinal plants can also be affected by other plants, other living organisms and by human activities

Current Good Cultivation Practices

✓ The introduction of non-indigenous medicinal plant species into cultivation may have a detrimental impact on the biological and ecological balance of the region

✓ The social impact of cultivation on local communities should be examined to ensure that negative impacts on local livelihood are avoided.

✓ If large-scale medicinal plant cultivation is or has been established, care should be taken that local communities benefit directly from, for example, fair wages, equal employment opportunities and capital reinvestment.

Current Good Cultivation Practices

Climate :

✓Climatic conditions, for example, length of day, rainfall (water supply) and field temperature, significantly influence the physical, chemical and biological qualities of medicinal plants

✓The duration of sunlight, average rainfall, average temperature, including daytime and night-time temperature differences, also influence the physiological and biochemical activities of plants, and prior knowledge should be considered

Current Good Cultivation Practices

Soil:

✓ Soil should contain appropriate amounts of nutrients, organic matter and other elements to ensure optimal medicinal plant growth and quality

✓ Optimal soil conditions, including soil type, drainage, moisture retention, fertility and pH

✓ The use of fertilizers is often indispensable in order to obtain large yields of medicinal plants. It is, however, necessary to ensure that correct types and quantities of fertilizers are used through agricultural research

✓ In practice, organic and chemical fertilizers are used

Current Good Cultivation Practices

✓Human excreta must not be used as a fertilizer owing to the potential presence of infectious microorganisms or parasites

✓Animal manure should be thoroughly composted to meet safe sanitary standards of acceptable microbial limits

✓Any applications of animal manure should be documented. Chemical fertilizers that have been approved by the countries of cultivation and consumption should be used

Current Good Cultivation Practices

✓All fertilizing agents should be applied sparingly and in accordance with the needs of the particular medicinal plant species and supporting capacity of the soil

✓Growers should implement practices that contribute to soil conservation and minimize erosion

Current Good Cultivation Practices

Irrigation and drainage:

- Irrigation and drainage should be controlled and carried out in accordance with the needs of the individual medicinal plant species during its various stages of growth
- Water used for irrigation purposes should comply with local, regional and/or national quality standards
- Care should be exercised to ensure that the plants under cultivation are neither over- nor under-watered.

Current Good Cultivation Practices

Plant maintenance and protection:

✓ The growth and development characteristics of individual medicinal plants, as well as the plant part destined for medicinal use, should guide field management practices

✓ The timely application of measures such as pruning and shading may be used to control the growth and development of the plant, thereby improving the quality and quantity of the medicinal plant material being produced

Current Good Cultivation Practices

✓Any agrochemicals used to promote the growth of or to protect medicinal plants should be kept to a minimum, and applied only when no alternative measures are available

✓Integrated pest management should be followed, only approved pesticides and herbicides should be applied at the minimum effective level, in accordance with the labelling and/or package insert instructions

✓Only qualified staff using approved equipment should carry out pesticide and herbicide applications.

Current Good Cultivation Practices

✓ The minimum interval between such treatments and harvest should be consistent with the labelling and/or package insert

✓Growers and producers should comply with maximum pesticide and herbicide residue limits, as stipulated by local, regional and/or national regulatory authorities

✓International agreements such as the International Plant Protection Convention and Codex Alimentarius should also be consulted on pesticide use and residues

Summary

✓ Site selection - Same species can show significant differences in quality when cultivated at different sites, owing to the influence of soil, climate and other factors

✓ Differences may relate to physical appearance or to variations in their constituents, the biosynthesis

✓ Ecological environment and social impact

✓ Climatic conditions, for example, length of day, rainfall (water supply) and field temperature

✓ Soil - appropriate amounts of nutrients, organic matter and other elements, Irrigation and water

Lecture No.12
Organic Farming

At the end of this lecture, student will be able to

- Discuss the objectives of organic farming

Organic Farming

- Organic farming is a method of crop production with an objective not to use pesticides, fertilizers, genetically modified organisms, antibiotics and growth hormones
- The principal goal of organic production is to develop enterprises that are sustainable and in agreement with the environment
- organic farming system depend upon crop rotations, use of crop residues, animal manures, legumes, green manures, off farm organic wastes, bio fertilizers, mineral bearing rocks, biological control to maintain soil productivity and to supply plant nutrients and to control insect, weeds and other pests

Organic Farming

- Use of excessive chemical fertilizers and toxic pesticides polluted the land and water deeply. This leads to severe environmental penalty like loss of topsoil, decrease in soil fertility, surface and ground water contamination and loss of genetic diversity
- Organic farming is a production management system that promotes and improves agro-ecosystem health like biodiversity, biological cycles, and soil biological activity. Organic farming methods produce even higher yields than conventional methods

Organic Farming

Objectives of organic farming

- To protect the environment, decrease soil degradation and erosion, decrease pollution, optimize biological productivity and promote a sound state of health
- To maintain long-term soil fertility by optimizing conditions for biological activity within the soil
- To maintain biological diversity within the system
- To recycle materials and resources to the greatest extent possible within the project

Organic Farming

- To provide considerate care that promotes health and meets the behavioural needs of livestock
- To prepare organic products by careful processing, and handling methods in order to maintain the organic integrity and vital qualities of the products at all stages of production
- To depend upon renewable resources in locally organised agricultural systems

Importance of organic farming

Organic farming provides many benefits like:-

- **Provides better nutrition:** organic food is rich in nutrients. Organic farming increases the nutrients of the soil which is passed on to the plants and animals
- **Helps us to stay healthy:** organic foods do not contain any chemical as organic farmers don't use chemicals at any stage of the food-growing. Organic farmers use natural farming techniques which do not harm humans and environment
- **Free of poison:** organic farmers do not make use of poisonous chemicals like pesticides and weedicides. As organic farming avoids these toxins, it reduces the chances of sickness and diseases

Importance of organic farming

- **Lower prices:** organic foods are cheaper as they don't use application of expensive pesticides, insecticides, and weedicides
- **Improved taste:** organic food tastes better than other food. The sugar content in organically grown fruits and vegetables provide them extra taste
- **Organic farming methods are eco-friendly:** organic farming does not utilize harsh chemicals so; the environment including plant life, animals, and humans remain protected
- **Longer shelf-life:** organic plants have greater metabolic and structural reliability in their cellular structure than conventional crops. This enables storage of organic food for a longer time

Organic farming

Organic farming includes:-

- **Fertilizers :**
- Organic farming does not use synthetic fertilizers and in order to build and maintain a rich, living soil addition of organic matter is done. This includes the application of manure, compost and animal by-products like feather meal or blood meal
- The USDA National Organic Standards direct that raw manure must be applied no later than 90 or 120 days before harvest, depending on whether the harvested part of the crop is in contact with the ground

Organic farming

- Compost adds organic matter to the soil and provides a wide range of nutrients for plants, and adds helpful microbes to the soil. These nutrients are mostly in an un-mineralized form which cannot be taken up by plants, soil microbes and it is required to break down organic matter into mineralized form
- Soil is maintained by planting and then ploughing in cover crops, which help to protect the soil from erosion and provide additional organic matter. The ploughing of nitrogen-fixing cover crops adds nitrogen to the soil. Cover crops are commonly planted before or after the main crop season or with crop rotation

Organic farming

Pest control

- Organic pesticides are generally used in organic farming and are derived from naturally occurring sources
- These include living organisms like Bacillus Thuringiensis, which is used to control caterpillar or plant derivatives like pyrethrins (from the dried flower heads of Chrysanthemum cinerariifolium) or neem oil (from the seeds of Azadirachta indica)
- Mineral-based inorganic pesticides like sulphur and copper are also used

Organic farming

- Along with the use of bio-pesticides, organic pest control utilizes biological, genetical control method to decrease pest damage.
- Biological control uses the natural enemies of pests
- For example certain wraps to attack insect pests
- Method of traditional plant breeding has produced numerous crop varieties that are resistant to particular pests

Organic farming

- **Soil:** Health of the soil maintained by adding manure, or compost and other organic material in place of synthetic fertilizers. Biological fertilizers like compost release the nutrients slowly, increase the capacity to retain the moisture and reduce the leaching of nitrates into ground water
- **Crop rotation:** Organic farmers do not grow the same crop on the same field year after year. Crop rotation naturally reloads the soil as different plants provide different nutrients to the soil. It also disrupts the habitats of insect pests and weeds and helps to control them

Organic Farming

Cover crops: Cover crops like clover, rye, and wheat are planted between growing seasons which help to refill the soil with nutrients and prevents soil erosion. They also control weeds by suffocating and shading by them

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

UNIT 1.3. AYURVEDIC DOSAGE FORMS

At the end of this lecture, student will be able to

- Differentiate ayurvedic dosage forms
- Explain the method of preparation of ayurvedic dosage forms
- Characteristics of ayurvedic dosage forms

Ayurvedic dosage forms

On the basis of physical form Ayurvedic dosage form are classified in to four groups

1. **Solid dosage form :** Gutika, vatika

2. **Liquid dosage form :** Asava, Arista, Taila, panak, arka

3. **Semi solid dosage form :** Avleha, paka, Lepa, ghrita

4. **Powder dosage form** : Bhasma, satva, pisti, lavana, churna

Preparation

Crude Drugs mentioned in the formula

Powdered drug/s

Asava	Arishta
Powdered drug	Decoction of powder

Transferred to Fermentation Vessel

↓

Solution of Sugar, Jaggery or Honey is added (Heated to Dissolve)

↓

For fermentation Dhatki Pushp *(Woodfordia fruticosa)* is added

↓

Flavouring agents are added

↓

Close the earthen lid sealed edges with clay smeared cloth

↓

Fermented at constant temp (1TO 3 MONTHS in a dark place without much circulation of air)

↓

Fluid decanted & filtered

↓

Filled in bottle and sealed

Arista and Asava

Arista and **Asava** – Medicinal preparations prepared by soaking the drugs either in the powder/decoction (kasaya) form in a solution of sugar or jaggery for a specific period of time, during which fermentation generating alcohol, thus facilitating the extraction of active principles present in the drug, it also serves as a preservative

Arista

- **Arista** : It is prepared by fermenting decoction of drugs along with sugar or jaggery

General composition:

Ingredient	Examples
Medicinal drugs	**Herbal** – Juice, decoction of various parts of the plant **Animals** – Ghee, honey **Minerals** – Iron, gold
Liquids	Water, gomutra, butter milk
Sweet substance	Jaggery (guda), sugar, madhuk pushpa
Prakshepaka Dravyas	Dhataki puspha

Arista

Method of Preparation:

- Kashaya is prepared from the coarsely powdered drugs as per the formula
- Obtained kashaya is strained and placed in fermentation vessel/pot
- Weighed quantity of sugar/jaggery according to the formula is dissolved in water, boiled and added
- Prakshepaka dravyas are added, if mentioned in the formula
- Contents are stirred with a wooden rod, which encourages the growth of yeast and play an imp role in fermentation

- Mouth of the vessel covered with an earthen lid
- Edges are sealed with clay smeared cloth wounded in seven layers
- Closed vessel is kept in a special room in an underground cellar or heap of paddy (To ensure constant temperature)
- Variation in temperature may accelerate or impede fermentation
- After specified period of time the contents are examined to ensure the fermentation is complete

Arista

At Onset of fermentation	At completion of fermentation
Prakshepaka dravyas float	Sink
Effervescence	No effervescence
Hissing sound	No sound
Extinguishing of burning candle	Continuation of burning
Lime water turns milky	No change

- Fluid is decanted and strained after 2-3 days, when fine particles settled at the bottom

Asava

- **Asava** : It is prepared by fermenting fine powder of drugs along with sugar or jaggery

General composition:

Ingredient	Examples
Medicinal drugs	Powdered drugs of herbal, animal or minerals
Liquids	Water, gomutra, butter milk
Sweet substance	Jaggery (guda), sugar, madhuk pushpa
Prakshepaka Dravyas	Dhataki puspha

Asava

Method of Preparation:

- Weighed quantity of sugar/jaggery according to the formula is dissolved in water, boiled and added to fermentation pot
- Weighed quantity of drug/s as per the formula in fine powder form are added
- Prakshepaka dravyas are added, if mentioned in the formula
- Contents are stirred with a wooden rod, which encourages the growth of yeast and play an imp role in fermentation

Asava

- Mouth of the vessel covered with an earthen lid
- Edges are sealed with clay smeared cloth wounded in seven layers
- Closed vessel is kept in a special room in an underground cellar or heap of paddy (To ensure constant temperature)
- Variation in temperature may accelerate or impede fermentation
- After specified period of time the contents are examined to ensure the fermentation is complete

Asava

At Onset of fermentation	At completion of fermentation
Prakshepaka dravyas float	Sink
Effervescence	No effervescence
Hissing sound	No sound
Extinguishing of burning candle	Continuation of burning
Lime water turns milky	No change

- Fluid is decanted and strained after 2-3 days, when fine particles settled at the bottom

Arista and Asava

Characters:

- Filtered preparations should be clear without froth at the top
- Should not be sour
- Posses characteristic aromatic alcohol odour

Storage: Should be stored in well stoppered bottles or jars

Examples:

Kanakasava : Chronic respiratory disorders

Madhukasava – Kshaya

Abhayarista – To relieve stress

Asokarista - Yoniruja

Summary

- Fermented preparations soaked in sugar/jaggery
- Generates alcohol during fermentation
- Arista is a decoction of the drugs soaked in sugar/jaggery
- Asava is a fine powder of the drugs soaked in sugar/jaggery
- Fermentation pot covered with clay smeared cloth
- Constant temperature
- Confirmation of fermentation
- Decant and strained
- Storage – Well stoppered bottles/jars

Avleha

Leha or avleha is a semi solid preparation of drugs which is prepared by boiling the prescribed swarasa, drug or decoction with sugar/jaggery

Composition :

- Kasaya or other liquids
- Jaggery/ sugar
- Powder/pulp of prescribed drugs
- Ghee or oil and honey

Method of preparation:

- Either jaggery or sugar is dissolved in the liquid
- Strained to remove the foreign particles
- Resultant solution is boiled over a moderate flame till the paka becomes thready
- It can be confirmed when the paka is pressed between fingers or sinks in water without getting dissolved easily
- Subsequently fine powder of drugs are added in small quantities and stirred continuously to get a homogenous mixture

Method of preparation:

- Finally ghee/oil if mentioned is added and mixed well while the preparation is still hot
- Honey may be added when the preparation is cool and mixed well if mentioned

Characters:

- Preparation should neither be hard nor viscous, it should have desirable consistency
- It should undergo neither decomposition nor fermentation
- It should be free from fungal growth
- It should retain its colour and odour

Storage:

- Should be stored in airtight glass containers
- Retain its potency indefinitely

Examples:

EXAMPLE	USE
Kantakari avleha	Sula and svasa
Chyavanprash	Immunity

Taila

Taila is the preparation in which the prescribed kasayas (Decoction) and kalkas (Pulp of drugs) are boiled in oil according to the formula

This process helps in absorption of therapeutic principles

Composition :

- **Drava dravyas** – Liquid or liquids – Kasaya/swarasa
- **Kalka** – a pulp or fine paste of drugs
- **Sneha dravya** – Oil (Taila)

General proportion of ingredients:

- General proportion of Kalka (fine paste of drugs), snehadravya (Oil) and drava dravyas (Liquid), is **1 : 4 : 16**
- When no drava dravyas is prescribed then water can be used
- If the drava dravya is swarasa, then it should be 1/8 of sneha
- When the number of drava dravyas prescribed is more than 4, then proportion of each drava dravya and sneha is **1 : 1**
- When the number of drava dravyas prescribed is 4 or less than 4, then proportion of each drava dravya and sneha is **4 : 1**
- Kasaya may be used as kalka if not prescribed in the formula

Method of preparation:

- Kalka and drava dravyas are mixed together and then boiled with taila
- Constant stirring is required to prevent the adherence of kalka to the bottom of the vessel
- In case of more number of drava dravyas, added in succession
- Next drava dravya is added when earlier added is completely evaporated

Method of preparation:

- On complete evaporation of all drava dravyas, mixture present in kalka begin to evaporate
- At this stage vigorous stirring is required otherwise kalka will stick to the bottom of the vessel
- Kalka should be tested from time to time to know the condition and stage of the paka
- Three types of pakas are described

- **Mrudu paka, madyama paka and khara paka**
- **Mrudu paka –** Kalka is waxy and rolls like a lac when rolled between fingers, suitable for nasya
- **Madhyama paka** – Kalka is harder and burns with no cracking sound , suitable for pana and vasti
- **Khara paka** – Final stage of paka, convenient for abhyanga
- Procedure is stopped when desired paka is attained as per the requirements

Characters:

- Should be of desired consistency
- Should not be sticky

Storage:

- Should be stored in airtight /well stoppered containers

Examples:

EXAMPLE	USE
Jatyadi taila	Wound healing
Narayana taila	Vata roga

Summary

- Avleha – semi solid, prescribed kasayas/swarasa boiled with sugar/jaggery
- Kasaya, swarasa, pulp, oil, honey
- Thready paka, fingers/sinks easily
- Should be neither hard nor viscous
- Taila – Prescribed kasaya or kalka boiled with taila
- Proportion of ingredients
- Continuous stirring to avoid adherence of paka
- Mrudu paka, madhyama paka and khara paka

Gutika

Gutika or pill is defined as the medicine prepared in the form of tablets or pills.

These are made up of one or more drugs of plant and mineral origin

Composition :

- Plant, mineral drugs
- Suganda dravya
- Jaggery/ sugar

Method of preparation:

- Herbal drugs are dried and powdered separately
- In case of minerals drugs made in to bhasmas
- if the formula contains gandhaka, then kijjali is prepared first and later remaining drugs are added one by one according to the formula
- Drugs are made into paste in kalva with prescribed liquids, in case more than one liquid add in succession

Method of preparation:

- Sugandha dravyas like kasturi, karpura are added when the mass attains the suitable state for molding into pills, then it is ground again
- Final stage is the one where the mass is non sticky to the fingers when rolled and punch the tablets
- Finally the pills are dried in shade or sun
- If sugar/Jaggery is prescribed, paka is prepared on mild fire, powdered drugs are added to this paka and mixed briskly

Characters:

- Should not loose colour, taste, odour and form

Storage:

Pills of plant origin in air tight containers can be used for 2-3 years

Those of mineral origin can be used indefinately

Pills with salt /Ksara should be kept away from moisture

EXAMPLE	USE
Astakshari Gutika	Athisara
Bilvadi Gutika	Jvara, Ajeerna
Lavangodi Gutika	Cough

Standardization of Gutika

Determination of

- Uniformity of weight
- Hardness
- Disintegration time
- Ash value
- Moisture content

Uniformity of weight:

- Twenty pills are selected randomly and weighed individually
- Average weight of each pill is determined
- Highest wt, lowest wt and average wt of each group of pills are calculated

Hardness:

- Place a pill in a hardness tester and rotate the knob to fix the pill in it
- Adjusted the scale to zero
- After the setting, pressure is increased by further rotating the knob
- When pill is broke down the hardness is recorded as indicated in scale
- Ten pills of each group are tested and calculated the average hardness of each pill

Disintegration time:

- Take 6 pills in the disintegration apparatus
- Adjust the apparatus in such a way that the complete up and down movement of both the tubes in a beaker containing distilled water was repeated for 30times per minute
- When the particles remain above the screen, which is readily passed through it was recorded as the disintegration time

Ash value:

- A porcelain crucible is weighed
- 2 gm of sample is taken in the weighed crucible
- Placed in an electric furnace/incinerator and gradually increase the temperature up to 700^0 C until the sample become carbon free
- Cooled and weighed

Moisture content: Loss on drying

- Take 1 gm of sample in pre-weighed watch glass
- Dry in an electric oven at 110^0 C to a constant weight
- Note down the weight at 30 min intervals
- Continue the process till the difference between two consecutive weights is not more than 5 mg

Summary

- Gutika – Pills
- Plant or mineral drugs
- Suganda dravya
- Standardization: Uniformity of weight, Hardness, Disintegration time, ash value, moisture content

Bhasma and Churna

Bhasma is a powder of the substance obtained by calcination

- Metal, mineral and animal products are calcinied in closed crucibles in pits with cow dung cakes by special process

Method of Preparation:

- **Sodhana**
- **Marana**

Sodhana:

- Sodhana is a purification process, it is a medicinal purification
- Chemical purification eliminates only foreign matter, but Sodhana aims

  - To eliminate harmful matter from the drug
  - To modify undesirable physical characters of the drug
  - To enhance the therapeutic activity of the drug

Types of Sodhana:

Samanya sodhana : Heating of thin sheets of metals by immersing in taila / gomutra

Visesa sodhana : Four types

- Bhavana – Grinding with special decoctions
- Svedana – Convert drug into a poultice
- Nirvapana – Incinerating to red hot and dipping into taila
- Mardana – Triturating /rubbing with some dravyas

Marana

- Purified drug obtained from sodhana is placed in kalva
- Ground with specified quantities of kasaya/swarasa
- Resultant material is made into small cakes
- Size and thickness of the cakes – Heaviness of the drug
- Heavier the drug thinner are the cakes and vice versa
- Cakes are dried and placed in a shallow earthen plate and closed with another

Marana

- Edges are sealed with a clay smeared cloth in seven consecutive layers and again dried
- A pit is dug in an open space
- Half of the pit is filled with cow dung cakes
- Earthen plates holding the cakes of metal/mineral is placed on cow dung cakes
- Pit is then completely filled with cow dung cakes

Marana

- Cow dung cakes are set fire all the four sides and also in the middle of the pit
- After burning allowed to cool
- Earthen plates are removed and seal is opened
- Contents are ground again in kalva into a fine powder

Characters: Bhasma should comply the following

- No metallic luster
- Float on cold water
- Not revert to original state
- Very fine, so that it get easily to the finger lines when taken between index finger and thumb
- No characteristic taste

Storage:

- Should be stored in airtight glass/earthen containers
- Retain its potency indefinitely

Examples:

EXAMPLE	USE
Svarna bhasma	Hrudroga
Rajata bhasma	Jvara, Buddhimandya

Churna is a fine powder of drug or drugs

Method of preparation:

- Drugs are cleaned and dried properly
- Finely powdered and sieved

Conditions:

- When more than one drug, each drug is weighed separately according to the formula, powdered and sieved

- As some drugs contain more fibrous matter, separate powdering, sieving and mixing is preferred
- Certain drugs like camphor, salt and sugar are to be powdered separately and mixed at the end
- Drugs like asafoetida are roasted, powdered and mixed at the end
- Drugs which are to be taken in the fresh conditions like satavari, guduchi etc are made in to paste, dried and then added to the rest

Characters:

- Should be a very fine powder of at least 80# sieve
- Should not be sticky

Storage:

- Should be stored in airtight containers

Examples:

EXAMPLE	USE
Jataphaladya churna	Atisara
Karpuradi churna	Svasa, ksaya

Summary

- Bhasma – calcination process
- Metal, mineral drugs
- Sodhana and marana
- Sodhana – medicinal purification, Bhavana, svedhana, nirvapana and mardana
- Kalva, cakes, sealed with clay smeared cloth
- Pit, cow dung cakes, fire, cool, grind into a fine powder
- Churna – fine powder of drug/s, dried, sieved and finely powdered
- Conditions for preparing churna

Lecture No.4
Avleha and taila

At the end of this lecture, student will be able to

- Define avleha and taila
- Explain the method of preparation of avleha and taila

Content
Avleha and taila

At the end of this lecture, student will be able to

- Definition of avleha and taila
- Method of preparation of avleha and taila
- Characteristics of avleha and taila

Avleha

Leha or avleha is a semi solid preparation of drugs which is prepared by boiling the prescribed swarasa, drug or decoction with sugar/jaggery

Composition :

- Kasaya or other liquids
- Jaggery/ sugar
- Powder/pulp of prescribed drugs
- Ghee or oil and honey

Avleha

Method of preparation:

- Either jaggery or sugar is dissolved in the liquid
- Strained to remove the foreign particles
- Resultant solution is boiled over a moderate flame till the paka becomes thready
- It can be confirmed when the paka is pressed between fingers or sinks in water without getting dissolved easily
- Subsequently fine powder of drugs are added in small quantities and stirred continuously to get a homogenous mixture

Avleha

Method of preparation:

- Finally ghee/oil if mentioned is added and mixed well while the preparation is still hot
- Honey may be added when the preparation is cool and mixed well if mentioned

Avleha

Characters:

- Preparation should neither be hard nor viscous, it should have desirable consistency
- It should undergo neither decomposition nor fermentation
- It should be free from fungal growth
- It should retain its colour and odour

Avleha

Storage:

- Should be stored in airtight glass containers
- Retain its potency indefinitely

Examples:

Example	Use
Kantakari avleha	Sula and svasa
Chyavanprash	Immunity

Taila

Taila is the preparation in which the prescribed kasayas (Decoction) and kalkas (Pulp of drugs) are boiled in oil according to the formula

This process helps in absorption of therapeutic principles

Composition :

- **Drava dravyas** – Liquid or liquids – Kasaya/swarasa
- **Kalka** – a pulp or fine paste of drugs
- **Sneha dravya** – Oil (Taila)

Taila

General proportion of ingredients:

- General proportion of Kalka (fine paste of drugs), snehadravya (Oil) and drava dravyas (Liquid), is **1 : 4 : 16**
- When no drava dravyas is prescribed then water can be used
- If the drava dravya is swarasa, then it should be 1/8 of sneha
- When the number of drava dravyas prescribed is more than 4, then proportion of each drava dravya and sneha is **1 : 1**
- When the number of drava dravyas prescribed is 4 or less than 4, then proportion of each drava dravya and sneha is **4 : 1**
- Kasaya may be used as kalka if not prescribed in the formula

Taila

Method of preparation:

- Kalka and drava dravyas are mixed together and then boiled with taila
- Constant stirring is required to prevent the adherence of kalka to the bottom of the vessel
- In case of more number of drava dravyas, added in succession
- Next drava dravya is added when earlier added is completely evaporated

Taila

Method of preparation:

- On complete evaporation of all drava dravyas, mixture present in kalka begin to evaporate
- At this stage vigorous stirring is required otherwise kalka will stick to the bottom of the vessel
- Kalka should be tested from time to time to know the condition and stage of the paka
- Three types of pakas are described

Taila

- **Mrudu paka, madyama paka and khara paka**
- **Mrudu paka –** Kalka is waxy and rolls like a lac when rolled between fingers, suitable for nasya
- **Madhyama paka** – Kalka is harder and burns with no cracking sound , suitable for pana and vasti
- **Khara paka** – Final stage of paka, convenient for abhyanga
- Procedure is stopped when desired paka is attained as per the requirements

Taila

Characters:

- Should be of desired consistency
- Should not be sticky

Storage:

- Should be stored in airtight /well stoppered containers

Examples:

Example	Use
Jatyadi taila	Wound healing
Narayana taila	Vata roga

Summary

- Avleha – semi solid, prescribed kasayas/swarasa boiled with sugar/jaggery
- Kasaya, swarasa, pulp, oil, honey
- Thready paka, fingers/sinks easily
- Should be neither hard nor viscous
- Taila – Prescribed kasaya or kalka boiled with taila
- Proportion of ingredients
- Continuous stirring to avoid adherence of paka
- Mrudu paka, madhyama paka and khara paka

Lecture No 1
Traditional system of medicines - Ayurveda

At the end of this lecture, student will be able to

- Discuss the role of Ayurveda in traditional systems of medicine
- Explain the principle of Ayurveda

Content
Traditional system of medicines
Ayurveda

- Role of Ayurveda in traditional systems of medicine
- Principle of Ayurveda

Traditional systems of medicine

- Traditional systems like Ayurveda, Siddha and Unani impart knowledge about folklore practices and medicinal importance of drugs of natural origin
- The standardization of these drugs is essential since, these drugs are used to treat various ailments of human being
- The role of medicinal plants in traditional system made them back bone of these systems
- Traditional medicine is the sum of the knowledge, skills and beliefs of different cultures of different countries for the maintenance of health

Ayurveda

- **Ayurveda** – Oldest system of traditional medicine
- Dominant herbal tradition in India
- Enjoys a faith of large number of people
- Spectrum of influence is being enlarged as it is encouraged in many countries like Japan, Germany etc
- Ayurveda – Two Sanskrit words

  Ayur – Life, **Veda** – Knowledge /Science

  Ayurveda is knowledge of life or science of life

Ayurveda

- Ayurveda – Incorporates Science and religion
- Aim include enhancing well being and increasing longevity
- Essence of Ayurveda lies in providing **“ Swasthya “** which is a union of physical, emotional and spiritual health
- About 5000 years evolved from the deep wisdom of rishies of Himalaya
- Knowledge had been transmitted orally from teachers to disciples
- Finally took the form of Vedas during 1500 BC

Ayurveda

- Punarvasu athreya – Ayurveda school
- Recorded medicinal knowledge of many plants
- **Charaka** – Charaka Samhitha, more than 1500 medicinal herbs
- **Sushrutha samhitha** – Basis for modern surgery
- About 75-80% of population is still relying on herbal medicine especially in developing countries because of better compatibility and lesser side effects.

