Lecture synopsis Sub: APET

Lecture No: 1

Name of topic/lesson – Herbal Drug Analysis

Subtopic: Social Relevance of natural product analysis, Difficulties

Objective: To Study Social Relevance of natural product analysis

Topic Outcomes: At the end of topic you will

1. Know the natural product analysis
2. able to explain the Difficulties in natural product analysis

A **natural product** is a chemical compound or substance produced by a living organism—that is, found in nature.[2][3] In the broadest sense, natural products include any substance produced by life. Natural products can also be prepared by chemical synthesis (both semisynthesis and total synthesis) and have played a central role in the development of the field of organic chemistry by providing challenging synthetic targets. The term natural product has also been extended for commercial purposes to refer to cosmetics, dietary supplements, and foods produced from natural sources without added artificial ingredients.

Natural products continue to provide a diverse and unique source of bioactive lead compounds for drug discovery, but maintaining their continued eminence as source compounds is challenging in the face of the changing face of the pharmaceutical industry and the changing nature of biodiversity prospecting brought about by the Convention of Biodiversity. This review provides an overview of some of these challenges, and suggests ways in which they can be addressed so that natural products research can remain a viable and productive route to drug discovery. Results from International Cooperative Biodiversity Groups (ICBGs) working in Madagascar, Panama, and Suriname are used as examples of what can be achieved when biodiversity conservation is linked to drug discovery.

Technical Difficulties

In addition to the problems with HTS noted above, the isolation of bioactive compounds from plants and marine organisms faces a number of technical challenges. These include the variability of the source material (since an activity found in one collection may be absent in another), the difficulty of isolating the active constituents, the possibility that the active compound is a known compound (thus not protectable by composition-of-matter patents), and the costs of collection. However, as will be discussed below, new methods and techniques offer exciting opportunities to avoid or at least ameliorate many of these difficulties.

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Lecture synopsis Sub: APET

Lecture No: 2

Name of topic/lesson – Extraction techniques

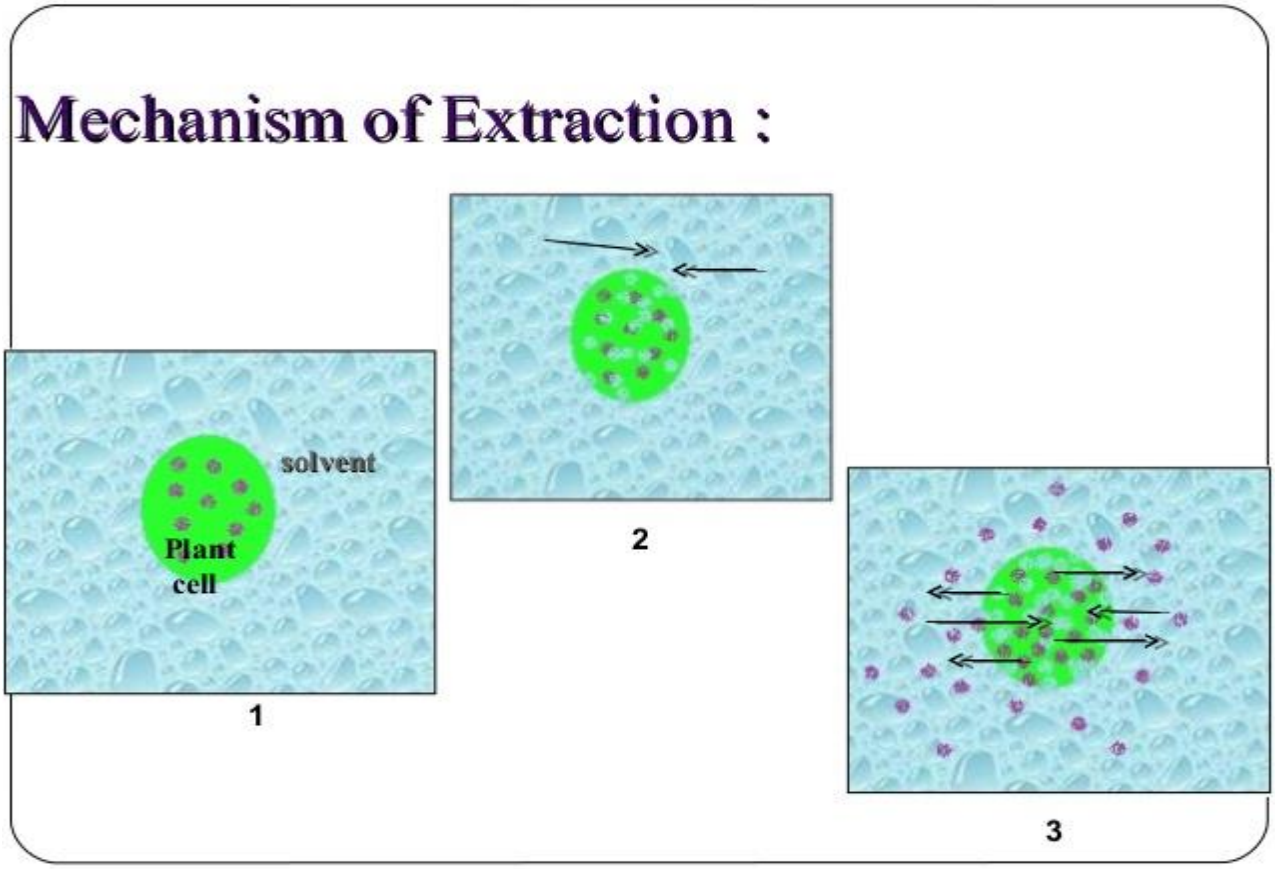
Subtopic: Theory, Principle of Mass Transfer

Objective: To Study Theory, Principle of Mass Transfer

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Mass Transfer
2. mass transfer fundamental & its use in different extraction methods

Mass transfer is the net movement of **mass** from one location, usually meaning stream, phase, fraction or component, to another. **Mass transfer** occurs in many processes, such as absorption, evaporation, drying, precipitation, membrane filtration, and distillation.



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Lecture synopsis Sub: APET

Lecture No: 3

Name of topic/lesson – Extraction techniques

Subtopic: Maceration, Decoction

Objective: To Study Theory, Principle of Maceration, Decoction

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Maceration & Decoction
2. Able to differentiate between Maceration & Decoction.

Various types of maceration process are

- Simple Maceration: A process for tinctures made from organized drug e.g. roots, stems, leaves etc.
- Maceration with Adjustment: A process for tinctures made from unorganized drugs such as oleo resins and gum resins.
- Double Maceration and Triple Maceration Process: for concentrated preparations.

Decoction is a method of extraction by boiling herbal or plant material to dissolve the chemicals of the material, which may include stems, roots, bark and rhizomes. Decoction involves first mashing the plant material to allow for maximum dissolution, and then boiling in water to extract oils, volatile organic compounds and other various chemical substances.

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1. Handa S. S., SumanPreet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh,Extraction technologies for medicinal & aromatic plants, International centrefor science and high technology, Trieste, Italy, 2008
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Lecture synopsis Sub: APET

Lecture No: 4

Name of topic/lesson – Extraction techniques

Subtopic: Infusion, Percolation

Objective: To Study Theory, Principle of Infusion, Percolation

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Infusion, Percolation
2. Able to differentiate between Infusion, Percolation

Infusion

Infusion is the process of extracting chemical compounds or flavors from plant material in a solvent such as water, oilor alcohol, by allowing the material to remain suspended in the solvent over time (a process often called steeping). An infusion is also the name for the resultant liquid. The process of infusion is distinct from both decoction—a method of extraction involving boiling the plant material—and percolation, in which water is passed through the material. nfusion is a very simple chemical process used with botanicals that are volatile and dissolve readily, or release their active ingredients easily in water, oil, or alcohol. The botanicals are typically dried herbs, flowers or berries. The liquid is typically boiled (or brought to another appropriate temperature) and then poured over the herb, which is then allowed to steep in the liquid for a period of time. The liquid may then be strained or the herbs otherwise removed from the liquid, creating *an infusion*. Unless the infusion is to be consumed immediately, it may then be bottled and refrigerated for future use.

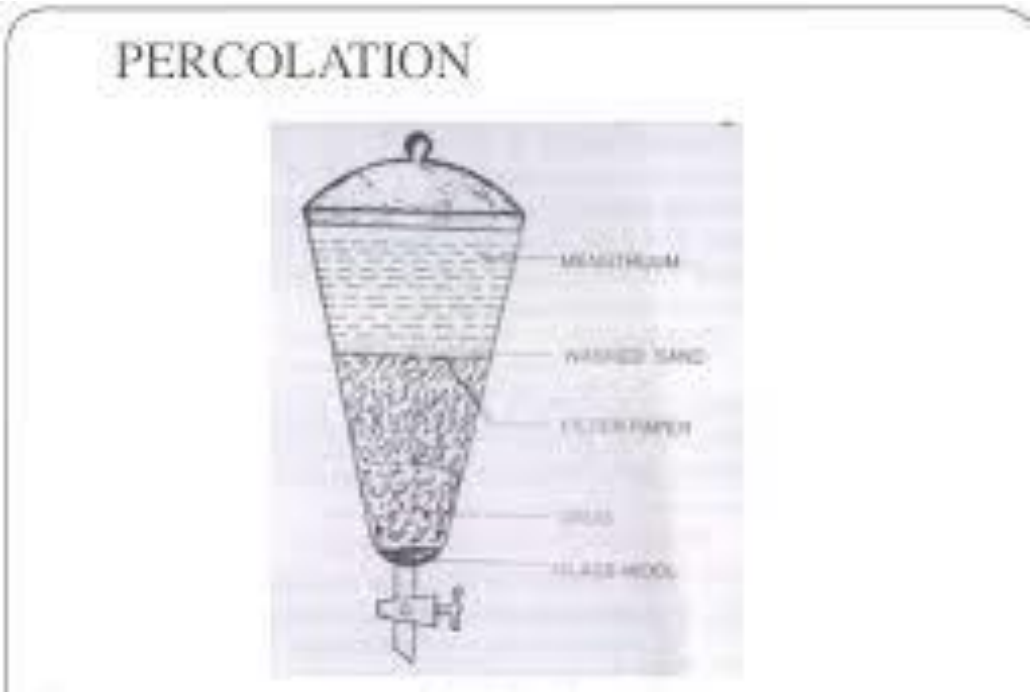
The amount of time the herbs are left in the liquid depends on the purpose for which the infusion is being prepared. Infusion times can range anywhere from seconds to hours, days, or months

There have been several accessories and techniques for removing the steeped or left over products that were used to infuse liquids such as water, oil, or alcohol. The use of a metal steeper, which looks like a metal clamp. Tea infusers work as strainers and assist in removal of used herbs,leaves, etc., from over steeping or leaving residues. French presses are commonly used to infuse water with various teas and coffee. Lastly, and most commonly used, the tea bag. Tea bags today are made with filter paper and filled with various tea flavors.

Lecture synopsis Sub: APET

PERCOLATION:

Percolation is the process of a liquid slowly passing through a filter. It's how coffee is usually made.Percolation comes from the Latin word percolare, which means "to strain through." Percolation happens when liquid is strained through a filter, like when someone makes coffee. In physics, chemistry and materials science, percolation (from Latin percōlāre, "to filter" or "trickle through") refers to the movement and filtering of fluids through porous materials. Broader applications have since been developed that cover connectivity of many systems modeled as lattices or graphs, analogous to connectivity of lattice components in the filtration problem that modulates capacity for percolation.



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Lecture synopsis Sub: APET

Lecture No: 5

Name of topic/lesson – Extraction techniques

Subtopic: Soxhlet Extraction

Objective: To Study Theory, Principle, Working, Application of Soxhlet Extractor

Topic Outcomes: At the end of topic you will
1. Know the basic Theory, Principle of Soxhlet Extractor
2. Able to Know about Hot Extraction methods

Soxhlet Extraction

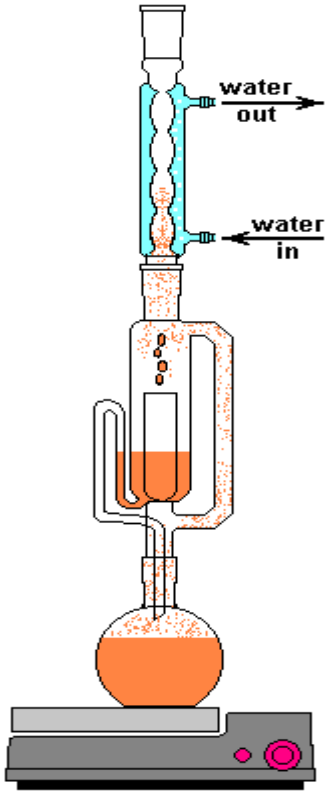
Normally a solid material containing some of the desired compound is placed inside a thimble made from thick filter paper, which is loaded into the main chamber of theSoxhlet extractor. The Soxhlet extractor is placed onto a flask containing theextraction solvent. The Soxhlet is then equipped with a condenser.

A Soxhlet extractor is a kind of laboratory equipment. It is made of glass. Franz von Soxhlet invented it in 1879. It has a flask, an extraction chamber, and a condenser. It can be used for solid-liquid extractions.

In this discontinuous extraction process, the extraction solvent inside the boiling flask is evaporated and re-condensed in the distillation column above. It then falls down onto the solid material requiring extraction. The chamber containing the solid material is connected to the boiling flask below by a syphoning mechanism seen in the Pythagorean cup, which allows the chamber to fill to a point, at which it will empty its contents and start to fill again and the extracted compounds will accumulate in the boiling flask below.

Soxhlet extraction is a very useful tool for preparative purposes in which the analyte is concentrated from the matrix as a whole or separated from particular interfering substances. Sample preparation of environmental samples has been developed for decades using a wide variety of techniques. Solvent extraction of solid samples, which is commonly known as solid}liquid extraction (also referred to as leaching or Lixiviation in a more correct use of the physicochemical terminology), is one of the oldest methods for solid sample pretreatment. Conventional Soxhlet extraction remains as one of the most relevant techniques in the environmental extraction Reld. This assertion is supported by the double use of conventional Soxhlet: as an extraction step in a given method, and/or as a well-established model for comparison of new extraction alternatives. In conventional Soxhlet, the sample is placed in a thimble-holder and during operation is gradually Rlled with condensed fresh solvent from a distillation Sask. When the liquid reaches an overSow level, a siphon aspirates the whole contents of the thimbleholder and unloads it back into the distillation Sask, carrying the extracted analytes in the bulk liquid. This operation is repeated until complete extraction is achieved.

This performance makes Soxhlet a hybrid continuous}discontinuous technique. Inasmuch as the solvent acts stepwise, the assembly can be considered as a batch system; however, since the solvent is recirculated through the sample, the system also bears a continuous character. Figure shows a scheme of a conventional Soxhlet device. As can be seen, Soxhlet extraction is a very simple technique. This simplicity makes the procedures for different samples very similar. For this reason, an overview of its extensive application in the environmental Reld during the last two decades is presented here, which cover the kind of samples, analytes, solvents, etc. used and the role of Soxhlet extraction in the overall analytical process.



Soxhlet Extraction

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Lecture synopsis Sub: APET

Lecture No: 6

Name of topic/lesson – Extraction techniques

Subtopic: Counter Current Extraction

Objective: To Study Theory, Principle, Working, Application of Counter Current Extraction

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Counter Current Extraction
2. Able to Know applications, merits, demerits Counter Current Extraction

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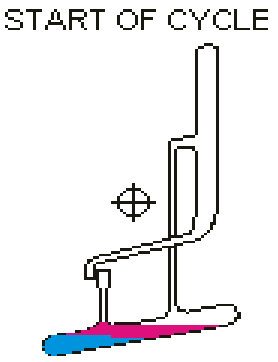
Theory

A method of multiple liquid-liquid extractions is countercurrent extraction, which permits the separation of substances with different distribution coefficients (ratios). A clever design known as Craig apparatus is used for this purpose (Lyman C. Craig, 1943).

Craig apparatus consists of a series of glass tubes (r: 0, 1, 2..) that are designed and arranged such that the lighter liquid phase is transferred from one tube to the next. The liquid-liquid extractions are taking place simultaneously in all tubes of the apparatus which is usually driven electromechanically. In the following animated picture of a single glass tube the typical "extraction/transfer" cycle is shown.



The lower (heavier) phase of the two-phase solvent system (e.g. water, blue layer in the picture) is the "stationary phase", whereas the upper (lighter) phase (e.g. hexane, red layer in the picture) is the "mobile phase".

In the beginning, tube #0 contains the mixture of substances to be separated in the heavier solvent and all the other tubes contain equal volumes of the same solvent. The lighter solvent is added to tube #0, extraction (equilibration) takes place and the phases are allowed to separate. The upper phase of tube #0 is then transferred to tube #1 and fresh solvent is added to tube #0, and the phases are equilibrated again. The upper layers of tubes #0 and #1 are simultaneously transferred to tubes #1 and #2 respectively. This cycle is repeated to carry on the process through the other tubes of the apparatus. Obviously, substances with higher distribution ratio move faster than those with a lower distribution ratio.

It is interesting to examine the distribution of a substance A in each tube after a given number of equilibration/transfer cycles.

