

UNIT - I

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Herbs =>

Any plant which has leaf, stem, flowers, root and seeds used as flavoring, food, medicine, perfume.

* Botanically hard seed bearing Plant which does not have a woody stem.

* Medicinal aromatic Plant constitute a major part of Plant kingdom which provide Raw material for used in the Pharmaceutical, cosmetic and drug industries.

* As per who it estimated about 80% of the population of developing country realize on Plant based for their health requirement.

* India and China are the two major Producing Country having 40% of the global diversity and availability of rare Plant species.

Herbal medicine =>

Isolated Compound from herb are not consider as herbal drug required modern license medicine.

⇒ Natural Product is wide form which includes the drug obtained from the various sources, such as Plant, animal as well as minerals.

⇒ Herbal drug which are derived from plants are called Herbal medicine.

* Herbal medicinal Product consist of an active medicinal agent, one or more Herbal substance, one or more Herbal Preparation, one or more Herbal substance in combination with one or more Herbal Preparation.

↳ Herbal drug Preparation

They are prepared from Herbal material by different processes which is i.e. extraction with various solvent, Purification, conc. and other processes.

If included such as Powders, extract, juices.

* Herbal medicine Preparation ~~must~~ ^{should} also contain vit. minerals

* It also contains chemically active substance, which are obtained by extraction and Purification on from plant material

Finished Herbal Product:-

finished Herbal Product consist of one or more herbal Preparation, one or more herbs.

* Product containing different Plant material called mixture ~~herbal product~~.

* Natural Product are an active agent isolated from Plant source.

all herbal drugs cannot be consider as ayurvedic medicine or regulatory authority has prescribed certain rules to avoid confusion related to herbal drugs

* In india ---- Drug and cosmetic act 1940, there are 54 traditional books, which are called as classical books.

⇒ If drug or formula is mentioned in these book then only it is considered as ayurvedic medicine.

Herbal Drug Preparation

Herbal drug Preparation are medicinally active Product that are isolated from various plant sources these extract contains primarily as well as secondary metabolites such as - Alkaloids, flavonoids, terpenoids, volatile oil etc.

Extract:-

These are preparation of liquid, semi solid (soft extract) or solid (dry extract) consistency obtained from herbal drug or animal matter.

Genuine Herbal Preparation:-

→ This is the Preparation without excipient.
 → However soft and liquid Preparation the genuine may contain variable amount of extract.

Herbal substance:-

These are substance mainly, fragmented or cut plant parts usually from fresh.

* Herbal substance also contain Caffeine - Product which are not subjected to any specific treatment they are also used as flavoring agent in different type of Food Preparation.

* Preparation obtained by subjecting Herbal substance to treatment such as extraction (Percolation, decoction, Infusion, digestion method), expression, fractionation, Purification, concentration, Fermentation, are called

Herbal drug Preparation.

Sug:-
Powder H. Subs., Tincture extract, essential oil, Express Juices. and Process organus substances.

Source of Herb :-

⇒ India is one of the biodiversity in world which contributed about 7% of total world biodiversity

⇒ As to data base NMPB (National medicine Plant Board) of out of 31000-18000 flowering Plant species in india more 4000 medicinal Plant.

⇒ Herbs can be obtained from different sources, herbs can be collected from wild sources or cultivated sources.

⇒ Cultivation of herbs is becoming common practice all over world because it's give better quality of raw material as well as Phytochemicals.

S. No.	Source	Significant ↗	Example ↗
1)	Plant drug	most imp. source of drug widely available with low constituent.	→ Digitalis. B.M. - Digitalis Purpurea - Vinca. B.H. - Vincristine.
2).	marine's Source	numerous nrbol medicinal agent derived from marine organism	- Algal, fungi; Sea horse, Antibiotics Murexide
3)	mineral sources	Naturally occurring mineral salts, which are used as medicine from ancient time. They are stable and effective chalk on various diseases	- Shilajit - zinc oxide, calomel - Bentonite.
4)	Animal Sources	Provides many active agent, enzymes, hormone etc.	- Honey, Bee wax ; wool, fat card, lecithin blood, vaccines

S.No.	Source	Significant	Example.
5)	Micro-organism	Now days many of new drugs invented from microorganism.	Antibiotics Antimicrobial enzyme vitamins.
6)	Plant tissue culture as a source of drug	modern approach for the production of clone individuals in a limited period of time and limited space under aseptic condition	secondary metabolites flavonoid volatile oil