Ayurveda

Principle:

- Based on concept of five basic elements (Pancha mahabhuthas) and tri doshas
- Whole universe is made up of five basic elements
- Whole universe – Material world, plant kingdom an other living beings
- All the five elements – Basis of all matter

Ayurveda

Basic elements

English Name	Sanskrit Name
Ether	Akasha
Air	Vayu
Fire	Agni
Water	Jala
Earth	Prithvi

Ayurveda

Properties, location / manifestations

English Name	Sanskrit Name	Property	Location
Ether	Akasha	Non-resistance	Body cavities, mouth, thorax, lung cavity
Air	Vayu	Movements, vibrations	Movement of muscles, pulsation of heart, contraction of lungs
Fire	Agni	Radiation	Digestion, metabolism, vision and Intelligence
Water	Jala	Force	Blood, salivary glands, gastric juice
Earth	Pruthvi	Resistance and solidarity	Hair, nails, bones, skin

Ayurveda

Tri Doshas

Dosha	Combination of
Vata (Air principle)	Ether and air
Pitta (Fire principle)	Fire and water
Kapha (Water principle)	Earth and water

Ayurveda

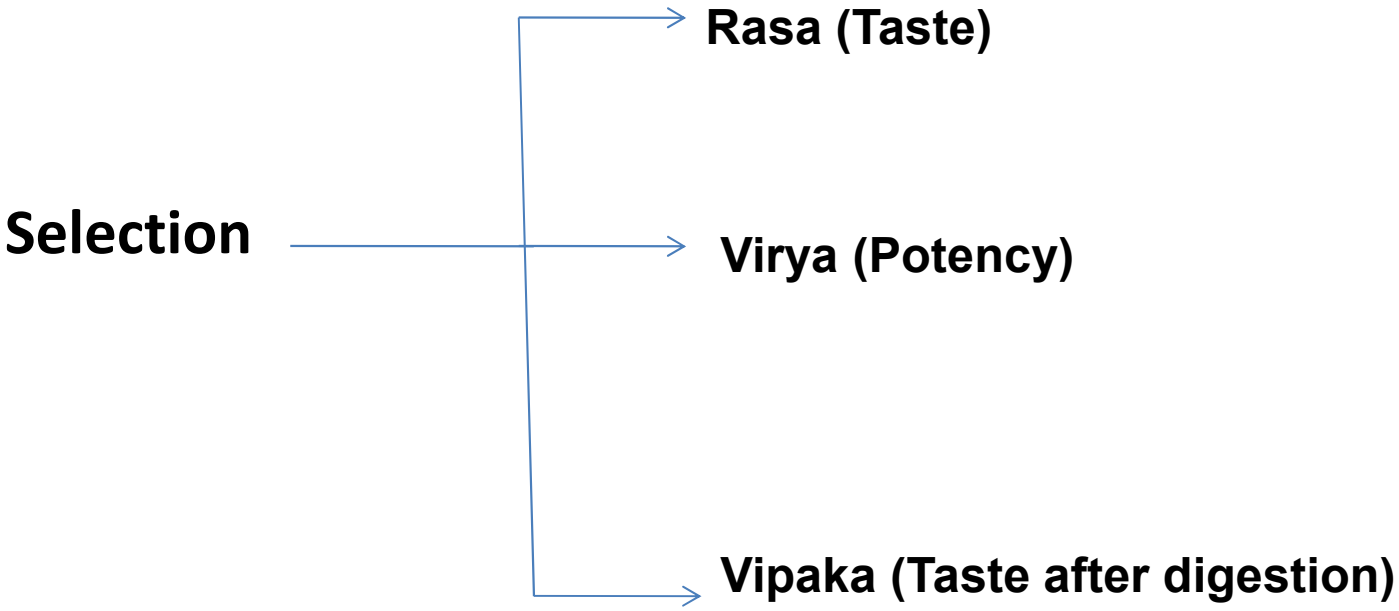
- Tridoshas exist in everything and influence physical and mental processes
- Tridoshas in hormony with each other, however one of them is dominating in every human being
- Determines **Prakruthi** of the person
- Body type, temperament, susceptibility to illness – influenced by predominant dosha
- Man is born with a particular balance of doshas
- Balance of doshas of parents at the time of conception determines the proportion of doshas

Ayurveda

- Health – Total harmony of vata, pitta and kapha
- Sickness – Imbalance of any one or more of doshas
- Aggregation of pitta – Indigestion, skin diseases, liver problems
- Aggregation of vata – Nerve problems
- Aggregation of kapha – Gastric problems
- Physical, mental and environmental factors contribute for the imbalance of doshas

Ayurveda

Selection of drugs:



Ayurveda

Rasa (Taste) :

Taste	Combination of	Influence on doshas
Sweet	Earth and water	Kapha increases, vata and pitta decreases
Sour	Water and fire	Pitta increases
Saline	Fire and earth	Pitta increases
Bitter	Air and fire	Pitta increases
Pungent	Air and ether	Kapha and pitta decreases
Astringent	Air and earth	Pitta decreases, vata increases

Role of herbs in cosmetics

Virya : Hot drug and cold drugs

- Hot drugs – Drumstick, garlic
- Cold drugs – Jeera, Amla

Vipaka : Taste after digestion

Taste	Aggravates	Allevietes
Sweet	Kapha	Pitta and vata
Sour	Pitta	Kapha and vata
Pungent	Vata	Kapha

Summary

- Science/knowledge of life
- Five basic elements and tridoshas
- Akasha, vayu, jala, agni, and pruthvi – basis for all matters
- Kapha, pitta and vata
- Tridohas – combination of different elements
- Doshas – Nature of person, imbalance leads to sickness
- Selection of drugs – Rasa, virya and vipaka
- Six rasas, three vipakas
- Virya – hot and cold

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

UNIT 1.3. AYURVEDIC DOSAGE FORMS

At the end of this lecture, student will be able to

- Differentiate ayurvedic dosage forms
- Explain the method of preparation of ayurvedic dosage forms
- Characteristics of ayurvedic dosage forms

Ayurvedic dosage forms

On the basis of physical form Ayurvedic dosage form are classified in to four groups

1. **Solid dosage form :** Gutika, vatika
2. **Liquid dosage form :** Asava, Arista, Taila, panak, arka
3. **Semi solid dosage form :** Avleha, paka, Lepa, ghrita
4. **Powder dosage form** : Bhasma, satva, pisti, lavana, churna

Preparation

Crude Drugs mentioned in the formula

Powdered drug/s

Asava — Powdered drug

Arishta — Decoction of powder

Transferred to Fermentation Vessel

Solution of Sugar, Jaggery or Honey is added (Heated to Dissolve)

For fermentation Dhatki Pushp *(Woodfordia fruticosa)* is added

Flavouring agents are added

Close the earthen lid sealed edges with clay smeared cloth

Fermented at constant temp (1TO 3 MONTHS in a dark place without much circulation of air)

Fluid decanted & filtered

Filled in bottle and sealed

Arista and Asava

Arista and **Asava** – Medicinal preparations prepared by soaking the drugs either in the powder/decoction (kasaya) form in a solution of sugar or jaggery for a specific period of time, during which fermentation generating alcohol, thus facilitating the extraction of active principles present in the drug, it also serves as a preservative

Arista

- **Arista** : It is prepared by fermenting decoction of drugs along with sugar or jaggery

General composition:

Ingredient	Examples
Medicinal drugs	**Herbal** – Juice, decoction of various parts of the plant **Animals** – Ghee, honey **Minerals** – Iron, gold
Liquids	Water, gomutra, butter milk
Sweet substance	Jaggery (guda), sugar, madhuk pushpa
Prakshepaka Dravyas	Dhataki puspha

Arista

Method of Preparation:

- Kashaya is prepared from the coarsely powdered drugs as per the formula
- Obtained kashaya is strained and placed in fermentation vessel/pot
- Weighed quantity of sugar/jaggery according to the formula is dissolved in water, boiled and added
- Prakshepaka dravyas are added, if mentioned in the formula
- Contents are stirred with a wooden rod, which encourages the growth of yeast and play an imp role in fermentation

- Mouth of the vessel covered with an earthen lid
- Edges are sealed with clay smeared cloth wounded in seven layers
- Closed vessel is kept in a special room in an underground cellar or heap of paddy (To ensure constant temperature)
- Variation in temperature may accelerate or impede fermentation
- After specified period of time the contents are examined to ensure the fermentation is complete

Arista

At Onset of fermentation	At completion of fermentation
Prakshepaka dravyas float	Sink
Effervescence	No effervescence
Hissing sound	No sound
Extinguishing of burning candle	Continuation of burning
Lime water turns milky	No change

- Fluid is decanted and strained after 2-3 days, when fine particles settled at the bottom

Asava

- **Asava** : It is prepared by fermenting fine powder of drugs along with sugar or jaggery

General composition:

Ingredient	Examples
Medicinal drugs	Powdered drugs of herbal, animal or minerals
Liquids	Water, gomutra, butter milk
Sweet substance	Jaggery (guda), sugar, madhuk pushpa
Prakshepaka Dravyas	Dhataki puspha

Asava

Method of Preparation:

- Weighed quantity of sugar/jaggery according to the formula is dissolved in water, boiled and added to fermentation pot
- Weighed quantity of drug/s as per the formula in fine powder form are added
- Prakshepaka dravyas are added, if mentioned in the formula
- Contents are stirred with a wooden rod, which encourages the growth of yeast and play an imp role in fermentation

Asava

- Mouth of the vessel covered with an earthen lid
- Edges are sealed with clay smeared cloth wounded in seven layers
- Closed vessel is kept in a special room in an underground cellar or heap of paddy (To ensure constant temperature)
- Variation in temperature may accelerate or impede fermentation
- After specified period of time the contents are examined to ensure the fermentation is complete

Asava

At Onset of fermentation	At completion of fermentation
Prakshepaka dravyas float	Sink
Effervescence	No effervescence
Hissing sound	No sound
Extinguishing of burning candle	Continuation of burning
Lime water turns milky	No change

- Fluid is decanted and strained after 2-3 days, when fine particles settled at the bottom

Arista and Asava

Characters:

- Filtered preparations should be clear without froth at the top
- Should not be sour
- Posses characteristic aromatic alcohol odour

Storage: Should be stored in well stoppered bottles or jars

Examples:

Kanakasava : Chronic respiratory disorders

Madhukasava – Kshaya

Abhayarista – To relieve stress

Asokarista - Yoniruja

Summary

- Fermented preparations soaked in sugar/jaggery
- Generates alcohol during fermentation
- Arista is a decoction of the drugs soaked in sugar/jaggery
- Asava is a fine powder of the drugs soaked in sugar/jaggery
- Fermentation pot covered with clay smeared cloth
- Constant temperature
- Confirmation of fermentation
- Decant and strained
- Storage – Well stoppered bottles/jars

Avleha

Leha or avleha is a semi solid preparation of drugs which is prepared by boiling the prescribed swarasa, drug or decoction with sugar/jaggery

Composition :

- Kasaya or other liquids
- Jaggery/ sugar
- Powder/pulp of prescribed drugs
- Ghee or oil and honey

Method of preparation:

- Either jaggery or sugar is dissolved in the liquid
- Strained to remove the foreign particles
- Resultant solution is boiled over a moderate flame till the paka becomes thready
- It can be confirmed when the paka is pressed between fingers or sinks in water without getting dissolved easily
- Subsequently fine powder of drugs are added in small quantities and stirred continuously to get a homogenous mixture

Method of preparation:

- Finally ghee/oil if mentioned is added and mixed well while the preparation is still hot
- Honey may be added when the preparation is cool and mixed well if mentioned

Characters:

- Preparation should neither be hard nor viscous, it should have desirable consistency
- It should undergo neither decomposition nor fermentation
- It should be free from fungal growth
- It should retain its colour and odour

Storage:

- Should be stored in airtight glass containers
- Retain its potency indefinitely

Examples:

EXAMPLE	USE
Kantakari avleha	Sula and svasa
Chyavanprash	Immunity

Taila

Taila is the preparation in which the prescribed kasayas (Decoction) and kalkas (Pulp of drugs) are boiled in oil according to the formula

This process helps in absorption of therapeutic principles

Composition :

- **Drava dravyas** – Liquid or liquids – Kasaya/swarasa
- **Kalka** – a pulp or fine paste of drugs
- **Sneha dravya** – Oil (Taila)

General proportion of ingredients:

- General proportion of Kalka (fine paste of drugs), snehadravya (Oil) and drava dravyas (Liquid), is **1 : 4 : 16**
- When no drava dravyas is prescribed then water can be used
- If the drava dravya is swarasa, then it should be 1/8 of sneha
- When the number of drava dravyas prescribed is more than 4, then proportion of each drava dravya and sneha is **1 : 1**
- When the number of drava dravyas prescribed is 4 or less than 4, then proportion of each drava dravya and sneha is **4 : 1**
- Kasaya may be used as kalka if not prescribed in the formula

Method of preparation:

- Kalka and drava dravyas are mixed together and then boiled with taila
- Constant stirring is required to prevent the adherence of kalka to the bottom of the vessel
- In case of more number of drava dravyas, added in succession
- Next drava dravya is added when earlier added is completely evaporated

Method of preparation:

- On complete evaporation of all drava dravyas, mixture present in kalka begin to evaporate
- At this stage vigorous stirring is required otherwise kalka will stick to the bottom of the vessel
- Kalka should be tested from time to time to know the condition and stage of the paka
- Three types of pakas are described

- **Mrudu paka, madyama paka and khara paka**
- **Mrudu paka –** Kalka is waxy and rolls like a lac when rolled between fingers, suitable for nasya
- **Madhyama paka** – Kalka is harder and burns with no cracking sound , suitable for pana and vasti
- **Khara paka** – Final stage of paka, convenient for abhyanga
- Procedure is stopped when desired paka is attained as per the requirements

Characters:

- Should be of desired consistency
- Should not be sticky

Storage:

- Should be stored in airtight /well stoppered containers

Examples:

EXAMPLE	USE
Jatyadi taila	Wound healing
Narayana taila	Vata roga

Summary

- Avleha – semi solid, prescribed kasayas/swarasa boiled with sugar/jaggery
- Kasaya, swarasa, pulp, oil, honey
- Thready paka, fingers/sinks easily
- Should be neither hard nor viscous
- Taila – Prescribed kasaya or kalka boiled with taila
- Proportion of ingredients
- Continuous stirring to avoid adherence of paka
- Mrudu paka, madhyama paka and khara paka

Gutika

Gutika or pill is defined as the medicine prepared in the form of tablets or pills.

These are made up of one or more drugs of plant and mineral origin

Composition :

- Plant, mineral drugs
- Suganda dravya
- Jaggery/ sugar

Method of preparation:

- Herbal drugs are dried and powdered separately
- In case of minerals drugs made in to bhasmas
- if the formula contains gandhaka, then kijjali is prepared first and later remaining drugs are added one by one according to the formula
- Drugs are made into paste in kalva with prescribed liquids, in case more than one liquid add in succession

Method of preparation:

- Sugandha dravyas like kasturi, karpura are added when the mass attains the suitable state for molding into pills, then it is ground again
- Final stage is the one where the mass is non sticky to the fingers when rolled and punch the tablets
- Finally the pills are dried in shade or sun
- If sugar/Jaggery is prescribed, paka is prepared on mild fire, powdered drugs are added to this paka and mixed briskly

Characters:

- Should not loose colour, taste, odour and form

Storage:

Pills of plant origin in air tight containers can be used for 2-3 years

Those of mineral origin can be used indefinately

Pills with salt /Ksara should be kept away from moisture

EXAMPLE	USE
Astakshari Gutika	Athisara
Bilvadi Gutika	Jvara, Ajeerna
Lavangodi Gutika	Cough

Standardization of Gutika

Determination of

- Uniformity of weight
- Hardness
- Disintegration time
- Ash value
- Moisture content

Uniformity of weight:

- Twenty pills are selected randomly and weighed individually
- Average weight of each pill is determined
- Highest wt, lowest wt and average wt of each group of pills are calculated

Hardness:

- Place a pill in a hardness tester and rotate the knob to fix the pill in it
- Adjusted the scale to zero
- After the setting, pressure is increased by further rotating the knob
- When pill is broke down the hardness is recorded as indicated in scale
- Ten pills of each group are tested and calculated the average hardness of each pill

Disintegration time:

- Take 6 pills in the disintegration apparatus
- Adjust the apparatus in such a way that the complete up and down movement of both the tubes in a beaker containing distilled water was repeated for 30times per minute
- When the particles remain above the screen, which is readily passed through it was recorded as the disintegration time

Ash value:

- A porcelain crucible is weighed
- 2 gm of sample is taken in the weighed crucible
- Placed in an electric furnace/incinerator and gradually increase the temperature up to 700^0 C until the sample become carbon free
- Cooled and weighed

Moisture content: Loss on drying

- Take 1 gm of sample in pre-weighed watch glass
- Dry in an electric oven at 110^0 C to a constant weight
- Note down the weight at 30 min intervals
- Continue the process till the difference between two consecutive weights is not more than 5 mg

Summary

- Gutika – Pills
- Plant or mineral drugs
- Suganda dravya
- Standardization: Uniformity of weight, Hardness, Disintegration time, ash value, moisture content

Bhasma and Churna

Bhasma is a powder of the substance obtained by calcination

- Metal, mineral and animal products are calcinied in closed crucibles in pits with cow dung cakes by special process

Method of Preparation:

- **Sodhana**
- **Marana**

Sodhana:

- Sodhana is a purification process, it is a medicinal purification
- Chemical purification eliminates only foreign matter, but Sodhana aims

  - To eliminate harmful matter from the drug
  - To modify undesirable physical characters of the drug
  - To enhance the therapeutic activity of the drug

Types of Sodhana:

Samanya sodhana : Heating of thin sheets of metals by immersing in taila / gomutra

Visesa sodhana : Four types

- Bhavana – Grinding with special decoctions
- Svedana – Convert drug into a poultice
- Nirvapana – Incinerating to red hot and dipping into taila
- Mardana – Triturating /rubbing with some dravyas

Marana

- Purified drug obtained from sodhana is placed in kalva
- Ground with specified quantities of kasaya/swarasa
- Resultant material is made into small cakes
- Size and thickness of the cakes – Heaviness of the drug
- Heavier the drug thinner are the cakes and vice versa
- Cakes are dried and placed in a shallow earthen plate and closed with another

Marana

- Edges are sealed with a clay smeared cloth in seven consecutive layers and again dried
- A pit is dug in an open space
- Half of the pit is filled with cow dung cakes
- Earthen plates holding the cakes of metal/mineral is placed on cow dung cakes
- Pit is then completely filled with cow dung cakes

Marana

- Cow dung cakes are set fire all the four sides and also in the middle of the pit
- After burning allowed to cool
- Earthen plates are removed and seal is opened
- Contents are ground again in kalva into a fine powder

Characters: Bhasma should comply the following

- No metallic luster
- Float on cold water
- Not revert to original state
- Very fine, so that it get easily to the finger lines when taken between index finger and thumb
- No characteristic taste

Storage:

- Should be stored in airtight glass/earthen containers
- Retain its potency indefinitely

Examples:

EXAMPLE	USE
Svarna bhasma	Hrudroga
Rajata bhasma	Jvara, Buddhimandya

Churna is a fine powder of drug or drugs

Method of preparation:

- Drugs are cleaned and dried properly
- Finely powdered and sieved

Conditions:

- When more than one drug, each drug is weighed separately according to the formula, powdered and sieved

- As some drugs contain more fibrous matter, separate powdering, sieving and mixing is preferred
- Certain drugs like camphor, salt and sugar are to be powdered separately and mixed at the end
- Drugs like asafoetida are roasted, powdered and mixed at the end
- Drugs which are to be taken in the fresh conditions like satavari, guduchi etc are made in to paste, dried and then added to the rest

Characters:

- Should be a very fine powder of at least 80# sieve
- Should not be sticky

Storage:

- Should be stored in airtight containers

Examples:

EXAMPLE	USE
Jataphaladya churna	Atisara
Karpuradi churna	Svasa, ksaya

Summary

- Bhasma – calcination process
- Metal, mineral drugs
- Sodhana and marana
- Sodhana – medicinal purification, Bhavana, svedhana, nirvapana and mardana
- Kalva, cakes, sealed with clay smeared cloth
- Pit, cow dung cakes, fire, cool, grind into a fine powder
- Churna – fine powder of drug/s, dried, sieved and finely powdered
- Conditions for preparing churna

Lecture No.3
Bhasma and Churna

At the end of this lecture, student will be able to

- Define bhasma and churna
- Explain the method of preparation of Bhasma and churna

Content
Bhasma and Churna

- Definition of bhasma and churna
- Method of preparation of Bhasma and churna
- Characteristics of bhasma and churna

Bhasma

Bhasma is a powder of the substance obtained by calcination

- Metal, mineral and animal products are calcinied in closed crucibles in pits with cow dung cakes by special process

Method of Preparation:

- **Sodhana**
- **Marana**

Bhasma

Sodhana:

- Sodhana is a purification process, it is a medicinal purification
- Chemical purification eliminates only foreign matter, but Sodhana aims

  - To eliminate harmful matter from the drug
  - To modify undesirable physical characters of the drug
  - To enhance the therapeutic activity of the drug

Bhasma

Types of Sodhana:

Samanya sodhana : Heating of thin sheets of metals by immersing in taila / gomutra

Visesa sodhana : Four types

- Bhavana – Grinding with special decoctions
- Svedana – Convert drug into a poultice
- Nirvapana – Incinerating to red hot and dipping into taila
- Mardana – Triturating /rubbing with some dravyas

Bhasma

Marana

- Purified drug obtained from sodhana is placed in kalva
- Ground with specified quantities of kasaya/swarasa
- Resultant material is made into small cakes
- Size and thickness of the cakes – Heaviness of the drug
- Heavier the drug thinner are the cakes and vice versa
- Cakes are dried and placed in a shallow earthen plate and closed with another

Bhasma

Marana

- Edges are sealed with a clay smeared cloth in seven consecutive layers and again dried
- A pit is dug in an open space
- Half of the pit is filled with cow dung cakes
- Earthen plates holding the cakes of metal/mineral is placed on cow dung cakes
- Pit is then completely filled with cow dung cakes

Bhasma

Marana

- Cow dung cakes are set fire all the four sides and also in the middle of the pit
- After burning allowed to cool
- Earthen plates are removed and seal is opened
- Contents are ground again in kalva into a fine powder

Bhasma

Characters: Bhasma should comply the following

- No metallic luster
- Float on cold water
- Not revert to original state
- Very fine, so that it get easily to the finger lines when taken between index finger and thumb
- No characteristic taste

Bhasma

Storage:

- Should be stored in airtight glass/earthen containers
- Retain its potency indefinitely

Examples:

Example	Use
Svarna bhasma	Hrudroga
Rajata bhasma	Jvara, Buddhimandya

Churna

Churna is a fine powder of drug or drugs

Method of preparation:

- Drugs are cleaned and dried properly
- Finely powdered and sieved

Conditions:

- When more than one drug, each drug is weighed separately according to the formula, powdered and sieved

Churna

- As some drugs contain more fibrous matter, separate powdering, sieving and mixing is preferred
- Certain drugs like camphor, salt and sugar are to be powdered separately and mixed at the end
- Drugs like asafoetida are roasted, powdered and mixed at the end
- Drugs which are to be taken in the fresh conditions like satavari, guduchi etc are made in to paste, dried and then added to the rest

Churna

Characters:

- Should be a very fine powder of at least 80# sieve
- Should not be sticky

Storage:

- Should be stored in airtight containers

Examples:

Example	Use
Jataphaladya churna	Atisara
Karpuradi churna	Svasa, ksaya

Summary

- Bhasma – calcination process
- Metal, mineral drugs
- Sodhana and marana
- Sodhana – medicinal purification, Bhavana, svedhana, nirvapana and mardana
- Kalva, cakes, sealed with clay smeared cloth
- Pit, cow dung cakes, fire, cool, grind into a fine powder
- Churna – fine powder of drug/s, dried, sieved and finely powdered
- Conditions for preparing churna

Lecture No.6
Gutika

At the end of this lecture, student will be able to

- Define gutika
- Explain the method of preparation of Gutika

Content
Gutika

At the end of this lecture, student will be able to

- Definition of Gutika
- Method of preparation of Gutika
- Characteristics of Gutika

Gutika

Gutika or pill is defined as the medicine prepared in the form of tablets or pills.

These are made up of one or more drugs of plant and mineral origin

Composition :

- Plant, mineral drugs
- Suganda dravya
- Jaggery/ sugar

Gutika

Method of preparation:

- Herbal drugs are dried and powdered separately
- In case of minerals drugs made in to bhasmas
- if the formula contains gandhaka, then kijjali is prepared first and later remaining drugs are added one by one according to the formula
- Drugs are made into paste in kalva with prescribed liquids, in case more than one liquid add in succession

Gutika

Method of preparation:

- Sugandha dravyas like kasturi, karpura are added when the mass attains the suitable state for molding into pills, then it is ground again
- Final stage is the one where the mass is non sticky to the fingers when rolled and punch the tablets
- Finally the pills are dried in shade or sun
- If sugar/Jaggery is prescribed, paka is prepared on mild fire, powdered drugs are added to this paka and mixed briskly

Gutika

Characters:

- Should not loose colour, taste, odour and form

Storage:

Pills of plant origin in air tight containers can be used for 2-3 years

Those of mineral origin can be used indefinately

Pills with salt /Ksara should be kept away from moisture

Gutika

Example	Use
Astakshari Gutika	Athisara
Bilvadi Gutika	Jvara, Ajeerna
Lavangodi Gutika	Cough

Standardization of Gutika

Determination of

- Uniformity of weight
- Hardness
- Disintegration time
- Ash value
- Moisture content

Standardization of Gutika

Uniformity of weight:

- Twenty pills are selected randomly and weighed individually
- Average weight of each pill is determined
- Highest wt, lowest wt and average wt of each group of pills are calculated

Standardization of Gutika

Hardness:

- Place a pill in a hardness tester and rotate the knob to fix the pill in it
- Adjusted the scale to zero
- After the setting, pressure is increased by further rotating the knob
- When pill is broke down the hardness is recorded as indicated in scale
- Ten pills of each group are tested and calculated the average hardness of each pill

Standardization of Gutika

Disintegration time:

- Take 6 pills in the disintegration apparatus
- Adjust the apparatus in such a way that the complete up and down movement of both the tubes in a beaker containing distilled water was repeated for 30times per minute
- When the particles remain above the screen, which is readily passed through it was recorded as the disintegration time

Standardization of Gutika

Ash value:

- A porcelain crucible is weighed
- 2 gm of sample is taken in the weighed crucible
- Placed in an electric furnace/incinerator and gradually increase the temperature up to 700^0 C until the sample become carbon free
- Cooled and weighed

Standardization of Gutika

Moisture content: Loss on drying

- Take 1 gm of sample in pre-weighed watch glass
- Dry in an electric oven at 110^0 C to a constant weight
- Note down the weight at 30 min intervals
- Continue the process till the difference between two consecutive weights is not more than 5 mg

Summary

- Gutika – Pills
- Plant or mineral drugs
- Suganda dravya
- Standardization: Uniformity of weight, Hardness, Disintegration time, ash value, moisture content

Lecture No.5
Siddha, homeopathy, Unani

At the end of this lecture, student will be able to

- Discuss the role of Siddha, Homeopathy and Unani in traditional systems of medicine
- Explain the principle of Siddha, homeopathy and Unani

Content
Siddha, homeopathy, Unani

- Role of Siddha, Homeopathy and Unani in traditional systems of medicine
- Principle of Siddha, homeopathy and Unani system

Traditional systems of medicine

- Traditional systems like Ayurveda, Siddha and Unani impart knowledge about folklore practices and medicinal importance of drugs of natural origin
- The standardization of these drugs is essential since, these drugs are used to treat various ailments of human being
- The role of medicinal plants in traditional system made them back bone of these systems
- Traditional medicine is the sum of the knowledge, skills and beliefs of different cultures of different countries for the maintenance of health

Siddha

- Ayurveda and Siddha – Truly Indian in their origin and development
- Ayurveda is practiced through out India, Siddha is restricted to Tamil Nadu
- Exclusively linked with Tamil culture and civilization
- Siddha system was flourished during first Tamil sangram
- Earliest references on Siddha medicine – Tholakapium and Thirumandiram
- Information on medicinal plants, astrology philosophy and yoga are described

Siddha

- This acquired information gradually sysytemized and developed into Siddha system
- Agasthier - First Siddha physician
- Origin of Siddha system – Devine theory
- Devine theory – origin is credited to god shiva
- Siddha – Therapeutics, astrology, yoga and philosophy

Siddha

Principle: According to Siddha system

- Human body is not merely a composite of muscles, bones, tissues and nerves
- There is a close relation and intimate connections between nature and man
- Man is not free from the influence of nature
- Five elements (Earth, water, air, fire and ether), mind and soul are the basic requirements of creation, preservation and destruction

Siddha

Origin of Diseases:

1. **Disturbance to soul:** Disturbance to soul (Inner man) leads to diseases as soul and mind are integral parts of man's true constitution
2. **Imbalance of humors:** Vazhi, Azal and Iyyam, imbalance of these humors i.e, Increase or decrease of one or more of them cause diseases
3. **Poisonous substances:** Entry of impure and injurious elements through food, drink, inhalation or absorption through skin causes diseases

Siddha

4. **Psycological causes :** Psychological states such as passion, evil desires, disordered thoughts and morbid imaginations produce physiological changes in the body leading to diseases

5. **Spiritual causes :** Morbid imaginations may produce abnormal secretions and also either increase or decrease the levels of hormones and their stimulants and these changes results in diseases

6. **Astral influence :** Astral influences only those places where causes of infection exists but not the whole world.