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Lecture synopsis Sub: APET

Lecture No: 7

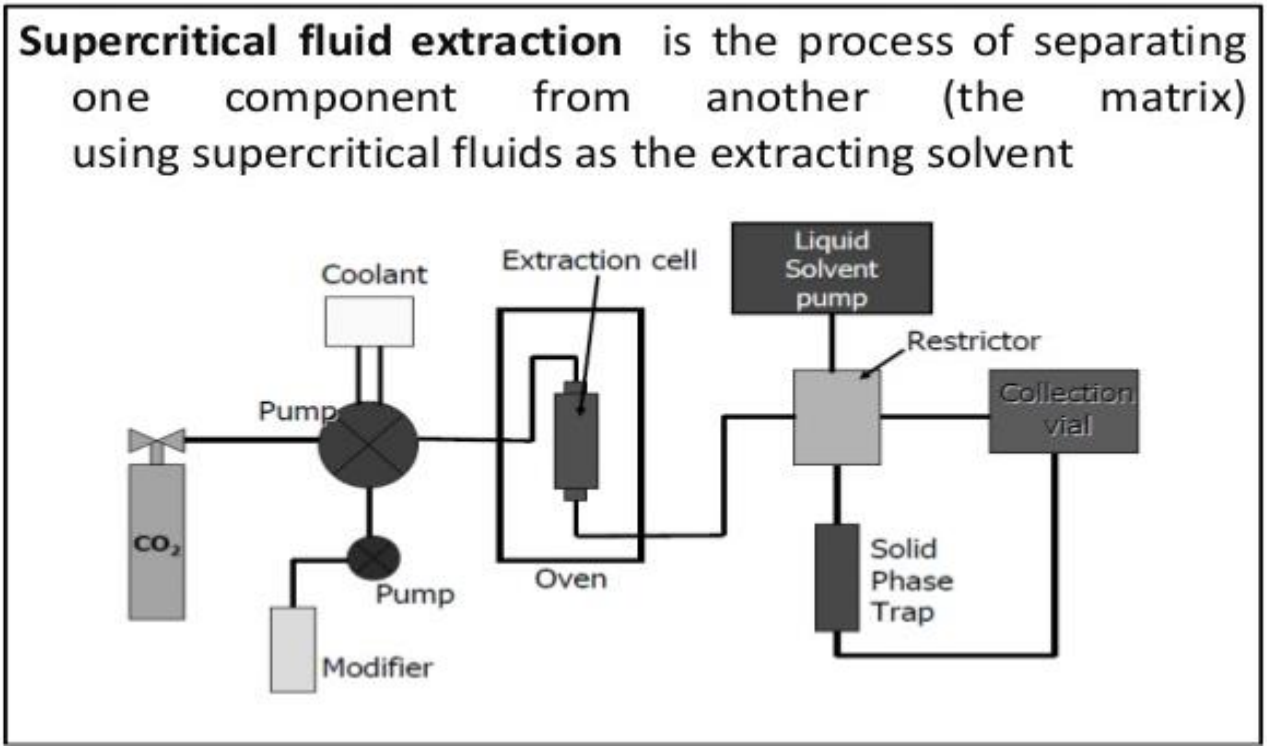
Name of topic/lesson – Extraction techniques

Subtopic: Supercritical Fluid Extraction

Objective: To Study Theory, Principle, Working, Application of Supercritical Fluid Extraction

Topic Outcomes: At the end of topic you will
1. Know the basic Theory, Principle of Supercritical Fluid Extraction
2. Able to Know applications, merits, demerits Supercritical Fluid Extraction

Supercritical fluid extraction (SFE) is the process of separating one component (the extractant) from another (the matrix) using supercritical fluids as the extracting solvent. Extraction is usually from a solid matrix, but can also be from liquids. SFE can be used as a sample preparation step for analytical purposes, or on a larger scale to either strip unwanted material from a product (e.g. decaffeination) or collect a desired product (e.g. essential oils). These essential oils can include limonene and other straight solvents. Carbon dioxide (CO_2) is the most used supercritical fluid, sometimes modified by co-solvents such as ethanol or methanol. Extraction conditions for supercritical carbon dioxide are above the critical temperature of 31 °C and critical pressure of 74 bar. Addition of modifiers may slightly alter this. The discussion below will mainly refer to extraction with CO_2, except where specified.



Properties of supercritical fluid (i) Supercritical fluids have highly compressed gases, which combine properties of gases and liquids in an intriguing manner. (ii) Supercritical fluids can lead to reactions, which are difficult or even impossible to achieve in conventional solvents. (iii) Supercritical fluids have solvent power similar to light hydrocarbons for most of the solutes. However, fluorinated compounds are often more soluble in supercritical CO2 than in hydrocarbons; this increased solubility is important for polymerization. (iv) Solubility increases with increasing density (that is with increasing pressure). Rapid expansion of supercritical solutions leads to precipitation of a finely divided solid. This is a key feature of flow reactors. (v) The fluids are commonly miscible with permanent gases (e.g. N2 or H2) and this leads to much higher concentrations of dissolved gases than can be achieved in conventional solvents.

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Lecture synopsis Sub: APET

Lecture No: 8

Name of topic/lesson – Extraction techniques

Subtopic: Solid Phase Extraction

Objective: To Study Theory, Principle, Working, Application of Solid Phase Extraction

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Solid Phase Extraction
2. Able to Know applications, merits, demerits Solid Phase Extraction

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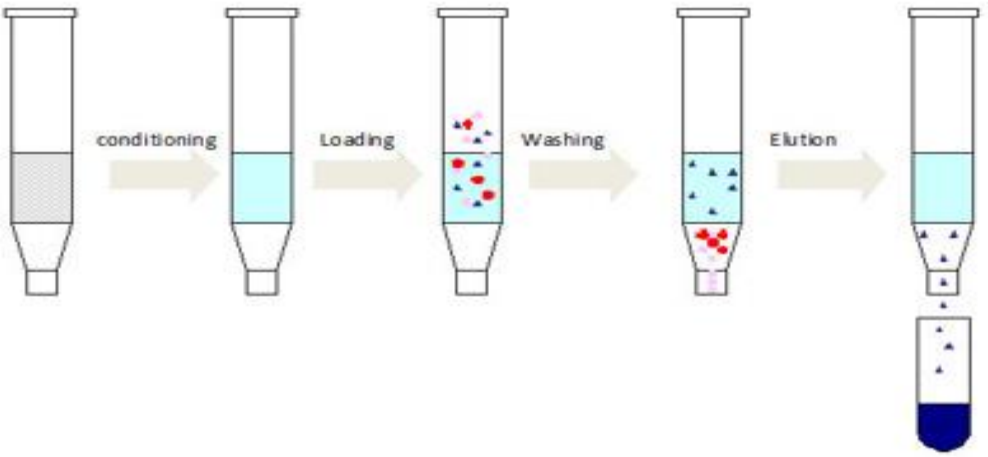
Solid-phase extraction (SPE) is a sample preparation process by which compounds that are dissolved or suspended in a liquid mixture are separated from other compounds in the mixture according to their physical and chemical properties. Analytical laboratories use solid phase extraction to concentrate and purify samples for analysis. Solid phase extraction can be used to isolate analytes of interest from a wide variety of matrices, including urine, blood, water, beverages, soil, and animal tissue.

SPE uses the affinity of solutes dissolved or suspended in a liquid (known as the mobile phase) for a solid through which the sample is passed (known as the stationary phase) to separate a mixture into desired and undesired components. The result is that either the desired analytes of interest or undesired impurities in the sample are retained on the stationary phase. The portion that passes through the stationary phase is collected or discarded, depending on whether it contains the desired analytes or undesired impurities. If the portion retained on the stationary phase includes the desired analytes, they can then be removed from the stationary phase for collection in an additional step, in which the stationary phase is rinsed with an appropriate eluent.



SPE technique is a useful tool for many purposes through its versatility. Isolation, concentration, purification and clean-up are the main approaches in the practices of this method. Food structures represent a complicated matrix and can be formed into different physical stages, such as solid, viscous or liquid.

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Lecture synopsis Sub: APET

Lecture No: 9

Name of topic/lesson – Extraction techniques

Subtopic: Microwave assisted Extraction

Objective: To Study Theory, Principle, Working, Application of Microwave assisted Extraction

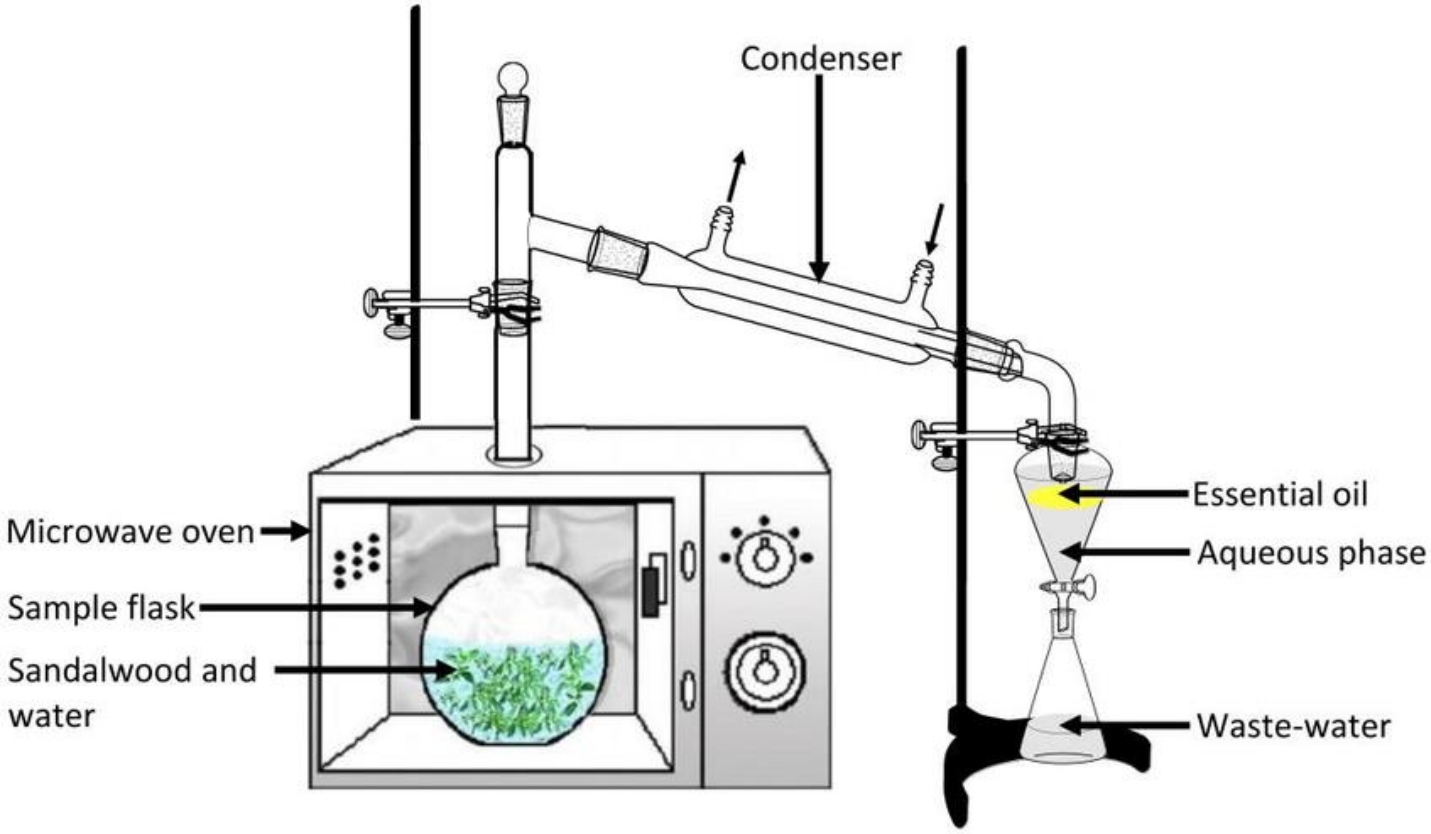
Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Microwave assisted Extraction

2. Able to know applications, merits, demerits of Microwave assisted Extraction

Microwave assisted extraction (MAE) is based on heating the solvent through absorption of microwave energy by polar molecules, thus increasing the solvent penetration into the sample matrix. MAE has been applied to the extraction of organic compounds from very different types of matrix because it saves solvent and it is rapid and efficient in terms of energy use. This method allows the acceleration of energy transfer, facilitating the solvation of analytes, and also promoting the disruption of weak hydrogen bonds. The effects of microwave energy depend on several factors, such as the nature of both solvents and solid matrix, the type of target analyte to be extracted, and especially the sample and solvent dielectric constants. The dielectric constants of the system are crucial to MAE, since higher dielectric constants promote an increasing of the amount of energy absorbed. Although this method cannot be applied to extract termolabile compounds, it becomes an important tool for green analytical chemistry, mainly for the extraction of natural products from marine sources, since it reduces significantly solvent volume and extraction times. Recently, a review paper centered its attention on a new solvent-free MAE technique (SFME) that has additional advantages since it reduces energy consumption, solvent use, and CO_2 emissions, which is advantageous for the extraction of bioactive compounds from natural sources. For example, SFME could reduce an extraction time of 3 hr to only 15 min, achieving similar yields to those observed by conventional methods . Compared to traditional extraction techniques, the use of microwaves decreases extraction times, consequently also decreasing the amount of solventneeded
Sulphated polysaccharides, such as fucoidans, were extracted from brown seaweed *Fucus vesiculosus* using MAE, by Rodriguez-Jasso *et al.*. Some parameters such as pressure (30–120 psi), extraction time (1–31 min), and alga/water ratio (1/25–5/25 g/mL) were evaluated and optimized by the application of an experimental design. All studied variables affect the extraction process presenting significant main effects, and the optimal extraction conditions were found as 120 psi for 1 min and using 1g of alga per 25 mL of water, which allowed an extraction yield of 18.22%. Balasubramanian *et al.* recovered palmitic acid from green algae *Scenedesmus obliquus*, by MAE, which was performed at different temperatures (80 and 95 °C) for a period of 30 min and using a ratio of green algae/water of 1:1. Balsubramanian *et*

al. have found that the extraction yield of oil was higher at 95 °C with a total recovery value of 76–77% (w/w). When compared to a conventional water bath heater, the extraction of palmitic acid by MAE is approximately 10-fold lower in terms of processing time, increasing the heating rates 4× to 5 × .



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Lecture synopsis Sub: APET

Lecture No: 10

Name of topic/lesson – Extraction techniques

Subtopic: Ultrasound Extraction (Sonication)

Objective: To Study Theory, Principle, Working, Application of Ultrasound Extraction

Topic Outcomes: At the end of topic you will

1. Know the basic Theory, Principle of Ultrasound Extraction
2. Able to Know applications, merits, demerits Ultrasound Extraction

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Sonication is the act of applying sound energy to agitate particles in a sample, for various purposes such as the extraction of multiple compounds from plants, microalgae and seaweeds. Ultrasonic frequencies (>20 kHz) are usually used, leading to the process also being known as ultrasonication or ultra-sonication.

In the laboratory, it is usually applied using an ultrasonic bath or an ultrasonic probe, colloquially known as a sonicator. In a paper machine, an ultrasonic foil can distribute cellulose fibres more uniformly and strengthen the paper.

Applications

Sonication can be used for the production of nanoparticles, such as nanoemulsions, nanocrystals, liposomes and wax emulsions, as well as for wastewater purification, degassing, extraction of seaweed polysaccharides[1] and plant oil, extraction of anthocyanins and antioxidants, production of biofuels, crude oil desulphurization, cell disruption, polymer and epoxy processing, adhesive thinning, and many other processes. It is applied in pharmaceutical, cosmetic, water, food, ink, paint, coating, wood treatment, metalworking, nanocomposite, pesticide, fuel, wood product and many other industries.

Sonication can be used to speed dissolution, by breaking intermolecular interactions. It is especially useful when it is not possible to stir the sample, as with NMR tubes. It may also be used to provide the energy for certain chemical reactions to proceed. Sonication can be used to remove dissolved gases from liquids (degassing) by sonicating the liquid while it is under a vacuum. This is an alternative to the freeze-pump-thaw and sparging methods.

In biological applications, sonication may be sufficient to disrupt or deactivate a biological material. For example, sonication is often used to disrupt cell membranes and release cellular contents. This process is called sonoporation. Small unilamellar vesicles (SUVs) can be made by sonication of a dispersion of large multilamellar vesicles (LMVs). Sonication is also used to fragment molecules of DNA, in which the DNA subjected to brief periods of sonication is sheared into smaller fragments.

Sonication is commonly used in nanotechnology for evenly dispersing nanoparticles in liquids. Additionally, it is used to break up aggregates of micron-sized colloidal particles.