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Important Natural Product isolated from Plant Sources

Name of Natural Product	Name of Plant	Common Use.
- Digitoxin	Digitalis Purpurea	Cardiotonic
- Atropine	Aconia belladonna	Anticholinergic
- Morphine	Papaver Somniferum	Morcatic opioid Analgesic
- Reserpine	Rauwolfia serpentina	Antihypertensive
- Vincristine - Vinblastine	Vinca rosea	Anticancer

Name of M.P.	Name of Plant	Common use.
- Glycyrrhizin	Glycyrrhiza glabra	Expectorant
- Quinine	Cinchona officinalis	Antimalarial
- Quinidine	" "	Antiarrhythmic

Selection \Rightarrow

Altogether there are -

Plant based medicine for their Primary Health care needs. In almost all the traditional medicine the medicinal plant play a major role and constitute the back bone of the traditional medicinal.

Selection of plant can be done by various approaches like - random selection, ecological approach, chemo-synthetic approach and ~~ethno~~ ethnobotanical approach.

(a) Random Selection \Rightarrow

In this method Plant material is selected randomly from forest or nearby local area for main drug discovery.

Success Rate is low but this method offers wide range of variety of diversity and Plant material is available easily.

(b) Ecological approach \Rightarrow (Zoo Pharmacognosy) \Rightarrow

Zoo Pharmacognosy is observation of animal behavior for discovery and development of new medicinal agent from plant sources.

This is also known as ecological approach.
Ecological observations includes biosynthesis of certain secondary metabolites by Plant for insect response.

Chemosynthetic approach (Phytochemical Approach)

If plant biology contain taxa is therapeutically active then their higher chances of other plant from same taxa can be and possible activity of plant gives idea about biochemical diversity and activity.

D) Ethno Pharmacology / Ethnobotany =

Ethnobotany is branch of Sciences which observe knowledge, people, their tradition and beliefs for discovery and development of drugs. EthnoPharmacology is also related with pharmacological Significance of crude drug.

Ethnomedicine involves study of use of medicines by different indigenous region including traditional medicine. This type of selection of plant mathematical uses success rate b/c plant is already known.

Success rates b/c for activity, source, time.

Identification and authentication of Herbal drugs

Correct botanical identification of drug is very imp. for good quality of finished product. Substitution or adulteration with morphologically similar or chemically similar Plant is becoming common practice.

in herbal drug industry.

Extreme豪華 can increase in science based research in ASO (ayurvedic, Siddha, Unani) for the purpose of globalization one of the most critical issue involves in research. Study is the quality of test material.

⇒ A study can math be consider significantly valid if the material tested is not authentic is characterized by approved taxonomist.

⇒ Correct identification and quality assurance of the starting material is therefore one essential component to insure quality and efficacy of herbal medicine.

⇒ Several method are considered for the authentication and characterisation of ASU herbal medicines

A) Taxonomic method

The initial step is the identification and authentication of botanical material and its source. The crude drug is identified by its botanical name, vernacular name, sight of collection, habit and habitat, season of collection, altitude and part collected.

B) Herbarium Sample -

The sample of collected material should be kept as a herbarium sample in the herbarium and can be submitted to approved research institute for future reference.

C) Microscopic method

Microscopic identification of botanical material is based on parameter like shape, size, colour

Torture, odour, surface characteristic, fracture characteristic, taste and other organoleptic property.

D) Microscopic methods

Microscopy is used to determine the structural cellular, histological and internal cell arrangement of botanicals.

E) Physicochemical method \Rightarrow

This includes total ash, water soluble ash, acid insoluble ash, extractive values, moisture content (loss on drying), solubility, pH, melting point, refractive index.

These values of the individual drug can be compared with the standard values of IR, for correct identification and confirmation.

F) Chromatography methods

Chromatography method is an modern tool for the quality control analysis of Herbal mixture or extract. HPLC, HPTLC, column chromatography, gas chromatography and TLC are the most popular analytical method for the standardization of Herbal drugs.

* Marker Compound \Rightarrow

Molecular marker generally refers to botanical constituent including T.P.M and secondary metabolite and other macromolecule - nucleic acid (DNA, RNA)

G) Spectroscopic method \Rightarrow

IR spectrometry, Electron spectroscopy

chemical analysis, mass spectrometry, UV-visible spectrophotometry, atomic absorption spectroscopy, X-ray diffraction analysis, X-ray fluorescence analysis, are some analytical tool used for complete standardization of herbal drugs.