   They cause no harm in the absence of germs in atmosphere, water or in the human body but cause diseases if germs exist

Siddha contd.

Diagnosis

- For diagnosis, pulse reading and examination of the organs other than those directly affected are carried out
- The climate, strength and power of digestion, temperament, age, habits and habitat of the patient are also observed

Therapeutics

- The material medica of siddha system contains vegetables, minerals, metals, marine and animal products

Homeopathy

- Homeopathy is comparatively a recent system of medicine
- It has been developed in 18th century by Samuel Hahnemann, an internationally reputed physician and chemist
- The drugs, which produce symptoms in a healthy person, can remove the same symptoms in an ill person and this forms the basis of Homeopathy
- Samuel Hahnemann compiled all his findings in Organan of Medicine

Homeopathy contd.

Principle

- The axiom discovered by Hahnemann is 'Law of Similar' – Similia Similabus Curentur, means let likes treated by likes
- The cause of the disease itself can be its treatment and is the fundamental principle of homeopathy
- According to Hahnemann, diseases are congenital and caused by gene mutations, hence homeopathy is called as Genetic medicine
- Miasms are of three types,
    - Psora
    - Psychosis
    - Syphilis

Homeopathy contd.

- These exist in a suppressed or sleeping state in a person
- As long as they are in that state, the person does not suffer from diseases due to resistance power
- If any one of them is stimulated, then the person loses his resistance power and suffers from diseases related to it
- The interesting point is that Hahnemann discovered the drugs by testing them on humans but not on animals
- Animals reveal only the physical changes whereas man can express the psychological changes also

Homeopathy contd.

- The drug is administered to a healthy person to excite any one of the miasms ie, Psora, Psycosis or syphilis and the symptoms of the drugs are discovered
- Another important and significant feature, which is exclusively of homeopathy, is the theory of Dynamization (Potentiation)
- **Theory of Dynamization**
- It is the process by which the quality of the medicine is improved
- In this process, the medicine is subjected to shaking and friction in a medium
- By this, the bigger molecules undergo division to form more number of smaller molecules resulting in improved potency

Homeopathy contd.

Treatment

- The purpose of administration of the drug is to stimulate natural and inherent powers of the body
- Thus, it stresses the cure for disease in a natural way
- It mobilizes the defense mechanism of the body against offending agents
- Therefore it achieves an ideal cure devoid of side effects
- The treatment is based on the concept of proving and prover
    - Prover; The healthy person
    - Proving: The symptoms (physical, mental, emotional changes) that are caused in prover by the various potencies of medicines

Homeopathy contd.

- For treatment, the symptoms of the drugs are compared with the symptoms of the patient
- Homepathic medicines are available in the form of mother tinctures
- On dilution, the different potencies are obtained in terms of decimal and centesimal potencies

Unani

- In Arabic, Unani means Greece and Tibb means medicine
- Unani Tibb denotes and old system of medicine of Greece origin
- Greece system of medicine began with God Apollo, the mentor of healing art, who chases away all ills
- Hippocrates is credited with this system and learned the “Concept of Crisis”, “Critical days” and “Healing power of nature” from Pythagoras
- The theory was based on the fundamentals known as “Theory of Humours”

Unani contd.

- The four humours (fluids) are Blood, Phlegm, Yellow bile and Black bile
- Health and illness are due to balance and imbalance of these humours respectively
- Aristotle, the Father of Natural history made significant contributions for the development of this system
- Galen and others contributed for the stabilization of system

Unani contd.

Principle - Unani Tibb is based on two theories, they are

- Hippocrates 'Theory of four Humours'
- Pythagoras 'Theory of four proximate qualities'
- The four proximate qualities are the states of living human body like hot, cold, moist and dry, representing fire, water, air and earth respectively
- Arab physicians put all these together as seven working principles – elements, temperament, humours, organs, life, spirit energy and action
- These principles are responsible for body constitution, health and disease condition

Unani contd.

Diagnosis and treatment

- Unani aims at treating the cause of disease rather the symptoms
- Diagnosis includes pulse reading, urine and stool's examination
- Since, disease is understood as the imbalance of humours, treatment is given accordingly
- Polyherbal preparations are produced as their collective effect is considered

Summary

- Siddha - Disturbance to soul, imbalance of humors, poisonous substance, psychological cause, spiritual causes, astral influence
- Homeopathy - Samuel Hahnemann, Psora, Psychosis, Syphilis
- Unani - Theory of Humours, Blood, Phlegm, Yellow bile and Black bile

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Lecture No.13
Nutraceuticals

At the end of this lecture, student will be able to

- Discuss the Market and growth of nutraceuticals
- Describe Health benefits of nutraceuticals in diabetes , CVD, Cancer and irritable bowel syndrome and GID

Content
Nutraceuticals

- Market and growth
- Health benefits and role of nutraceuticals in Diabetes, CVD, Cancer and irritable bowel syndrome and GID

Market and growth of Nutraceuticals

- Internationally nutraceuticals are gaining importance and are becoming a part of the consumers daily diet
- Major reasons for this changes are the increasing occurrence of life style diseases and people intentionally taking preventive health care measures
- Developed markets like USA and Europe are discovering the unexploited segment of modified products based on health claims

Nutraceuticals

- In 2010, the Indian nutraceuticals industry was estimated at $ 2 billion, roughly 1.5% of the global nutraceuticals industry
- The total Indian nutraceuticals market was approximately $ 5 billion in 2015
- Global market size is expected to reach $ 300 billion by 2022
- Nutraceutical has spectacular annual growth rate of 25% in indian health care market
- Nutraceutical market is predicted to record revenue of USD 671 billion by 2024

Health benefits of nutraceuticals in Diabetes

Nutraceuticals may offer many benefits to our health like

- Increases the health value of our diet
- Help us to live longer
- Help us to stay away from particular medicinal conditions
- May be supposed to be more natural medicine than traditional medicine and do not produce unpleasant side effects

Health benefits of nutraceuticals in Diabetes

Vitamin C :

- It is a chain breaking antioxidant and prevents the propagation of chain reactions
- Vitamin C (800 mg/day) replenishes the Vitamin C levels in patients with type II Diabetes mellitus
- Low Vitamin C level impair insulin resistance levels

Health benefits of nutraceuticals in Diabetes

Calcium/Vitamin D:

- High calcium intake acts as protective to develop diabetes
- it acts by suppressing secretion of Para Thyroid Harmone (PTH) and help to preserve insulin sensitivity

Vitamin E

- Essential fat soluble vitamin and acts mainly as an anti oxidant
- Low levels of vitamin E produces increased frequency of diabetes
- Doses of vitamin E up to 400 IU are generally safe to use

Health benefits of nutraceuticals in Diabetes

Fats:

- High fat diet can damage glucose tolerance and promote obesity and these abnormalities can be improved by reducing saturated fat intake. Mono saturated fat such as olive and peanut oils have low glycemic index

Fibres:

- Foods rich in fibres like fruits, vegetables and whole cereals provede protective effects against chronic diseases and in lipid and glycemic metabolism
- An intake of 26 g and 38 g is recommended for women and men respectively

Health benefits of nutraceuticals in Diabetes

Chromium:

- Chromium supplements may increase glucose tolerance and insulin sensitivity in patients with Type II Diabetes mellitus

Magnesium:

- Magnesium rich diets significantly improves the insulin sensitivity (Adiposite insulin sensitivity)

Alpha Lipoic acid:

- Naturally occurring antioxidant involve in chelation of heavy metals and regeneration of other antioxidants such as glutathione, vitamine C and E.
- Protects the injury to the retina which leads to visual loss (Diabetic retinopathy)

Health benefits of nutraceuticals in Diabetes

Vanadium:

- Acts similar to insulin in transporting glucose in to the cells and useful in both type I and type II Diabetes mellitus
- 45 – 150 mg/day useful in decreasing fasting blood glucose levels

Proteins:

- Stimulates insulin secretion but excessive intake should be avoided as it may lead to diabetic nephropathy
- Vegetable protein is preferred over animal protein as it is better for reducing serum cholesterol and in the management of nephropathy
- Soya, rice, egg, milk products etc

Health benefits of nutraceuticals in CVD

- Majority of the cardio vascular diseases can be prevented and controlled
- Low intake of vegetables and fruits is connected with a high mortality in CVD
- Nutraceuticals in the form of anti oxidants, dietary fibres, PUFA, vitamins and minerals recommended for prevention and treatment of CVD

Health benefits of nutraceuticals in CVD

Phytosterols:

- Plant sterols are known as phytosterols
- Present in plants – Fruits, vegetables, nuts and cereals
- Inhibit intestinal absorption of cholesterol, but do not affect HDL and VLDL. Form micelle with bile salts, thus improve serum lipid profile and decrease the risk of CVD

Poly phenols:

- Include flavonoids, phenolic acids and stilbenes, found in fruits, vegetables, cereals, beverages
- Exert anti athero-sceroticeffects in the initial stages of atherosclerosis development and increase nitric oxide release, which acts as a potent vasodilator and protects against myocardial ischemia

Health benefits of nutraceuticals in CVD

Flavonoids:

- Present in vegetables, fruits, beverages like cocoa, tea and wine
- Flavonoids exert their effect on heart due to their antioxidant activity
- Inhibits platelet aggregation and loweroxide superoxide production

Spirulina and Soy nutrients:

- Spirulina is a rich source of proteins, vitamins, minerals, carotenoids
- Spirulina supplementation alters the blood lipid profile
- Soy products are rich in PUFA, fibre, vitamins and minerals, have low saturated fat content

Health benefits of nutraceuticals in CVD

Curcumin:

- Curcumin prevents cardiac hypertrophy and heart failure
- Decreases serum lipid peroxides and total serum cholesterol
- Reduces chronic inflammation induced by obesity and improves their vascular function

Omega 3- fatty acid:

- Decrease inflammation and platelet aggregation, cause vasodilation and improve myocardial function
- Most commonly used for primary and secondary CVD

Health benefits of nutraceuticals in CVD

Tomato and lycopene:

- Lycopene is a carotenoid present in red fruits and vegetables like papayas, tomato, watermelon, red pepper etc
- Lycopene reduces myocardial infarction and angina pectoris
- Most powerful anti oxidant and plays imp role in preventing CVD

Garlic:

- Garlic is composed of sulphur compounds, proteins and amino acids
- It contains allicin (diallyl thiosufinate) has potent anti platelet activity
- Inhibits platelet aggregation, enhances vasodilation and fibrinolysis

Health benefits of nutraceuticals in Cancer

- Fibre content in fruits and vegetables may reduce the risk of cancer
- Plant derivative polysaccharides act as protective role in development of cancer lesions
- Dietary supplements such as microalgae, plant derivatives and vegetables are a rich source of vitamins, minerals, amino acids and other micro nutrients
- Adequate utilization of dietary nutraceuticals is a sensible way to maintain health and avoid the formation of cancer

Health benefits of nutraceuticals in Cancer

Chestnut:

- Chest nut extract possesses antioxidant activity and is protective against gastric cancer
- Mild protective effect against prostate and breast cancer

Berries:

- Blue, black and strawberries are good source of antioxidants and phenolic compounds
- These berries act as chemo protective against breast cancer
- Exerts anti cancer effect by inhibiting growth of cancer cells by which activities of proteins involved in the oncogenesis gets interrupted in their path way

Health benefits of nutraceuticals in Cancer

Soy:

- Soy contains iso flavones, which reduce the risk of breast cancer particularly in postmenopausal women
- Intake of high amount of soy reduced the risk of colorectal cancer

Garlic:

- Garlic is composed of sulphur compounds, proteins and amino acids
- Diallyl trisulphide prevents the development of prostate cancer and lung cancer
- Acts by inhibiting the expression of androgen receptor which is actively involved in the development of prostate cancer
- Garlic oil effective against liver cancer

Health benefits of nutraceuticals in Cancer

Green Tea:

- Green tea contains polyphenols which prevent the advancement of cancer
- Protects the bladder against cell death, antioxidant potency of green tea reduces the oxidative stress induced by hydrogen peroxide in malignant/normal bladder cells

Grape Seed:

- Effective in the prevention of skin cancer (UV rays induced) and decreases risk of squamous cell carcinoma as it contains polyphenols and proanthocyanidin
- It also inhibit blood cancer and prostate cancer when taken as supplements

Health benefits of nutraceuticals in Cancer

Tomato and Red pepper:

- Tomato contain lycopene (carotenoid) is a potent antioxidant , which is chemo-protective against prostrate, breast and lung cancer
- Lycopene reduces myocardial infarction and angina pectoris
- Capsiacin an active component of pepper inhibits the migration of skin cancer cells to other body parts

Dietary fibre:

- These fibres prevents constipation by increasing bulk of stool and hence reduces the risk of colorectal cancer
- Also reduce the risk of breast cancer in postmenopausal women
- Broccoli, cabbage, cauliflower, sprouts contain dietary fibres

Health benefits of nutraceuticals in irritable bowel and GID

Curcumin:

- Derived from rhizomes of Curcuma longa, Zingiberaceae
- Used both in Ayurveda and Chinese medicine, especially in abdominal pain and bloating
- Curcumin has anti-inflammatory activity and reduces mucosal injuries and useful in peptic ulcer

Garlic:

- Garlic is composed of sulphur compounds, proteins and amino acids
- Garlic oil prevents ethanol induced gastric injury and this protective effect has been recognized for its anti oxidant activity
-

Health benefits of nutraceuticals in irritable bowel and GID

Aloe Vera:

- Contains potential anthroquinones, salicylates, lupeol, acemannan
- Acemanan prevents stress induced gastric ulceration
- Stimulates the collagen synthesis, thus increases the ulcer healing process

Bael:

- Ripe/half ripe fruits of Aegle marmelos, Rutaceae
- Luvangetin, a pyranocoumarin isolated from the seeds has been shown to protect gastric mucosa in gastric ulceration

Health benefits of nutraceuticals in irritable bowel and GID

Honey:

- It has capacity to stimulate tissue growth, enhance re- epithelization and minimize scar formation
- Effective against gastric ulcers induced by acetyl salicylic acid
- Inhibits the growth of H Pylori responsible for gastritis, peptic ulcer

Vitamins:

- Fat soluble vitamins A and D have protective role in irritable bowel syndrome
- Vitamin D deficiency produces mucosal inflammation

Health benefits of nutraceuticals in irritable bowel and GID

Probiotics:

- Describing as a living organisms
- When ingested with or without food improves the intestinal microbial balance and consequently the health and functioning of large intestine
- Approximately 95% of bacteria found in colon of human body, some of them are useful and some of them harmful
- Natural balance between these two play an imp role in the health and functioning of large intestine

Health benefits of nutraceuticals in irritable bowel and GID

- Probiotics available in the form of tablets, capsules, powders and food form

Eg: Bifido bacteria found in yoghurt prevent young children suffering from diarrhoea

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Source and Nutraceutical / Health benefits of

- 1. Alfa Alfa, 2. Ashwagandha, 3. Amla
- 4. Chicory,
- 5. Fenugreek
- 6. Garlic, 7. Ginger, 8. Ginseng
- 9. Honey
- 10. Spirulina

1. Alfa Alfa

Botanical name : Leaves, seeds and stems of the plant *Medicago sativa*

Family: Fabaceae

Alfa Alfa

Alfa Alfa is one of the most nutrient rich plants known as father of foods

Constituents:

Vitamins – B1, B6 and C

Minerals: Calcium, zinc and iron

Phytoestrogens: Alfalfa coumestrol, genistein, biocanine, Triterpenoid saponins, amino acid – L-Canavanine,

Alfa Alfa

Health benefits:

Healthy skin :

- Alfa Alfa chlorophyll is rich in vitamin A and enzymes. Vit A helps to maintain and construct a healthy and glowing skin, helps to cure dry skin

Healthy hair:

- Rich in Vitamin B1, B6 and Vit C and minerals, essential for proper growth and health of hair, used to treat baldness and prevent of hair loss
- Rich in proteins- helps in healthy hair

Alfa Alfa

Cardiac disease: Helps in elimination of bad cholesterol and control the level, thereby decreasing the risk of heart diseases

Digestive problems: Gastritis, stomach ulcers, bloating, nausea can be prevented. Alfa sprouts are also used in treating chronic constipation due to its high fibre content

Cancer : Prevents the risk of cancer as it contains an amino acid known as canavanine

UTI: It has diuretic property, which prevents disorders of kidney like water retention and prevents developing of UTI

Alfa Alfa

Menopausal symptoms: Alfalfa coumestrol, genistein, bio canine counter the symptoms of menopause. As a part of diet, fight vaginal dryness, postmenopausal osteoporesis

Anti diabetic: Diuretic nature of alfa alfa keeps the increased sugar levels under control

Weight loss: Being rich in fibres and proteins , helps those who are on weight loss regime

Depression: Alfa alfa known to have tranquillizing and sedating effect on nervous system. It is also known to be quite effective in solving insomnia and other sleep disorders

2. ASHWAGANDHA

Botanical name : Dried leaves, roots and stem bases of *Withania somnifera*

Family: Solanaceae

Chemical constituents :

Triterpene lactones : Withanolides- which include withaferin-A, alkaloids, steroidal lactones, tropine and cuscohygrine

Health benefits of Ashwagandha

- Reduces blood sugar levels
- Anti-cancer properties
- Reduces cortisol levels
- Boosts testosterone and increase fertility in men
- Increase muscle mass and strength
- Reduces inflammation
- Lowers cholesterol and triglycerides
- Improve brain function and memory

3. AMLA

Biological source:

Fresh/dried fruits of Emblica officinalis /*Phyllanthus emblica*

Family: Rutaceae

Amla is a subtropical plant, is small or medium sized tree, fruits are fleshy.

Constituents:

Vitamins - Amla is a rich source of vit C (760mg/100g)

Minerals – Zinc, copper, Chromium

Amino acids – Alanine, lysine, proline, aspartic acid

Phyto constituents: Phyllemblin and curcuminoides

Health benefits of Amla

- Immunity booster
- Treats respiratory disorders
- Manages diabetes
- Remedy for heart disorder
- Cures eye disorder
- Prevents aging
- Cures anaemia
- Enhances food absorption
- Helps urinary system
- Good for skin
- Promotes healthier hair
- Remedy for Scurvy

4. Chicory

Botanical name : Leaves, flowers & Roots of *Cichorium intybus*

Family: Asteraceae

Chicory

Constituents:

Vitamins – A, B6, C, E and K

Minerals: Zinc, magnesium, manganese, calcium, iron

Volatile oil

Phyto chemicals – Inulin, oligo fructose, coumarins, flavanoids, tannins, alkaloids and sesquiterpene lactones

Chicory

Health benefits:

Digestion: Good for digestion as it contains inulin, which is a powerful prebiotic. It is effective against acid reflux, heart burn as it reduces the acidity

Cardiac diseases: Inulin reduces the level of bad cholesterol, which is main cause for atherosclerosis and high blood pressure, also contributes for heart attack and stroke

- As it is low calorie vegetable acts as anti arrythemic agent

Chicory

Anti cancer: Reduces tumor growth in various type of cancers, due to the presence of various fructans which have anti oxidant properties

Arthritis: used in the treatment of arthritis as it has anti-inflammatory properties and reduces the pain in conditions like osteoarthritis

Weight loss : Chicory is an excellent source of oligo fructose and inulin, which helps in the management of weight by promoting weight loss. These help in the regulation of ghrelin, an amino acid mainly connected with feelings of hunger.

Constipation: Inulin is a natural fibre and helps in bowel movements and peristaltic motions as well as secretion of gastric juices. As a result digestion is improved and constipation is reduced

Chicory

Improves immunity: Powerful booster for immune system, it has anti bacterial effects and act as immune system booster. Various phyto chemicals present in it acts as antioxidants and improves immunity

Relieves anxiety: Chicory has sedative effects, which reduce anxiety and soothe the mind, thereby relieve stress

Kidney disorders: Root extract has diuretic effect which increaser urine volume. Frequent urination helps to eliminate toxins stored in liver and kidney, thus prevent the dangerous condition that occur when toxins are allowed to remain in the body

5. Fenugreek

Botanical name : Dried leaves and seeds of *Trigonella foenum graecum*

Family: Fabaceae

Fenugreek

Constituents:

Vitamins – Riboflavin, thiamine, niacin, Vit C

Minerals: Zinc, calcium, iron, Phosphorous

23-26% Proteins, 58% Carbohydrates, 25% dietary fibre

Phyto chemicals – Steroidal sapogenin and diosgenin

Alkaloids **–** Trigo coumarin, trigonelline

Saponins - graecunin

Fenugreek

Health benefits:

- To enhance milk production in new mothers
- Fenugreek seeds commonly used as a supplement to control blood glucose level, especially to prevent or treat diabetes
- To enhance libido in both men and women
- Used to treat skin inflammation as it has anti inflammatory and anti oxidant activities
- To reduce appetite , menustrual cramps and fever, to balance cholesterol, to sooth muscle pain

6. GARLIC

Biological source:

Garlic, *Allium sativum* (Family Lilliaceae) has been associated with humans and their food since ancient times. It is grown and used as food and medicine in all temperate climatic regions of the world.

Garlic contains

carbohydrates(31%),

proteins (5-6%, fat(0.2%) and

high amounts phosphorous, potassium and calcium.

Garlic contains a sulphur basic compounds called Allin (present in cell vacoules). When the cells are broken it is converted to allicin and finally di allyl sulphide. Both of them are strong smelling and fiery tasting compounds.

Garlic reduces *serum lipid levels* because it causes,(i) reduction or inhibition of lipogenesis and (ii) enhancing breakdown and excretion of lipids.

It *increases HDL* (High Density Lipoproteins) and reduces LDL(Low Density Lipoproteins).Overall, Garlic is used to reduce serum cholesterol and also in treatment of atherosclerosis.

Garlic has also been found to *reduce platelet aggregation.*

Allicin from Garlic shows *antibiotic activity* against Mycobacterium tuberculosis, *Staphylococcus aureus* and *Staphylococcus faecalis.* Garlic is useful in treatment of amoebic dysentery and parasites like tapeworm and hookworm.

Garlic exerts strong *antioxidant effect*, prevents lipid peroxidation and hence protects liver cells from various toxins including mutagenic chemicals.

Anti-carcinogenic, Anti-inflammatory, Garlic and diabetes, Anti-thrombotic.

7. GINGER

8. Ginseng

Botanical name : Roots of *Panax ginseng*

Family: Araliaceae

Constituents:

Vitamins – Niacin and Riboflavin

Minerals – Iron, manganese, zinc, Copper

Phyto chemicals – Ginseng saponins – Gensenosides or Panaxosides, triterpens of dammarane and oleanane

Health benefits:

Alzheimer's Disease: Root of ginseng Improves the mental performance in people with alzheimer"s disease

Chronic Obstructive Pulmonary disease: Improves lung function and ,many symptoms of COPD

Mental function: Ginseng improves abstract thinking, mental arithmetic skills in healthy middle aged people. In combination with ginkgo leaf extract improves memory

Erectile dysfunction: Improves sexual function in men with erectile dysfunction and also helps to prevent premature ejaculation

Flu: Reduces the risk of getting cold or flu by improving immunity

Diabetes: Help to lower blood sugar by stimulating the production of insulin in pancreas

Increases energy: Stimulates the physical and mental activity in people who weak and tired

9. HONEY

B Source: Honey is viscous, sugary secretion obtained from honey comb of *Apis mellifera* and *Apis dorsata*

Family: Apidae

Bees produce honey from nectar of flowers by enzymatic activity

Honey is collected from honey comb, either from wild bee colonies or from hives of domesticated bees.

Constituents:

- Honey is composed of carbohydrates- fructose, glucose and sucrose, proteins, vitamins, amino acids, minerals and organic acids
- Pure honey also contains flavonoids, polyphenols, reducing compounds, alkaloids, glycosides, anthraquinones and volatile compounds

Health benefits of Honey

- **Wound healing activity**: Has antibacterial, antiviral, anti-inflammatory and antioxidant activity. Activates immune response to infection
- **Anti Diabetic**: Honey reduces blood lipids, homocysteine and c-reactive protein contents
- **Anti-cancer effects**: Honey modifies immune responses, prevent cell proliferation, induces apoptosis, antimutagenic etc

- **Cardiovascular diseases:** (Flavonoids, polyphenolics, vit C and monophenolics) Improves coronary vasodilation, reduces the ability of platelets in blood to clot and inhibits low density lipoproteins from oxidizing.
- **Neurological diseases**: (Polyphenols)Prevents memory disorders and induce memory production at the molecular level.
- **Gastrointestinal diseases**: Exerts antibacterial activity against Helicobacter pylori, also treats gastroenteritis.

10. SPIRULINA– A GREEN FACTORY

Biological source : spirulina is a blue algae S*pirulina platensis* or *Spirulina maxima* family- Oscllatoriaceae.

This group of algae is considered to be one of the remarkable groups of photosynthetic simple plant forms.

It represents a link between green plants and bacteria. It has a soft cell wall made up of complex sugars and proteins and is different from most algae, that it is easily digested.

WHAT IS SPIRULINA?

A single cell organism with a spiral physical configuration that comes from the blue green freshwater algae.

Spirulina is a superfood with a remarkable ability to synthesize concentrated food efficiently. It is loaded with 60% highly digestible protein. A low-calorie super green with an excellent amount of chlorophyll, vitamins, essential minerals, nucleic acids, antioxidants, polysaccharides including a high concentration of omega 6 fatty acids.

10 SUPERIOR BENEFITS OF SPIRULINA

1. A great ***immune system*** booster
2. A natural ***antioxidant*** and ***anti-inflammatory*** agent
3. Improves ***digestive system*** and ***gastrointestinal tract***
4. Balances the body's ***pH level***
5. Regulates ***blood pressure***
6. Regulates the ***hormone system***
7. Lowers blood ***cholesterol level***
8. Reduces ***food craving*** and ***insulin intake***
9. Eliminates ***heavy metals*** in the body
10. One of the ***best nutritional supplements*** from nature

Chemical composition:

✓Spirulina contains proteins (50-70%),

✓proteinous nitrogen (11.36%),

✓total organic nitrogen (13.35%),

✓nitrogen from nucleic acids (1.9%).

✓It has net protein utilization (NPU) upto 62%.

✓It contains lipids (5-6%) having mostly essential fatty acids, composed of oleic, linoleic, gamma linoleic, palmitic, palmitoleic, heptadecanoic acids.