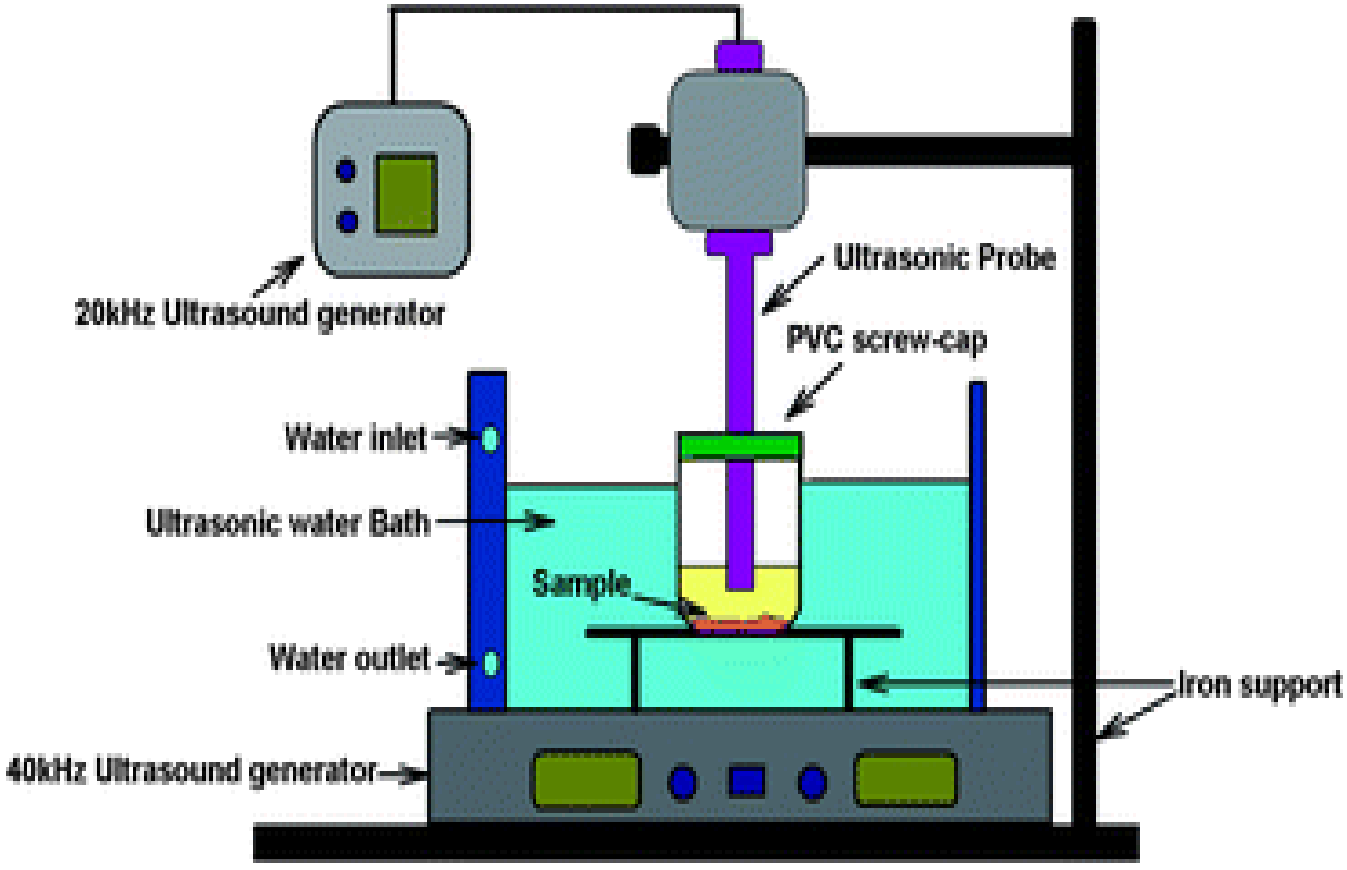
Sonication can also be used to initiate crystallisation processes and even control polymorphic crystallisations. It is used to intervene in anti-solvent precipitations (crystallisation) to aid mixing and isolate small crystals.

Sonication is the mechanism used in ultrasonic cleaning—loosening particles adhering to surfaces. In addition to laboratory science applications, sonicating baths have applications including cleaning objects such as spectacles and jewelry.

Sonication is used in food industry as well. Main applications are for dispersion to save expensive emulgators (mayonnaise) or to speed up filtration processes (vegetable oil etc.). Experiments with sonification for artificial ageing of liquors and other alcoholic beverages were conducted.

Soil samples are often subjected to ultrasound in order to break up soil aggregates; this allows the study of the different constituents of soil aggregates (especially soil organic matter) without subjecting them to harsh chemical treatment.[9]

Sonication is also used to extract microfossils from rock.



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Lecture No: 11

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic: Fractional Distillation

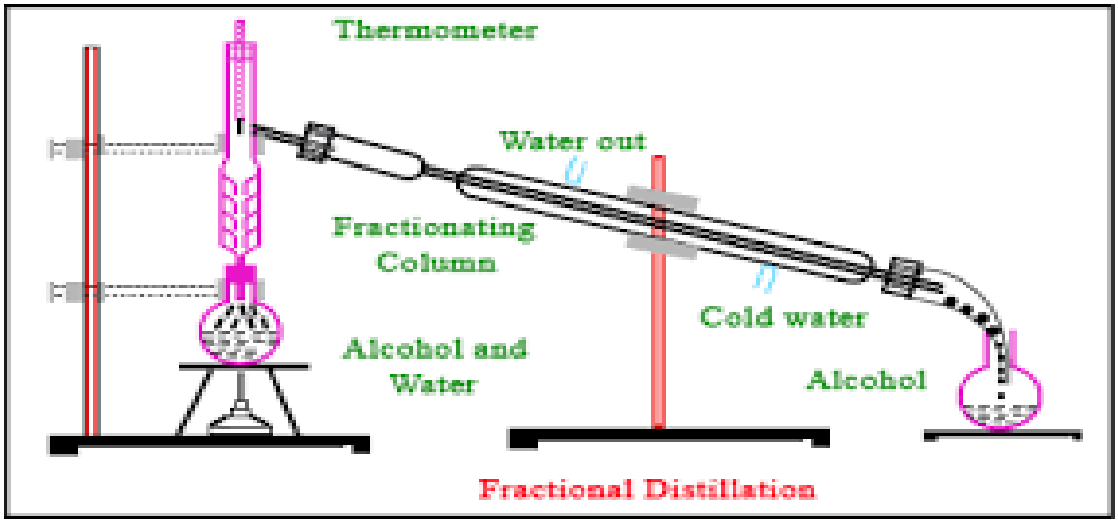
Objective: To Study Fractional Distillation

Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Fractional Distillation
2. Able to Know Working & applications of Fractional Distillation

Fractional distillation is the separation of a mixture into its component parts, or fractions. Chemical compounds are separated by heating them to a temperature at which one or more fractions of the mixture will vaporize. It uses distillation to fractionate. Generally the component parts have boiling points that differ by less than 25 °C (77 °F) from each other under a pressure of one atmosphere. If the difference in boiling points is greater than 25 °C, a simple distillation is typically used.

Apparatus

- heat source, such as a hot plate with a bath
- distilling flask, typically a round-bottom flask
- receiving flask, often also a round-bottom flask
- fractionating column
- distillation head
- thermometer and adapter if needed
- condenser, such as a Liebig condenser or Allihn condenser
- vacuum adapter (only required if performing vacuum distillation; not used in image to the right). Standard laboratory glassware with ground glass joints, e.g. quickfit apparatus.



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Lecture No: 12

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic: Fractional Liberation

Objective: To Study Fractional Liberation

Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Fractional Liberation
2. Able to Know Working & applications of Fractional Liberation

Fractional liberation. This process involves separation of phytochemicals on the basis liberation of compounds from mixture into solvent with the help of various chemical reactions.

A mixture of alkaloid salts in aqueous solution, when treated with aliquots of alkali gives first the weakest base in the free state followed by base liberation in ascending order of basicity.

If the mixture is shaken with organic solvent after each addition of aliquot of a alkali, a fractional series of bases shall be obtained.

Eg - a mixture of alkaloid salts in aqueous solution, when treated with aliquots of alkali gives first the weakest base in the free state followed by base liberation in ascending order of basicity .

Solvent extraction has been an important separation technique since the early days of the Manhattan Project, when scientists extracted uranyl nitrate into diethyl ether to purify the uranium used in the first reactors. Solvent extraction, or liquid-liquid extraction, is a technique used both in the laboratory and on the industrial scale. However, current laboratory trends are away from this technique, mainly because of the costs of materials and because it is becoming more difficult and costly to dispose of the mixed waste generated from the large volumes of solvents required. The technique also tends to be labor intensive because of the need for multiple extractions using separatory funnels. Nonetheless, solvent extraction remains a powerful separation technique worthy of consideration

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Lecture No: 13

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic: Sublimation

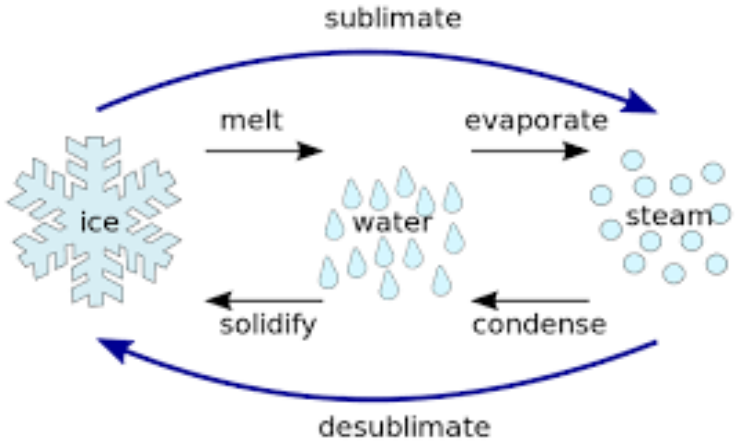
Objective: To Study Sublimation

Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Sublimation
2. Able to Know Working & applications of Sublimation

Sublimation is a type of phase transition, or a change in a state of matter, just like melting, freezing, and evaporation. Through sublimation, a substance changes from a solid to a gas without ever passing through a liquid phase. Dry ice, solid CO2, provides a common example of sublimation. Sublimation is the transition of a substance directly from the solid to the gas phase, without passing through the intermediate liquid phase.[1]Sublimation is an endothermic process that occurs at temperatures and pressures below a substance's triple point in its phase diagram, which corresponds to the lowest pressure at which the substance can exist as a liquid. The reverse process of sublimation is deposition or desublimation, in which a substance passes directly from a gas to a solid phase.[2] Sublimation has also been used as a generic term to describe a solid-to-gas transition (sublimation) followed by a gas-to-solid transition (deposition).[3] While a transition from liquid to gas is described as evaporation if it occurs below the boiling point of the liquid, and as boiling if it occurs at the boiling point, there is no such distinction within the solid-to-gas transition, which is always described as sublimation

Examples of Solid to Gas (Sublimation)

Dry Ice - Solid carbon dioxide is known as "dry ice" and sublimates at room temperature. Freeze-drying - Water can be sublimated in a food product by using a vacuum.



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Lecture No: 14

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic:Chemical Derivatization

Objective: To Study Chemical Derivatization

Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Chemical Derivatization
2. Able to Know Working & applications of Chemical Derivatization

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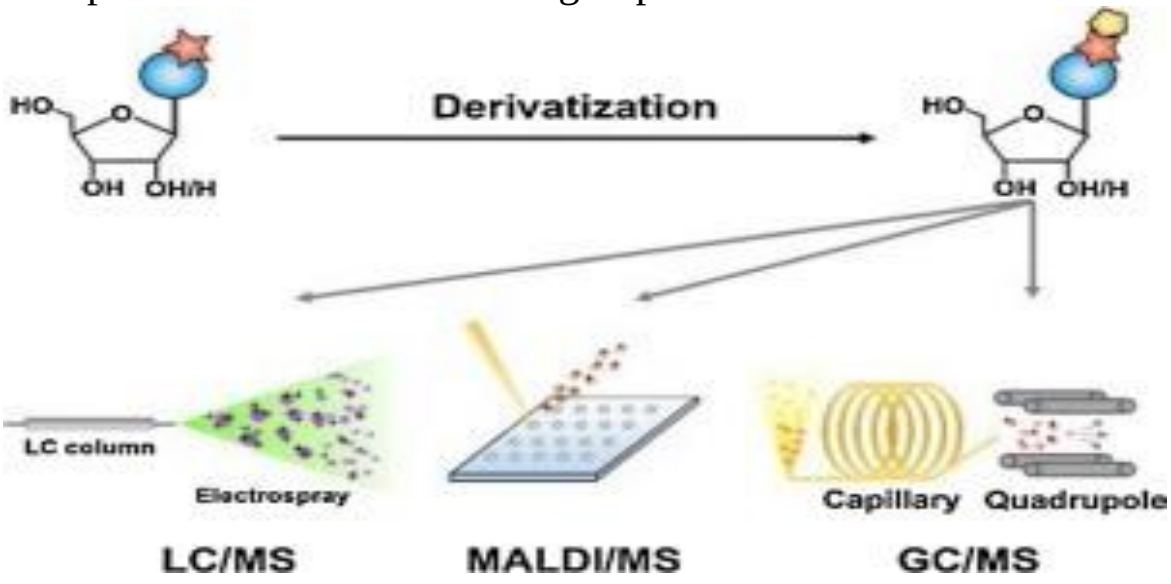
Derivatization is a technique used in chemistry which transforms a chemical compound into a product (the reaction's derivate) of similar chemical structure, called a derivative.

Generally, a specific functional group of the compound participates in the derivatization reaction and transforms the educt to a derivate of deviating reactivity, solubility, boiling point, melting point, aggregate state, or chemical composition. Resulting new chemical properties can be used for quantification or separation of the educt.

Derivatization techniques are frequently employed in chemical analysis of mixtures and in surface analysis, e.g. in X-ray photoelectron spectroscopy where newly incorporated label characteristic group



- **Derivatization** is a technique used in chemistry which transforms a chemical compound into a product (the reaction's **derivate**) of similar chemical structure called a derivative.

- Generally, a specific functional group of the compound participates in the derivatization reaction and transforms the it to a derivate of deviating reactivity, solubility, boiling point melting point,aggregate state, or chemical composition.

- Resulting new chemical properties can be used for quantification or separation of the compound

References

1. Handa S. S., SumanPreet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh,Extraction technologies for medicinal & aromatic plants, International centrefor science and high technology, Trieste, Italy, 2008.
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Lecture No: 15

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic: Fractional Crystallization

Objective: To Study Fractional Crystallization

Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Fractional Crystallization
2. Able to Know Working & applications of Fractional Crystallization

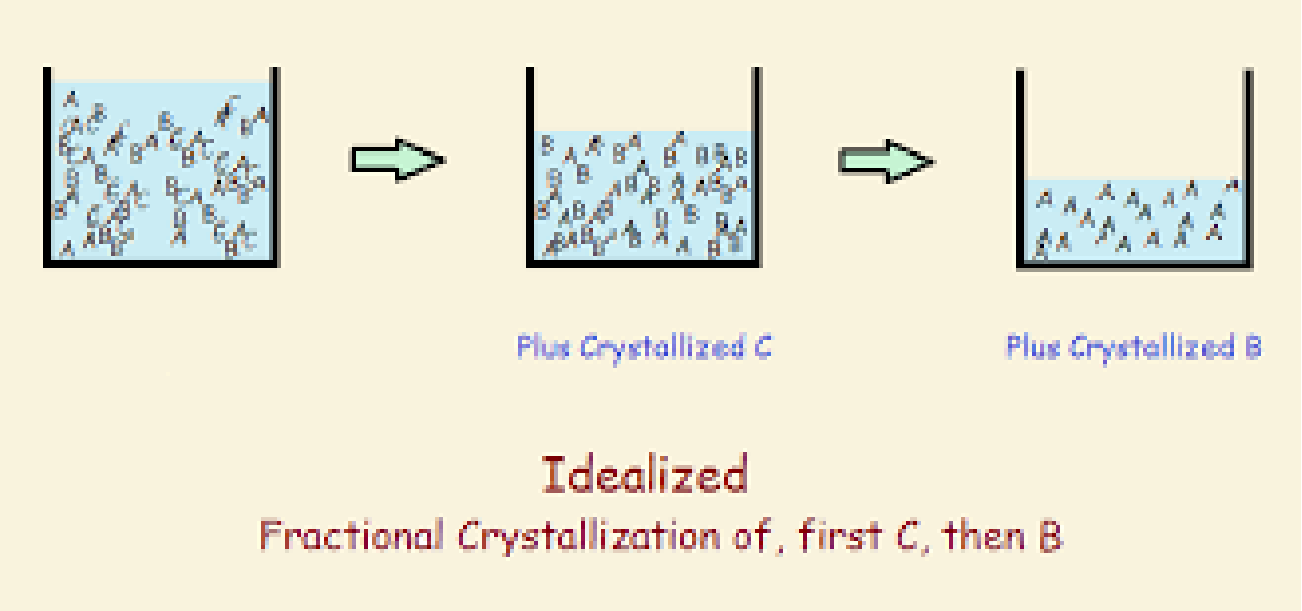
fractional crystallization is a method of refining substances based on differences in solubility. It fractionates via differences in crystallization (forming of crystals). If a mixture of two or more substances in solution are allowed to crystallize, for example by allowing the temperature of the solution to decrease or increase, the precipitate will contain more of the least soluble substance. The proportion of components in the precipitate will depend on their solubility products. If the solubility products are very similar, a cascade process will be needed to effectuate a complete separation. This technique is often used in chemical engineering to obtain very pure substances, or to recover saleable products from waste solutions. Fractional crystallization can be used to separate solid-solid mixtures. An example is separating KNO_3 and $KClO_3$.

❖ **Purpose:**

- Use the technique of vacuum filtration to separate a heterogeneous mixture into its components.
- Use the technique of fractional crystallization to separate a homogeneous mixture into its components.

❖ **Safety Considerations:**

- Exercise care not to burn yourself on hot ringstands, rings, and beakers.
- Dispose of all waste materials in the appropriately labeled containers in the hood.



Fractional crystallization involves dissolving the salt mixture in water, concentrating the solution by evaporating the water, and allowing some crystals to form. The first crystals would incorporate the most radium. Many collections of these crystals would be collected together and dissolved.