I) Immuno assay ⇒

- ELISA (Enzyme linked immuno sorbent assay)
- Polyacrylamide gel electrophoresis (PAGE).

Processing of Herbal and Materia Medica ⇒

- ⇒ Processing is the entire process of raw material from field into finished product.
- ⇒ Processing involves various steps due to the nature of crude drug.
- ⇒ Major steps involved in processing of raw material are:
 - Collection of cultivated plants.
 - A fresh herb is not supposed to be use immediately. It should be dried to prevent deterioration.
 - Again drying is selected depending upon the nature of herb. After drying it can be cleaned for removal of impurities.
 - Dressing or grading is done in order to make herb more presentable before sending to market.
 - Storage of crude drug also need special precaution. Before storage herbed materials should be packed in suitable container.
 - Crude Corn undergoes extraction procedure as per

- Requirement: Extraction method can be selected according to nature of herb.
- ⇒ Extract can be characterised by chromatographic techniques, analytical techniques followed by bioassay.
- ⇒ Herbs after determination of one or more active constituents, these extract can be recognised as Standardised extract.
- ⇒ Std. extract shows uniformity in pharmacological action and don't have much variation.
- These extract can be converted into suitable Herbal drugs form or can undergo further isolation, Refined purification process.
- ② Collection of crude drug ⇒ Collection of crude drug is very imp. step to determined the quality and purity of crude drug.
- After extract botanical identification, collection can be done.
- ⇒ Time, place, and method of collection are determine the quality of the drug.
- Chemical constituent in any plant are subjected to changes due to time of collection, season, geography stage of maturity, sex, age of plant.

b) Harvesting of crude drugs

Harvesting is an operation which

is actual collection of crude drug from field.

⇒ Harvesting also includes processing of drugs like - removal of soil coat, cover etc.

⇒ Now a day Harvesting is carried out by machine as compare to conventional method.

c) Type of Harvesting

- * Manual or skilled worker
- * Mechanical machines
- * Mechanical Shaker
- * Seed stripper separator

(c) Drying or Garbling of crude drugs

Garbling need is Preparation

of drug for market by removing sand, dirt, insect, mould, and impurities, adulterant or unwanted matter.

(D) Drying

Drying is simple procedure and consist of removal of moisture.

⇒ drying of crude drug generally followed immediately after collection, in general herbs, flowers, are dry at 20-40°C and bark, root, stem, seeds can be dried at 30-60°C

c) Advantage of drying

- * It help life and storage of drug.
- * It help size reduction and packaging of crude drug
- * drying is recommended before transport of drug as it reduces weight and save space before packing.

* Drying prevent growth of microbe and maintain uniform quality of crude drug.

Types of dryings

- (A) drying under sun \Rightarrow no cost but time consuming and possibility of contamination with dust.
→ fading of colour due to sun light.

(B) Under shades

Avoid photo-degradation of heat, light sensitive drugs, but it takes long for drying.

(C) Tumbler dryer / Hot air oven

Quick method for large scale drying.

In spray dryer \Rightarrow suitable for heat sensitive material, liquid or ~~sharp~~ sharp.

e) Vacuum dryer / freeze dryer \Rightarrow Suitable for heat and moisture sensitive drug.

(E) Packagings

After granulating then freeze drying the coarse drugs are packed in suitable container.
→ Packaging is imp. for storage and transport of the coarse drug. Paper packing helps in rising shelf life of coarse drugs.

= Types of Packaging \Rightarrow

\Rightarrow Gummy bags \Rightarrow It allows rough handling, Supply air to keep material fresh.

⇒ Tin / metal container -

To prevent oxidation and photodegradation

and TSE self life.

Expt =

Volatile Resin

⇒ Plastic container -

Drug sensitive to oxidation Packed in air tight Plastic containers

⇒ Polythene bag ⇒

Suitable for hygroscopic material, specially for powder drug.

⇒ Wooden box / card board ⇒

Soft fruit are kept wooden boxes.

(F) Storage of crude drug ⇒

Storage of crude drug is very imp step to maintain quality of drug and increases self life.

⇒ Different drug b/c of their different physicochemical nature needs separate storage conditions.