✓About 40% of the fats include glycolipids including sulfolipids (2-5%) which have significant anti-HIV activity.

✓Spirulina provides 8-14% of recommended daily allowance (RDA) of fats.

Spirulina contains the carbohydrates in the form of glycogen and rhamnose which are easily digestible and require less insulin.

Among the vitamin content, it mainly possesses natural beta carotene with 9-cis-carotenoid isomer, which has more anti-oxidant capacity. The other vitamins present are B1, B2, B3, B6, B12 and E3.

The mineral content (3-6%) mainly includes iron which is reported to be better absorbed than other natural iron, because of its soluble complexes with phycocyanin, (phycobiliprotein) which is an algal protein having the linear tetrapyrrole viz. Phycocyanobilin and resembles haemoglobin.

Phycocyanin, which is a blue green pigment is believed to enhance general immunity and useful lymphocytic activity against cancer.

Spirulina has an enzyme content in the form of super oxide dismutase (SOD). This enzyme is known for its free radical scavenging effects and plays vital role pathophysiological conditions like atherosclerosis, arthritis, cataract, diabetes and also in emotional stress and aging process. Spirulina also contains crude fibres (0.8%) and ash (6%).

Biological role:

- Spirulina has been subjected to thorough screening for its biological role. Some of the findings are promising.
- It has immuno-stimulant activities. It stimulates the production and activity of bone marrow stem cells, macrophages and T-cells. Spleen and thymus gland shows enhanced function.
- In-vitro studies on spirulina indicate that it enhances cell nucleus enzyme activity and DNA repair and hence it has possible role in cancer treatment.
- Water extract of spirulina inhibits HIV-1 replication in human derived T cell lines and in human peripheral blood mononuclear cells. Calcium spirulan inhibits in-vitro replication of HIV-1, Herpes simplex, Human cytomegalovirus, Influenza virus, Mumps and Measle virus.
- Gamma linolenic acid of spirulina helps to reduce cholesterol levels. It has appetite suppressing activity.

Uses:

- Spirulina is simple and is having fast growth rate since cultivation of spirulina can be undertaken even in waste water, this helps to solve the problems of water pollution.
- Spirulina grows well in sewage water which is best material for bio-degradations.
- Spirulina can fix atmospheric nitrogen during its growth; can be used as a source of nitrogenous fertilizer.

Honey

B Source: Honey is viscous, sugary secretion obtained from honey comb of *Apis mellifera* and *Apis dorsata*

Family: Apidae

- Bees produce honey from nectar of flowers by enzymatic activity
- Honey is collected from honey comb, either from wild bee colonies or from hives of domesticated bees.

Honey

Constituents:

- Honey is composed of carbohydrates- fructose, glucose and sucrose, proteins, vitamins, amino acids, minerals and organic acids
- Pure honey also contains flavonoids, polyphenols, reducing compounds, alkaloids, glycosides, anthraquinones and volatile compounds

Health benefits of Honey

- **Wound healing activity**: Has antibacterial, antiviral, anti-inflammatory and antioxidant activity. Activates immune response to infection
- **Anti Diabetic**: Honey reduces blood lipids, homocysteine and c-reactive protein contents
- **Anti-cancer effects**: Honey modifies immune responses, prevent cell proliferation, induces apoptosis, antimutagenic etc

Health benefits of Honey

- **Cardiovascular diseases:** (Flavonoids, polyphenolics, vit C and monophenolics) Improves coronary vasodilation, reduces the ability of platelets in blood to clot and inhibits low density lipoproteins from oxidizing.
- **Neurological diseases**: (Polyphenols)Prevents memory disorders and induce memory production at the molecular level.
- **Gastrointestinal diseases**: Exerts antibacterial activity against Helicobacter pylori, also treats gastroenteritis.

Amla

B Source: fresh/dried fruits of Emblica officinalis /*Phyllanthus emblica*

Family: Rutaceae

- Amla is a subtropical plant, is small or medium sized tree, fruits are fleshy.

Amla

Constituents:

- **Vitamins** - Amla is a rich source of vit C (760mg/100g)
- **Minerals –** Zinc, copper, Chromium
- **Amino acids –** Alanine, lysine, proline, aspartic acid
- **Phyto constituents**: Phyllemblin and curcuminoides

Health benefits of Amla

- Immunity booster
- Treats respiratory disorders
- Manages diabetes
- Remedy for heart disorder
- Cures eye disorder
- Prevents aging
- Cures anaemia
- Enhances food absorption
- Helps urinary system
- Good for skin
- Promotes healthier hair
- Remedy for Scurvy

Ashwagandha

Biological Source : Dried leaves, roots and stem bases of *Withania somnifera*

Family: Solanaceae

- Short perennial shrub

Ashwagandha

Chemical constituents

Triterpene lactones : Withanolides- which include withaferin-A,

alkaloids, steroidal lactones, tropine and cuscohygrine

Health benefits of Ashwagandha

- Reduces blood sugar levels
- Anti-cancer properties
- Reduces cortisol levels
- Boosts testosterone and increase fertility in men
- Increase muscle mass and strength
- Reduces inflammation
- Lowers cholesterol and triglycerides
- Improve brain function and memory

HERB-FOOD INTERACTIONS

Herb-food interactions

- A food – drug interaction occurs when a food, or one of its components, interferes with the effects of a drug in the body
- The content of certain foods interact with some drugs and produce alterations in the pharmacokinetics and pharmacodynamics of the drug

Adverse Drug-food interactions

- Prevent the therapeutic effect of a medicine
- Exaggerate the therapeutic effect of a medicine
- Make a side effect worst
- Cause a new side effect

Liquorice / Licorice

Licorice

- Common interactions with:
- Antihypertensive, Digoxin, immunosuppressant's, (cyclosporine), Diuretics
- Results in:
- Glycyrrhetinic acid in licorice which blocks activity of 11B-hydroxsteroid dehydrogenase ultimately causing high blood pressure and salt and water retention
- It decreases antihypertensive effect
- **Solution:**
- Avoid licorice derivatives when suffering from Hypertension, Conn's Disease, and when using antihypertensive

Omega 3 rich fishes

Tuna, Sardine, Salmon, Mackerel, etc.

- Common interactions with:
- Antiplatelets and anticoagulants (aspirin, clopidogrel, warfarin, heparin, alteplase, etc)
- **Results in:**
- Increased risk of bleeding

Solution:

- Avoid concomitant use of omega 3 – Containing foods with the above Drugs

Caffeine Drinks

Coffee, tea, energy drinks, soft drinks, etc

Common interactions with:

- Theophylline, Prednisolone, OCPs, Ciprofloxacin, Cimetidine

Results in:

- Inhibition of Theophylline metabolism with subsequent adverse effects of it. (Jitteriness, Insomnia, and Cardiac arrhythmias)
- Reduced caffeine metabolism leads to subsequent increased effects of caffeine

Grape Juice

Common interactions with:

- Statins (increased risk of rhabdomyolysis), erythromycin, domperidone, amiodarone (increased risk for QT prolongation), immuno suppressants (cyclosporine, Tacrolimus,, inhibiting its metabolism with increased risk of nephrotoxity), opioids (fentanyl, ketamine, oxycodone, inhibiting their metabolism with increased risk of respiratory depression).

Vit K rich foods

Foods rich in Vit K - Kale, Collards, Spinach, Turnip greens, Brussels sprouts and Broccoli, etc

Common interactions with:

- Warfarin (Blood thinning agents that prevents blood clots)

Results in:

- Increased intake of vit K foods - risk of thrombosis(blood clots).
- Reduced intake - increase risk of bleeding

Other Interactions

- **High Fat Meals** may **e**levate the plasma levels of Griseofulvin. Patients should be instructed not to take griseofulvin after a high-fat content meal

- **Protein Rich Foods** may increase the bioavailability of Propranolol

- **Orange juice** may interact with drugs like Fexofenadine, Atenolol or Fluoroquinolones

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Lecture No 18
Scope and future prospects of Herbal Drug Industry

At the end of this lecture, student will be able to

- Explain the scope and future prospects of herbal drug industry
- Identify the research institutions involved in herbal drug research

HERBAL FORMULATION

Scope of Herbal Drug Industry

- Worldwide herbal drug industry is growing up at a fast speed
- Herbal Medicine is defined as branch of science in which plant based formulations are used to alleviate the diseases
- In the early twentieth century, when synthetic analgesics and antibiotics were not yet widely available, herbal medicine was the predominant mode of treatment
- With increasing use of allopathic system of medicine, herbal medicine gradually lost its popularity among people
- Almost a century has passed and it has witnessed limitations of allopathic system of medicine

Scope of Herbal Drug Industry

- Lately herbal medicine has gained momentum and it is evident from the fact that certain herbal remedies are more effective
- Substances derived from the plants remain the basis for a large proportion of the commercial medications used today for the treatment of heart disease, high BP, pain, asthma, etc
- For example, Ephedra is a herb used in Traditional Chinese Medicine for more than two thousand years to treat asthma and other respiratory problems

Scope of Herbal Drug Industry

- Another example of the use of a herbal preparation in modern medicine is the foxglove plant
- This herb had been in use since 1775
- At present, the powdered leaf of this plant is known as the cardiac stimulant to the millions of heart patients
- Usage of herbs to treat a variety of different ailments is universal, and exists in every human culture on Earth

Scope of Herbal Drug Industry

- Because of the high costs involved with manufacturing modern medicines, many people living in developing nations simply do not have the financial resources to pay for them
- As a result, they are forced to use natural herbs as an affordable alternative
- In recent years, many people living in developed countries have begin taking a second look at herbal medicines due to the rising cost of medicine and healthcare in their own nations

Scope of Herbal Drug Industry

Herb :

Herbs are crude drugs of plant origin that are used in the treatment of disease states, often of a chronic nature, or to attain or maintain a condition of improved health

Advantages of herbal drugs:

- Non – toxic
- No/less side effects
- Easily available
- Affordable prices

Scope of Herbal Drug Industry

India is one of the major producer of medicinal plants, because

- Availability of vast areas
- Wide variations in climate, soil, attitude
- Presence of rich flora
- China and India are the two great producers of medicinal plants – 40%
- Global traditional market – 7-15 % annually
- According to NMPB, Govt of India , India has 17,000-18,000 species of flowering plants

Scope of Herbal Drug Industry

- 6000-7000 species have medicinal properties that are of use in folk and documented in Ayurveda, Siddha etc
- 960 species – Traded
- 178 species – Annual level consumption level in excess of 100 metric tonnes
- Western Ghats, Eastern Himalayas and Andaman and Nicobar island
- India – World's Herbal Garden

Scope of Herbal Drug Industry

Medicinal plant based industries

- Products based on Indian system of medicine – Ayurveda, siddha and Unani
- Plant products and extracts
- Essential oils
- Phytopharmaceuticals
- Nutraceuticals – Herbal teas, anti oxidants, probiotic, prebiotic etc
- Herbal cosmetics

Future prospects

Future prospects of herbal drug industry are very bright in India

- WHO has stressed on the need of better utilization of the indigenous system of medicine which is based on the local availability of medicinal plants in the country. Therefore there is tremendous increase in the use of plant derived products
- Drug development from medicinal plants is cheaper as compared to synthetic drug development

Future Prospects

- Agro climatic conditions in India, which vary from mild temperate to tropical regions with abundant rains and sunshine make it an ideal place for the growth of the flora
- India is enriched with 25% of the biodiversity of the world and there is no short of herbal raw materials for herbal drug industry
- There has been increased demand of raw medicinal herbs of Indian origin from western countries

Future Prospects

- India has an impressive medical heritage, which comprises various systems of medicine such as Ayurveda, Siddha, Unani and Homeopathy
- India is the source of cheap labour and skilled man power, which readily absorbs and adopts technological change
- Being strategically located in the world map, India could become a potential supplier of phytopharmaceuticals an raw medicinal herbs in near future for the growing world market

Herbal Drug Industries

Name of the company	Examples of products
Himalaya Drug Company	Liv 52, Bonnisan, Mentat, Septilin
Dabur Pharmaceuticals	Chyawanprash, Hajmola, Pudinhara
Emami Drugs	Navaratna oil, Boroplus, Fast relief
Baidyanath	Chyawanprash, Mahabhringharaj oil
Pankaja kasturi Pharmaceuticals	Pankaja kasturi breath, Mygrane oil
Zandu Pharmaceuticals	Triphala Guggul, Pancharista, Keasri jeevan
Cholayil Pharmaceuticals	Rumacide G, Medimix, cuticura talc

Research Institutions/Centres

Name	City
CCRAS (Central Council for Research in Ayurveda and Siddha)	New Delhi
NBRI (National Botanical Research Institute)	Lucknow
National Institute of Ayurveda	Jaipur
National Medicinal Plants Board	New Delhi
Regional Medical Research Centre	Belgaum
CDRI (Central Drug Research Institute)	Lucknow
National Buraeu of Plant Genetic Resources	New Delhi
FRHLT (Foundation for Revitalisation of Local Health Traditions)	Bangalore

Summary

- Herbal Medicine is defined as branch of science in which plant based formulations are used to alleviate the diseases
- Botanical medicine or phytomedicine
- Herbs - plant origin that are used in the treatment of disease states, No/less side effects, easily available, affordable prices
- Future prospects
- Herbal drug industries and research institutions

Lecture No 19

Herbal Drug industries and Research Institutions

At the end of this lecture, student will be able to

- Recognize various herbal drug industries
- Identify herbal research institutions involved in the herbal drug research

Herbal Drug Industries

Name of the company	Examples of products
Himalaya Drug Company	Liv 52, Bonnisan, Mentat, Septilin
Dabur Pharmaceuticals	Chyawanprash, Hajmola, Pudinhara
Emami Drugs	Navaratna oil, Boroplus, Fast relief
Baidyanath	Chyawanprash, Mahabhringharaj oil
Pankaja kasturi Pharmaceuticals	Pankaja kasturi breath, Mygrane oil
Zandu Pharmaceuticals	Triphala Guggul, Pancharista, Keasri jeevan
Cholayil Pharmaceuticals	Rumacide G, Medimix, cuticura talc

Himalaya Drug Company

- Himalaya's story began way back in 1930
- A curious young man riding through the forests of Burma saw restless elephants being fed the root of a plant, *Rauwolfia serpentina,* which helped pacify them
- Fascinated by the plant's effect on elephants, this young man, Mr. M. Manal, the founder of Himalaya, wanted to scientifically test the herb's properties
- With no money and only a pocketful of dreams, he pawned his mother's jewellery to buy a hand-operated tableting machine

Himalaya Drug Company

- He spent his days learning about herbs from neighbourhood healers
- His vision was to 'bring the traditional Indian science of Ayurveda to society in a contemporary form‘
- After four years of researching the herb Rauwolfia serpentina, Serpina, the world's first natural antihypertensive drug was launched in 1934.
- The discovery set the future course for Himalaya

Himalaya Drug Company

- In 1955, Himalaya introduced Liv. 52, a liver formulation that ensures optimum liver function and the product soon became top selling herbal medicine
- Other brands soon followed including Cystone, Bonnisan and Rumalaya forte, products that went on to become household names
- Today, the Himalaya brand is synonymous with safe and efficacious herbal products
- Starting off operations in Dehradun way back in the 1930s, the company later spread its wings to Mumbai and across the country. In 1975, the company set up an advanced manufacturing facility in Makali, Bengaluru, India. In 1991, the company relocated its R&D facility to Bengaluru

Himalaya Drug Company

Abana:

- **Arjuna** - *P*otent hypolipidemic responsible for reducing total cholesterol and triglyceride levels, thereby helping in the management of atherosclerosis. As a cardioprotective, the herb prevents oxidative damage to the heart and stabilizes blood pressure.
- **Indian Bdellium** *(Guggul)* effectively lowers triglyceride levels, total cholesterol levels and free fatty acid levels, through liver lipolysis

Himalaya Drug Company

Diabecon

- **Shilajeet** decreases hepatic glucose production and prevents hyperglycemia.
- **Gymnema's** *(Meshashringi)* principal constituent is gymnemic acid, which has antidiabetic properties. It reduces excessive blood sugar. It also has a regenerative effect on pancreatic beta cells
- **Indian Kino Tree's** *(Pitasara)* principal constituent, epicatechin, has alpha-glucosidase inhibitory properties and regularizes key metabolic enzymes involved in carbohydrate metabolism

Himalaya Drug Company

Gasex Tablet

- Improves digestion
- **Gasex Tablet** renormalizes the intestinal transit time. Gasex tablet has prebiotic, antiflatulent and antacid, antiulcer, anti-inflammatory, hepatoprotective, cholagogue and membrane-modulating, antimicrobial, and antioxidant actions
- **Gasex Tablet** exerts carminative and antispasmodic actions that support the digestive function

Dabur Pharmaceuticals

- Dabur India Ltd. is one of India's leading FMCG Companies with **Revenues of over Rs 7,680 Crore & Market Capitalisation of over Rs 48,800 Crore.**
- Dabur India is also a world leader in Ayurveda with a portfolio of over 250 Herbal/Ayurvedic products. Dabur's FMCG portfolio today includes **five flagship brands** with distinct brand identities -- **Dabur** as the master brand for natural healthcare products, **Vatika** for premium personal care, **Hajmola** for digestives, **Réal** for fruit juices and beverages and **Fem** for fairness bleaches and skin care products
-

Dabur Pharmaceuticals

- Dabur's products also have huge presence in the overseas markets and are today **available in over 120 countries across the globe**. Its brands are highly popular in the Middle East, SAARC countries, Africa, US, Europe and Russia
- The 132-year-old ayurvedic company, promoted by the Burman family, started operating in 1884 as an Ayurvedic medicines company
- Dabur today operates in key consumer product categories like **Hair Care, Oral Care, Health Care, Skin Care, Home Care and Foods**. The Ayurvedic company has a wide distribution network, covering 6 million retail outlets with a high penetration in both urban and rural markets

Dabur Pharmaceuticals

Dabur Chyawanprash – One of the Best Ayurvedic Chyawanprash

- Derived from 2,500-year-old Ayurvedic formula
- Totally chemical-free, natural and safe
- Combination of herbs and plant extracts in a base of Amla fruit pulp
- Dabur Chyawanprash has a tangy sweet-sour taste and the consistency of jam. It can be taken directly or with milk and as bread spread.

Dabur Pharmaceuticals

Dabur's Honitus Cough Syrup

- Provides effective relief from cough, without side-effects
- Dabur Honitus Cough Syrup is an ayurvedic medicine for cough that is fortified with Tulsi , Mulethi & Banapsha and other powerful scientifically proven medicinal plants as recommended by Ayurveda
- The formulation is clinically proven and provides fast relief against acute cough and throat irritation

Patanjali Ayurveda Limited

- **Patanjali Ayurved Limited** is an Indian FMCG company. Manufacturing units and headquarters are located in the industrial area of Haridwar while the registered office is located at Delhi
- -The company manufactures mineral and herbal products. It also has manufacturing units in Nepal under the trademark Nepal Gramudhyog
- Patanjali is the fastest growing FMCG company in India. It is valued at ₹30 billion(US$470 million) and revenues of ₹5,000 crores (US$780 million) for the year 2015–16

Patanjali Ayurveda Ltd

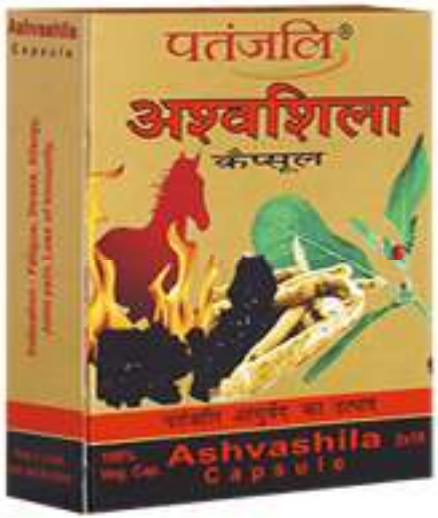
- Ramdev established the Patanjali Ayurved Limited in 2006 along with Acharya Balakrishna with the objective of establishing science of Ayurveda in accordance and coordination with the latest technology and ancient wisdom

Year	Revenues (In Rs Crore)
2009-10	165
2010-11	317
2011-12	446
2012-13	850
2013-14	1200
2014-15	2006
2015-16	5008
2016- 17	10561

Patanjali Ayurveda Ltd

ASHVASHILA (CAPSULE)

- Patanjali Ashvashila capsule is a combination of Ashwagandha and Shilajit which makes it a powerful remedy in Sexual weakness, fatigue, stress, generalized weakness, asthma, allergy, diabetes, diabetic neuropathy, urinary disorders and loss of immunity



Patanjali Ayurveda Ltd

ASHWAGANDHA (CAPSULE)

- It is beneficial for fatigue, restiveness and general weakness. It also treats muscles deficiency, gastric problems, arthritis and others. Helps to increase energy of body cells naturally. Ashwagandha is a natural herbal tonic for increasing memory and brain power

Research Institutions/Centres

Name	City
CCRAS (Central Council for Research in Ayurveda and Siddha)	New Delhi
NBRI (National Botanical Research Institute)	Lucknow
National Institute of Ayurveda	Jaipur
National Medicinal Plants Board	New Delhi
Regional Medical Research Centre	Belgaum
CDRI (Central Drug Research Institute)	Lucknow
National Buraeu of Plant Genetic Resources	New Delhi
FRLHT (Foundation for Revitalisation of Local Health Traditions)	Bangalore

FRLHT

FRLHT

- **Foundation for Revitalisation of Local Health Traditions** (FRLHT) is a registered Public Trust and Charitable Society, which started its activities in 1993
- Indian ministry of Science and Technology recognizes FRLHT as a scientific and research organization
- Ministry of Environment and Forests has designated FRLHT as a National Centre of Excellence for medicinal plants and traditional knowledge
- The foundation plans to "revitalize Indian medical heritage" through creative applications of traditional health sciences for enhancing the quality of health care in rural and urban India and globally

FRLHT

- Conservation of threatened natural resources in use by Indian Systems of Medicine
- Generate well trained human resources with knowledge and skills to disseminate the traditional health sciences both in India and globally.

CCRAS

CCRAS

- Central Council for Research in Ayurvedic Sciences (CCRAS) is an autonomous body of the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy), Government of India.
- It is an apex body in India for the formulation, coordination, development and promotion of research on scientific lines in Ayurveda

CCRAS

Research activities:

- Medicinal plant research
- Clinical research
- Drug standardization
- Tribal health care research
- Data base on medicinal plants

Summary

- Himalaya Drug Company – Manal, Liv 52, Bonnisan, Mentat, Septilin
- Dabur Pharmaceuticals - Chyawanprash, Hajmola, Pudinhara
- Patanjali - Ashwashila, aswagandha, lauh bhasma, Spatica bhasma
- **FRLHT** -a registered Public Trust and Charitable Society, 1993
- CCRAS - Ministry of AYUSH , Government of India
- Medicinal plant research, Clinical research, Drug standardization

Tribal health care research, Data base on medicinal plants

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Lecture No. 20

Schedule T – Good Manufacturing Practice of Indian system of medicine

At the end of this lecture, student will be able to

- Describe the objectives of GMP
- Discuss the various aspects of GMP

GMP (Schedule – T) objectives and its components

Objectives

- 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

GMP (Schedule – T) objectives Contd.

- To achieve the objectives, 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 G.M.P

GMP – 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

GMP – General requirements

Location and surroundings

- Shall be so situated and shall have such construction as to avoid contamination from open sewerage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust or smoke

Buildings

- Permit production of drugs under hygienic conditions
- Free from cobwebs and insects/rodents
- Adequate provision of light and ventilation
- Floor and the walls should not be damp or moist
- Conformity with the provisions of the Factory Act

GMP – General requirements

Water Supply

- The water used in manufacture shall be pure and of potable quality
- Adequate provision of water for washing the premises shall be made

Disposal of Waste

- Waste water and the residues shall be disposed off after suitable treatment as per guidelines of pollution control authorities

Containers' Cleaning

- Adequate arrangement for washing, cleaning and drying of containers such as glass bottles, vials and jars should be provided

GMP – General requirements

Stores

- Should have proper ventilation and shall be free from dampness
- Should provide independent adequate space for storage of different types of material, such as raw material, packaging material and finished products

Raw Materials

- Raw materials procured shall be stored in the raw materials store
- Appropriate containers to protect the quality of the raw material as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation shall be used

GMP – General requirements

Raw Materials

- While designing containers, cabins or areas in the raw materials store, care may be taken to handle the following different categories of raw materials
    - Raw material of metallic origin
    - Raw material of mineral origin
    - Raw material from animal source
    - Fresh Herbs
    - Dry Herbs or plant parts
    - Volatile oils/perfumes & flavours
    - Plant concentrates/extracts and exudates/resins

GMP – General requirements

Raw Materials

- Status of raw material such as 'UNDER TEST' or 'APPROVED' or 'REJECTED'
- Batch No. or Lot. No. and the date of receipt of consignment
- Rejected raw material should be removed from other raw materials
- Store
- Procedure of 'First in first out' should be adopted for raw materials
- Records of the receipt, testing and approval or rejection and use of raw material shall be maintained

GMP – General requirements

Packaging Materials

- All packaging materials such as bottles, jars, capsules, etc. shall be stored properly
- All containers and closures shall be adequately cleaned and dried before packing the products

Finished Goods Stores

- Finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores within an area marked “Quarantine”
- “Approved Finished Goods Stock” area

GMP – General requirements

Finished Goods Stores

- "Approved Finished Goods Stock" area
- Only approved finished goods shall be dispatched
- Distribution records shall be maintained

Working Space

- Provide adequate space (manufacture and quality control) for orderly placement of equipment and material used

GMP – General requirements

Health, Clothing, Sanitation and Hygiene of Workers

- Workers employed in the factory shall be free from contagious diseases
- Clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean
- Uniform shall also include cloth or synthetic covering for hands, feet and head wherever required
- Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided
- Separate provision shall be made for lavatories to be used by men and women

GMP – General requirements

Medical Services

- The manufacturer shall also provide
- Adequate facilities for first aid;
- Medical examination of workers at the time of employment and periodical check

Machinery and Equipments

- Suitable equipment either manually operated or operated semi-automatically or fully automatic machinery shall be made available
- Machines for crushing, grinding, powdering, boiling, mashing, burning, roasting,filtering, drying, filling, labeling and packing, etc

GMP – General requirements

Machinery and Equipments

- Adequate space shall be provided to ensure between two machines or rows of machines for the workers to move freely
- Proper standard operational procedures (SOPs) for cleaning maintaining and performance of every machine should be maintained

Batch Manufacturing Records

- Shall maintain batch manufacturing record of each batch
- Shall be duly signed by Production and Quality Control Personnel

GMP – General requirements

Distribution Records

- Records of sale and distribution of each batch of shall be maintained
- Duration of record keeping should be the date of expiry of the batch
- In some cases, records need to be maintained up to 5 years of the exhausting of stock

Record of Market Complaints

- Manufacturers shall maintain a register to record
- Once in a period of six months the manufacturer shall submit the record such complaints to the Licensing Authority
- Reports of any adverse reactions shall also be maintained

GMP – General requirements

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

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	

GMP – General requirements

Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
Churna	200 sq feet	Grinder/disintegrator/Pulveriser/ Powder mixer/sieves/shifter
Capsules	100 sq feet	AC, De-humidifier, hygrometer, thermometer, Capsule filling machine and chemical balance
Asava / Arista	200 sq. ft	Fermentation tanks, containers and distillation plant where necessary, Filter Press
Taila	100 sq. ft	Bhatti, Kadahi/S.S. Patila S.S.Storage Containers, Filtration equipment, filling tank with tap/Liquid filling machine

GMP – General requirements

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

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	

GMP – General requirements

Category of Medicine	Minimum manufacturing space required	Machinery/equipment recommended
Sufoof (Powder)	200 sq. feet	Grinder / pulveriser, Sieves, Trays, Scoops, Powder mixer
Raughan (oils) (Crushing and boiling)	100 sq. feet	Oil Expeller, S.S. Patilas Oil filter bottle, Filling machine, Bottle drier, Bhatti
Shiyaf, Surma, Kajal	100 sq. feet	End runner, mixing S.S. Vessel
Kushta	100 sq. feet.	Bhatti, Kharal, Sil Batta, Earthen pots

GMP – General requirements

List of equipment recommended for in-house quality control section

Chemistry section

- Alcohol Determination Apparatus
- Volatile Oil Determination Apparatus
- Boiling Point Determination Apparatus
- Melting Point Determination Apparatus
- Refractometer
- Polarimeter
- Stage Micrometer
- Viscometer