References

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Lecture No: 16

Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic: Centrifugation

Objective: To Study Centrifugation

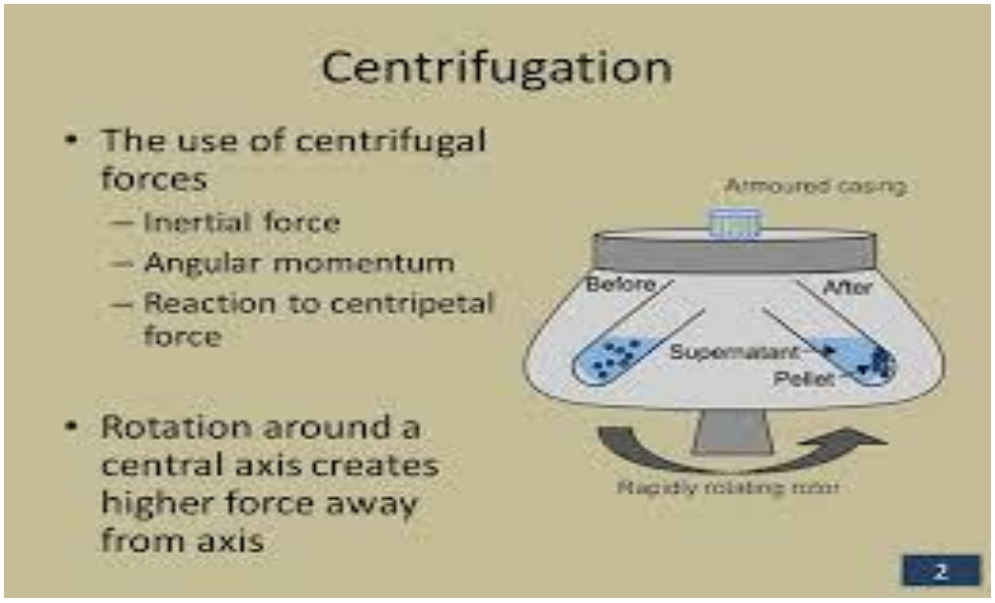
Topic Outcomes: At the end of topic you will
1. Know the basic Principle of Centrifugation
2. Able to Know Working & applications of Centrifugation

Centrifugation is a technique used for the separation of particles from a solution according to their size, shape, density, viscosity of the medium and rotor speed. The particles are suspended in a liquid medium and placed in a centrifuge tube. The tube is then placed in a rotor and spun at a define speed.
Separation through sedimentation could be done naturally with the earth gravity, nevertheless, it would take ages. Centrifugation is making that natural process much faster.
Rotation of the rotor about a central axis generates a centrifugal force upon the particles in the suspension.

Which factors have an influence on centrifugation :

- Density of both samples and solution
- Temperature/viscosity
- Distance of particles displacement
- Rotation speed

A centrifuge is a device that separates particles from a solution through use of a rotor. In biology, the particles are usually cells, subcellular organelles, or large molecules, all of which are referred to here as particles.
There are two types of centrifuge procedures; one is preparative, the purpose of which is to isolate specific particles, and the other is analytical, which involves measuring physical properties of the sedimenting particles.
As a rotor spins in a centrifuge, a centrifugal force is applied to each particle in the sample; the particle will then sediment at the rate that is proportional to the centrifugal force applied to it. The viscosity of the sample solution and the physical properties of the particles also affect the sedimentation rate of each particle.
At a fixed centrifugal force and liquid viscosity, the sedimentation rate of a particle is proportional to its size (molecular weight) and to the difference between the particle density and the density of the solution.



Applications

- separating chalk powder from water
- Removing fat from milk to produce skimmed milk
- Separating particles from an air-flow using cyclonic separation
- The clarification and stabilization of wine
- Separation of urine components and blood components in forensic and research laboratories
- Aids in separation of proteins using purification techniques such as salting out, e.g. ammonium sulfate precipitation.

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Lecture No: 17

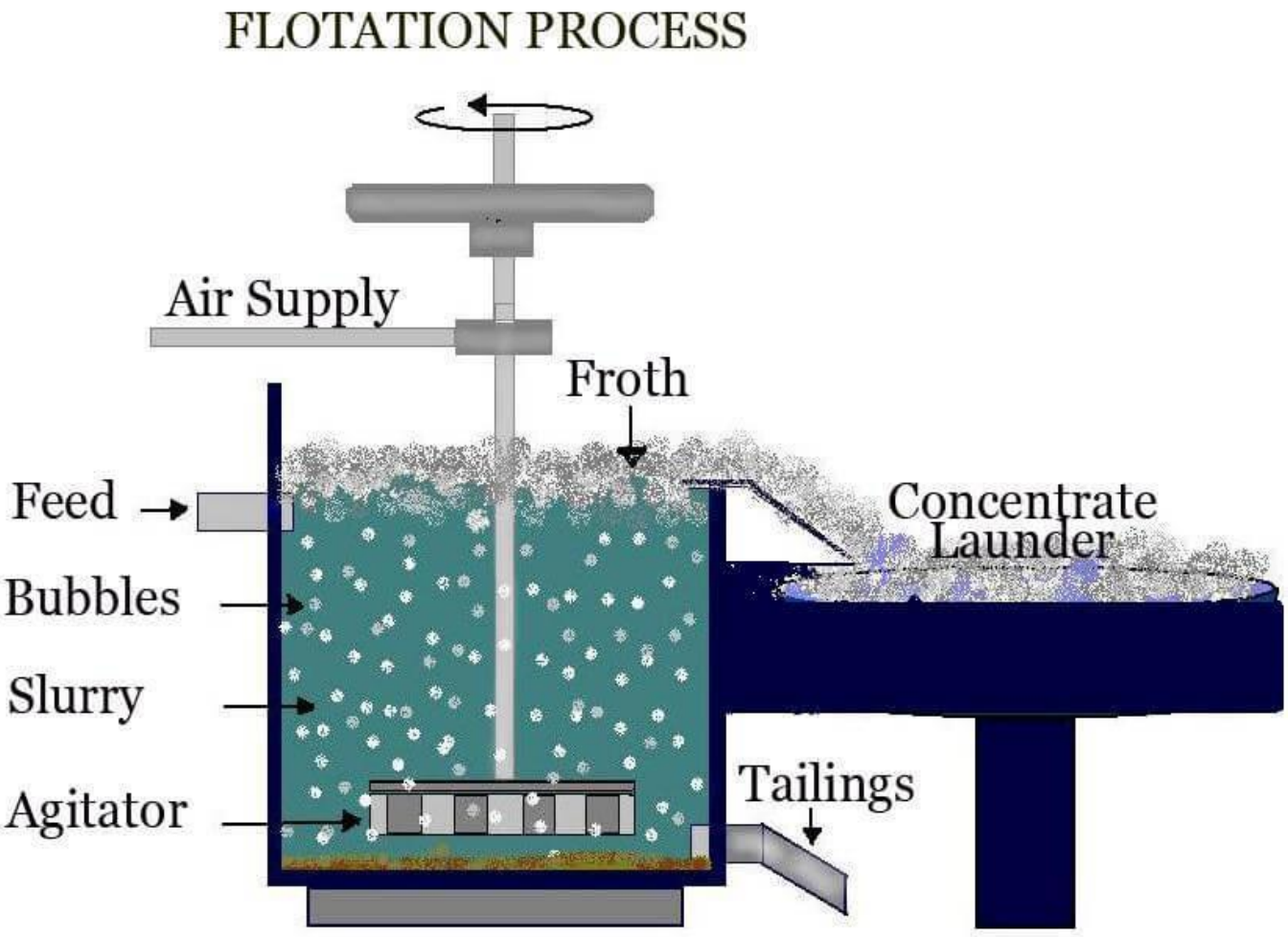
Name of topic/lesson – Non Chromatographic Separation Techniques

Subtopic:Froath Flotation Technique

Objective: To Study Froath Flotation Technique

Topic Outcomes: At the end of topic you will

1. Know the basic Principle of Froath Flotation Technique
2. Able to Know Working & applications of Froath Flotation Technique



Froth Flotation

Froth flotation is considered to be the most widely used method for ore beneficiation. In ore beneficiation, flotation is a process in which valuable minerals are separated from worthless material or other valuable minerals by inducing them to gather in and on the surface of a froth layer. Sulfide and non-sulfide minerals as well as native metals are recovered by froth flotation. This process is based on the ability of certain chemicals to modify the surface properties of the mineral(s). Other chemicals are used to generate the froth and still others are used to adjust the pH. Certain chemicals are even capable of depressing the flotation of minerals that are either to be recovered at a later time or are not to be recovered.

The process of froth flotation entails crushing and grinding the ore to a fine size. This fine grinding separates the individual mineral particles from the waste rock and other mineral particles. The grinding is normally done in water with the resultant slurry called the pulp. The pulp is processed in the flotation cells, which agitate the mixture and introduce air as small bubbles.

References

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Lecture No: 18

Name of topic/lesson –Chromatographic Separation Techniques

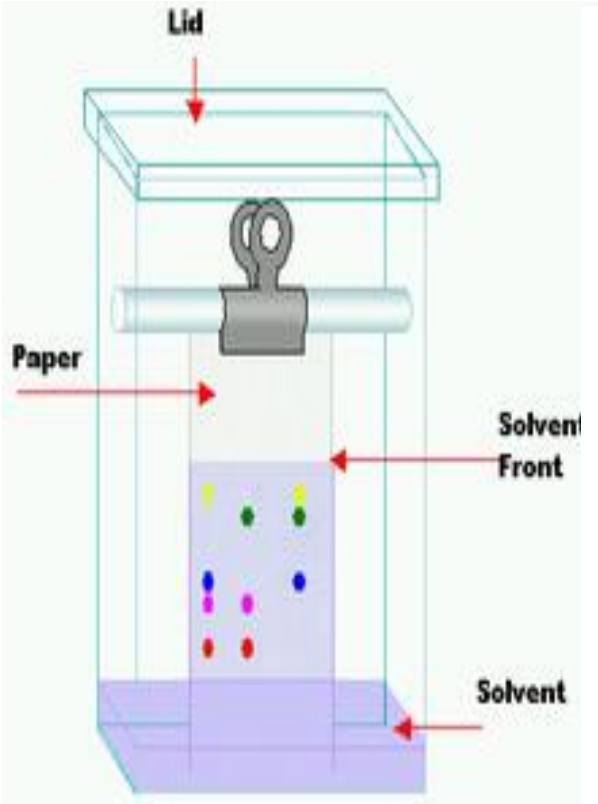
Subtopic: Principle and applications of Paper Chromatography

Objective: To Study Principle and applications of Paper Chromatography

Topic Outcomes: At the end of topic you will

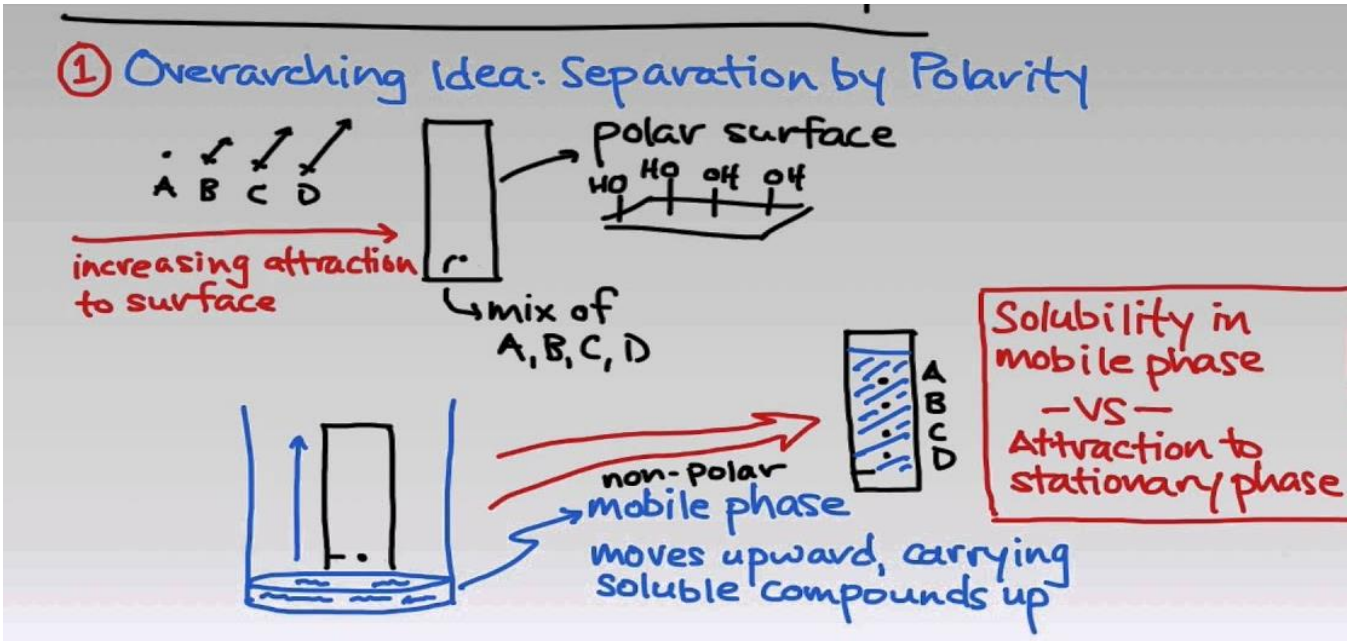
1. Know the basic Principle of Paper Chromatography
2. Able to Know Working & applications of Paper Chromatography

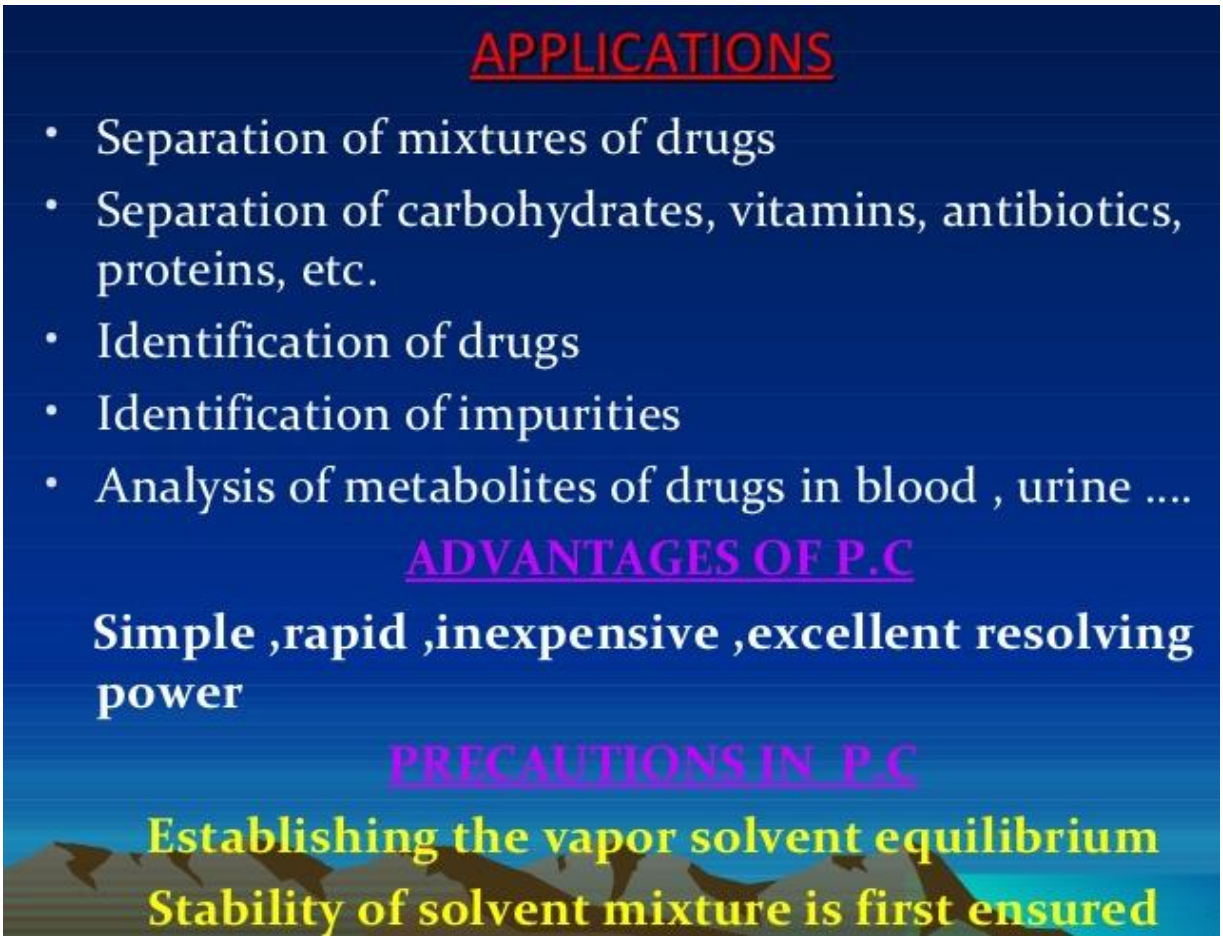
Paper chromatography is an analytical method used to separate colored chemicals or substances. It is primarily used as a teaching tool, having been replaced by other chromatography methods, such as thin-layer chromatography.



A paper chromatography variant, two-dimensional chromatography involves using two solvents and rotating the paper 90° in between. This is useful for separating complex mixtures of compounds having similar polarity, for example, amino acids.

The setup has three components. The mobile phase is a solution that travels up the stationary phase, due to capillary action. The mobile phase is generally mixture of non-polar organic solvent, while the stationary phase is polar organic solvent in water. Paper is used to support stationary phase (polar organic solvent). Difference between TLC and paper





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Lecture No: 19

Name of topic/lesson –Chromatographic Separation Techniques

Subtopic: Principle and applications of TLC,HPTLC

Objective: To Study Principle and applications of TLC,HPTLC

Topic Outcomes: At the end of topic you will

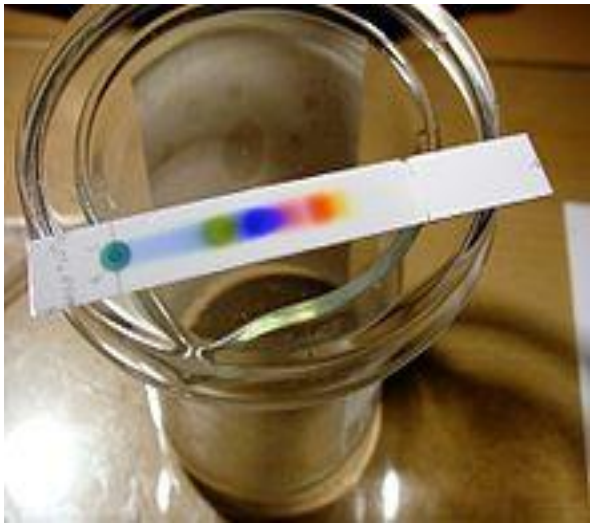
1. Know the basic Principle of TLC,HPTLC
2. Able to Know Working & applications of TLC,HPTLC

Thin-layer chromatography (TLC) is a chromatography technique used to separate non-volatile mixtures. Thin-layer chromatography is performed on a sheet of glass, plastic, or aluminium foil, which is coated with a thin layer of adsorbent material, usually silica gel, aluminium oxide (alumina), or cellulose. This layer of adsorbent is known as the stationary phase.