⇒ Temp, light, oxygen and moisture are the imp factors to maintain the quality and self life of crude drug.

⇒ Proper care should be taken while storing volatile oil containing drugs which may loss / loose aroma by using temp.

generally the oil is kept in ~~in~~ amber coloured glass bottle or stainless steel containers for storage.

⇒ Crude drug should be stored in optimum storage condition

⇒ Crude drug should be protected from direct sun light and excessive temp variation.

⇒ Properly shield container which are impermeable for insect and might can be employed to ISO the storage life.

Common factor to affect storage condition =

a) Temperature →

High temp. Iso degradation of drug such as protein, enzyme, A.A., they are highly sensitive to heat.

b) light →

Iso photodegradation, decomposition and bleaching of drug.

c) Oxygen →

Responsible for oxidation of drug, consistency of oil and resinification of volatile oil.

d) moisture →

Responsible to Iso in weight of crude drug, encourage growth of fungus, mold and bacteria.

Biodynamic Agriculture

Biodynamic agriculture is a practice of agriculture. Includes avoiding chemical soil fertilizers and chemical pesticides to enhance the productivity of herbal drug without affecting ecosystem.

"This practice is started by a german philosopher and scientist dr. Rudolf Steiner in 1924."

- ⇒ Biodynamic agriculture includes manure manure and composted which are prepared ecologically.
- ⇒ Biodynamic agriculture means keep in existence long term support.
- ⇒ B.D.A. is environment friendly, resource conserving, economical, socially supportive and commercially competitive.
- ⇒ The method do not use any synthetic chemical fertilizer and pesticides, Biodynamic farming involve greater earthworm population and less energy used for production as compared with other conventional farming method.

Biodynamic agriculture involves -

- ⇒ use of natural method for crop improvement.
- ⇒ use of natural manures and composted fertiliser.
- ⇒ Soil rotation to increase yield and soil health.
- ⇒ Prohibition of any synthetic Fertilizer and Pesticide.
- ⇒ management of Pest by natural way, involve certification of product to insure quality of plant.

→ The concept of biodynamic agriculture Rudolf Steiner in 1924.

⇒ To check the Idea of biodynamic agriculture a group of more than 800 farmer was formed in Europe and America named as "Agricultural Experimental Circle of ~~and~~ Anthroposophical Farmer and Gardener of the general Society."

⇒ The term Bio indicate as living entity while term dynamic indicate Energy.

↳ Organic Farming

It is defined as Production of Crop, animal and other product without application of harmful chemical like Synthetic chemical fertilizer, pesticide; genetically modified or transgenic species or antibiotic and growth enhancing Phyto hormone.

⇒ Organic farming is also known as ecological farming.

↳ Objectives of organic Farming

- * Production of food and herbal medicine of high quality and insufficient quantity.
- * Controlling of all form of pollution.
- * Production of biodegradable organic product.
- * Consideration of wider social and ecological impact of the organic production.
- * Maintenance of long term fertility of soil.

- * maintenance of genetic diversity of the plant.
- * Promotion of healthy use and proper care of water resources.
- * Processing of products by using renewable resources.

Effect of organic farming =>

- * Improve the biodiversity.
- * Improve soil quality and microbial biomass.
- * Biofertilizer contains microbial consortium of Loosening cell of microorganism like - bacterial, algae, fungi; alone or combination which use crop productivity.
- * Nitrogen fixing bacteria - like - Azotobacter, Symbiont species are Nitrogen fixing organism, capable of forming and symbiotic relation with the root of several crops.
- * Organic farming can act on Plant growth directly through the production of Phytohormone or indirectly through nitrogen fixation or Production of bio-control agent against Soil born Pathogen for better yield.
- * Organic agriculture is a production system that maintain the health of Soil, ecosystem and people.
- * Organic agriculture combines traditional and innovation and science to benefit the environment and promote fair relationship and good quality of life for all involved.

Good Agricultural Practice (GAP)

In India about 92% of the Production of medicinal Plant are cultivated through Scientific way for the Production of best quality of Raw material.

⇒ Domestic demand of medicinal Plant has been estimated One lack five thousand Mt. for the year of 2014-15. Total Consumption of herbal raw material in the Country for the year 2014-15 has been estimated five lack twelve thousand mt. thousand

Needs of GAP

Use of medicinal plant is continuously increasing world wide. Last few decades no. of People Using herbal medicine there is rise in concern about Safety. On this background quality assurance and quality control of herb medicine need attention.