GMP – General requirements

Chemistry section

- Tablet Disintegration Apparatus
- Chemicals, Glassware etc
- Moisture Meter
- Muffle Furnace
- Electronic Balance
- Magnetic Stirrer
- Hot air oven
- Refrigerator

GMP – General requirements

Chemistry section

- Glass/Steel Distillation Apparatus.
- LPG Gas Cylinders with Burners
- Water Bath
- Heating Mantles/ Hot Plates
- TLC Apparatus with all accessories (Manual)
- Paper Chromatography apparatus with accessories
- Sieve size 10 to120 with Sieve shaker
- Centrifuge Machine
- Dehumidifier
- pH Meter
- Limit Test Apparatus

GMP – General requirements

Pharmacognosy section

- Microscope Binoculor
- Dissecting Microscope
- Microtome
- Physical Balance
- Aluminium Slide Trays
- Stage Micrometer
- Camera Lucida
- Chemicals, Glassware etc

Summary

- GMP principles - Must be built into manufacturing process
- Prevents errors that cannot be eliminated through quality control of finished product
- Ensures all units of a medicine are of the same (within specified parameters) quality
- Poor medicines leads to loss of credibility for everyone: manufacturers, health care workers and governments

Lecture No.7
Nutraceuticals

At the end of this lecture, student will be able to

- Define nutraceuticals
- Classify nutraceuticals with examples

Content
Nutraceuticals

- Definition of nutraceuticals
- Classification of nutraceuticals

Nutraceuticals

Nutraceuticals

"Any substance may be considered as food or part of food , which in addition to its normal nutritive value provides health benefits including prevention of diseases or promotion of health"

Diabetes – Garlic, momordica

Cancer – Flax seeds, green tea

Immunomodulator - Ginseng

Classification of Nutraceuticals

- Inorganic mineral supplements
- Vitamin supplements
- Digestive enzymes
- Probiotics
- Prebiotics
- Dietary fibres
- Health drinks
- Antioxidants
- PUFA
- Herbs as functional foods

Classification of Nutraceuticals

Inorganic mineral supplements:

- Large number of elements control variety of physiological and biochemical functions of human body
- Most of the minerals are provided through diet, Deficiency of minerals in food may lead to various diseases

Eg: **Calcium** – Imp in the treatment of bone loss and prevention, sufficient intake of Ca post menopause significantly reduce the risk of bone fracture

Manganese – bone formation and cartilage

Zinc – Antioxidant

Classification of Nutraceuticals

Vitamin supplement:

- Necessary for maintenance of human life in small quantities
- Vit B complex – Specific vitamin B recommended for to combat high levels of **homocysteine**
- Niacinamide deficiency – Neurological and skin problems
- Vitamin C – Anti oxidant, Necessary for proper maintenance for bones

Classification of Nutraceuticals

Digestive enzymes:

- Use to help absorb and digest food material
- Pepsin of digestive juice – Digestive aid for proteins
- Amylase – Digest carbohydrates
- Pancrilipase – Breakdown of fat in small intestine
- Papain and bromelain – In digestive disorders

Classification of Nutraceuticals

Probiotics:

- Describing as a living organisms
- When ingested with or without food improves the intestinal microbial balance and consequently the health and functioning of large intestine
- Approximately 95% of bacteria found in colon of human body, some of them are useful and some of them harmful
- Natural balance between these two play an imp role in the health and functioning of large intestine

Classification of Nutraceuticals

Eg: Bioyoghurts – Lactobacillus acidophilus reduces the incidence of vaginal infections

Bifido bacteria found in yoghurt prevent young children suffering from diarrhoea

Prebiotics:

- Food components that escape digestion by normal human digestive enzymes and reach the colon after passage through the stomach and small intestine
- selectively promote the growth of probiotics

Classification of Nutraceuticals

Eg: Fructo oligosaccharide used in food supplements encourage the growth of Bifido bacteria already present in the gut

Dietary fibres: Necessary for our body to function properly

Water insoluble fibre:

- Absorbs water to certain extent
- Mainly contributes to bulking of stool
- Allows quick passage of wastes

Eg : Whole grain cereals, wheat, fruits and vegetables

Classification of Nutraceuticals

Water soluble fibre:

- Get dissolved in a water and forms a gel that binds the stool
- Slows down the absorption of glucose and reduce the cholesterol levels

Eg : Oats, legumes, fruits and vegetables

Health drinks:

- Health drinks are incorporated with antioxidants, Vit A, C and E and herbal extracts

Eg : Tropicana fruit juice fortified with Calcium provide 365 mg/250 ml

Classification of Nutraceuticals

Anti oxidants:

- Deficiency of antioxidants leads to variety of diseases like diabetes, cardiac diseases, arthritis etc

True antioxidants:

- React with free radicals and block the chain reaction of free radicals

Antioxidant synergists:

- Very low antioxidant potential, but enhance the effect of true antioxidants by reacting with heavy metals which catalyse the auto oxidation

Classification of Nutraceuticals

Examples:

- Vitamin C - Citrus fruits
- Lycopene – Tomato
- β-carotene – Carrot, sweet potato
- Rutin – Buck wheat, eucalyptus
- Quercetin – Onion, apple, black grapes
- Betalaines – Beet root

Classification of Nutraceuticals

Poly unsaturated fatty acid (PUFA)

- Human body is capable of synthesizing most of the fatty acids except two major Poly unsaturated fatty acids omega-3-fatty acid and omega -6-fatty acid
- These are precursors for arachidonic acid and docosohexanoic acid (DHA)
- These acids found to regulate Blood pressure, heart rate, blood clotting etc

Classification of Nutraceuticals

- Essential for the development of foetus and also during first 6 months after birth
- Breast milk is a rich source for DHA

Herbs as functional foods: Various herbs used in prevention of disease

Eg: Garlic, spirulina, momordica, flax seed, tomato, turmeric, Ginkago biloba etc

Summary

- Nutraceuticals – Nutritional value as well as health benefits
- Classification - Inorganic mineral supplements, Vitamin supplements

  Digestive enzymes, Probiotics, Prebiotics, Dietary fibres, Health drinks
- Antioxidants, Poly unsaturated fatty acids, Herbs as functional foods

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

Lecture No
Herbal excipients

At the end of the session, student will be able to

- Explain the various excipients used for formulating cosmetics

Herbal excipients

- Excipients are defined as ‘the substance used as a medium for giving a medicament
- Pharmaceutical excipients can be defined as non active ingredients that are mixed with therapeutically active compound(s) to form medicines.
- The ingredient which is not an active compound is regarded as an excipients. Excipients affect the behavior and effectiveness of the drug product more and more functionality and significantly.
- Plant derived polymers
- Synthetic polymers

Herbal excipients

Plant derived polymers

Advantages

- renewable
- can be cultivated or harvested in sustainable manner
- can supply constant availability of raw material

Disadvantages

- synthesized in small quantities
- In mixtures that are structurally complex, which may differ according to the location of the plants as well as other variables such as the season
- Result in a slow and expensive isolation and purification process.

Classification

Excipients are commonly classified according to their application and function in the drug products:

- Binders, Diluents
- Lubricants, Glidants, Disintegrants
- Polishing Film formers and coatings agents
- Plasticizers, Colorings
- Suspending agents Preservatives, antioxidants

Raw materials - colors

Annatto - carotenoids

Biological source: Dried seeds – Bixa orellana

Family : Bixaceae

Physical properties: Yellow orange in color

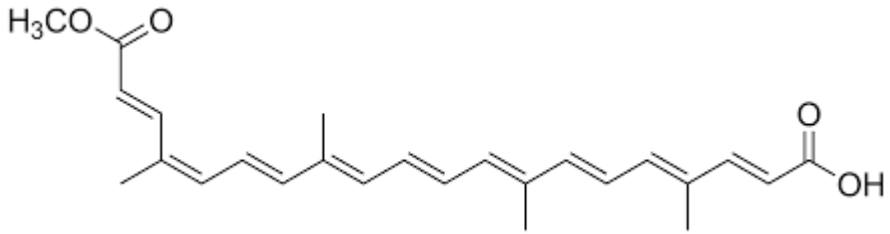
Soluble in alcohol, ether, insoluble in water

Chemical constituents: oleo resin – Bixin (yellow colored carotenoid) – 2.5%

Raw materials - colors

Annatto - carotenoids

Uses: coloring agent – cosmetics, food, beverages



Raw materials - colors

Chlorophyll

Biological source: Green leaves of higher plants and green algae (PRESENT IN CHLOROPLAST)

- Mixture of 4 pigments – Chlorophyll a (blue black)

  Chlorophyll b (Green black)

  Carotene (Orange red)

  Xanthophyll (Yellow)

Raw materials - colors

Chlorophyll

Physical properties: Soluble in organic solvent, Slightly soluble in water

Uses: Coloring agents – soaps, oils and cosmetics

Raw materials - colors

Cochineal

Biological source: Dried female insects Dactilopius coccus

Family : Coccidae

Production: Bugs –collected – autumn –protected winter

- Killed –immersion in hot water or exposure to hot sun
- Natural exposure - sun – good quality and variety of dye

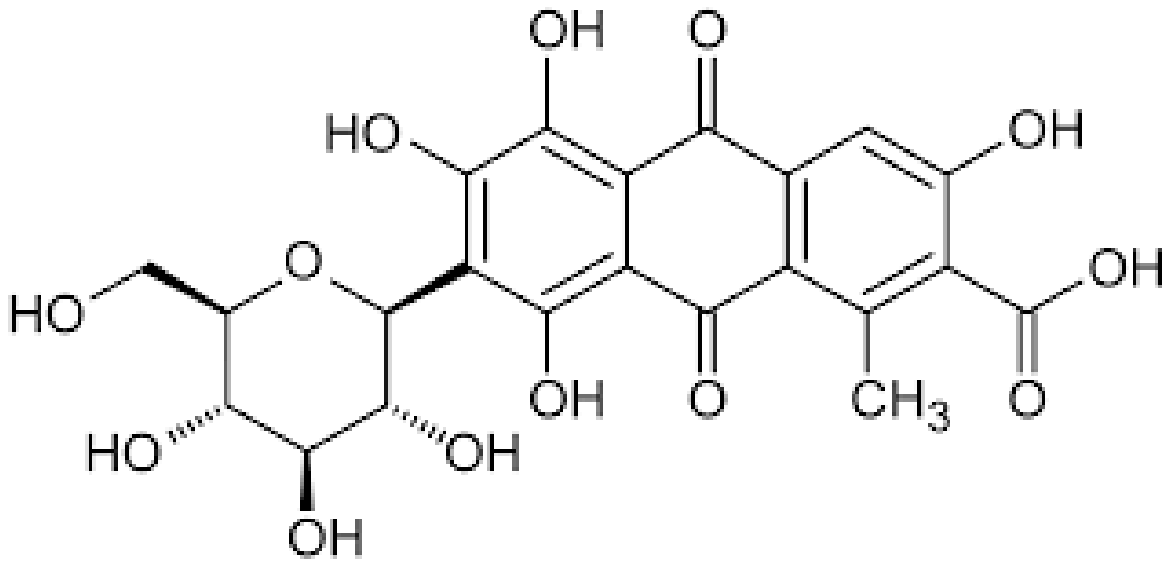
Raw materials - colors

- Heating - sun –color changes to purplish black color – black grains
- Burning – sulphur and charcoal fumes –develop purple grey color – black grains
- Tubular glands - surface – wax

Chemical constituents: 10 % anthroquinone dye – Carminic acid , 10% fat, 2% wax

Raw materials - colors

- Uses: Coloring agent – cosmetics, drug, liquid and solid food preparations



Raw materials - colors

Henna (Lawsonia)

Biological source: Dried leaves – Lawsonia inermis

Family : Lythraceae

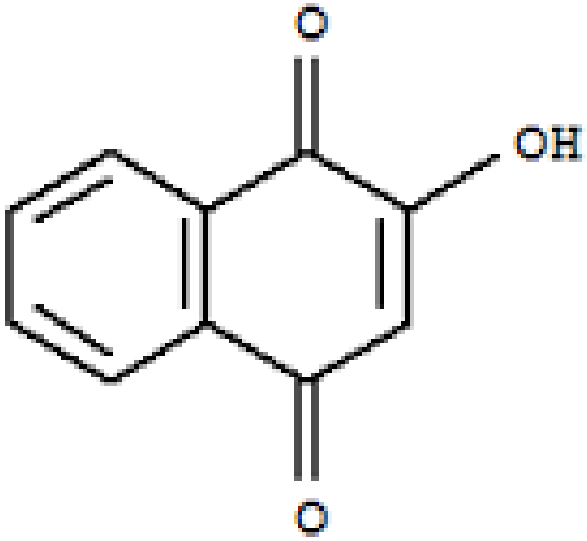
Chemical constituents: Lawsone – 2,5 – diOH-1,4-naphthoquinone (orange dye)

Uses: Hair dye

Along with dihydroxy acetone –sunscreen agent

Raw materials - colors

Lawsone



Raw materials – colors

Curcumin - Turmeric

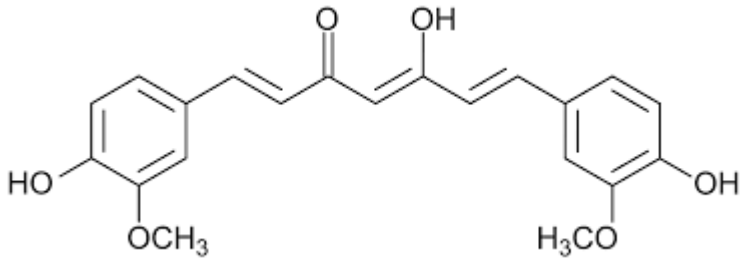
Biological source: Bright yellow coloring material obtained from the rhizomes of *Curcuma longa*

Family : Zingiberaceae

Solubility: soluble – ethanol, acetic acid

Insoluble – water, ether

Raw materials – colors



Uses: Food colouring agent

Raw materials - colors

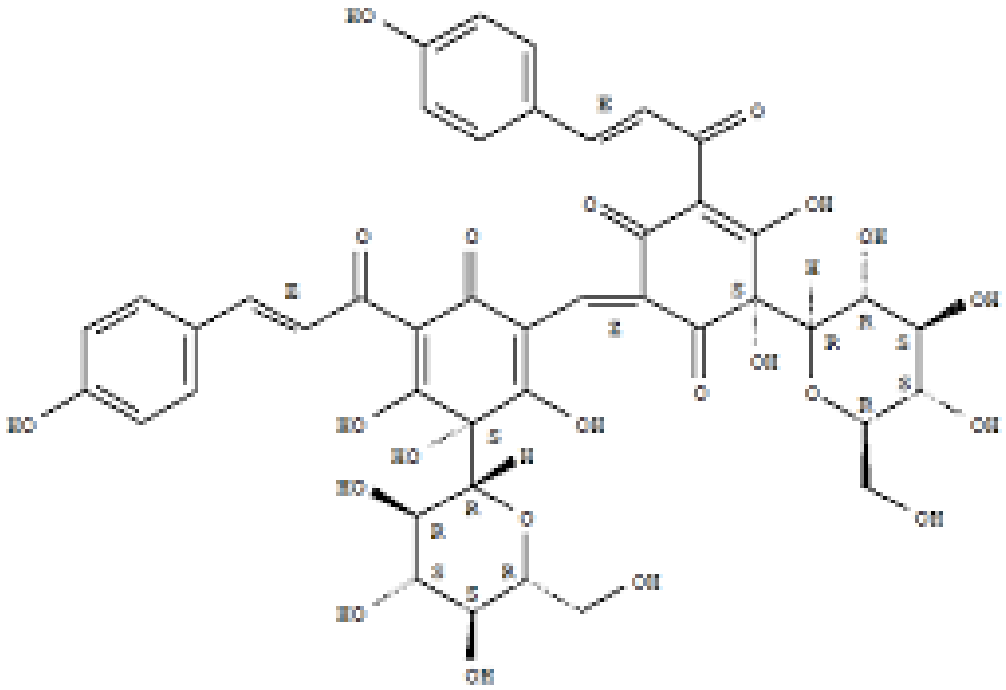
Carthamine

Biological source: Carthamin is a natural red pigment derived from safflower, Carthamus tinctorius

Family : Asteraceae

Uses: It is used as a dye and a food coloring. As a food additive, it is known as Natural Red 26. Carthamin was used as a dye in ancient Egypt. It was used extensively in the past for dyeing wool for the carpet industry in European countries

Raw materials - colors



Raw materials - colors

Crocin (Saffron)

Biological source: Golden yellow – orange carotenoid pigment obtained from the dried stigmas and upper parts of styles of *Crocus sativus*

Family : Iridaceae

Solubility: Soluble in hot water and insoluble in absolute alcohol

Uses : Food colourant

Raw materials - colors

Raw materials - colors

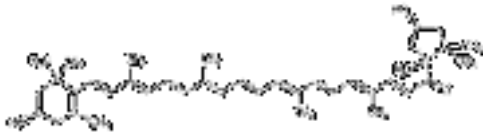
Capsanthin (Paprika)

Biological source: Red colour carotenoid pigment obtained from the fruit of *Capsicum annum*

Family : Solanaceae

Constituents: Carotenoid - Capsanthin

Uses: Coloring agent for food, pharmaceutical, cosmetics and beverages



Raw materials - colors

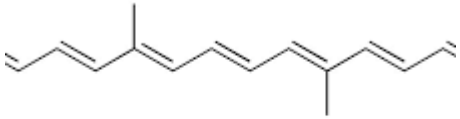
Lutein (Tagetus)

Biological source: Yellow orange colour carotenoid pigment obtained from the flower of *Tagetus erecta*

Family : Compositae

Uses: Coloring agent for food, pharmaceutical

Used as additive of chicken feed to give colour to



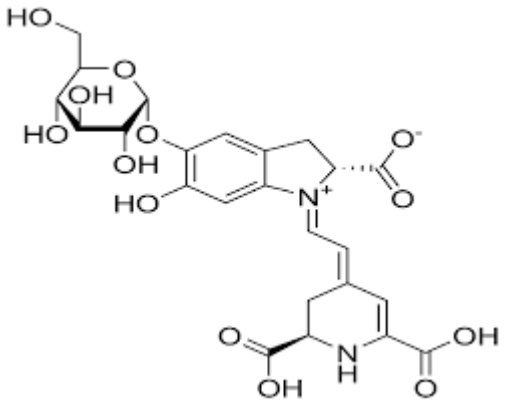
Lutein

Raw materials - colors

Betanin (Beet root)

Biological source: Red glycoside obtained from the beet root,

Beta vulgaris



Family :

Uses: Coloring agent for ice cream,

powdered soft drink beverages, soups, in som

sugar confectionery

Summary

- Colorant : Substances added to cosmetics products to colour the product and /or to impart color to the skin and /or its appendages
- Natural pigments

PATENTENTING AND RGULATORY REQUIREMENTS OF NATURAL PRODUCTS

Lecture No
Patenting of natural products

At the end of this lecture, student will be able to

- Discuss Indian Patent act 1970
- Explain patentable and non patentable natural products

Content
Patenting of natural products

- Indian Patent act 1970
- Patentable and non patentable natural products

Indian Patent Act

- In India the grant of patents is governed by the patent Act 1970 and Rules 1972
- The patents granted under the act are operative in the whole of India
- With reference to IPR, we will have 3 distinct phases

  The patent act 1970

  Transition period

  Post GATT period

Indian Patent Act

1. Patent act 1970

- Most significant act in the legislature of protection of IPR
- Act came into force on 20th 1972
- As per this act the major prerequisites for patenting in India are

  - A new invention

  - Should be new and non obvious with respect to the prior art

  - It must be useful

  -Not previously in use in India

Indian Patent Act

Invention, as per the act may be defined as any new and useful

- Art, process, method of manufacture
- Machine, apparatus or other article
- Substances produced by manufacture, including any new and useful improvements of any of them

Indian Patent Act

Some examples in Pharmacy, which are patentable are

- New process of manufacture
- New Chemical Entities (NCE)
- New formulation process
- New composition of matter

Rights of a Patentee

to exploit the patent

- The p**Right** atentee has a right to prevent 3rd parties, from exploiting the patented invention

Right to grant license

- The patentee has a power to assign rights or grant license

Right to surrender

- The patentee is given the right to surrender the patent by giving notice in prescribed manner to the controller.

Rights of a Patentee

Right to sue for infringement

- A patentee is given the right to institute proceeding for infringement of the patent in a district court

Indian Patent Act

Following are non patentable in India

- Discoveries
- Method of detection, diagnosis or treatment of diseases
- Analytical methods
- Methods of agriculture/cultivation
- Animals, plants and biological methods for rearing and growing them
- Products made by chemical synthesis

Indian Patent Act

2. Transition period

- By becoming a member of WTO and accepting GATT (General Agreement on Trade and Tariffs), it has become obligatory for our country to implement TRIPS
- TRIPS – Trade Related Intellectual Property Agreement
- TRIPS were signed in 1995 in Uruguay, which try to enforce a common patent law to all its 117 signatory countries
- Trips specifies product patent with a validity of 20 years

Indian Patent Act

3. Post GATT period

- Govt of India timely introduced a bill for the introduction of product patent regime in place of process patent as per trips

Indian patent act 1970	Post GATT
Process patent	Product patent
Indian context	Common patent system in all 117 countries
Period of validity: 5 years from the date of patent grant/7 years from the date of filing the application for drugs and food substances	A period of 20 years

Patenting of natural products

- In general naturally occurring plant materials as such are not patentable
- Therefore medicinal plants are to be redefined as per the concepts of patent
- European commission on patents suggests that a patent can not simply be denied because it involves living matter
- European patent office stipulates certain regulations for patenting of natural products
- It clearly distinguished an invention from discovery

Patenting of natural products

Discovery: Finding out a substance occurring free in nature

Invention: Novel isolation process of a natural constituent from its surroundings

Non patentable natural products:

- Plants growing wild
- Plants adopted for cultivation
- Hybrids of other cultural varieties, which have been tried for a particular use

Patenting of natural products

Patentable natural products:

- A novel isolation process
- Characterization of the new product
- A new application
- Biotechnology related products

Patenting of natural products

1. **A novel isolation process of natural products from its surroundings**

- An Indian patent, NCL, Poona – For the process of isolation of azadirachtin from the seeds of neem and also its storage
- An Indian patent – For the processing technology of taxol isolation from taxus species, CIAMP
- A Chinese patent – Extraction of curcumin from turmeric
- A poland patent – Isolation of artemisin from Artemesia annua
- An US patent, processing technology for the isolation of curcuminoids from turmeric

Patenting of natural products

2. **Characterization for new product-** By its structure or by other physical parameters

3. **A new application of an isolated compound**

- A Japanese patent – For the use of turmeric as a stabilizing agent for menadione, an anti fungal agent
- A Belgian patent – Turmeric as an ingredient for imparting flash of golden yellow colour to hair/hair dye preparation

Patenting of natural products

A number of Indian traditional plants have been patented for various uses in US

Name of the herb	Traditional use	In US patented for
Pomegranate	Anti bacterial	Anti viral
Bitter guard	Leaves – Anti diabetic	Anti tumour
Neem	Anti bacterial	40 patents for various uses
Pepper	Digestant	Decrease the dose of Rifamycin

Patenting of natural products

4. **Patenting in relation with Bio technology**

a. Patenting of biological matter:

- Before 1980 life forms were not patented in US
- First time the invention of oil eating bacterium (Pseudomonas) was patented
- Patentable microbial inventions are methods for producing new organisms like reducing pathogenesity, increasing biological activity
- Antibiotics and other products, invention of media or culture conditions
- Gene recombination or cell fusion

Patenting of natural products

b. Non naturally occurring , non human multicellular organisms:

- Transgenic plants and transgenic animals
- Transgenic plants – Herbicidal resistant cotton, insecticidal resistant tobacco
- Transgenic animal – Oncomouse is patented

c. **Patenting of the secondary metabolites by cell culture**

- Production of taxol from taxus species
- Cantharanthine and ajamalicine from Cantharanthus roseus
- Production of shikonin – Lithospermum erythrorhizon

At the end of the session, student will be able to

- Identify factors affecting herb quality
- Evaluate crude drugs for presence of microorganisms, heavy metals and Aflotoxins

Contents

- **Factors affecting herb quality**

- Cultivation factors
- Collection
- Drying
- Garbling
- Packaging
- Storage
- Preservation

Contents

- Limit test for Arsenic
- Limit test for Cadmium and lead
- Determination of Microorganisms
- Determination of Aflotoxins

Factors Affecting Herb Quality

1. Cultivation factors

a. Soil

b. Environmental factors

- Temperature
- Rainfall
- Climate
- Light
- Humidity
- Altitude

Factors Affecting Herb Quality

2. Collection

3. Drying

4. Garbling

5. Packaging

6. Storage

7. Preservation

Cultivation Factors - Soil

- Soil content
- Soil PH
- Different plant species – varies - soil and nutritive requirements
- Soil – good – half of pores – water and rest with air
- **Basic characters of soil affecting growth and plant development**

1. Physical properties – particle size
2. Chemical properties – Composition of nutrients
3. Microbial properties – microorganisms present

Cultivation Factors - Soil

- PH – quality and content of secondary metabolites
- Acidic soil – not suitable for Leguminous plants – due to poor development
- Ground nut, sunflower seeds, cotton and rice - grow better – alkaline soil
- Acidic PH – disadvantages – solubilize - more iron
- Tobacco, cinchona, tea and potatoes – acidic soil

Cultivation Factors - Soil

- Alkaline soil – phosphorous - converted – insoluble form – calcium phosphate – cannot be made available for plants
- PH range – 6.5 -7.5

Environmental Factors – Temperature

- Major factor – control – development and metabolism of plant
- Excessive temperature or frost –quality
- Eg. Cinchona – 60 -75˚C
- Coffee – 55 -70 ˚C
- Tea – 70 -90 ˚C
- Annual temperature variation – affects – plant cultivation
- Singapore -1.5 ˚C, Moscow – 29.3 ˚C

Environmental Factors – Temperature - Examples

- Nicotiana rustica – Nicotine - 20 ˚C – decreases – 11-12 ˚C and 30 ˚C
- Quality of cotton – temp ↑ - molecule – fatty material –cuticle – reoriented – water cannot penetrate – extremely thin layer -volatile
- Cotton - absorbent – non absorbent
- Other drug – volatile oil – Buchu, chamomile, ginger and asafoetida

Environmental Factors – Climate

- Each plant species – specific climate condition – grow well – maximum concentration of secondary metabolites
- Tropical and subtropical plant will grow in temperate region
- Continuous rain – loss of water soluble substances from leaves and roots by leaching
- Low yield – wet seasons

Environmental Factors – Climate

- Cassia angustifolia – short term drought - ↑ concentration of Sennosides A and B – Long term - causes loss of leaf biomass

Environmental Factors – Light

- Amount and intensity of light – plant - varies
- Wild state – shade requirements –fulfilled – under cultivation – similar shade should be provided
- Full sunshine - higher content of alkaloids – than shade – solanaceous drugs and cinchona
- Datura stramonium var tatula – long exposure – intense light – sharp ↑ - Hyoscine content – flowering

Environmental Factors – Light

- Peppermint leaves – long day - menthone, menthol and traces of menthofuran
- Plants grown – short day – menthofuran as major constituents – volatile oil
- Hirata et al – Planta medica – irradiation – intact plants – near ultraviolet range – 290-380nm – synthesis of dimeric alkaloid
- Flavonoids and anthocyanin – uv – ß radiation
- Ocimum basilicum – raised under glass – received no uv radiation - ↑level of both phenyl propanoids and terpenoids - leaves

Environmental Factors – Altitude

- Important factor – production of secondary metabolites
- Some plants - altitudes – some – lower levels
- Coconut palm – maritime climate – sugar cane – lower land plant
- Tea, coffee, cocao, rhubarb, tragacanth and cinchona – elevation
- Cinchona succirubra – grow well in low levels – no alkaloids production

Environmental Factors – Altitude

- Bitter principle - gentian - ↑ - altitude
- Alkaloids of Aconitum napeullus and Lobelia inflata , oil content

  Thyme, peppermint decreases
- Pyrethrum - best yield - flower heads and pyrethrin – high altitude