After the sample has been applied on the plate, a solvent or solvent mixture (known as the mobile phase) is drawn up the plate via capillary action. Because different analytes ascend the TLC plate at different rates, separation is achieved.[2] The mobile phase has different properties from the stationary phase. For example, with silica gel, a very polar substance, non-polar mobile phases such as heptane are used. The mobile phase may be a mixture, allowing chemists to fine-tune the bulk properties of the mobile phase.

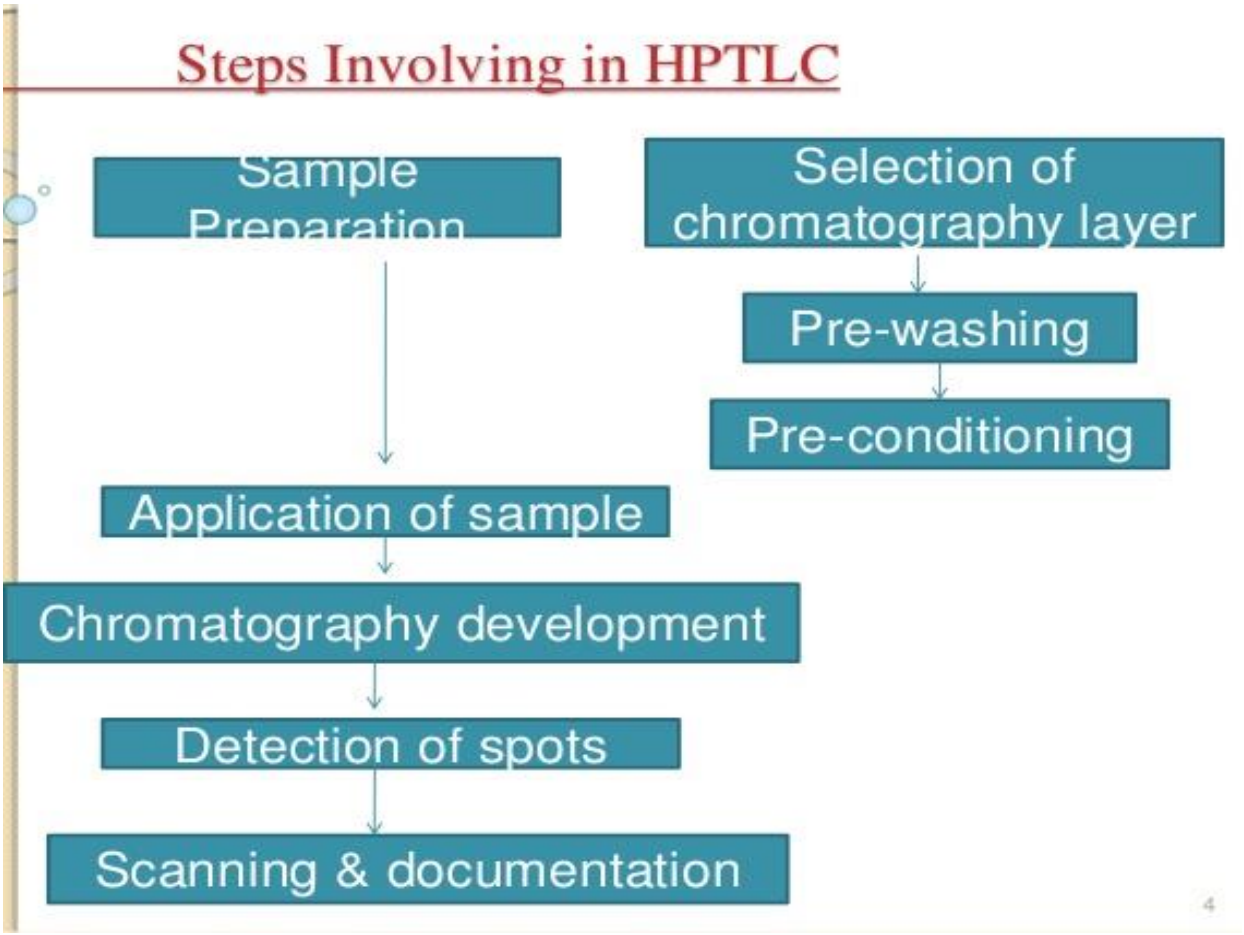
After the experiment, the spots are visualized. Often this can be done simply by projecting ultraviolet light onto the sheet; the sheets are treated with a phosphor, and dark spots appear on the sheet where compounds absorb the light impinging on a certain area. Chemical processes can also be used to visualize spots; anisaldehyde, for example, forms colored adducts with many compounds, and sulfuric acid will char most organic compounds, leaving a dark spot on the sheet.

To quantify the results, the distance traveled by the substance being considered is divided by the total distance traveled by the mobile phase. (The mobile phase must not be allowed to reach the end of the stationary phase.) This ratio is called the retardation factor (R_f). In general, a substance whose structure resembles the stationary phase will have low R_f, while one that has a similar structure to the mobile phase will have high retardation factor. Retardation factors are characteristic, but will change depending on the exact condition of the mobile and stationary phase. For this reason, chemists usually apply a sample of a known compound to the sheet before running the experiment.



High-performance thin-layer chromatography (**HPTLC**) is an enhanced form of thin-layer chromatography(TLC). A number of enhancements can be made to the basic method of thin-layer chromatography to automate the different steps, to increase the resolution achieved and to allow more accurate quantitative measurements.

Automation is useful to overcome the uncertainty in droplet size and position when the sample is applied to the TLC plate by hand. One recent approach to automation has been the use of piezoelectric devices and inkjet printers for applying the sample.



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Lecture No: 20

Name of topic/lesson –Chromatographic Separation Techniques

Subtopic: Principle and applications of TLC,HPTLC

Objective: To Study Principle and applications of TLC,HPTLC

Topic Outcomes: At the end of topic you will

1. Know the basic Principle of **TLC,HPTLC**
2. Able to Know Working & applications of **TLC,HPTLC**

Thin-layer chromatography (TLC) is a chromatography technique used to separate non-volatile mixtures. TLC system components consist of

1. **TLC plates,** preferably ready-made with a stationary phase: These are stable and chemically inert plates, where a thin layer of stationary phase is applied on its whole surface layer. The stationary phase on the plates is of uniform thickness and is in fine particle size.
2. **TLC chamber.** This is used for the development of the TLC plate. The chamber maintains a stable environment inside for proper development of spots. It also prevents the evaporation of solvents and keeps the process dust-free.
3. **Mobile phase.** This comprises of a solvent or solvent mixture. The mobile phase used should be particulate-free and of the highest purity for proper development of TLC spots. The solvents recommended are chemically inert with the sample, a stationary phase.
4. **A filter paper.** This is moistened in the mobile phase, to be placed inside the chamber. This helps develop a uniform rise in a mobile phase over the length of the stationary phase.

Applications

1. To check the purity of the given samples.
2. Identification of compounds like acids, alcohols, proteins, alkaloids, amines, antibiotics, and more.
3. To evaluate the reaction process by assessment of intermediates, reaction course, and so forth.
4. To purify samples, i.e., for the purification process.
5. To keep a check on the performance of other separation processes.

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2. Sethi, P. D. (2011): Sethi's HPTLC, High Performance Thin Layer Chromatography. Content Uniformity of Pharmaceutical Formulations. Kongposh Publications, New Delhi, ISBN 978-81-906264-3-9

Lecture synopsis Sub: APET

Lecture No: 21

Name of topic/lesson – Application of Extraction Techniques

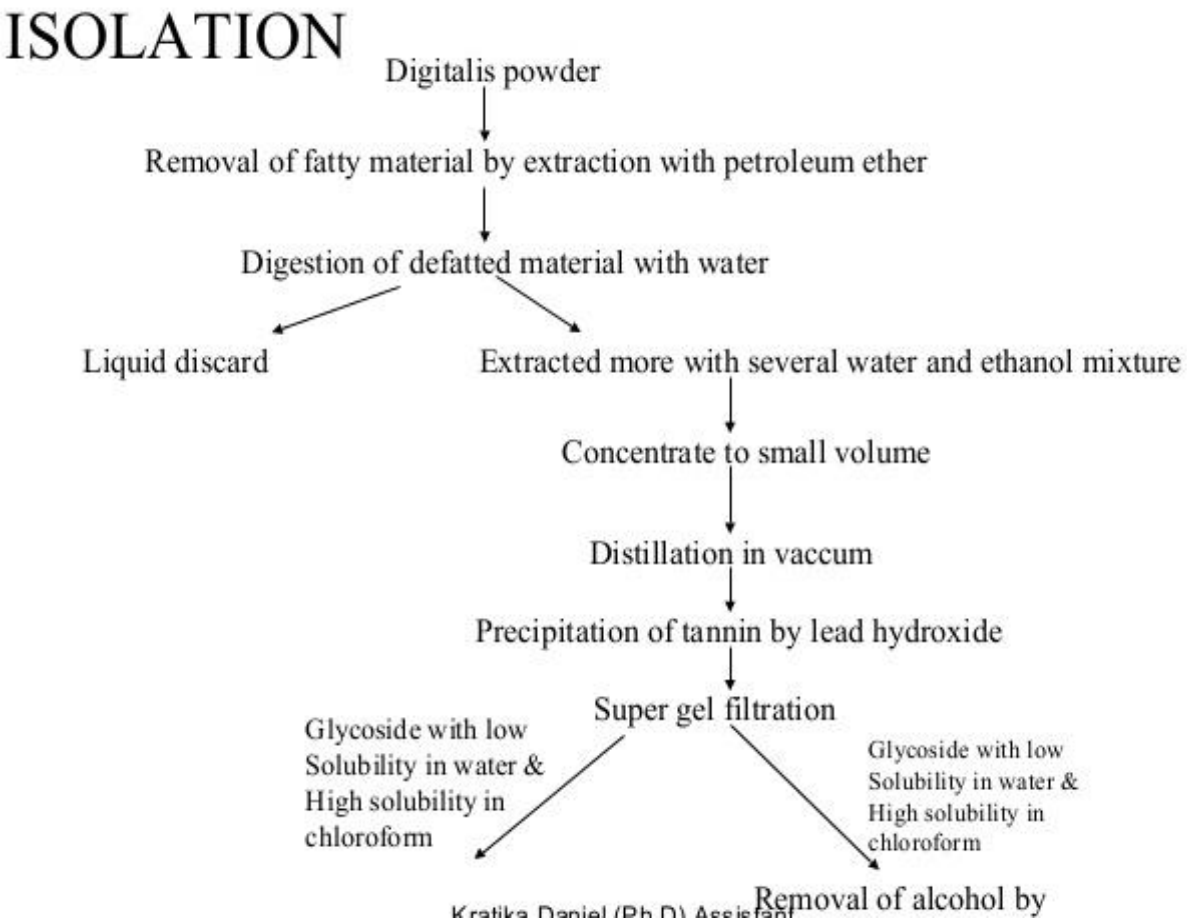
Subtopic: Direct solvent extraction

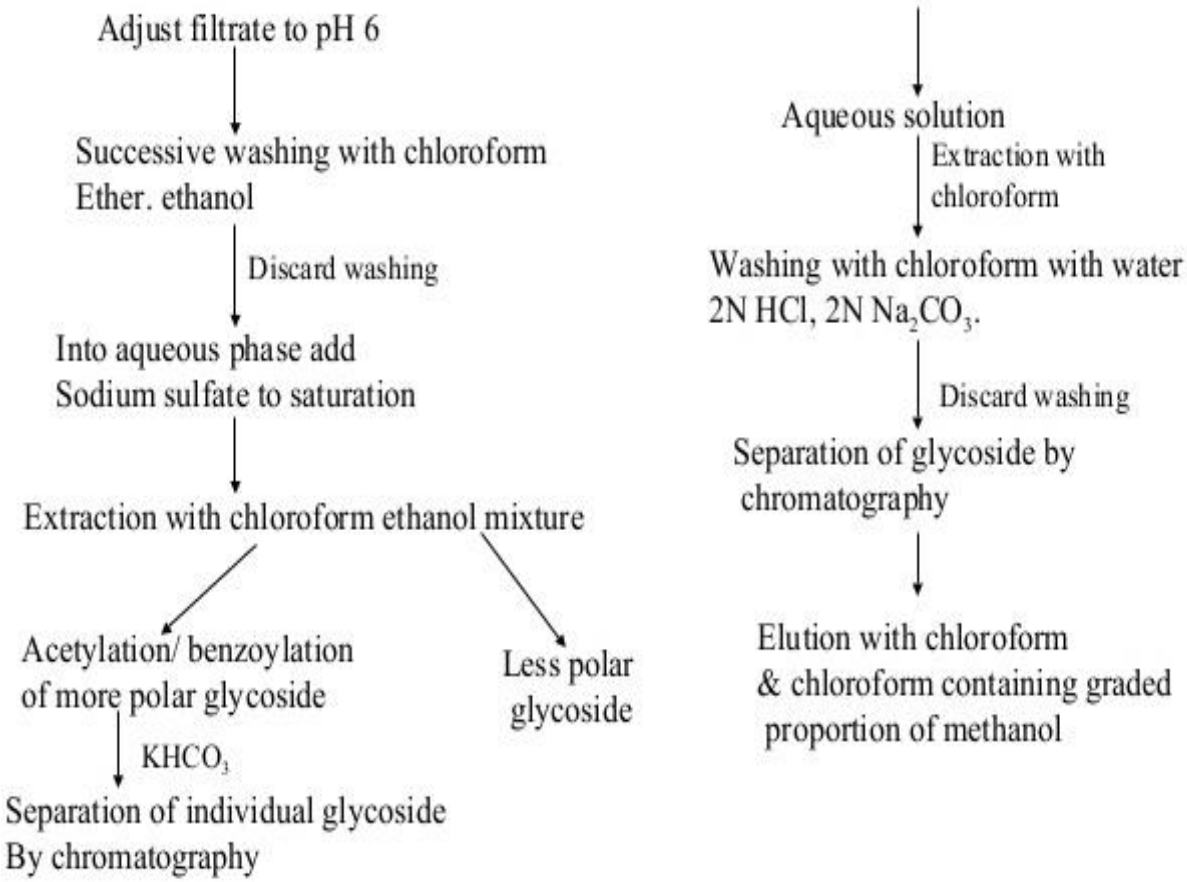
Objective: To Study Source & Extraction Methods.

Topic Outcomes: At the end of topic you will

1. Know the different extraction methods

2. able to explain the source, schematic representation of extraction methods.





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Lecture synopsis Sub: APET

Lecture No: 22

Name of topic/lesson – Application of Extraction Techniques

Subtopic: Direct solvent extraction

Objective: To Study Extraction Methods for Strychnine, Atropine & Reserpine

Topic Outcomes: At the end of topic you will

1. Know the different extraction methods

2. able to explain the source, schematic representation of Strychnine, Atropine & Reserpine

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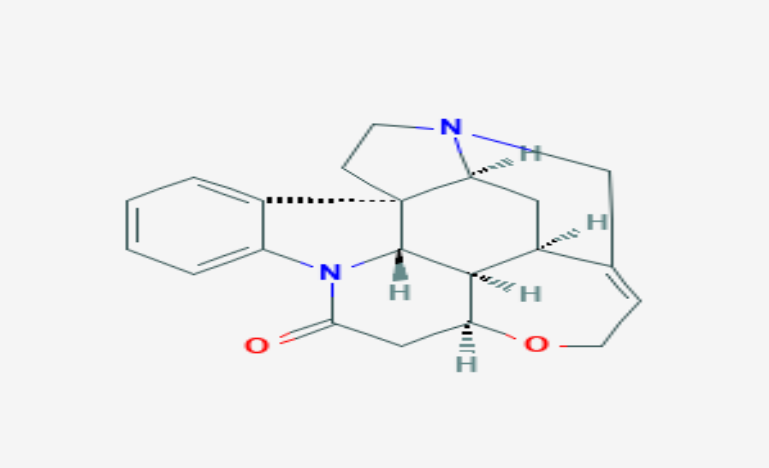
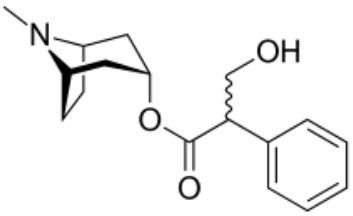
Strychnine

Strychnine - is a highly toxic, colorless, bitter, crystalline alkaloid used as a pesticide, particularly for killing small vertebrates such as birds and rodents. Strychnine, when inhaled, swallowed, or absorbed through the eyes or mouth, causes poisoning which results in muscular convulsions and eventually death through asphyxia.[5] While it has no known medicinal effects, in the past the convulsant effect was believed to be beneficial in small doses. The most common source is from the seeds of the Strychnos nux-vomica tree.