Poor quality of herbal medicine is most of the time b/c of Poor quality of starting material in order to ensure quality, Safety and efficacy of Herbal medicine, WHO had identified importance of agricultural and collection practices.

WHO Guidelines provides detail description of GAP for Herbal medicine.

These are guideline which are supposed to be followed for the crop improvement

GAP for medicinal Plant

(A) Selection of Plant material \Rightarrow

- Plant material should be selected as per Specification of National Pharmacopoeia
- \Rightarrow In case of new Plant material, Identity of the material selected for cultivation should be confirmed and documented

(B) Botanical Identity

Correct botanical identity of medicinal plant -

- ~~Including:- genus, order, family and local name should be documented.~~
- \Rightarrow In case of doubt identification ~~boucher~~ specimen should be submitted to National or local Herbarium for identification.

(C) Good cultivation Practices (GCP) \Rightarrow

(i) Environmental factors

* Climate \Rightarrow

Climatic condition like- length of day, sunlight, Rainfall or irrigation (if any), Temp. and night variation and many more factor should be study.

* Soils

Soil & soil fertility, nutrient content of soil, soil type, pH (6.5), water retention should be considered before selecting Plant material.

* Use of fertilizers \Rightarrow

Needs of suitable type of fertilizer and its quantity needed to be consider.

\Rightarrow Animal excreta should be completely decomposed before using.

Fertilizer should be approved by respective country.
⇒ Irrigation system should be selected to plant need.
⇒ Chemical use should be as less as possible and is to be done when there is no other alternative.

* ~~Harvesting~~ ⇒

Medicinal plant should be harvested only during best optimal season to produce best possible product quality.

⇒ National Pharmacopeia published Standard or other Reference book's should be consider the report deciding time of harvesting.

⇒ Best time of the season and day for Harvest should be determined quality and quantity of biologically active constituent.

⇒ Care should be taken to insure no foreign matter are available in authentic drug.

* Good collection Practices

Collection of any plant from wild resources should be done with Prior permission from govt authority before initiation of collection. Prior study of geographical distribution and population of medicinal plant is needed.

Post harvesting Processing ⇒

Primary Processing ⇒ Plant material should be protected from rain, water, moist, or other condition which can be harmful to plant.

⇒ Drying ⇒

⇒ Storage

Storage of Plant material is very impo to improve shelf life, quality of finished product.

⇒ Building Should have adequate space, Hygein, tempr control, humidity control, Cleaning facility, building should prevent entry of pollutant, pest and animal.

⇒ Generally fresh Plant material Should be preserved b/w 2-8°C while frozen material should be kept at -20°C.

Quality assurance

Major measure should be taken through regular audits carried by export professional as per Regulatory body requirement.

⇒ Pest and Post management

Due to increase in population day by day consumption of crude drug rises but the production of drug is reduced or harvesting is reduced due to presence of various type of pest. that why the cost of the raw material is increases.

Pest

Pest is undesirable animal or plant species or insects which disrupts the crop.

Pesticides

(A) Mechanical method \Rightarrow

By Using manual labour, or using different devices.

- * Hand picking.
- * Pruning.
- * Burning.
- * Trapping.

(B) Agricultural method \Rightarrow

It covers advanced Plant breeding technique capable of producing genetic manipulation resulting in production of pests significant resistance.

- * Crop rotation - obstruction in their life cycle
- * Deep Plugging -
- * Production of pest resistant species by genetic manipulation.

(C) Biological method \Rightarrow

This method is Practised by combating the pest mostly the insect with other living organisms.

* The chemical substances produced and released by some female insects are capable of eliciting a sexual response from the opposite sex which could be properly exploited for biological control of Pest. Such eliciting substances are called as - sex-pheromones.

* This method is more effective, safe, economical for Pest Control.

(D) Chemical controls

Control of Pest by chemical substances from synthetic as well as natural sources.

Ideal Properties of Pesticides

- * It should be non-toxic and non-injurious to medicinal plant and human being.
- * It should be selective in action and highly toxic to insect/Pest in small concn.
- * The pesticide should be stable under ordinary condition of storage, non-inflammable, non-corrosive and free from bad odour.
- * Inherently less harmful and less environmental load.
- # Design to effect only one specific Pest or a few target organism.