Collection

- Drugs – collected – wild or cultivated plants
- Task – casual, unskilled – Ipecac
- Skilled labor – Highly scientific manner
- Season – drug collected - importance – amount and nature of Phyto constituents
- Rhubarb – no anthraquinone derivatives – winter
- Warmer climate – by oxidation - anthranols - converted – anthraquinones

Collection

- Age - not only the total quantity of active constituents – relative proportions – components in active mixture
- Mentha piperita – Young leaves – pulegone as leaves mature – menthone and menthol
- Digitalis pupurea – glycoside content varies – age – Pupurea glycoside A – formed last but reaches - 50 % total glycoside content
- Papaver somniferum – morphine content – highest after 2-3 weeks of flowering

Collection

- Ammi visnaga – unripe fruit – rich in Khellin and visnagin
- Leaves – flowers begin to open
- Flowers – just before – fully expanded
- Under ground part – aerial parts die down
- Leaves, flowers and fruits – not collected - covered dew or rain
- Discolored, attacked by insects – rejected

Collection

- Hand picking – difficult – make leaves, flowers – entirely free from other parts
- Barks – after damp weather – separate more readily from wood
- Gums gum resin – dry weather – exclude vegetable debris
- Under ground organs – shaking the drug –before, after and during drying or brushing – sufficient to remove sandy soil
- Clay or heavy soil – washing is essential

Collection

- Valerian – washed in streams – in which they grow – wormy or diseased rejected
- Small size – replanted
- Larger roots and rhizomes – sliced before drying
- Gentian roots – before drying – made in to heaps – ferment
- Seeds – nuxvomica and cocoa – mucilaginous fruits – washed free from pulp before drying

Drying

- Duration – few hours to weeks
- Open air drying and shade drying
- Artificial drying – spray dryer, Tray dryers
- Open air drying – cardamom, cinnamon, clove
- Drying - artificial – rapid - open air drying
- Often necessary in tropical countries – humid is high
- Europe – continuous belt dryers – large crops – Digitalis

Drying

- Rapid drying – leaves and flowers to retain aroma – temp – constituents and physical property
- Leaves, herbs, flowers – 20 -40 ˚C
- Barks – 30 -65 ˚C
- Digitalis – BPC &BP –temp NMT 65 ˚C
- Solar dryers – advantages- conventional
- Unorganized drug – spray drying

Drying

- Length of drying – affects the quality
- TAXOL from Taxus species – length of drying extended – 15 days – recovery of Taxol is affected

Garbling

- Preparation of drug to market
- After collection and drying – drug – scrutinized – to remove unwanted materials
- Dried crude drug – checked – foreign organic and extraneous matter
- Foreign organic matter – other parts of plant than the official part
- Extraneous matter – sand, silica, animal excreta, moulds, insects

Garbling

- Example – stems - Senna leaves
- Stalks and blown clove - clove bud
- Wood – bark
- Fine clay, sand, finer crude drugs – removed – shake seivers
- More specific treatments – product –more appealing
- Yellow bees wax – sunlight – slow bleaching
- Ginger – liming / dusting with calcium carbonate - whitening

Packaging

- Dried drugs –packed- characters and quantity
- Sacks –containers
- Crude drugs – moisture – plastic containers/ bags
- Ergot –paper bags/cardboard containers
- Opium – wrapped in sheets
- Poisonous drugs – dried separately – containers –well labelled

Storage

- Storage – prevent detoriation of drugs – enzymatic hydrolysis
- Drugs stored – usual containers – sacks, bales, wooden cases, cardboard boxes and paper bags – tend to absorb -10 -12% moisture
- Digitalis, Indian hemp – stored
- Large quantities – sealed containers – dehydrating agent – bottom – quick lime separated from drug –perforated grid

Storage

- Lime - moist –renewed
- Volatile oil and fixed oils –sealed well filled containers – dark, cool place
- Air – container – inert gas
- Air dried drugs – susceptible – attack – insects and other pests – examined periodically during storage
- Any mould or worminess – rejected or treated

Storage

- Avoid – microbial contamination – some drugs require –sterilization
- Ethylene oxide or methyl chloride
- Drugs so treated – comply acceptable limit for toxic residues
- Senna pods – 50 ppm – ethylene oxide

Limit Test for Arsenic

- Toxic and cumulative

The plant materials may contain Arsenic traces due to

- Application of pesticides
- Environmental pollution
- Manufacturing process
- Process equipment and storage container(due to solvent action the metals may leach into the final product)

Principle

Sample dissolved in acid → Arsenic acid → reduced reducing agent

KI, Stannated acid, Zn

nascent hydrogen

arsenious acid → arsine gas (ASH_3)

(H)

react with mercuric chloride paper

Yellow stain

Principle

- Intensity of stain directly proportional - amount of arsenic present
- The rate of evolution of gas - maintained by using a particular size of Zinc
- Any impurity coming along with ASH_3 (like H_2S) - trapped by lead acetate soaked cotton plug
- All reagents used should be arsenic free and mentioned as AsT

Procedure

- Limit test is performed by matching the depth of color with that of a standard stain

- **Preparation of sample by acid digestion method:**

35 to 70g of coarse plant material

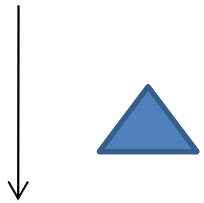
↓ Kjeldahl flask

↓ add

10-25ml of water and 25ml of nitric acid

↓

20 ml of sulphuric acid



HNO_3 added drop by drop

Organic matter destroys (indicated by darkening of solution

Vapours of SO_3 evolves

Cool, add 75 ml of water & 25 ml of ammonium oxalate

Until SO_3 vapours develop

Transfer and makeup to 250 ml with water

Method: Gutzeit test

- Moisten some cotton wool - lead acetate - allow to dry- pack it in to a tube - which fits in to the wide mouthed bottle
- Between the flat surfaces of the tubes - place a piece of mercuric bromide paper that is large enough to cover their openings
- The mercuric bromide paper can be fitted by any means provided that

Procedure

- The whole of the evolved gas passes through the paper
- The portion of the paper in contact with the gas is a circle(6.5mm in diameter)
- The paper is protected from sunlight during the test

Procedure

25 – 50 ml sample aliquot

↓

wide mouthed bottle

↓

1 g – KI and 10 g - granulated zinc, 5 ml – stannous chloride

↓

keep the assembly in position

↓

Allow the reaction for 40 min

↓

Compare yellow stain on the mercuric chloride paper with standard stain – known quantity of dilute arsenic AsTS

Preparation of Standard Stain

10 ml stannated hydrochloride + 1 ml dilute arsenic

50 ml water

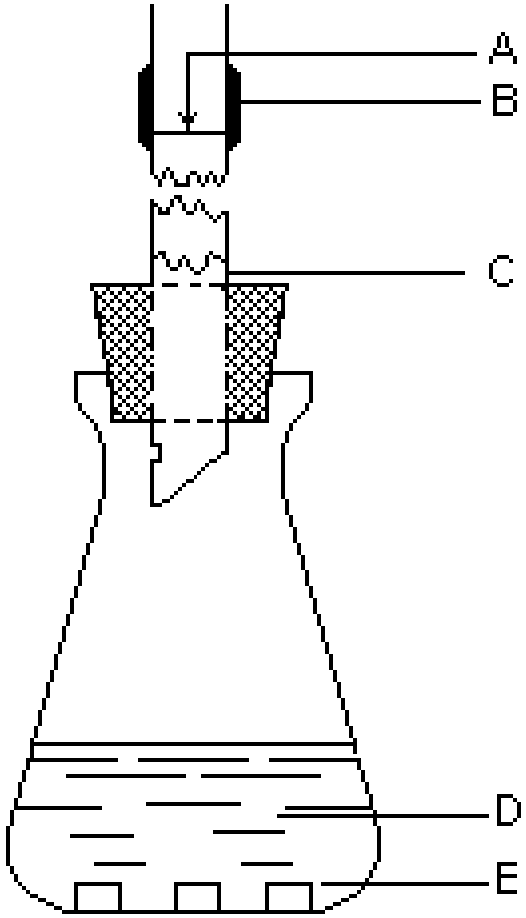
↓

resulting solution exposed to same condition

↓

Yellow stain - mercuric chloride paper AsR - Standard stain

APPARATUS FOR LIMIT TEST FOR ARSENIC



A. Mercuric chloride test paper disc
B. Rubber connexion
C. Cotton gauze saturated with lead acetate
D. Test solution
E. Aluminum squares

Limit Test for Cadmium and Lead

Apparatus used

- The apparatus consist of a digestion vessel, consisting of a silica crucible (62mm height, 50mm diameter) of capacity 75ml, with a silica cover or lid

Reagents required

- Digestion mixture for up to 3 hrs
- 2 parts by weight of nitric acid and 1 part by weight of perchloric acid

Standard reference material

- Olive leaves (Olea europaea) and hay powder

Limit Test for Cadmium and Lead

Wet digestion method

200-250mg - finely cut air dried plant material - clean silica crucible

1.0ml of the digestion mixture

cover the crucible – oven - heat slowly

100˚C - maintain temperature - up to 3

hrs - 120˚C and maintain at this temperature for 2 hrs

Limit Test for Cadmium and Lead

Raise the temperature - very slowly to 240˚C, avoiding losses

↓

dry inorganic residue + 2.5ml nitric acid

↓

Atomic absorption Spectrophotometry

Limit Test for Cadmium and Lead

- The maximum amounts in dried plant materials, which are based on ADI values are
- Lead – 10mg/kg
- Cadmium – 0.3 mg/kg.

Determination of Microorganism

- Indicate the quality - production and harvesting practices
- Medicinal plant – normally carry bacteria and moulds
- Current practices – harvesting, handling and production – may cause additional contamination and microbial growth

Determination of Microorganism

Pretreatment of material being examined

For water soluble materials

10 g or 10 ml plant material

↓ Dissolve/dilute

Lactose broth or any other media (not having any antimicrobial activity)

↓

Adjust the volume to 100 ml

↓

PH 7

Determination of Microorganism

For non - fatty materials insoluble in water

10 g or 10 ml of plant material

↓ Dissolve/dilute

Lactose broth or any other media (not having any antimicrobial activity)

↓

Adjust the volume to 100 ml + polysarbate 80R

↓

Adjust the PH - 7

Determination of Microorganisms

For fatty materials

10 g or 10 ml of plant material

↓ homogenised with 5 gm polysorbate 80

▲ **40**˚C

85ml lactose broth or any other media (not having any antimicrobial activity)

↓

Adjust the volume to 100 ml

↓

Adjust the PH - 7

Test for Specific Microorganisms

- Prepared pretreated material - detection of different bacterias – enterobacteria and certain gram –ve bacteria
- Homogenised/pretreated material - incubated – 30-37˚C – 25hrs

Test for Specific Microorganism - *Enterobacteria*

- Anaerobic bacteria – Septicemia, urinary tract infection, wound, burn and meningitis

1gm/ml pretreated material - homogenized

+

Enterobacteria enriched broth mossel

↓ Incubated 37˚C 18-48 hrs

prepare subculture – plate- violet red bile agar with glucose and lactose

↓ Incubate

Red color colonies – presence of *enterobacteria*

Test for Specific Microorganism – *E.coli*

- Anaerobic bacteria – Diarrhea, urinary tract infection, wound, burn and meningitis

Pretreated material - homogenized + Lactose broth

↓

Incubated 43 - 47˚C 18-24 hrs

1ml/gm - Macconkey's broth

↓

prepare subculture – plate- Macconkey's broth

↓

Incubate – same condition

↓

Red color colonies, rod shaped with reddish zone – presence of *E.coli*

Test for Specific Microorganism – *Salmonella Species*

- Anaerobic gram –ve bacteria – Typhoid, enteric fever, GIT infection and septicemia

Pretreated material - homogenized + Nutrient broth

↓

Incubate 35 - 37˚C 5 -24 hrs

10ml – 100 ml Tetrathionate bile brilliant green broth

↓

Incubate 42- 43˚C 5 -24 hrs

prepare subculture – Nutrient agar

↓

Incubate 35 - 37˚C 5 -24 hrs

↓

Colorless to pink-red or black colonies – presence of ***Salmonella Species***

Test for Specific Microorganism – *Pseudomonus aeruginosa*

- Aerobic gram –ve bacteria – Respiratory tract infection

Pretreated material - buffered Nacl peptone solution – PH 7

↓

1gm/ml – Soyabean casein digest broth

↓ Incubate 35 - 37˚C 5 -24 to 48 hrs

Subculture – Cetrimide agar plate

↓ Incubate 35 - 37˚C 24 to 48 hrs

Green fluorescence – presence of ***Pseudomonas aeruginosa***

Test for Specific Microorganism – *Pseudomonus aeruginosa*

Biochemical test

2 or 3 drops – freshly prepared N,N,N',N'-tetramethyl-p-phenylenediamine dihydrochloride on a filter paper + apply a smear of suspected colony – purple color 5 – 10 sec – presence of *Pseudomonas*

Material passes test – colonies do not appear or confirmatory biochemical test is –ve

Test for Specific Microorganism – *Staphylococcus spp*

- Gram +ve bacteria – extracellular toxins

Pretreated material - buffered Nacl peptone solution – PH 7

↓

1gm/ml – Soyabean casein digest broth

↓ Incubate 35 - 37˚C 5 -24 to 48 hrs

Subculture – Baird – parker agar media

↓ Incubate 35 - 37˚C 24 to 48 hrs

Black colonies– presence of ***Staphylococcus species***

Total Viable Count

Total viable count of the material being examined

- Membrane filtration
- Plate count
- Serial dilution

Membrane Filtration

- Use membrane filter – nominal pore size – not greater than 0.45µm

  – can effectively retain bacteria

- Eg. Cellulose nitrate filters – oily and weakly alcoholic solution

- Cellulose acetate filters – strongly alcoholic solution

- Keep filter paper – filtration apparatus – sterilize

- Filter 10ml – material soln – to be tested

Membrane Filtration

- Filter paper - washed – buffer – fatty substances –wash with surfactants - polysorbate 80R, 20R
- Filter paper – plate - suitable media
- Incubate - 30 - 35˚C - 5 days
- No of colonies counted
- Calculate no of microorganism per ml of solution

Plat Count Method

- 9 -10 cm plate
- 1 ml treated material + 15 ml liquified casein –soyabean digest agar
- Temp ≤ 45 ˚C
- Spread pretreated material on the surface, solify
- Incubate 30 - 35˚C - 5 days
- No of colonies counted
- Calculate no of microorganism per ml of solution

Serial Dilution Method

- 12 tubes – 9-10 ml - soyabean casein digest agar medium
- First 3 tubes + 1 ml of 1:10 dilution pretreated material and media
- Next 3 tubes + 1 ml of 1:100 dilution pretreated material and media
- Next 3 tubes + 1 ml of 1:1000 dilution pretreated material and media
- Last 3 tubes + only diluent or media

Serial Dilution Method

- **Incubate** 30 - 35˚C - 5 days
- Last 3 tubes – no microbial growth
- Calculate no of microorganism per g or per ml of the material tested

Determination of Aflatoxins

- **Aflatoxins** - poisonous cancer-causing chemicals - certain molds (*Aspergillus flavus* and *Aspergillus parasiticus*) - grow in soil, decaying vegetation, hay, and grains
- Regularly found - improperly stored staple commodities
- Contaminated poultry feed - high percentages of samples of aflatoxin - contaminated chicken meat and eggs in Pakistan

Determination of Aflatoxins

- Childrens – Stunded growth, delayed development
- Adults – tolerance –risk
- Most carcinogenic substance known
- Metabolized – liver – reactive epoxide intermediate – aflaoxin M1
- Most commonly ingested – Aflatoxin B1 – permeate through skin – most toxic

Determination of Aflatoxins

- FDA – levels in food or feed – 20 to 300 ppb
- 14 types – nature
- Aflatoxin B_1 and B_2, produced by *Aspergillus flavus* and *A. parasiticus*
- Aflatoxin G_1 and G_2, produced by *Aspergillus parasiticus*
- Aflatoxin M_1, metabolite of aflatoxin B_1 in humans and animals

  (exposure in ng levels may come from a mother's milk)

Determination of Aflatoxins

- Aflatoxin M_2, metabolite of aflatoxin B_2 in milk of cattle fed on contaminated foods
- Aflatoxicol
- Aflatoxin Q_1 (AFQ_1), major metabolite of AFB_1 in *in vitro* liver preparations of other higher vertebrates

Preparation of Sample

- Grind or reduce NLT 100 g - crude drug
- Larger the sample –chances of detecting greater

Weigh 50 g powdered material – conical flask + 170 ml methanol R + 30 ml water

↓ Shake vigorously - 30 min - filter

Collect 100 ml filtrate A

↓

Discard first 50 ml and collect 40 ml of filtrate B

Preparation of Sample

Eliminate pigments – special clean up procedures

100 ml filtrate A - 250 ML BEAKER + 20 ML Zinc acetate/aluminium chloride + 80 ml water

↓ stir allow to stand for 5 min

diatomaceous earth – mix – filter

↓

Discard first 50 ml, collect 80 ml - C

Preparation of Sample

Transfer B or C - Separating funnel + 40 ml sodium chloride + 25 ml light petroleum – shake 1 min

↓

allow layers to separate-lower layer - another separating funnel

↓

Extract twice 25 ml dichloromethane shake for 1 min

↓

Allow layers to separate, combine both lower layers – 125 ml conical flask – boiling chips –evaporate to dryness

Procedure – B1,B2,G1 & G2

- Residue + 0.2 ml of mixture (98 :2) chloroform : acetonitrile – close vial – shake vigorously until residue dissolves
- TLC – silica gel G
- Mobile phase – chloroform : acetone :2-propanol (85:10:5)
- Standard mixture – Aflatoxin
- Apply standard and sample

Procedure

- Develop and observe under UV 365nm
- Std shows blue fluorescence
- If residue shows - +ve
- Estimation – comparing the intensity of spots with standard mixtures

Summary

- Determination of microorganisms - Indicate the quality - production and harvesting practices
- Medicinal plant – normally carry bacteria and moulds
- Current practices – harvesting, handling and production – may cause additional contamination and microbial growth
- Aflotoxin - liver cancer
- Detected by simple chromatography

Determination of Haemolytic Activity

- Caryophyllaceae, Araliaceae, Sapindaceae, Primulaceae, and Dioscoreaceae - contain **Saponins**
- **Saponins** - ability to cause haemolysis
- Comparison with that of a reference material, saponin R, which has a haemolytic activity of 1000 units per g
- Suspension of erythrocytes + equal volumes of a serial dilution of the herbal material extract
- **Lowest concentration** to effect complete haemolysis is determined
- Similar test is carried out simultaneously with **Saponin R**

Determination of Haemolytic Activity

Procedure

Erythrocyte suspension

- Fill a glass-stoppered flask to one tenth of its volume with sodium citrate (36.5 g/l) TS, swirling to ensure sufficient volume of blood freshly from a healthy ox, shake
- Citrated blood- can be stored for about 8 days at 2−4 °C
- 1 ml of citrated blood in a 50-ml volumetric flask with phosphate buffer pH 7.4 TS - **diluted blood suspension** (2% solution)

Determination of Haemolytic Activity

Procedure

Reference solution

10 mg of Saponin R add phosphate buffer pH 7.4 TS to make 100 ml

Preliminary test

Serial dilution - herbal material extract with phosphate buffer pH 7.4 TS and blood suspension (2%) using four test-tubes

	Tube no.			
	1	2	3	4
Herbal material extract (ml)	0.10	0.20	0.50	1.00
Phosphate buffer pH 7.4 TS (ml)	0.90	0.80	0.50	—
Blood suspension (2%) (ml)	1.00	1.00	1.00	1.00

Determination of Haemolytic Activity

Procedure

- ✓ Gently invert - mix
- ✓ Shake again after a 30-minute interval
- ✓ Allow to stand for six hours at room temperature
  - ❖ Examine the tubes
  - ❖ Record the dilution at which total haemolysis has occurred
    - ➢ **Total heamolysis** - clear, red solution without any deposit of erythrocytes

Determination of Haemolytic Activity

If total haemolysis

- **only in tube 4:** original herbal material extract **directly** for the **main test**
- **In tubes 3 and 4: two-fold dilution** of the original herbal material extract
- **In tubes 2, 3 and 4: five-fold dilution** of the original herbal material extract
- **In all four tubes**: **ten-fold dilution** and carry out the **preliminary test again**
- **Not observed in any of the tubes: Repeat** the preliminary test using a **more concentrated** herbal material extract

Determination of Haemolytic Activity

Main test

- Prepare a serial dilution - **undiluted or diluted** herbal extracts
- Blood suspension (2%) using 13 test-tubes

	Tube no.												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Herbal material extract (diluted if necessary) (ml)	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	1.00
Phosphate buffer pH 7.4 TS (ml)	0.60	0.55	0.50	0.45	0.40	0.35	0.30	0.25	0.20	0.15	0.10	0.05	—
Blood suspension (2%) (ml)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

- Observe the results after 24 hours

Determination of Haemolytic Activity

Calculate

- ✓ Amount of herbal material in g or ml that produces total haemolysis
- ✓ Quantity of saponin R in g that produces total haemolysis

Calculation of haemolytic activity of the herbal material

$$1000 \times \frac{a}{b}$$

1000 = the defined haemolytic activity of saponin R in relation to ox blood

a = quantity of saponin R that produces total haemolysis (g)

b = quantity of herbal material that produces total haemolysis (g)

Determination of Swelling Index

- ✓ **Swelling properties**

  Especially gums, appreciable amount of mucilage, pectin or hemicellulose

- ✓ **Swelling index**

  Volume in ml taken up by the swelling of 1 g of herbal material under specified conditions

Determination of Swelling Index

Procedure

✓ Atleast three simultaneously determinations

Accurately weighed sample

25-ml glass-stoppered measuring cylinder

(Internal diameter around 16 mm, length of graduated portion about 125 mm marked in 0.2- ml divisions from 0 to 25 ml)

Add 25 ml of water, Shake thoroughly every 10 minutes for 1 hour

Allow to stand for 3 hours at room temperature

Measure the volume in ml occupied by the material, including any sticky mucilage

Calculate the mean value

Summary

- ✓ **Saponins** - ability to cause haemolysis, Lowest concentration to effect complete haemolysis is determined, Similar test is carried out simultaneously with Saponin R
- ✓ **Swelling index** - Volume in ml taken up by the swelling of 1 g of herbal material under specified conditions

Content

WHO guidelines for the standardization of crude drugs and extracts with special emphasis on pharmacological and toxicological evaluation

- ✓ Foaming index
- ✓ Aflatoxins
- ✓ Arsenic

Objectives

- **At the end of this lecture, student will be able to**

✓ Discuss the principle and procedure involved in the determination of

- ➢ Foaming index
- ➢ Aflatoxins
- ➢ Arsenic

Determination of Foaming Index

- **Saponins** - persistent foam - shaken
- **Foaming ability** - measured in terms of **Foaming Index**

Determination of Foaming Index

Procedure

1 g of coarsely powdered herbal material

↓

transfer to a 500-ml conical flask

↓

100 ml of boiling water

↓

Moderate boiling for 30 minutes

↓

Cool and filter into a 100-ml volumetric flask

↓

Add sufficient water through the filter to dilute to volume

↓

Pour the decoction into 10 stoppered test-tubes (height 16 cm, diameter 16 mm)

(successive portions of 1 ml, 2 ml, 3 ml up to 10 ml)
adjust the volume with water to 10 ml

Determination of Foaming Index

Procedure

Stopper, shake in lengthwise for 15 seconds, two shakes per second

Allow to stand for 15 minutes

Measure the foam height

.

Determination of Foaming Index

Evaluation of result

If the height of the foam in every tube is less than 1 cm

Foaming index is less than 100

If a **height** of foam of **1 cm** is measured in **any tube,**

the volume of the herbal material decoction in this tube (a) is used to determine the index

If this tube is the first or second tube in a series, an intermediate dilution is prepared in a similar manner to obtain a more precise result

If the **height** of the foam is **more than 1 cm in every tube**

Foaming index is over 1000

Repeat the determination using a new series of dilutions of the decoction

Determination of Foaming Index

Calculate the foaming index

$$\frac{1000}{a}$$

a = the volume in ml of the decoction used for preparing the dilution in the tube where foaming to a height of 1 cm is observed

Determination of Aflatoxins

- ✓ Only products that have a history of aflatoxin contamination need to be tested

Tests for aflatoxins

- ✓ Detect the presence of aflatoxins B1, B2, G1 and G2, which are highly toxic contaminants in any material of plant origin

Procedure

- ✓ Does not require the use of toxic solvents like
  - Chloroform
  - Dichloromethane etc
- ✓ Multifunctional column
  - ➢ Lipophilic and charged active sites
  - ➢ High-performance liquid chromatography (HPLC)
  - ➢ Fluorescence detection to determine aflatoxins B1, B2, G1 and G2

Determination of Aflatoxins

Advantages of multifunctional column

- ✓ High total recoveries of aflatoxins B1, B2, G1 and G2 (>85%)
- ✓ Column can be kept at room temperature for long time prior to use

Standard solutions of aflatoxin B1, B2, G1 and G2 (2.5 ng/ml)

Standard stock solution

Weigh exactly 1.0 mg each of aflatoxins B1, B2, G1 and G2

↓

Dissolve in 50 ml of **toluene-acetonitrile** (9:1) (20 µg/ml)

↓

keep in a tightly sealed container and store in refrigerator at $4^{O}C$ in dark

Determination of Aflatoxins

Working standard solution

0.5 ml of standard stock solution added to toluene acetonitrile (9:1)

to 200 ml (50 ng/ml)

Standard solution

1.0 ml of working standard solution, add to toluene acetonitrile (9:1)

solution to 20 ml

(Final standard solution) (2.5 ng/ml)

Determination of Aflatoxins

Standard solution for liquid chromatography analysis

Transfer 0.25 ml of the final standard solution to a glass centrifuge tube

↓

Evaporate to dryness at $40^{O}C$ or by using a nitrogen air stream

To derivatize aflatoxins B1 and G1 (precolumn derivatization)

Add 0.1 ml of trifluoroacetic acid to the residue in the tube

↓

Tightly seal and shake vigorously

↓

Allow to stand at room temperature for 15 min in dark

↓

Add 0.4 ml of acetonitrile : water (1:9)

↓

20-µl portion of the solution - subjected to liquid chromatography

Determination of Aflatoxins

Preparation of sample

Grind the herbal material

↓

50-g test sample with 400 ml of acetonitrile-water (9:1)

↓

Extract by shaking for 30 minutes or by mechanical blender for 5 minutes

↓

Filter or centrifuge

Transfer 5-ml portion or the top clean layer, to a multifunctional column (MultiSep #228 cartridge column or Autoprep MF-A)

Flow rate of 1 ml/minute

↓

Aflatoxins present pass through the column as the first eluate

↓

First 1-ml of the eluate collected as test solution

Determination of Aflatoxins

Preparation of sample

Evaporate 0.5 ml of test solution to dryness at 40^{O}C or by using a nitrogen air

↓

To derivatize aflatoxins B1 and G1 (precolumn derivatization)

↓

Add 0.1 ml of trifluoroacetic acid to the residue in the tube

↓

Tightly seal and shake vigorously

↓

Allow to stand at room temperature for 15 min in dark

↓

Add 0.4 ml of acetonitrile : water (1:9) solution

↓

20-µl portion of the sample solution - subjected to liquid chromatography

Determination of Aflatoxins

Method

Liquid chromatography conditions

- ✓ Mobile phase - acetonitrile-methanol-water (1:3:6)
- ✓ De-gas the mobile phase by sonication
- ✓ Octadecyl-silica gel (ODS) column (Inertsil ODS-3 (4.6 mm ID × 250 mm, 3 µm)
- ✓ Column temperature: 40^0C
- ✓ Flow rate - 1 ml/minute
- ✓ Aflatoxin and its derivatives detected at the excitation and emission wavelengths of 365 nm and 450 nm, respectively
- ✓ Injection volume is 20 µl

If impurity peak overlaps the peaks corresponding to aflatoxins – alternative liquid chromatography conditions

Determination of Aflatoxins

Method

Alternative liquid chromatography conditions

- ✓ Mobile phase - methanol-water (3:7)
- ✓ De-gas mobile phase by sonication
- ✓ Fluorocarbonated column (Wako-pack Fluofix 120E)
- ✓ Column temperature 40^0C
- ✓ Flow rate - 1 ml/minute
- ✓ Aflatoxin and its derivatives are detected at the excitation and emission wavelengths of 365 nm and 450 nm, respectively
- ✓ Injection volume is 20 µl