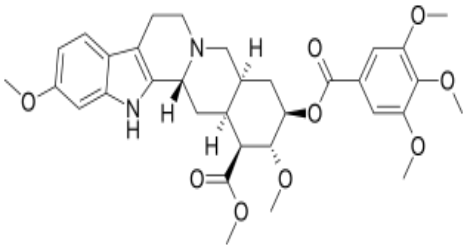
Atropine

Tropane alkaloids are toxic secondary metabolites produced by Solanaceae plants. Among them, plants from Datura genus produce significant amounts of scopolamine and hyoscyamine; the latter undergoes racemization to atropine during isolation. Because of their biological importance, toxic properties and commonly reported food and animal feed contamination by different Datura sp. organs, there is a constant need for reliable methods for the analysis of tropane alkaloids in many matrices. In the current study, three extraction and sample-clean up procedures for the determination of scopolamine and atropine in plant material were compared in terms of their effectiveness and repeatability.



Reserpine

Reserpine is an adrenergic blocking agent used to treat mild to moderate hypertension via the disruption of norepinephrine vesicular storage. The antihypertensive actions of **Reserpine** are a result of its ability to deplete catecholamines from peripheral sympathetic nerve endings.



Isolation of Reserpine

Roots are powdered & moisten with 10 % $NaHCo_3$ & ext. with benzene untill give positive reaction with HgI_2

↓

Conc. It & add ether & dil. HCl again conc. It & separate acid layer.

Again washed with ether. Make it alkaline with NH_3

↓

Then ext. with $CHCl_3$

↓

The $CHCl_3$ ext. washed with 10% Na_2CO_3

↓

Dry it & purify it by using methanol

↓

Get pure crystal of Reserpine

References

1. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach toEvaluation of Botanicals. Business Horizons, 2002. ISBN 8190078844.
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Lecture synopsis Sub: APET

Lecture No: 23

Name of topic/lesson – Application of Extraction Techniques

Subtopic: Chromatographic Separation Techniques

Objective: To Study Principle & Application of Column chromatography

Topic Outcomes: At the end of topic you will

1. Know the Principle of Column chromatography
2. able to explain the Instrumentation & application of Column chromatography

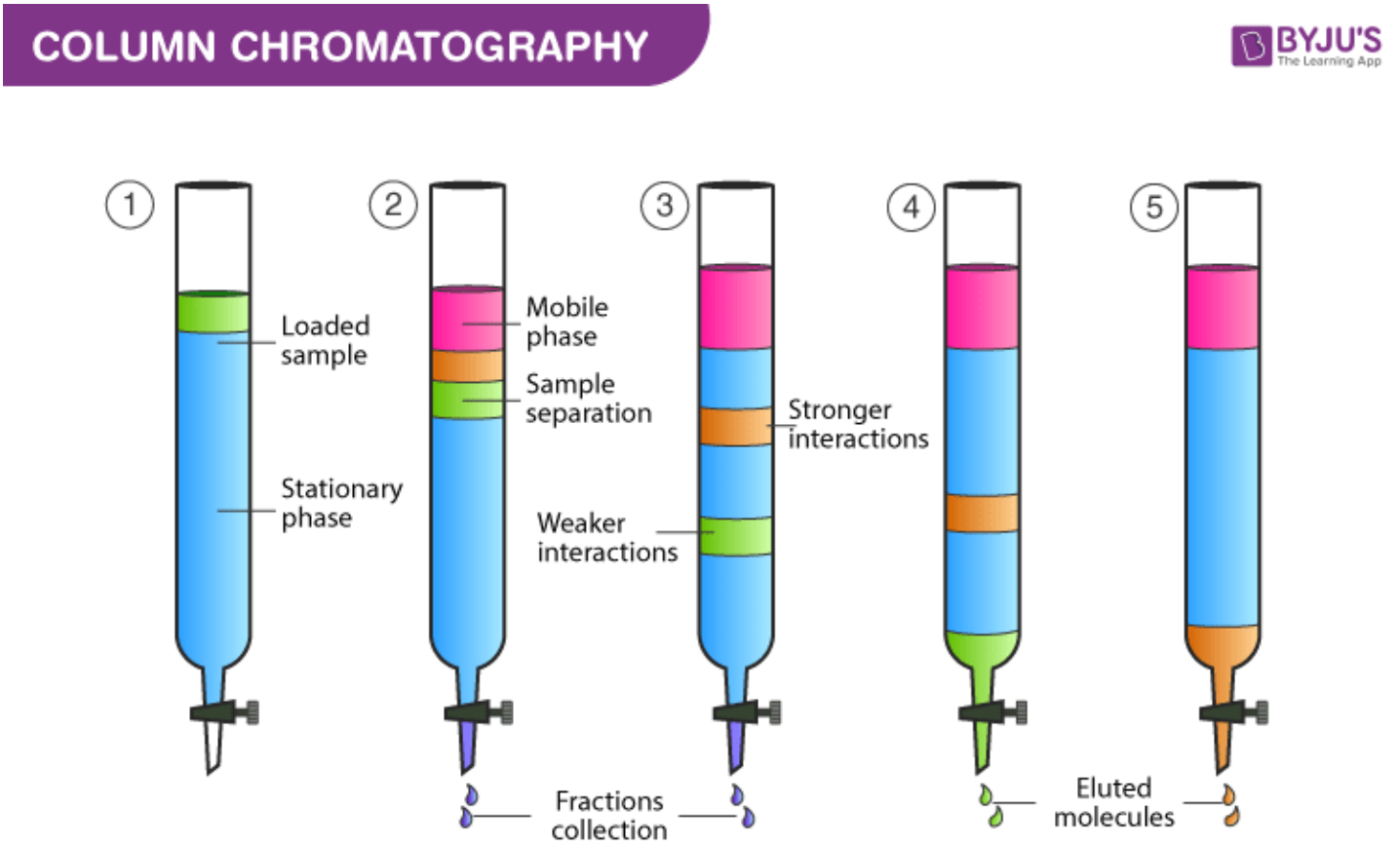
Column chromatography

is a common technique used to separate individual compounds from a mixture. You can use **column chromatography** on both a small or large scale to isolate and purify material for use on a later experiment.

stationary phase or adsorbent in column chromatography is a solid. The most common stationary phase for column chromatography is silica gel, the next most common being alumina. Cellulose powder has often been used in the past. A wide range of stationary phases are available in order to perform ion exchange chromatography, reversed-phase chromatography (RP), affinity chromatography or expanded bed adsorption (EBA).

The mobile phase or eluent is a solvent or a mixture of solvents used to move the compounds through the column. It is chosen so that the retention factor value of the compound of interest is roughly around 0.2 - 0.3 in order to minimize the time and the amount of eluent to run the chromatography. The eluent has also been chosen so that the different compounds can be separated effectively. The eluent is optimized in small scale pretests, often using thin layer chromatography (TLC) with the same stationary phase.

Principle of involved in this technique is separation of components by adsorbtion. The sample mixture is allowed to pass through a **column** of solid stationary phase under the force of a liquid mobile phase.



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Lecture synopsis Sub: APET

Lecture No: 24

Name of topic/lesson – Herbal drug Analysis

Subtopic: Types & Need, Meaning Of Identity, Purity, Potency & Safety

Objective: To Study Types & Need, Meaning Of Identity, Purity, Potency & Safety of Herbal drug Analysis

Topic Outcomes: At the end of topic you will

1. Know the Herbal deug Def, Evaluation parameters
2. able to explain the identity, purity, potency etc

Traditional herbal medicine and their preparations have been widely used for the thousands of years in developing and developed countries owing to its natural origin and lesser side effects or dissatisfaction with the results of synthetic drugs. However, one of the characteristics of oriental herbal medicine preparations is that all the herbal medicines, either presenting as single herbs or as collections of herbs in composite formulae, is extracted with boiling water during the decoction process. This may be the main reason why quality control of oriental herbal drugs is more difficult than that of western drug. As pointed in "General Guidelines for Methodologies on Research and Evaluation of Traditional Medicines (World Health Organization, 2000)", "Despite its existence and continued use over many centuries, and its popularity and extensive use during the last decade, traditional medicine has not been officially recognized in most countries. Consequently, education, training and research in this area have not been accorded due attention and support. The quantity and quality of the safety and efficacy data on traditional medicine are far from sufficient to meet the criteria needed to support its use world-wide. The active principles are extracted from the plants and purified for therapeutic utility for their selective pharmacological activity. So quality control of herbal crude drugs and their constituents is of great importance in modern system of medicine. Lack of proper standard parameters for the standardization of herbal preparation and several instances of substandard herbs, adulterated herbs come into existence. To meet new thrust of inquisitiveness, standardization of herbals is mandatory (Chaudhry, 1999; Kokate, 2005; Raina, 2003; Raven, 1999; Yan, 1999). www.intechopen.com 24 Drug Discovery Research in Pharmacognosy Hence every single herb needs to be quality checked to ascertain that it confirms to quality requirement and delivers the properties consistently. Standardization assures that products are reliable in terms of quality, efficacy, performance and safety. It is however observed that the drugs in commerce are frequently adulterated and do not comply with the standards prescribed for authentic drug.

Purity – the extent of foreign organic material present in a crude drug. • Importance of evaluation of crude drugs: •¬ Quality – the quantity of the active constituents present. ¬ Identity – identification of biological source of the drug. ¬ Purity – the extent of foreign

organic material present in a crude drug. • Importance of evaluation of crude drugs: • Determination of Biochemical variation in the drugs • Identification of deterioration due treatment and storage • Repoting Substitution and adulteration, as result of carelessness, ignorance and fraud Drug evaluation may be defined as the determination of identity, purity and quality of a drug. ¬ Quality – the quantity of the active constituents present. ¬ Identity – identification of biological source of the drug. ¬Drug evaluation may be defined as the determination of identity, purity and quality of a drug.

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1. Handa S. S., SumanPreet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh,Extraction technologies for medicinal & aromatic plants, International centrefor science and high technology, Trieste, Italy, 2008.
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Lecture synopsis Sub: APET

Lecture No: 25

Name of topic/lesson – Application of Extraction Techniques

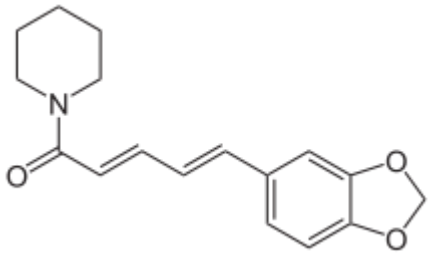
Subtopic: Piperine, Taxol, Sennosides.

Objective: To Study Source & Extraction Methods.

Topic Outcomes: At the end of topic you will

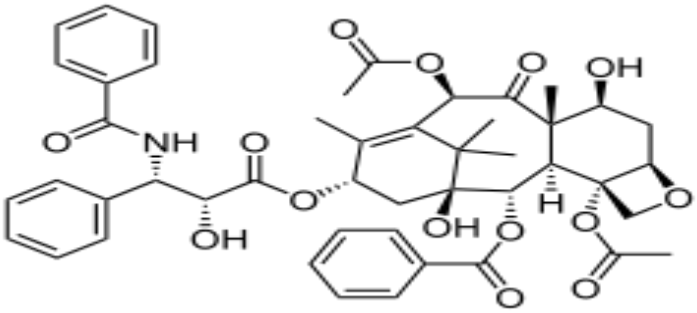
1. Know the extraction methods for Piperine, Taxol, Sennosides
2. able to explain the source, schematic representation of extraction methods.

Piperine is an alkaloid that gives black pepper (Piper nigrum) its pungency. It is slightly soluble in water and highly soluble in alcohol, chloroform and ether. Piperine has a long history of use in some types of traditional medicine. Its primary commercial use is in modern herbal medicine.



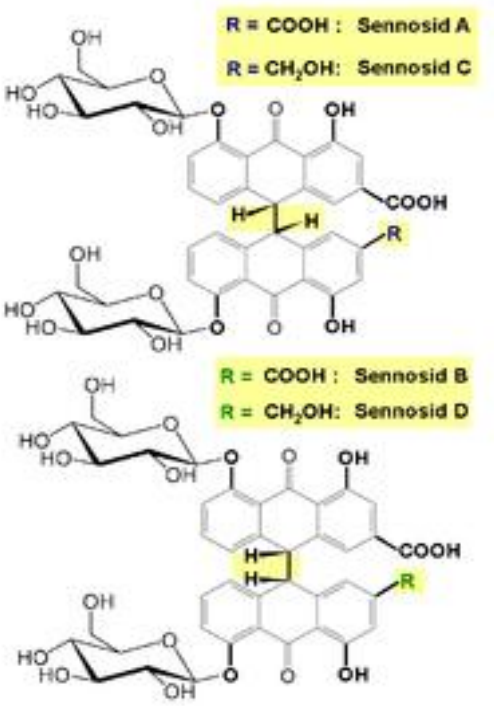
Taxol is an anti-cancer ("antineoplastic" or "cytotoxic") chemotherapy drug. Taxol is classified as a "plant alkaloid

USES Paclitaxel is approved in the UK for ovarian, breast,
lung, bladder, prostate, melanoma, esophageal, and other types of solid tumor cancers as well as Kaposi's sarcoma



Senna glycoside, also known as sennoside or senna, is a medication used to
treat constipation and empty the large intestine before surgery. The medication is taken by mouth or via the rectum. It typically begins working in minutes when given by rectum and within twelve hours when given by mouth. It is a weaker laxative than bisacodyl or castor oil.

Common side effects of senna glycoside include abdominal cramps. It is not recommended for long-term use, as it may result in poor bowel function or electrolyte problems. While no harm has been found to result from use while breastfeeding, such use is not typically recommended. It is not typically recommended in children.[1] Senna may change urine to a somewhat reddish color. Senna derivatives are a type of stimulant laxative and are of the anthraquinone type. While its mechanism of action is not entirely clear, senna is thought to act by increasing fluid secretion within and contraction of the large intestine



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Lecture synopsis Sub: APET

Lecture No: 26

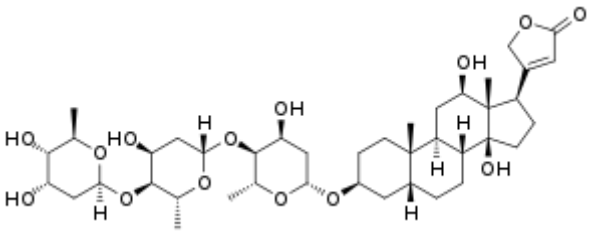
Name of topic/lesson – Application of Extraction Techniques
Subtopic: Digoxine, Diosgenin
Objective: To Study Source & Extraction Methods.
Topic Outcomes: At the end of topic you will

1. Know the extraction methods for Digoxine, Diosgenin

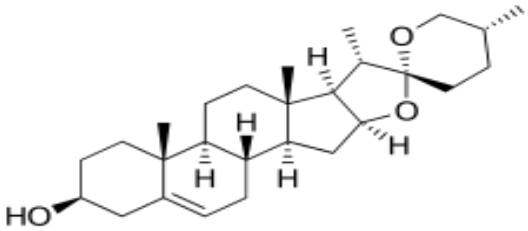
2. able to explain the source, schematic representation of extraction methods.

Digoxin, sold under the brand name Lanoxin among others, is a medication used to treat various heart conditions. Most frequently it is used for atrial fibrillation, atrial flutter, and heart failure. Digoxin is taken by mouth or by injection into a vein.

Common side effects include breast enlargement with other side effects generally due to an excessive dose. These side effects may include loss of appetite, nausea, trouble seeing, confusion, and an irregular heartbeat. Greater care is required in older people and those with poor kidney function. It is unclear whether use during pregnancy is safe. Digoxin is in the cardiac glycoside family of medications. The most common indications for digoxin are atrial fibrillation and atrial flutter with rapid ventricular response, though beta blockers and/or calcium channel blockers are often preferred



Diosgenin, a phytosteroid sapogenin, is the product of hydrolysis by acids, strong bases, or enzymes of saponins, extracted from the tubers of Dioscorea wild yam, such as the Kokoro. The sugar-free (aglycone) product of such hydrolysis, diosgenin is used for the commercial synthesis of cortisone, pregnenolone, progesterone, and other steroid products.



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Lecture synopsis Sub: APET

Lecture No: 27

Name of topic/lesson – Herbal drug analysis

Subtopic: proximate phytochemical analysis: meaning, significance & method

Objective: To Study proximate phytochemical analysis: meaning, significance & method

Topic Outcomes: At the end of topic you will

1. Know the meaning, significance of proximate phytochemical analysis
2. able to explain the methods of proximate phytochemical analysis.

Nature has been a source of medicinal agents since time immemorial. The importance of herbs in the management of human ailments cannot be over emphasized. Plants can act as herbal drugs, neutraceuticals, food supplements, folk medicine, pharmaceuticals intermediates and new chemical entities for synthetic drugs, sweetness, fragrance and number of healthcare products. The medicinal power of plants mainly depends on phytochemical constituents that have great pharmacological significance Phytochemical Screening Phytochemical analysis for various phytoconstituents of the extracts was undertaken using standard qualitative methods. The extracts were screened for the presence of biologically active compounds like alkaloids, flavonoids, tannins, glycosides, terpenoids, steroids, fat and oil, saponins, protein etc.

successive solvent extraction

Extraction methods used pharmaceutically involves the separation of medicinally active portions of plant tissues from the inactive/inert components by using selective solvents. During **extraction**, solvents diffuse into the solid plant material and solubilise compounds with similar polarity.

Lecture synopsis Sub: APET

Lecture No: 28

Name of topic/lesson – Herbal drug analysis

Subtopic: adulteration:definition & types of adulteration.

Objective: To Study adulteration:definition & types of adulteration.

Topic Outcomes: At the end of topic you will

1. Know the Definition of Adulteration.

2. able to explain the Types of Adulteration.

An adulterant is a substance found within other substances such as food, cosmetics, pharmaceuticals, fuel or other chemicals that compromises the safety or effectiveness of said substance.

It will not normally be present in any specification or declared contents of the substance, and may not be legally allowed. The addition of adulterants is called adulteration. The most common reason for adulteration is the use by manufacturers of undeclared materials that are cheaper than the correct and declared ones. The adulterants may be harmful, or reduce the potency of the product, or they may be harmless.