Interpretation of the results

- ✓ Compare the retention time of peak area or peak heights standard and sample
- ✓ If sample bigger than standard - positive

Determination of Arsenic

Limit test for arsenic

- ✓ Abundant in nature
- ✓ Test method uses colorimetry, **NOT** toxic mercuric bromide paper
- ✓ Method uses ***N*-*N*-diethylmethyldithiocarbamate in pyridine**

  and it reacts with **hydrogen arsenide** to afford a **red–purple complex**
- ✓ Limit expressed in terms of **arsenic (III) trioxide** (As_2O_3)

Determination of Arsenic

Preparation of test solution

Sample in crucible of platinum, quartz or porcelain

↓

Add 10 ml of magnesium nitrate hexahydrate in ethanol (95) (1 in 10)

↓

Burn ethanol, heat gradually, ignite to incinerate

↓

If carbonized material still remains

↓

Moisten with a small quantity of nitric acid and ignite again

↓

After cooling, add 3 ml of hydrochloric acid

↓

Heat in a water bath to dissolve the residue

(Test solution)

Determination of Arsenic

Standard solutions

Absorbing solution for hydrogen arsenide

Dissolve 0.50 g of silver *N,N*-diethyldithiocarbamate in pyridine to make 100 ml (protected from light, in a cold place)

Determination of Arsenic

Standard arsenic stock solution

Weigh accurately 0.100 g of finely powdered arsenic (III) trioxide

↓

Add 5 ml of NaOH solution

↓

Add dilute H_2SO_4 to neutralize

↓

Add a further 10 ml of dilute H_2SO_4

↓

Add freshly boiled and cooled water- make exactly 1000 ml

Determination of Arsenic

Standard arsenic solution

Pipette 10 ml of standard arsenic stock solution

↓

add 10 ml of dilute H_2SO_4

↓

Add freshly boiled and cooled water - make exactly 1000 ml

(Each ml of the solution contains 1 µg of arsenic (III) trioxide (A_s2O_3))

Determination of Arsenic

Procedure

Unless otherwise specified, use the mentioned apparatus

Test solution in the generator bottle A

↓

Add 1 drop of methyl orange

↓

Neutralize with ammonia, ammonia solution or dilute HCl

↓

Add 5 ml of dilute hydrochloric acid (1 in 2)

↓

Add 5 ml potassium iodide

↓

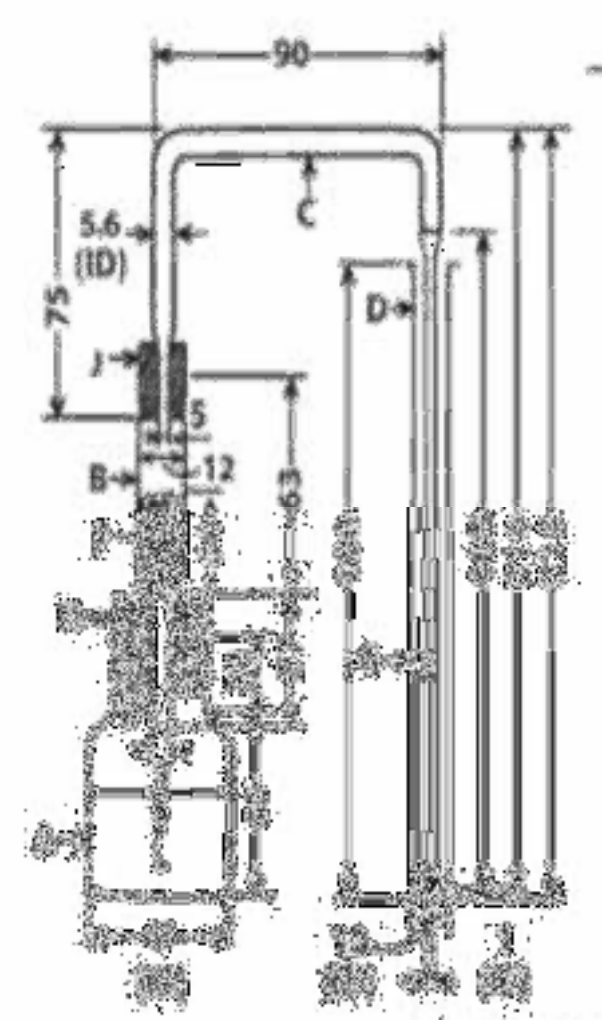
Allow to stand for 2–3 minutes

↓

Add 5 ml of acidic tin (II) chloride

↓

Allow to stand for 10 minutes



Determination of Arsenic

Procedure

Add water to make 40 ml

↓

Add 2 g of zinc for arsenic analysis and immediately connect the rubber stopper H fitted with B and C with the generator bottle A

↓

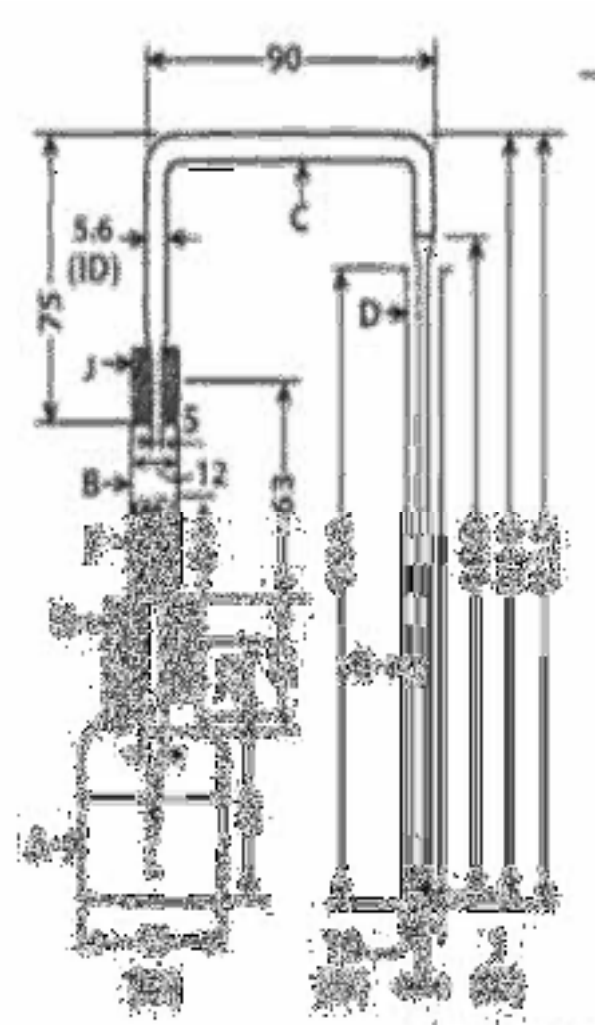
Transfer 5 ml of absorbing solution for hydrogen arsenide to the absorber tube D

↓

Insert the tip of C to the bottom of the absorber tube D
Immerse the generator bottle A up to the shoulder in water maintained at 25 °C

↓

Allow to stand for 1 hour



Determination of Arsenic

Procedure

Disconnect the absorber tube

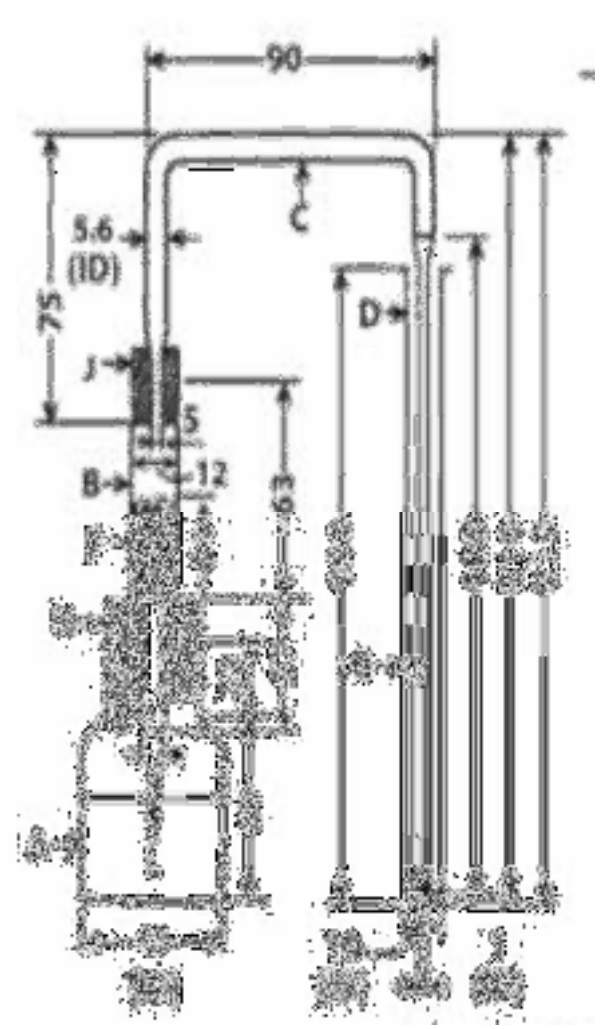
↓

Add pyridine to make 5 ml, if necessary

↓

Observe the colour of the absorbing solution

Colour produced is not more intense than the standard colour



Summary

- ✓ **Saponins** - persistent foam – shaken, Foaming ability - measured in terms of Foaming Index
- ✓ **Aflatoxins** - Only products that have a history of aflatoxin contamination need to be tested
- ✓ **Tests for aflatoxins**

  Detect the presence of aflatoxins B1, B2, G1 and G2, which are highly toxic contaminants in any material of plant origin
- ✓ **Arsenic** - Method uses N-N-diethylmethyldithiocarbamate in pyridine and it reacts with hydrogen arsenide to afford a red–purple complex
- ✓ Limit expressed in terms of arsenic (III) trioxide (As_2O_3)

Content

WHO guidelines for the standardization of crude drugs and extracts

Determination of pesticide residues

- Chlorides
- Phosphates

Objectives

- **At the end of this lecture, student will be able to**

✓ Discuss the principle and procedure involved in the determination of pesticide residues like

- ➢ Chlorides
- ➢ Phosphates

Determination of pesticide residues

Methods for the determination of pesticide residues

- ✓ Chromatography (mostly column and gas), Coupled with MS
- ✓ Samples are extracted by a standard procedure
- ✓ These techniques are not universally applicable
- ✓ Some pesticides -
  - ➢ Satisfactorily carried through the extraction and clean-up procedures
  - ➢ Recovered with a poor yield & some are lost entirely
  - ➢ After chromatography, the separations may not always be complete
  - ➢ Pesticides may decompose or metabolize

Determination of pesticide residues

Methods for the determination of pesticide residues

- ✓ Spectrum of pesticides to be tested -
  - ➢ Dependent on the specific pesticides used on the herbal material
  - ➢ History of use of persistent pesticides in the region
  - ➢ If the pesticide is known or can be identified- established method for particular pesticide residue should be employed

Determination of pesticide residues

General aspects of analytical methodology

- ✓ Samples should be tested as quickly as possible after collection
- ✓ If stored – should be preferably in airtight containers under refrigeration
- ✓ Water content - limited to 15% and below
- ✓ Light cause degradation of many pesticides
- ✓ Type of container or wrapping material used should not interfere
- ✓ Solvents and reagents used
  - ➢ Purified solvents or to be distilled
  - ➢ Blank determinations - should be carried out
- ✓ Simplest and quickest procedure should be used
- ✓ Process of concentrating solutions - avoid loss of pesticide residues

Determination of pesticide residues

Determination of total chlorine and phosphorus

Most pesticides contain organically bound chlorine or phosphorus

Procedure

Preparation of samples

Herbal material to fine powder

↓

Extract with a mixture of water and acetonitrile

(Most pesticides soluble in this mixture, while most cellular constituents are sparingly soluble and hence removed)

↓

Then transfer pesticide to light petroleum

Pesticides with chlorine - further purification required

Pesticides with phosphorus - further purification by column chromatography

↓

Eluted with mixtures of light petroleum and ether

Determination of pesticide residues

Preparation of the column

- ✓ Use Florisil R grade 60/100 PR
- ✓ Activated at 650 °C
- ✓ Prepare a Florisil column (external diameter 22 mm) with 10 cm of activated Florisil topped with about 1 cm of anhydrous sodium sulfate
- ✓ Pre-wet column with 40–50 ml of light petroleum
- ✓ Place a graduated flask under the column to receive the eluate

Determination of pesticide residues

Method

Grind the material

↓

Place 20–50 g of the ground sample into a blender

↓

Add 350 ml of acetonitrile with a water content of 35%

↓

Blend for 5 minutes at high speed, filter

↓

Transfer the filtrate to a 250-ml measuring cylinder and record the volume

↓

Transfer the measured filtrate to separating funnel + 100 ml of light petroleum

↓

Shake vigorously

Determination of pesticide residues

Method

Add 10 ml of sodium chloride (40%) and 600 ml of water

Separating funnel in horizontal position, mix vigorously for 30–45 seconds

Allow to separate, discard the aqueous layer

Wash the solvent layer with two 100-ml portions of water

Transfer the solvent layer to a 100-ml glass-stoppered cylinder

Record the volume

Add about 15 g of anhydrous sodium sulfate & shake vigorously

Determination of pesticide residues

Method

Transfer the extract directly to a Florisil column

Flow rate not more than 5 ml/minute

Rinse the cylinder with two 5 ml of light petroleum & transfer to the column

Elute at the same rate with 200 ml of ether/light petroleum **(TS1)**

Change the receiver & elute with 200 ml of ether/light petroleum **(TS2)**

Again change the receiver and elute with 200 ml of ether/light petroleum **(TS3)**

Evaporate each eluate to a suitable volume for further testing

Determination of pesticide residues

Method

First elute

Chlorinated pesticides (aldrin, DDE, TDE, HCH, heptachlor, heptachlor epoxide, lindane, methoxychlor), polychlorinated biphenyls (PCB), and phosphated pesticides (carbophenothion, ethion and fenchlorphos)

Second elute

Chlorinated pesticides (dieldrin and endrin) and phosphated pesticides (methyl parathion and parathion)

Third elute

Phosphated pesticide (malathion)

Determination of pesticide residues

Combustion of the organic matter

Combustion of the organic matter in oxygen - preparatory step for the determination of chlorine and phosphorus

Pesticide extracted from sample and purified

Extract is concentrated, evaporated to dryness

Transferred to a sample holder

Burnt in suitable conical flask flushed with oxygen

Gases produced during combustion – absorbed in a suitable solution

Absorbed chlorine - determined as chloride (colorimetry)

Absorbed phosphorus - orthophosphate (colorimetry)

Determination of pesticide residues

Combustion Equipment

- ✓ Conical flask of borosilicate glass
- ✓ Stopper fused with platinum wire about 1 mm in diameter
- ✓ Free end of the wire attached to platinum gauze - holding the sample

Sample holder for chlorine-containing residues

- ✓ Halide-free filter-paper – solid
- ✓ Cone made from cellulose acetate film – liquid

Sample holder for phosphorus-containing residues

- ✓ Halide-free filter-paper

Combustion of chlorine-containing residues

Combustion of phosphorus-containing residues

Determination of pesticide residues

Determination of chloride

Procedure

Equipment

- ✓ Spectrophotometer at 460 nm
- ✓ Path-lengths of 2 cm and 10 cm

Method

15 ml of solution obtained after combustion in a 50-ml conical flask

↓

Add 1 ml of ferric ammonium sulfate (0.25 mol/l), 3 ml of mercuric thiocyanate

↓

Allow to stand for 10 minutes, transfer to a 2-cm cell

↓

Measure the absorbance at 460 nm using water as reference cell

Determination of pesticide residues

Standard

Sodium chloride with 5 µg of chloride per ml

↓

0 ml, 2 ml, 4 ml, 6 ml, 8 ml and 10 ml into a series of 50-ml conical flasks

↓

Dilute to 15 ml with water

↓

Develop the colour & measure the absorbance at 460 nm

↓

Plot the absorbances against the chloride content of the dilutions in µg/ml

↓

Interpolate the chloride content in the solution of the material under test

Determination of pesticide residues

Determination of phosphates

Procedure

Phosphomolybdate method

- ✓ Reaction of phosphate ions with ammonium molybdate to form a molybdophosphate complex
- ✓ Subsequently reduced to form a strongly blue-coloured molybdenum complex
- ✓ Intensity of blue colour measured spectrophotometrically
- ✓ Applicable for the determination of any phosphates
- ✓ Naturally occurring phosphates - removed during the clean-up procedure

Determination of pesticide residues

Equipment

- ✓ Spectrophotometer, absorbance at 820 nm
- ✓ Path-length - 1 cm

Method

- ✓ Place 7 ml of the solution after combustion in a calibrated 10-ml test-tube
- ✓ Add 2.2 ml of sulfuric acid (300 g/l) & mix
- ✓ Add 0.4 ml of ammonium molybdate (40 g/l) & mix
- ✓ Add 0.4 ml of aminonaphtholsulfonic acid & mix
- ✓ Heat to 100 °C for 12 minutes
- ✓ Cool & transfer a portion to a 1-cm cell
- ✓ Measure the absorbance at 820 nm using water in the reference cell

Determination of pesticide residues

Standard

Standard dilutions with a known content of phosphate

Measure the absorbance at 820 nm

Plot absorbances against the phosphate content

Interpolate the phosphate content of the solutions of the material tested

Summary

- ✓ Chromatography (mostly column and gas), Coupled with MS
- ✓ Preparation of
  - ➢ Sample
  - ➢ Column
  - ➢ Elution
  - ➢ Combusted material
- ✓ Determination of chlorides (spectrophotometry) and phosphates (phosphomolybdate method)

Content

WHO guidelines for the standardization of crude drugs and extracts

- ✓ Detection of Micro-organisms

Objectives

- **At the end of this lecture, student will be able to**
  - Discuss the principle and procedure involved in the detection of microorganisms in crude drugs and extracts

Determination of Microorganisms

- ✓ **Total viable aerobic count** determined
  - ➢ Membrane-filtration
  - ➢ Plate count or serial dilution
- ✓ Aerobic bacteria and fungi (moulds and yeasts) are determined by the TVC
- ✓ Usually if TVC exceeds maximum permitted level
  - ➢ Unnecessary to proceed with determination of specific organisms
  - ➢ Material should be rejected without further testing

Determination of Microorganisms

Pretreatment of the test herbal material

- ✓ Depending on the nature of the crude herbal material
  - ➢ Grind
  - ➢ Dissolve
  - ➢ Dilute
  - ➢ Suspend or
  - ➢ Emulsify
- ✓ Either phosphate buffer pH 7.2; buffered sodium chloride-peptone solution, pH 7.0; or fluid medium, used for the test, is used to suspend or dilute the test specimen materials with special requirements

Determination of Microorganisms

Materials containing tannins, antimicrobial substances

- ✓ Test specimens with antimicrobial activity or contain antimicrobial substances
- ✓ Any such antimicrobial properties are removed

Water-soluble materials

- ✓ Dissolve or dilute 10 g or 10 ml in lactose broth or another suitable medium with no antimicrobial activity
- ✓ Make the volume to 100 ml with the same medium
- ✓ Adjust the pH of the suspension to about 7, if required

Determination of Microorganisms

Non-fatty materials insoluble in water

- ✓ Suspend 10 g or 10 ml of the herbal material in lactose broth or another suitable medium with no antimicrobial activity
- ✓ Dilute to 100 ml with the same medium
- ✓ If required, divide the material, homogenize the suspension mechanically
- ✓ Surfactant - solution of polysorbate 20 R or 80 R (1mg/ml)
- ✓ Adjust the pH of the suspension to about 7

Determination of Microorganisms

Fatty materials

- ✓ Homogenize 10 g or 10 ml of material with 5 g of polysorbate 20 R or 80 R
- ✓ Heat to a temperature not exceeding 40 °C, if required
- ✓ Mix carefully while maintaining the temperature in a water-bath or oven
- ✓ Add 85 ml of lactose broth or another suitable medium with no antimicrobial activity
- ✓ Heat to 40^{O}C, Maintain this temperature for the shortest time until an emulsion is formed
- ✓ Adjust the pH of the emulsion to about 7

Determination of Microorganisms

Test procedure: Plate count - ***For bacteria***

- ✓ Petri dishes 9–10 cm in diameter
- ✓ To one dish - 1 ml of the pre-treated herbal material + 15 ml of liquefied *casein-soybean digest agar* at a temperature not exceeding 45 °C
- ✓ Alternatively, spread the material on the surface of the solidified medium
- ✓ Dilute the material to obtain an colony count of not more than 300, if needed
- ✓ Prepare at least two dishes using the same dilution
- ✓ Invert them and incubate them at 30–35 °C for 48–72 hours
- ✓ Count the number of colonies formed
- ✓ Calculate the results using the plate with the largest number of colonies, up to a maximum of 300

Determination of Microorganisms

Test procedure: Plate count - ***For fungi***

- ✓ Use Petri dishes 9–10 cm in diameter
- ✓ To one dish - mixture of 1 ml of the pretreated material + 15 ml of liquefied *Sabouraud glucose agar with antibiotics* or *potato dextrose agar with antibiotics*, temp NMT 45 °C
- ✓ Alternatively, spread the pretreated material on the surface of the solidified medium
- ✓ Dilute the material to obtain an expected colony count of not more than 100
- ✓ Prepare at least two dishes using the same dilution
- ✓ Incubate them upright at 20–25 °C for 5 days
- ✓ Count the number of colonies formed
- ✓ Calculate the results using the dish with not more than 100 colonies

Determination of Microorganisms

Membrane filtration

- ✓ Membrane filters - pore size NMT 0.45 µm
- ✓ Effective in retaining bacteria
- ✓ Cellulose nitrate filters - aqueous, oily and weakly alcoholic solutions,
- ✓ Cellulose acetate filters - strongly alcoholic solutions

Determination of Microorganisms

Detailed method

- ✓ Filter 10 ml or a solution containing 1 g of the material through two membrane filter apparatuses
- ✓ If necessary, dilute the pretreated material to obtain an expected colony count of 10–100
- ✓ Wash each membrane, with 3 or more successive quantities (100 ml) of a suitable liquid such as buffered sodium chloride-peptone solution at pH 7.0

Determination of Microorganisms

Detailed method

- ✓ Fatty materials – surfactant may be added (Polysorbate 20 R or 80 R)
- ✓ Transfer one of the membrane filters to the surface of a plate with ***soybean casein digest agar (Bacteria)*** other to the surface of a plate with ***Sabouraud glucose agar with antibiotics (Fungi)***
- ✓ Incubate the plates for 5 days at 30–35 °C (bacteria), 20–25 °C (fungi)
- ✓ Count the number of colonies formed
- ✓ Calculate the number of microorganisms per gram or per ml of the material tested

Determination of Microorganisms

Serial dilution

- ✓ Prepare a series of 12 tubes each containing 9–10 ml of *soybean-casein digest medium*
- ✓ To each of the:
  - ➢ **First group of three tubes*:*** 1 ml of the 1:10 dilution of dissolved, homogenized material (0.1 g or 0.1 ml of specimen)
  - ➢ **Second group of three tubes*:*** 1 ml of a 1:100 dilution of the material
  - ➢ **Third group of three tubes*:*** 1 ml of a 1:1000 dilution of the material
  - ➢ **Last three tubes*:*** add 1 ml of the diluent

Determination of Microorganisms

- ✓ Incubate at 30–35 °C for at least 5 days
- ✓ No microbial growth should occur in the last three tubes
- ✓ If the reading of the results is difficult or uncertain
  - ➢ Subculture in a liquid or a solid medium
- ✓ Determine the most probable number of microorganisms per gram or per ml of the material using table
- ✓ If, for the first column, the number of tubes showing microbial growth is two or less, the most probable number of microorganisms per g or per ml is less than 100

Determination of Microorganisms

Determination of total viable aerobic count

Number of tubes with microbial growth[a]			Most probable number of microorganisms per g or ml
100 mg or 0.1 ml per tube	10 mg or 0.01 ml per tube	1 mg or 0.001 ml per tube	
3	3	3	>1100
3	3	2	1100
3	3	1	500
3	3	0	200
3	2	3	290
3	2	2	210
3	2	1	150
3	2	0	90
3	1	3	160
3	1	2	120
3	1	1	70
3	1	0	40
3	0	3	95
3	0	2	60
3	0	1	40
3	0	0	23

[a] Amounts in mg or ml are quantities of original plant material.

Summary

- ✓ Total viable aerobic count determined
  - ➢ Membrane-filtration
  - ➢ Plate count or serial dilution
- ✓ Pretreatment of the test herbal material
- ✓ Plate count for bacteria and fungi
- ✓ Membrane filtration followed by serial dilution

Lecture No 15
Traditional system of medicines - Ayurveda

At the end of this lecture, student will be able to

- Discuss the role of Ayurveda in traditional systems of medicine
- Explain the principle of Ayurveda

Content
Traditional system of medicines
Ayurveda

- Role of Ayurveda in traditional systems of medicine
- Principle of Ayurveda

Traditional systems of medicine

- Traditional systems like Ayurveda, Siddha and Unani impart knowledge about folklore practices and medicinal importance of drugs of natural origin
- The standardization of these drugs is essential since, these drugs are used to treat various ailments of human being
- The role of medicinal plants in traditional system made them back bone of these systems
- Traditional medicine is the sum of the knowledge, skills and beliefs of different cultures of different countries for the maintenance of health

Ayurveda

- **Ayurveda** – Oldest system of traditional medicine
- Dominant herbal tradition in India
- Enjoys a faith of large number of people
- Spectrum of influence is being enlarged as it is encouraged in many countries like Japan, Germany etc
- Ayurveda – Two Sanskrit words

  Ayur – Life, **Veda** – Knowledge /Science

  Ayurveda is knowledge of life or science of life

Ayurveda

- Ayurveda – Incorporates Science and religion
- Aim include enhancing well being and increasing longevity
- Essence of Ayurveda lies in providing **“ Swasthya “** which is a union of physical, emotional and spiritual health
- About 5000 years evolved from the deep wisdom of rishies of Himalaya
- Knowledge had been transmitted orally from teachers to disciples
- Finally took the form of Vedas during 1500 BC

Ayurveda

- Punarvasu athreya – Ayurveda school
- Recorded medicinal knowledge of many plants
- **Charaka** – Charaka Samhitha, more than 1500 medicinal herbs
- **Sushrutha samhitha** – Basis for modern surgery
- About 75-80% of population is still relying on herbal medicine especially in developing countries because of better compatibility and lesser side effects.

Ayurveda

Principle:

- Based on concept of five basic elements (Pancha mahabhuthas) and tri doshas
- Whole universe is made up of five basic elements
- Whole universe – Material world, plant kingdom an other living beings
- All the five elements – Basis of all matter

Ayurveda

Basic elements

English Name	Sanskrit Name
Ether	Akasha
Air	Vayu
Fire	Agni
Water	Jala
Earth	Prithvi

Ayurveda

Properties, location / manifestations

English Name	Sanskrit Name	Property	Location
Ether	Akasha	Non-resistance	Body cavities, mouth, thorax, lung cavity
Air	Vayu	Movements, vibrations	Movement of muscles, pulsation of heart, contraction of lungs
Fire	Agni	Radiation	Digestion, metabolism, vision and Intelligence
Water	Jala	Force	Blood, salivary glands, gastric juice
Earth	Pruthvi	Resistance and solidarity	Hair, nails, bones, skin

Ayurveda

Tri Doshas

Dosha	Combination of
Vata (Air principle)	Ether and air
Pitta (Fire principle)	Fire and water
Kapha (Water principle)	Earth and water

Ayurveda

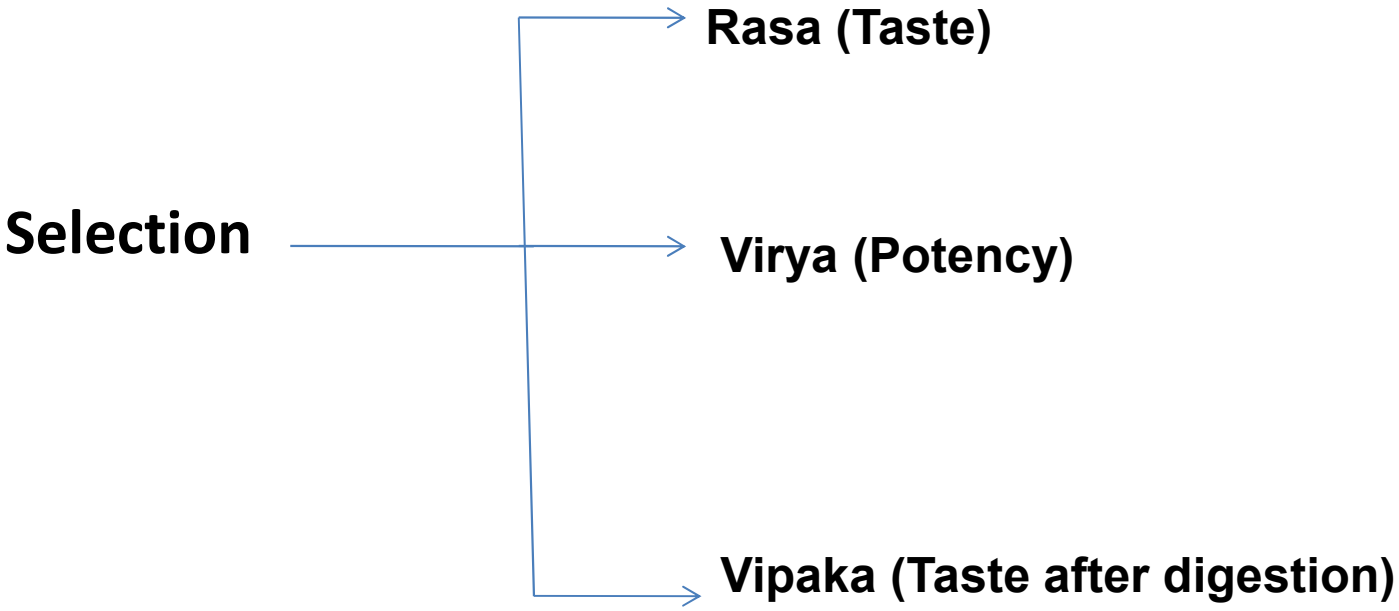
- Tridoshas exist in everything and influence physical and mental processes
- Tridoshas in hormony with each other, however one of them is dominating in every human being
- Determines **Prakruthi** of the person - Body type, temperament, susceptibility to illness – influenced by predominant dosha
- Man is born with a particular balance of doshas
- Balance of doshas of parents at the time of conception determines the proportion of doshas

Ayurveda

- Health – Total harmony of vata, pitta and kapha
- Sickness – Imbalance of any one or more of doshas
- Aggregation of pitta – Indigestion, skin diseases, liver problems
- Aggregation of vata – Nerve problems
- Aggregation of kapha – Gastric problems
- Physical, mental and environmental factors contribute for the imbalance of doshas

Ayurveda

Selection of drugs:



Ayurveda

Rasa (Taste) :

Taste	Combination of	Influence on doshas
Sweet	Earth and water	Kapha increases, vata and pitta decreases
Sour	Water and fire	Pitta increases
Saline	Fire and earth	Pitta increases
Bitter	Air and fire	Pitta increases
Pungent	Air and ether	Kapha and pitta decreases
Astringent	Air and earth	Pitta decreases, vata increases

Role of herbs in cosmetics

Virya : Hot drug and cold drugs

- Hot drugs – Drumstick, garlic
- Cold drugs – Jeera, Amla

Vipaka : Taste after digestion

Taste	Aggravates	Allevietes
Sweet	Kapha	Pitta and vata
Sour	Pitta	Kapha and vata
Pungent	Vata	Kapha

Summary

- Science/knowledge of life
- Five basic elements and tridoshas
- Akasha, vayu, jala, agni, and pruthvi – basis for all matters
- Kapha, pitta and vata
- Tridohas – combination of different elements
- Doshas – Nature of person, imbalance leads to sickness
- Selection of drugs – Rasa, virya and vipaka
- Six rasas, three vipakas
- Virya – hot and cold

Disclaimer

All data and content provided in the presentation are taken from the reference books, internet-websites and links for informational purpose only

NEUTRACEUTICALS

NEW ERA OF MEDICINE AND HEALTH

By

Swetha .k

(170212887009)

Under the guidance of

Dr. Sneha

DEFINITION

The term nutraceutical was coined by Stephen Defelice .

"A NEUTRACEUTICAL is any substance that is a food or a part of food and provides medical or health benefits, including the prevention and treatment of disease".

CLASSIFICATION

Neutraceuticals can be classified based on:

- Natural source
- Pharmacological conditions
- Chemical constitution

CLASSIFICATION BASED ON CHEMICAL GROUPS

s.no	Class	Examples
1	Inorganic mineral supplements	Minerals
2	Probiotics	Helpful bacteria
3	Prebiotics	Digestive enzymes
4	Dietary fibres	Fibres
5	Antioxidants	Natural antioxidants
6	Phytochemicals	
	Fatty acids	Omega 3 fatty acids
	Phenolics	Tea polyphenols
	Isoprenoids	carotenoids
	Lipids	Sphingolipids
	Proteins	soyaproteins
7	Herbs as functional food	--------

INORGANIC MINERAL SUPPLEMENT

Calcium

Magnesium

Manganese

Boron

Copper

Zinc

Phosphorus

PROBIOTICS

Live microorganisms which, when administered in adequate amounts, confer a health benefit on the host

- Species of *Lactobacillus*
- *Bifidobacterium*
- *yeast Saccharomyces cerevisiae*
- *some E. coli and Bacillus species are also used as probiotics*

PREBIOTICS

Nondigestible substances that provide a beneficial physiological effect for the host by selectively stimulating the favorable growth of a limited number of indigenous bacteria.

Commonly known prebiotics are:

- Oligofructose
- Inulin
- Galacto-oligosaccharides
- Lactulose

DIETARY FIBRES

Dietary fibers are of two types:

- Water insoluble fibers
- Water soluble fibers

Daily recommended intake is 30-40 gms.

SOURCES:

Whole grain cereals, wheat products.

Oats , dried beans, legumes.

ANTIOXIDANTS

Antioxidants are of 3 categories:

True antioxidants

Reducing agents

Antioxidant synergists

Deficiency causes diseases like cancers, rheumatoid arthritis, alzheimers disease, cardiovascular diseases.

ANTIOXIDANT	SOURCE
VITAMINS	
vitamin C	Citrus fruits, vegetables
vitamin E	Grains ,nuts, oils
CAROTENOIDS	
Lycopene	Tomatoes
Beta carotene	Carrots, sweet potato
XANTHOPHYLLS	
Beta cryptoxanthin	Mango ,papaya,oranges
FLAVANOIDS	
Rutin	Tobacco, eucalyptus species
Luteolin	Lemon, red pepper, olive
Quercitin	Onion, apple skin ,black grapes
Kaempferol	Grape fruit , tea
Liquiritin	liquorice

HERBS AS FUNCTIONAL FOODS

FLAX SEEDS

SOURCE : *Linum usitatissimum.*

FAMILY : Linaceae.

CHEMICAL CONSTITUENTS :

Gamma linolenic acid

Alpha linolenic acid

Secoisolariciresinol(SDG)

Lignans, proteins.

FLAX SEEDS

USES :

- Prevents mammary, colon and rectal cancers.
- Reduces BP in hypertensive patients.
- Reduces diabetes and coronary heart diseases.

GINKGO BILOBA

FAMILY : Ginkgoaceae

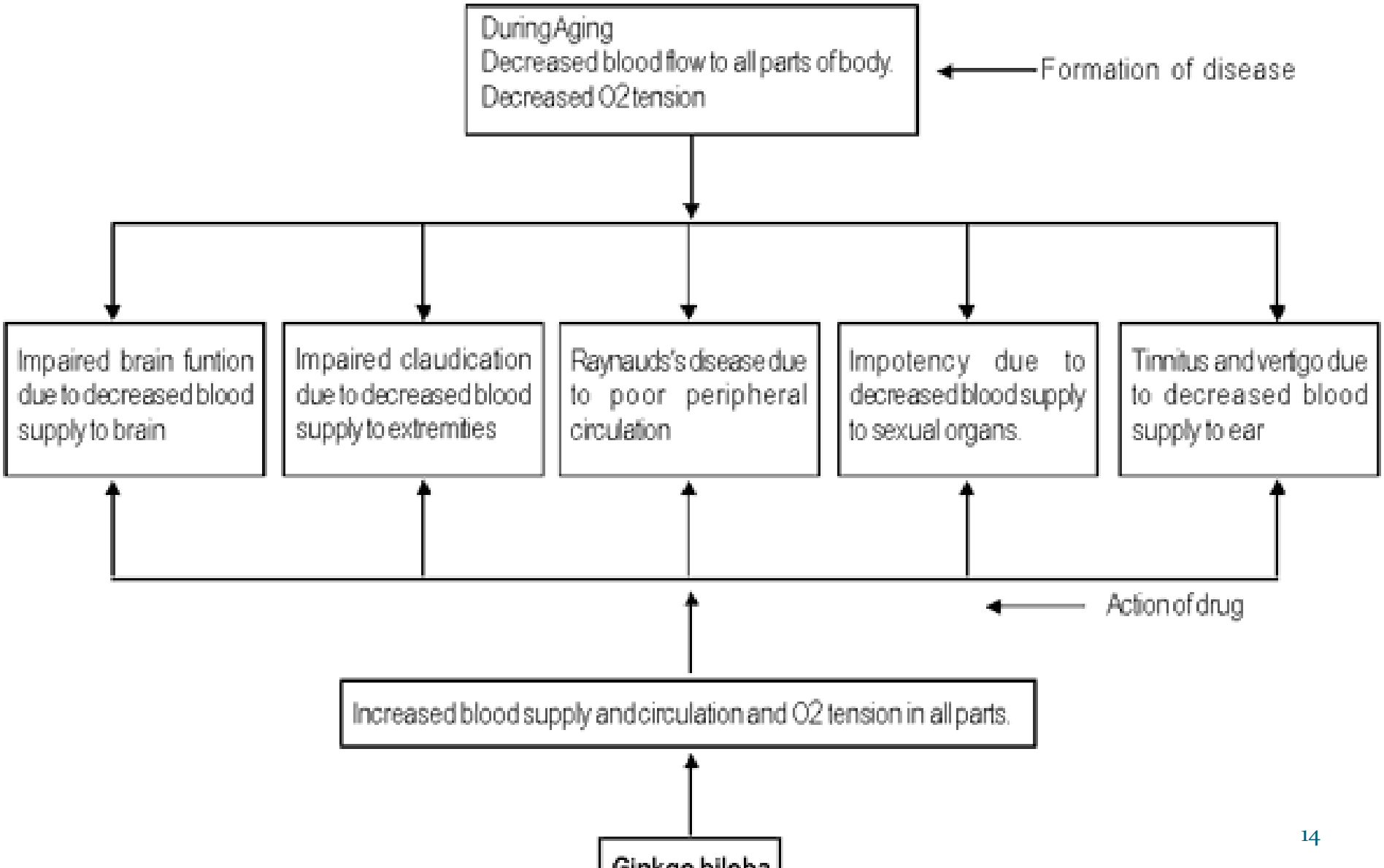
CHEMICAL CONSTITUENTS :

Bilobelin, ginkgetin, isoginkgetin, flavanols, ginkgolides A,B,C.

USES :

- In treating asthma, impairment of memory.
- Leaves are able to alleviate the adverse effects of PAF.

MECHANISM OF ACTION



SPIRULINA

SOURCE :

Spindina platensis or s.maxima

FAMILY :

Oscillatoriaceae

CHEMICAL CONSTITUENTS

Gamma linoleic acid,

Oleic acid ,

Glycolipids and sulpholipids.

Rich in vitamin B and betacarotenes.

Phycocyanin.

SPIRULINA

USES :

- Immunostimulant activity.
- Management of HIV and other viral infections such as herpes, cytomegalovirus, influenza, mumps
- To treat arthritis, atherosclerosis, diabetes and aging process

KARELA

SOURCE :

Momordica charantia

FAMILY :

Cucurbitaceae

USES :

- Hypoglycemic effect
- Extract of karela increases rate of glycogen synthesis by 4-5 fold in liver.

TURMERIC CURCUMINOIDS

SOURCE : *Rhizomes* of *Curcuma longa*

FAMILY : Zingiberaceae

CHEMICAL CONSTITUENTS :

Curcumin, desmethoxy curcumin, bisdesmethoxy curcumin

USES :

- Antimicrobial activity
- Recent findings indicate that it has integrase enzyme inhibitor activity

SOYA PRODUCTS

SOURCE : *Glycine max*

FAMILY: Leguminoseae

CHEMICAL CONSTITUENTS:

Daidzein, genistein

USES :

- Prevents estrogen–dependant cancers
- Geinstein inhibits protein tyrosine kinase and DNA topoisomerase-II

GARLIC

SOURCE :

Bulbs of *Allium sativum*

FAMILY: Liliaceae

CHEMICAL CONSTITUENTS :

Allicin , allin , ajoene

USES :

- In treatment of hyperlipidaemia.
- It shows antihypertensive, hypoglycemic, anti spasmodic activity.
- Prevents colon and lung cancers.

TOMATO LYCOPENES

SOURCE : *Lycopersicon esculentum*

FAMILY: Solanaceae

CHEMICAL CONSTITUENTS : Lycopene

USES :

- Prevents prostate cancer
- Reduces risk of cancers of digestive tract, pancreas, cervix, bladder and skin.

FENUGREEK

SOURCE :

Trigonella foenum-graecum

FAMILY: Leguminoseae

CHEMICAL CONSTITUENTS :

- Alkaloids

(gentianine and trigonelline)

flavanoids,

coumarins,

proteins,amino acids,

steroid saponins.

FENUGREEK

USES :

- In treatment of anorexia, gastritis.
- Fenugreek possess laxative, expectorant, demulcent properties.
- Shows hypoglycemic and hypocholesterolemic properties

GINSENG

SOURCE : *Panax ginseng*

FAMILY: Araliaceae

CHEMICAL CONSTITUENTS:

Protopanaxadiol

Polysaccharides

Starch, sterols

Polyacetylenes, choline,

Vitamins B1,B2,B12,

Pantothenic acid, biotin.

GINSENG

USES :

- Ginseng helps the body to cope with stress and fatigue
- In treatment of hypertension and hypoglycemia
- Modifies liver function and metabolism.

EXAMPLES OF NUTRACEUTICALS CURRENTLY AVAILABLE IN MARKET

VITAMIN AND MINERAL SUPPLEMENTS :

VitaminA (Beta- Carotene)

ADDITIONAL SUPPLEMENTS :

cod liver oil, primrose oil, glucosamine, garlic etc.

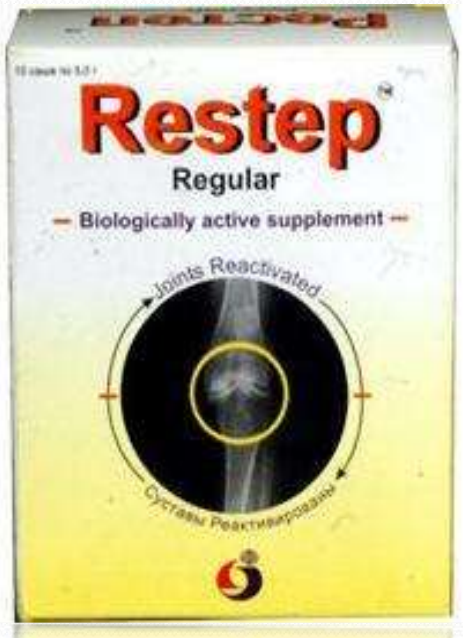
SPORTS PRODUCTS-

Glucon-D (Heinz),

Glucose D (Dabur)

The addition of a nutraceutical to a patient's diet will decrease or even eliminate his or her dry eye.

MARKETED PREPARATIONS



REFERENCES

- Text book of pharmacognosy and phytochemistry by Biren shah and A.K.Seth, pg.no-471-479.
- Probiotics: Applications in Gastrointestinal Health & Disease Presented in conjunction with the American College of Gastroenterology's 72nd Annual Scientific Meeting, Autumn 2007)
- http://www.fao.org/ag/agn/agns/micro_probiotics_en.asp
- De Felice L Stephen. The nutraceutical revolution, its impact on food industry. Trends in Food Sci. and Tech 1995; 6:59-61.
- Jack DB. Keep taking the tomatoes - the exciting world of nutraceuticals. Mol Med Today 1995; 1(3):118-21.
- Brower B. Nutraceuticals: poised for a healthy slice of the market. Nat Biotechnology 1998; 16: 728-33.

Mannion M. Nutraceutical revolution continues at foundation for innovation in medicine conference. Am J Nat Med 1998; 5:30-3.


Thank You!

NEUTRACEUTICALS

NEW ERA OF MEDICINE AND HEALTH

DEFINITION

The term nutraceutical was coined by Stephen Defelice (founder and chairman of Foundation for Innovation in Medicine (FIM)) in 1989

"A NEUTRACEUTICAL is any substance that is a food or a part of food and provides medical or health benefits, including the prevention and treatment of disease"- such products may range from:

- ✓**isolated nutrients**
- ✓**dietary supplements**
- ✓**specific diets to genetically engineered designer foods**
- ✓**herbal products**

CLASSIFICATION

1. Food source
2. Mechanism of action
3. Chemical nature
4. Their higher contents in specific foods items

1. Nutraceuticals according to food source:

Animals- Conjugated linoleic acid, EPA, DHA, lecithene, ubiquinone

Plants- Ascorbic acid, quercetin, lycopene, beta-carotene, catechins, alpha-tocopherol, pectin, allicin, geraniol

Microbes- Yeast, lactobacillus acidophilus, streptococcus salvaricus

2. Nutraceuticals according to actions:

Antioxidant- Ascorbic acid, beta-carotene, polyphenols, tocopherols, lycopene, ellagic acid, catechins

Anti-inflammatory-Curcumin, quercetin, capsaicin, lenolenic acid, EPA, DHA

Anti-cancer- Genestein, limonene, glycyrrhizin, diallyl sulphide, tocopherol

Bone Protectives-Soy-protein, genestein, calcium

Antibacterial- Garlic, curcumin.

3. Nutraceuticals according to chemical nature:

- •Phenolic- tannins, anthocyanins, isoflavonols, coumarins, lignin
- •Protein based-choline, isothio cyantes, capsaicinoids, amino acids, allyl thio compounds,
- •Isoprenoids- carotenoids, saponines, tocopherols, tocotrienols
- •Carbohydrate derivatives-oligosaccharides, non-starch products
- •Fatty acids- n 3 PUFA, MUFA
- •Minerals- Ca, Se, K, Zn, Fe
- •Microbial- pro and pre biotic.

4. Nutraceuticals according to their higher contents in specific foods

- •EPA & DHA -Fish Oils
- •Lycopene -Tomatoes
- •Iso thiocyantes -Vegetables of cruciferae family
- •CLA -Beef and dairy products
- •Isoflavones -Soyabean and legumes
- •Beta-Carotene - carrots, pumpkin
- •Curcumin -Turmeric
- •Catechin -Tea, berries
- •Quercetins -Citrus fruits, red grapes
- •Allyl sulphur compounds-Garlic, onion

The food products used as nutraceutical are categorized as:

• Probiotic • Pre biotic • Dietary fiber • Omega 3 fatty acid • Antioxidant

Probiotic: these are living organism, which when taken with or without food, improve the intestinal microbial balance and in turn functioning of the large intestine. It includes *bifido* bacteria, and *lactobacilli* species. These microorganisms exert their effects by producing substances and conditions which inhibit the harmful bacteria in the large intestine.

Prebiotic: Promotes the growth of colonic probiotic bacteria.
Example-inulin. It is a polyfructose obtained mainly from raw polysaccharide inulin. It is a soluble dietary fibre and resistant to digestive enzyme, it reaches to large intestine or colon essential intact, where it is fermented by the resident bacteria. *Lactobacilli* and *Biffidobacteria* digest inulin and feed themselves on it. Hence, prebiotics acts as fertilisers for these symbiotic bacteria. Inulin also serves the role of dietary fibre. Safety of inulin has been evaluated and accepted by FDA & United states.

Dietary fiber: fibers are non-digestible polysaccharides found in plant cell walls. They are present in food including fruits, vegetables, grains, and legumes. Thus fibers which we eat are called dietary fibers.

Classification and sources:

Soluble: oat, nuts, seeds, legumes, apples, pears, straw berries, blue berries,

Insoluble: whole plant, wheat bran, carrots, cucumbers, tomatoes, brown rice, whole grains.

Both soluble and insoluble fibers are very important in the diet & provide several benefits to the digestive tract by helping to maintain regularity. Soluble fibres are more beneficial since they reduce blood cholesterol and risks of heart attack.

Recommended dose of fibers for adults per day-30gm, for children-5-14gm

Poly Unsaturated Fatty Acids (PUFA): They are present in various vegetables and marine animals. These sources include safflower oil, corn oil, mustard oil, soybean oil. They help to reduce cholesterol formation/deposition. These vegetable oils mainly contain PUFA belonging to linoleic group (omega-6-type). Some marine fishes contain PUFA belonging to linolenic group.

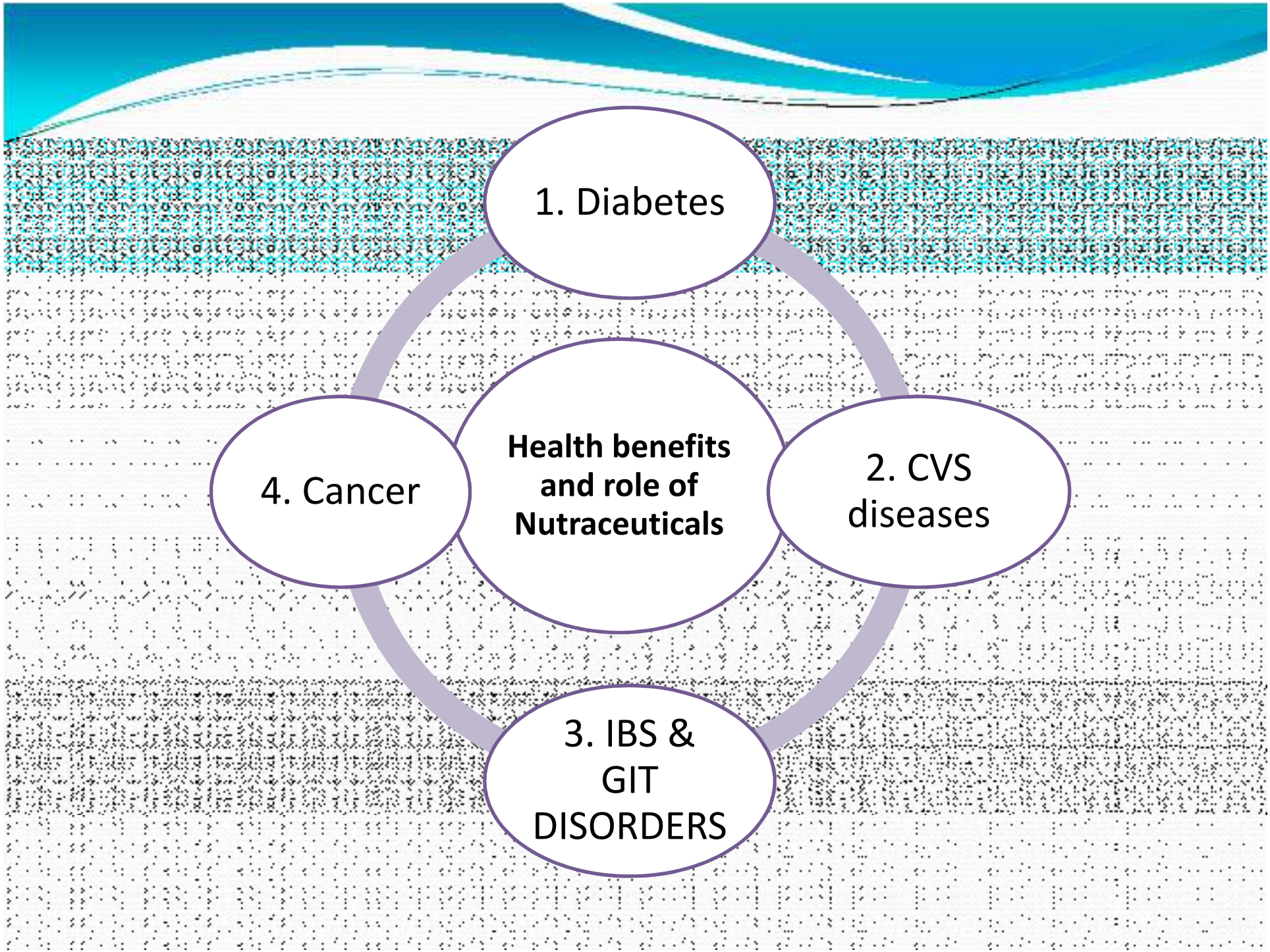
ANTIOXIDANTS

Antioxidants are of 3 categories:

- True antioxidants
- Reducing agents
- Antioxidant synergists

Deficiency causes diseases like cancers, rheumatoid arthritis, alzheimers disease, cardiovascular diseases.

ANTIOXIDANT	SOURCE
VITAMINS	
vitamin C	Citrus fruits, vegetables
vitamin E	Grains ,nuts, oils
CAROTENOIDS	
Lycopene	Tomatoes
Beta carotene	Carrots, sweet potato
XANTHOPHYLLS	
Beta cryptoxanthin	Mango ,papaya,oranges
FLAVANOIDS	
Rutin	Tobacco, eucalyptus species
Luteolin	Lemon, red pepper, olive
Quercitin	Onion, apple skin ,black grapes
Kaempferol	Grape fruit , tea
Liquiritin	liquorice


1. Diabetes
2. CVS diseases
3. IBS & GIT DISORDERS
4. Cancer
Health benefits and role of Nutraceuticals

1

Health benefits and role of Nutraceuticals in DIABETES

- ✓ **Lipoic acid** is a universal antioxidant, now used in Germany for the treatment of diabetic neuropathy. It is possible that lipoic acid may be more effective as a long-term dietary supplement aimed at the prophylactic protection of diabetics from complications.
- ✓ **Dietary fibers** from psyllium have been used extensively both as pharmacological supplements, food ingredients, in processed food to aid weight reduction, for glucose control in diabetic patients and to reduce lipid levels in hyperlipidemia.
- ✓ **Good magnesium** status reduces diabetes risk and improves insulin sensitivity,
- ✓ **Chromium picolinate**, calcium and vitamin D appear to promote insulin sensitivity and improve glycemic control in some diabetics,
- ✓ **Extracts of bitter melon** and of **cinnamon** have the potential to treat and possibly prevent diabetes

2

Health benefits and role of Nutraceuticals in CANCER

- ✓ **Flavonoids** which block the enzymes that produce estrogen reduce of estrogen induced cancers.
- ✓ **Phytoestrogens** is recommended to prevent prostate/breast cancer.
- ✓ **Soy foods** are source of Iso-flavones, curcumin from curry and soya isoflavones possess cancer chemo preventive properties.
- ✓ **Lycopene** concentrates in the skin, testes, adrenal and prostate protects against cancer.
- ✓ **Saponins** contains antitumor and antimutagenic activities.
- ✓ **Curcumin** (diferuloylmethane) which is a polyphenol of turmeric possesses anti-carcinogenic, antioxidative and anti-inflammatory properties.
- ✓ **Beet roots, cucumber fruits, spinach leaves,** and **turmeric** rhizomes were reported to possess anti-tumor activity.

3

Health benefits and role of Nutraceuticals in Cardiovascular discomforts

- ✓ Nutraceacids (n-3 PUFAs), vitamins, and minerals are recommended together with physical exercise for prevention and treatment of CVD.
- ✓ Polyphenols present in grapes and in wine alter cellular metabolism and signalling, which is consistent with reducing arterial disease.
- ✓ Flavonoids are widely distributed in onion, endives, cruciferous vegetables, black grapes, red wine, grapefruits, apples, cherries and berries.
- ✓ Flavones- apigenin found in chamomile
  Flavanones- hesperidins - citrus fruits; silybin- milk thistle
  Flavonols- tea: quercetin, kaempferol and rutin grapefruit; rutin buckwheat; ginkgo
- ✓ Flavonoids block the angiotensin-converting enzyme (ACE) that reduces blood pressure; by blocking the "suicide" enzyme cyclo-oxygenase that breaks down prostaglandins, they prevent platelet stickiness and hence platelet aggregation.
- ✓ Flavonoids also protect the vascular system and strengthen the tiny capillaries that carry oxygen and essential nutrients to all cells.