Adulterants added to reduce the amount of expensive product in illicit drugs are called cutting agents. Deliberate addition of toxic adulterants to food or other products for human consumption is poisoning.

Types of adulterants:

1. **Substitution with substandard commercial varieties(**.Examples: *Capsicum minimum* replaced by *Capsicum annuum*. *Indian senna*replaced by *Arabian senna* or *Dog senna*.)

2. **Substitution with superficially similar inferior drugs(**Examples: Bees wax is adulterated with Japan wax. Mother cloves and clove stalks are mixed with cloves.*Saffron* is adulterated with flowers of *Carthamus tinctorius*.)

3. **Substitution with artificially manufactured substance.** (Examples: Compressed chicory is used instead of coffee. Paraffin wax is made yellow and used instead of Bees wax.)

4. **Substitution of exhausted drugs:** The same drug is admixture but it is avoid of any medicinally active constituents as they are already extracted out e.g., volatile oil containing drugs
5. Sometimes, some synthetic chemicals are used to enhance the natural character like the addition of citral to citral oil.
6. **Presence of vegetative matter from the same plant:** Sometimes, other plants or parts from the same plant growing alone with medicinal plants are allowed to get mixed with drug due to their resembling colour, odour, and in some cases compounds.
7. Harmful adulterants: Sometimes, waste from market are mixed with authentic drugs.
8. **Adulteration of powders:** Sometimes powdered forms may also be adulterated.

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Lecture synopsis Sub: APET

Lecture No: 29

Name of topic/lesson – Application of Extraction Techniques

Subtopic: andrographolides, artemisinin

Objective: To Study Source & Extraction Methods.

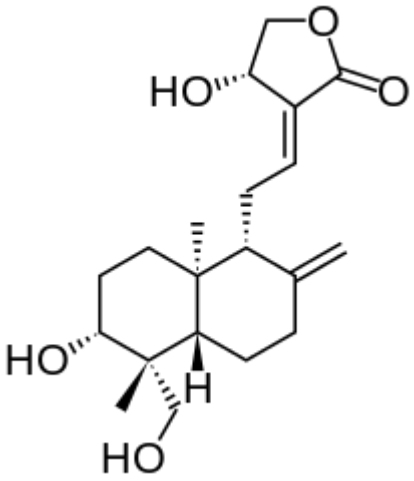
Topic Outcomes: At the end of topic you will

1. Know the extraction methods for andrographolides, artemisinin
2. able to explain the source, schematic representation of extraction methods.

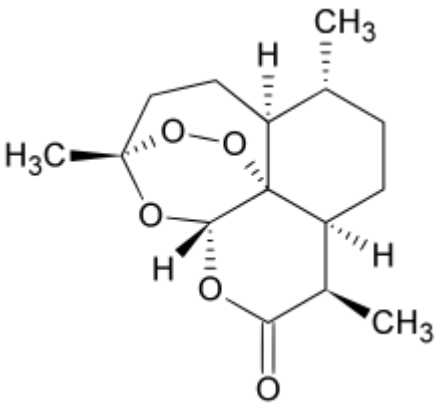
Andrographolide

Andrographolide is a diterpenoid that has been isolated from the stem and leaves of Andrographis paniculata. Andrographolide is an extremely bitter substance.

Andrographolide has been studied for its effects on cell signaling, immunomodulation, and stroke. Study has shown that andrographlide may bind to a spectrum of protein targets including NF-κB and actin by covalent modification



Artemisinin and its semisynthetic derivatives are a group of drugs used against malaria due to Plasmodium falciparum. Chemically, artemisinin is a sesquiterpene lactone containing an unusual peroxide bridge. This endoperoxide 1,2,4-trioxane ring is responsible for the drug's mechanism of action.



Few other natural compounds with such a peroxide bridge are known.

Artemisinin and its derivatives have been used for the treatment of malarial and parastic worm (helminth) infections. They have the advantage over other drugs in having an ability to kill faster and kill all the life cycle stages of the parasites. But low bioavailability, poor pharmacokinetic properties and high cost of the drugs are major drawbacks of their use.

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Lecture synopsis Sub: APET

Lecture No: 30

Name of topic/lesson – Herbal drug analysis

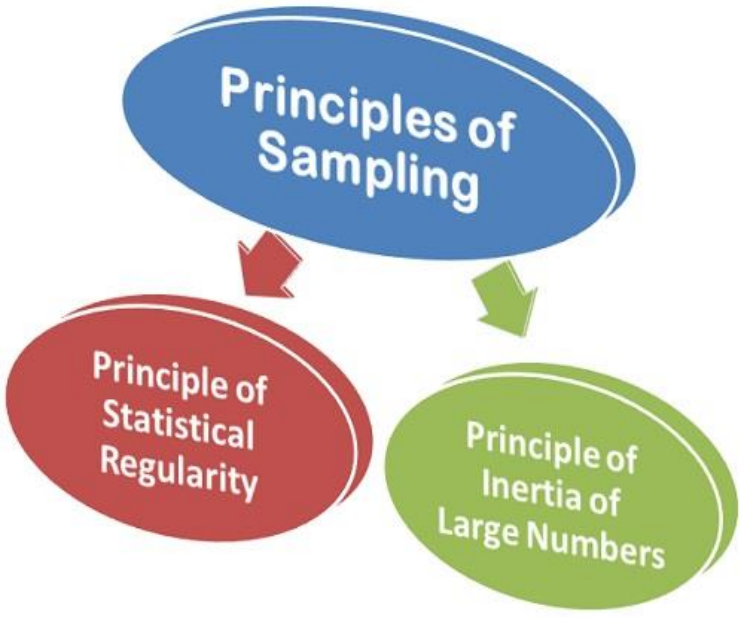
Subtopic: Sampling techniques: Principle & procedure of sampling

Objective: To Study Sampling techniques: Principle & procedure of sampling
Topic Outcomes: At the end of topic you will
1. Know the Principle & procedure of sampling.

Definition: The **Sampling** is a statistical analysis tool wherein the data are collected from a few representative items of the universe, called as a sample, on the basis of which the characteristic of the entire population can be ascertained. Sampling is the act, process, or technique of selecting a suitable sample, or a representative part of a population for the purpose of determining parameters or characteristics of the whole populations.
purpose• Economy : taking a sample requires a fewer resources than a census.• Timeliness : A sample may provide you with needed information quickly• The large size of many populations : many populations about which inferences must be made are quite large• Inaccessibility of some of the population : There are some populations that are so difficult to get access to that only a sample can be used

Principles of Sampling

There are two important principles of sampling on which the sampling theory depends on:



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Lecture synopsis Sub: APET

Lecture No: 31

Name of topic/lesson – Herbal drug analysis

Subtopic: Quality control parameters of herbal drugs: Principle, procedure &significance involved in determination of foreign matters, ash values

Objective: To Study Quality control parameters of herbal drugs

Topic Outcomes: At the end of topic you will

1. Know the Principle & procedure of foreign matters, ash values

2. able to explain the significance involved in determination of foreign matters, ash values

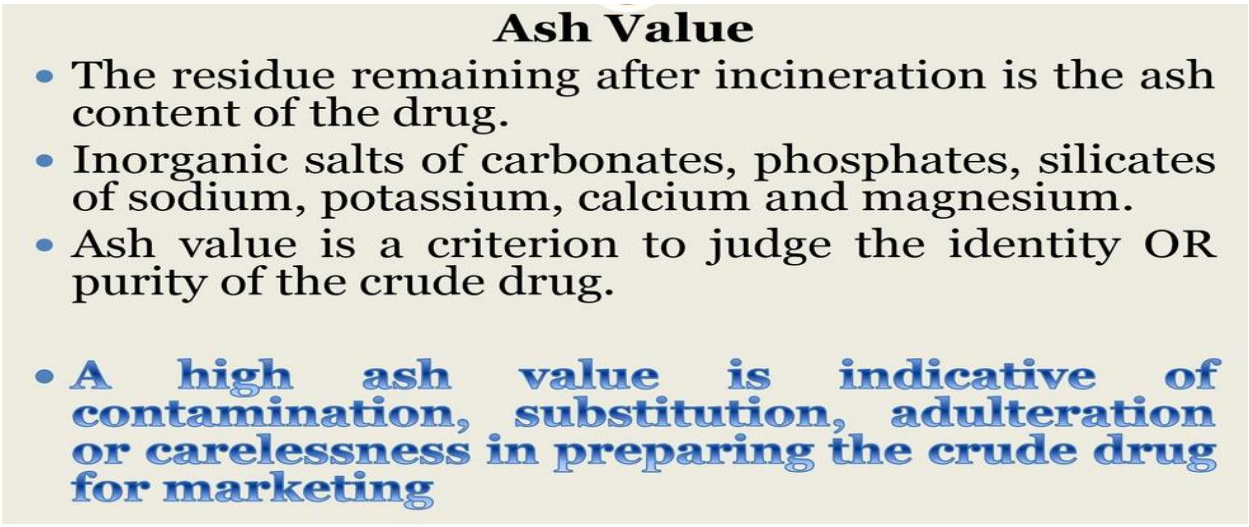
Foreign matter is defined as any kind of outside contaminant introduced to a food product at any point in its production or distribution. Problems with **foreign matter** may arise from equipment design flaws, structural issues, or employee handling.

Foreign matter is material consisting of any of the following –

(1) The biological origin of which isthe same asthatspecified in the monograph concerned but the appearance or botanical part is different.

(2) The biological origin of which differs from that specified in the monograph concerned.

(3) Foreign mineral matters such as stones, sand, lumps of soil.



Ash values are helpful in determining the quality and purity of crude drugs, especially in powder form. The objective of ashing vegetable drugs is to remove all traces of organic matter, which may otherwise interfere in an analytical determination. On incineration, crude drugs normally leave an ash usually consisting of carbonates, phosphates and silicates of sodium, potassium, calcium and magnesium.

References:

1. Quality control methods for medicinal plant materials, World HealthOrganization, Geneva, 1998. ISBN 9241545100
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Lecture synopsis Sub: APET

Lecture No: 32

Name of topic/lesson – Application of extraction techniques

Subtopic: boswellic acid,podophyllotoxin, curcumin

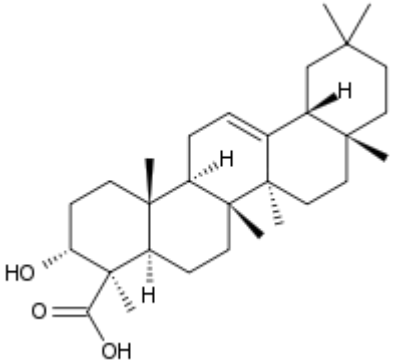
Objective: To Study boswellic acid,podophyllotoxin, curcumin.

Topic Outcomes: At the end of topic you will

1. able to draw schematic representation

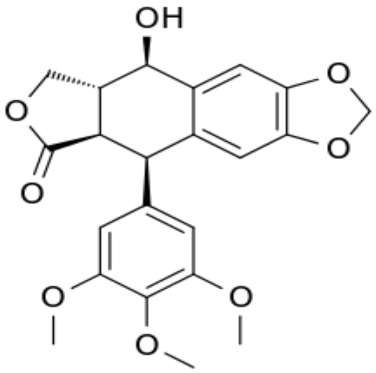
2. able to Explain source material & extraction methods of photochemical specified.

Boswellic acids are a series of pentacyclic triterpene molecules that are produced by plants in the genus *Boswellia*. The boswellic acids are organic acids, consisting of a pentacyclic triterpene, a carboxyl group and at least one other functional group. Beta-boswellic acid, keto-beta-boswellic acid, and acetyl-keto-beta-boswellic acid (AKBA) have been indicated in apoptosis of cancer cells, in particular brain tumors and cells affected by leukemia or colon cancer. Boswellic acids are also thought to decrease the symptoms of asthma.



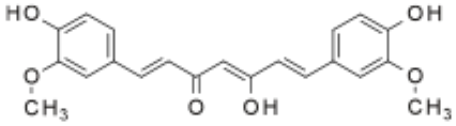
Podophyllotoxin

It is a non-alkaloid toxin lignan extracted from the roots and rhizomes of Podophyllum species. A less refined form known as podophyllum resin is also available, but has greater side effects.



Podophyllotoxin and its derivatives are used as cathartic, purgative, antiviral agent, vesicant, antihelmint hic, and antitumor agents. Podophyllotoxin derived antitumor agents include etoposide and teniposide.

Curcumin is a bright yellow chemical produced by Curcuma longa plants. It is the principal curcuminoid of turmeric (Curcuma longa), a member of the ginger family, Zingiberaceae. It is sold as an herbal supplement, cosmetics ingredient, food flavoring, and food coloring.



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Lecture synopsis Sub: APET

Lecture No: 33

Name of topic/lesson – Herbal drug analysis

Subtopic: Quality control parameters of herbal drugs: Principle, procedure &significance involved in determination of extractablematters, moisture content, volatile matters

Objective: To Study Quality control parameters of herbal drugs

Topic Outcomes: At the end of topic you will

1. Know the Principle, significance & procedure of extractable matters, moisture content, volatile matters

2. Able to apply theoretical knowledge obtained for extraction of photochemical

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Extractable matters :

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

moisture content & Volatile matters:

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

References

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Lecture synopsis Sub: APET

Lecture No: 34

Name of topic/lesson – Herbal drug analysis

Subtopic: Quality control parameters of herbal drugs: Principle, procedure &significance involved in determination of volatile oil, bitterness value, haemolytic activity

Objective: To Study Quality control parameters of herbal drugs

Topic Outcomes: At the end of topic you will

1. Know the Principle, significance & procedure of volatile oil, bitterness value, haemolytic activity matters

2. Able to apply theoretical knowledge obtained for extraction of phytochemicals

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volatile oil

Volatile oils are characterized by their odour, oil-like appearance and ability to volatilize at room temperature. Chemically, they are usually composed of mixtures of, for example, monoterpenes, sesquiterpenes and their oxygenated derivatives. Aromatic compounds predominate in certain volatile oils. Because they are considered to be the “essence” of the herbal material, and are often biologically active, they are also known as “essential oils”. The term “volatile oil” is preferred because it is more specific and describes the physical properties.

bitterness value

Herbal materials that have a strong bitter taste (“bitters”) are employed therapeutically, mostly as appetizing agents. Their bitterness stimulates secretions in the gastrointestinal tract, especially of gastric juice. Bitter substances can be determined chemically. However, since they are mostly composed of two or more constituents with various degrees of bitterness, it is first necessary to measure total bitterness by taste. The bitter properties of herbal material are determined by comparing the threshold bitter concentration of an extract of the materials with that of a dilute solution of quinine hydrochloride R. The bitterness value is expressed in units equivalent to the bitterness of a solution containing 1 g of quinine hydrochloride R in 2000 ml.

haemolytic activity

Many herbal materials, especially those derived from the families Caryophyllaceae, Araliaceae, Sapindaceae, Primulaceae, and Dioscoreaceae contain saponins. The most characteristic property of saponins is their ability to cause haemolysis: when added to a suspension of blood, saponins produce changes in erythrocyte membranes, causing haemoglobin to diffuse into the surrounding medium. The haemolytic activity of herbal materials, or a preparation containing saponins, is determined by comparison with that of a reference material, saponin R, which has a haemolytic activity of 1000 units per g. A suspension of erythrocytes is mixed with equal volumes of a serial dilution of the herbal material extract. The lowest concentration to effect complete haemolysis is determined after allowing the mixtures to stand for a given period of time. A similar test is carried out simultaneously with saponin R.

References

1. Quality control methods for medicinal plant materials, World HealthOrganization, Geneva, 1998. ISBN 9241545100

Lecture synopsis Sub: APET

Lecture No: 35

Name of topic/lesson – Application of extraction techniques

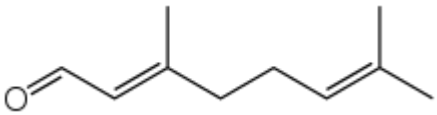
Subtopic: citral, eugenol& menthol

Objective: To Study citral, eugenol& menthol

Topic Outcomes: At the end of topic you will

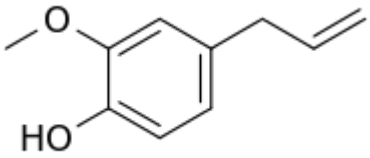
1. able to draw schematic representation of citral, eugenol & menthol
2. able to Explain source material & extraction methods of photochemical specified.

Citral is a main component of citrus fruit's peel oil. It is especially found in orange peel. **Citral** is a mixture of neral and geranial which are monoterpene aldehydes (Maarse, 1991). **Citral** has been applied to food, cosmetics, and beverages as a natural ingredient for its passionate lemon aroma and flavor.



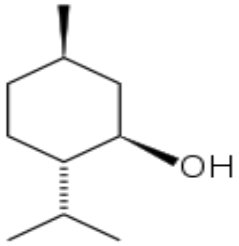
Geranial has a strong lemon (citrus) odor. Neral's lemon odor is less intense, but sweeter. Citral is therefore an aroma compound used in perfumery for its citrus effect. Citral is also used as a flavor and for fortifying lemon oil. It also has strong antimicrobial qualities, and pheromonal effects in insects.
Citral is used in the synthesis of vitamin A, lycopene, ionone, and methylionone, to mask the smell of smoke.

Eugenol is a naturally occurring phenolic molecule found in several plants such as cinnamon, clove, and bay leaves. It has been used as a topical antiseptic as a counter-irritant and in dental preparations with zinc oxide for root canal sealing and pain control.



Eugenol is used in perfumes, flavorings, and essential oils. It is also used as a local antiseptic and anaesthetic. Eugenol can be combined with zinc oxide to form zinc oxide eugenol which has restorative and prosthodontic applications in dentistry. For persons with a dry socket as a complication of tooth extraction, packing the dry socket with a eugenol-zinc oxide paste on iodoform gauze is effective for reducing acute pain. Eugenol-zinc oxide paste is also used for root canal sealing.

Menthol is an organic compound made synthetically or obtained from peppermint or mint oils with flavoring and local anesthetic properties. When added to pharmaceuticals and foods, **menthol** functions as a fortifier for peppermint flavors.



Menthol is included in many products, and for a variety of reasons. These include:

- In nonprescription products for short-term relief of minor sore throat and minor mouth or throat irritation.
  - Examples: lip balms and cough medicines

References

1. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach toEvaluation of Botanicals. Business Horizons, 2002. ISBN 8190078844.
2. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335
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Lecture synopsis Sub: APET

Lecture No: 36

Name of topic/lesson – Herbal drug analysis

Subtopic: Quality control parameters of herbal drugs: Principle, procedure &significance involved in determination of tannin content, swelling index, foaming index

Objective: To Study Quality control parameters of herbal drugs

Topic Outcomes: At the end of topic you will

1. Know the Principle, significance & procedure of tannin content, swelling index, foaming index
2. Able to apply theoretical knowledge obtained for extraction of phytochemicals

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Tannins (or tanning substances) are substances capable of turning animal hides into leather by binding proteins to form water-insoluble substances that are resistant to proteolytic enzymes. This process, when applied to living tissue, is known as an "astringent" action and is the reason for the therapeutic application of tannins. Chemically, tannins are complex substances; they usually occur as mixtures of polyphenols that are difficult to separate and crystallize. They are easily oxidized and polymerized in solution; if this happens they lose much of their astringent effect and are therefore of little therapeutic value.Many herbal materials are of specific therapeutic or pharmaceutical utility becauseof their swelling properties − especially gums and those containing an appreciable amount of mucilage, pectin or hemicellulose.

The **swelling index** is the volume in ml taken up by the swelling of 1 g of herbal material under specified conditions. Its determination is based on the addition of water or a swelling agent as specified in the test procedure for each individual herbal material (either whole, cut or pulverized). Using a glass-stoppered measuring cylinder, the material is shaken repeatedly for 1 hour and then allowed to stand for a required period of time. The volume of the mixture (in ml) is then read. The mixing of whole herbal material with the swelling agent is easy to achieve, but cut or pulverized material requires vigorous shaking at specified intervals to ensure even distribution of the material in the swelling agent.

Foaming Index Many herbal materials contain saponins that can cause a persistent foam when an aqueous decoction is shaken. The foaming ability of an aqueous decoction of herbal materials and their extracts is measured in terms of a foaming index.

References

1. Quality control methods for medicinal plant materials, World HealthOrganization, Geneva, 1998.

Lecture synopsis Sub: APET

Lecture No: 37

Name of topic/lesson – Herbal drug analysis

Subtopic: Quality control parameters of herbal drugs: Principle, procedure &significance involved in determination of pesticide residues, arsenic and toxicmetals

Objective: To Study Quality control parameters of herbal drugs

Topic Outcomes: At the end of topic you will

1. Know the Principle, significance & procedure of pesticide residues, arsenic and toxic metals.
2. Able to apply theoretical knowledge obtained for extraction of photochemical

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Chromatography (mostly column and gas) is recommended as the principal method for the determination of pesticide residues. These methods may be coupled with mass spectrometry (MS). Samples are extracted by a standard procedure, impurities are removed by partition and/or adsorption, and the presence of a moderately broad spectrum of pesticides is measured in a single determination. However, these techniques are not universally applicable. Some pesticides are satisfactorily carried through the extraction and clean-up procedures, others are recovered with a poor yield, and some are lost entirely. Following chromatography, the separations may not always be complete, pesticides may decompose or metabolize, and many of the metabolic products are still unknown. Consequently, as a result of limitations in the analytical technique and incomplete knowledge of pesticide interactions with the environment, it is not yet possible to apply an integrated set of methods that will be satisfactory in all situations.

Arsenic is abundant in nature and its presence in herbal materials should be no different to its wide occurrence in foods. A popular test method relies on the digestion of the herbal material matrix followed by subjection of the digestate to a comparative colorimetric test in a special apparatus.

The test method described below uses colorimetry and does not use toxic mercuric bromide paper. The method uses N-N-diethylmethyldithiocarbamate in pyridine and it reacts with hydrogen arsenide to afford a red–purple complex. The limit is expressed in terms of arsenic (III) trioxide (As_2O_3).

References

1. Quality control methods for medicinal plant materials, World Health Organization, Geneva, 1998.

Lecture synopsis Sub: APET

Lecture No: 38

Name of topic/lesson – Application of extraction techniques

Subtopic: Extraction by steam distillation: Peppermint oil, Extraction by enfleurage method: Rose oil

Objective: To Study Extraction by steam distillation, Extraction by enfleurage method

Topic Outcomes: At the end of topic you will

1. able to draw schematic representation of Peppermint oil, Rose oil
2. able to Explain source material & extraction methods of photochemical specified.

Enfleurage is a process that uses odorless fats that are solid at room temperature to capture the fragrant compounds exuded by plants. The process can be "cold" enfleurage or "hot" enfleurage.

- In this method, an odorless fixed oil or fat is spread in a thin layer on glass plates.
- The flower petals are placed on the fat for few hours.
- Then, repeatedly, the old petals are removed, and a new layer of petals is introduced.
- When the fat absorbs maximum fragrance, the oil may be removed by extraction with alcohol.
- It was formerly widely used in the production of perfumes and pomades.

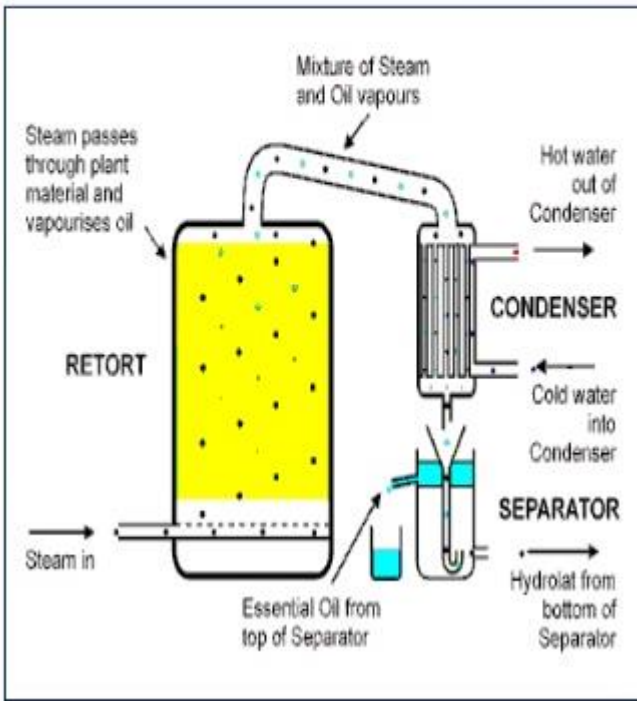
Steam Distillation is the most popular method used to extract and isolate essential oils from plants for use in natural products. This happens when the steam vaporizes the plant material's volatile compounds, which eventually go through a condensation and collection process.

Extraction of Peppermint oil

Peppermint oil is extracted from the whole plant above ground just before flowering.

The oil is extracted commercially by **steam distillation**

- Fresh or partly dried plant herb
- Yield is 0.1 - 1.0 %.



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Lecture synopsis Sub: APET

Lecture No: 39

Name of topic/lesson – Herbal drug analysis

Subtopic: Micro-organisms, aflatoxins, Radioactive contamination
Objective: To Study Micro-organisms, aflatoxins, Radioactive contamination Topic Outcomes:
At the end of topic you will
1. Know the Micro-organisms, aflatoxins, Radioactive contamination

2. Able to apply theoretical knowledge obtained for extraction of photochemical

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A microorganism, or microbe,[a] is a microscopic organism, which may exist in its single-celled form or in a colony of cells.

The possible existence of unseen microbial life was suspected from ancient times, such as in Jain scriptures from 6th century BC India and the 1st century BC book *On Agriculture* by Marcus Terentius Varro. Microbiology, the scientific study of microorganisms, began with their observation under the microscope in the 1670s by Antonie van Leeuwenhoek. In the 1850s, Louis Pasteur found that microorganisms caused food spoilage, debunking the theory of spontaneous generation. In the 1880s, Robert Koch discovered that microorganisms caused the diseases tuberculosis, cholera and anthrax.

Aflatoxins are poisonous carcinogens that are produced by certain molds (*Aspergillus flavus* and *Aspergillus parasiticus*) which grow in soil, decaying vegetation, hay, and grains. They are regularly found in improperly stored staple commodities such as cassava, chili peppers, corn, cottonseed, millet, peanuts, rice, sesame seeds, sorghum, sunflower seeds, tree nuts, wheat, and a variety of spices. When contaminated food is processed, aflatoxins enter the general food supply where they have been found in both pet and human foods, as well as in feedstocks for agricultural animals. Animals fed contaminated food can pass aflatoxin transformation products into eggs, milk products, and meat. For example, contaminated poultry feed is suspected in the findings of high percentages of samples of aflatoxin-contaminated chicken meat and eggs in Pakistan.

Radioactive contamination, also called radiological contamination, is the deposition of, or presence of radioactive substances on surfaces or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable (from the International Atomic Energy Agency (IAEA) definition).

Such contamination presents a hazard because of the radioactive decay of the contaminants, which produces such harmful effects as ionising radiation (namely α, β, and γ rays) and free neutrons. The degree of hazard is determined by the concentration of the contaminants, the energy of the radiation being emitted, the type of radiation, and the proximity of the contamination to organs of the body. It is important to be clear that the contamination gives rise to the radiation hazard, and the terms "radiation" and "contamination" are not interchangeable.

References

1. Quality control methods for medicinal plant materials, World Health Organization, Geneva, 1998.
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Lecture synopsis Sub: APET

Lecture No: 41

Name of topic/lesson – Overview of Good Practices for Pharmaceutical Q.C. Laboratories

Subtopic: GMP

Objective: To Study GMP

Topic Outcomes: At the end of topic you will

able to Understand meaning & significance of 'GMP'

Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS) MasterControl Inc. is a leading global provider of GxP process management software. Natural science companies regulated by the FDA and ISO know just how important regulatory compliance is to success. WHO-GMP certification – a Misnomer! The Good Manufacturing Practice (GMP) is a system (and part of quality assurance programme) to ensure that the pharmaceutical products are consistently produced and controlled according to quality standard. The first WHO GMP was developed during 1967-69 and revised it in 1975.

References

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2. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335
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Lecture synopsis Sub: APET

Lecture No: 42

Name of topic/lesson – Overview of Good Practices for Pharmaceutical Q.C. Laboratories

Subtopic: GMP

Objective: To Study GMP

Topic Outcomes: At the end of topic you will

able to Understand meaning & significance of 'GMP'

GMP refers to the **Good Manufacturing Practice** Regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act (See Chapter IV for food, and Chapter V, Subchapters A, B, C, D, and E for drugs and devices.) These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mixups, and errors. This protects the consumer from purchasing a product which is not effective or even dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

GMP regulations address issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

GMP is also sometimes referred to as "**cGMP**". The "c" stands for "current," reminding manufacturers that they must employ technologies and systems which are up-to-date in order to comply with the regulation. Systems and equipment used to prevent contamination, mixups, and errors, which may have been first-rate 20 years ago may be less than adequate by current standards. GMP protects patients. GMP ensures that they receive medicinal products of uncompromised high quality. Compliance with these quality standards is imperative during the manufacture, processing, packaging and storage of medicinal products. Manufacturing authorisation will be denied to any company that fails to comply with GMP regulations. This is governed all over the world by acts of law, regulations and guidelines issued by government bodies, ministries and international organisations. Their goal is to put safe and effective medicinal products on the market with no harm to the patients.

References

1. Quality control methods for medicinal plant materials, World Health Organization, Geneva, 1998.
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Lecture synopsis Sub: APET

Lecture No: 43

Name of topic/lesson –Extraction by SCF

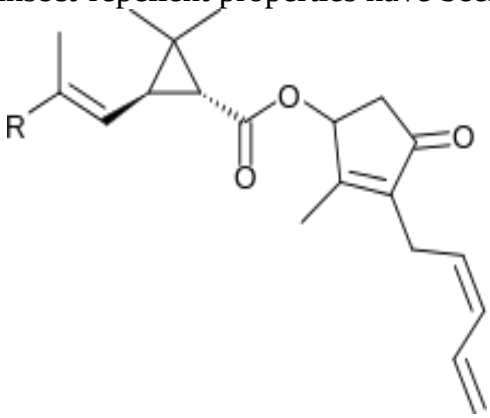
Subtopic: pyrethrins, Lycopenes

Objective: To Study Extraction pyrethrins, Lycopenes

Topic Outcomes: At the end of topic you will

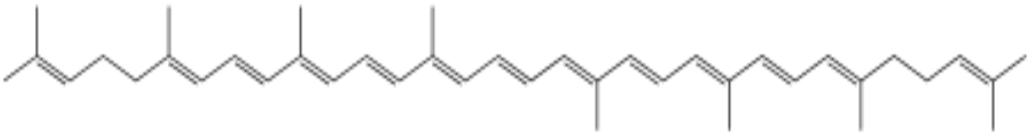
1. able to draw schematic representation of pyrethrins, Lycopenes
2. able to Explain source material & extraction methods of photochemical specified.

The pyrethrins are a class of organic compounds normally derived from *Chrysanthemum cinerariifolium* that have potent insecticidal activity by targeting the nervous systems of insects. Pyrethrin naturally occurs in chrysanthemum flowers and is often considered an organic insecticide when it is not combined with piperonyl butoxide or other synthetic adjuvants. Their insecticidal and insect-repellent properties have been known and used for thousands of years.



Pyrethrin is most commonly used as an insecticide and has been used for this purpose since the 1900s. In the 1800s, it was known as "Persian powder", "Persian pellitory", and "zacherlin". Pyrethrins delay the closure of voltage-gated sodium channels in the nerve cells of insects, resulting in repeated and extended nerve firings. This hyperexcitation causes the death of the insect due to loss of motor coordination and paralysis.

Lycopene (from the neo-Latin Lycopersicum, the tomato species) is a bright red carotenoid hydrocarbon found in tomatoes and other red fruits and vegetables, such as red carrots, watermelons, gac melons, and papayas, but it is not present in strawberries or cherries. Although lycopene is chemically a carotene, it has no vitamin A activity. Foods that are not red may also contain lycopene, such as asparagus and parsley



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Lecture synopsis Sub: APET

Lecture No: 44

Name of topic/lesson – Overview of Good Practices for Pharmaceutical Q.C. Laboratories

Subtopic: GMP

Objective: To Study GMP

Topic Outcomes: At the end of topic you will

able to Understand meaning & significance of 'GMP'

This guideline is intended to help manufacturers implementing modern quality systems and risk management approaches to meet the requirements of quality products to ensure their intended purpose and to protect the public health. The requirement in this guideline is established based on the mandate given to the Authority as stipulated in the Proclamation Number 661/2009 for the establishment of Food, Medicines and Healthcare Products in Ethiopia. GMP ensures that quality is built into the organization and processes involved in the manufacture of the products and all those operations should be carried out strictly according to cGMP. Principle Only the holder of a manufacturing authorisation must manufacture pharmaceutical productsso as to ensure that they are fit for their intended use, comply with the requirements of theMarketing Authorisation and do not place the user at risk due to inadequate safety, quality orefficacy.

The attainment of this quality objective is the responsibility of top management and requires the participation and commitment of staff working in different departments of the company.

To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice, Quality Control and Quality Risk Management. It should be fully documented and its effectiveness monitored. All parts of the Quality Assurance systems should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. There are additional legal responsibilities for the holder of the manufacturing authorisation and for the authorised person(s).

References

1. Good Manufacturing Practice Guideline For Pharmaceutical Products, Ethiopian Food, Medicine & Healthcare Administration & Control Authority (EFMHACA)
2. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335
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Lecture No: 45

Name of topic/lesson – Overview of Good Practices for Pharmaceutical Q.C. Laboratories

Subtopic: GMP

Objective: To Study GMP

Topic Outcomes: At the end of topic you will

able to Understand meaning & significance of 'GMP'

Good Manufacturing Practice for Products

Good Manufacturing Practice is that part of Quality Assurance which ensures that Medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that: a) All manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications and/or marketing authorization; b) Critical steps of manufacturing processes and significant changes to the process are validated; c) All necessary facilities for GMP are provided including: i. appropriately qualified and trained personnel; ii. adequate premises and space; iii. suitable equipment and services; iv. correct materials, containers and labels; v. approved procedures and instructions; d) Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided; e) Operators are trained to carry out procedures correctly; f) Records are made, manually and/or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected. Any significant deviations are fully recorded and investigated; g) Records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form; h) The distribution (wholesaling) of the products minimises any risk to their quality; i) A system is available to recall any batch of product, from sale or supply; j) Complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent re-occurrence.

References

1. Good Manufacturing Practice Guideline For Pharmaceutical Products, Ethiopian Food, Medicine & Healthcare Administration & Control Authority (EFMHACA)

2. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335
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Lecture synopsis Sub: APET

Lecture No: 46

Name of topic/lesson – Ultrasound-assisted & Microwave-assisted water extraction

Subtopic: Isoflavones of soy & Polyphenols of green tea

Objective: To Study Isoflavones of soy & Polyphenols of green tea

Topic Outcomes: At the end of topic you will

able to explain various parameters with their principles, significance & applications.

Soy isoflavones are phytochemicals of intense interest due to their association with a variety of health protective effects. Analytical techniques to identify and quantify these compounds vary in accuracy, reproducibility and sensitivity. In this study, solvent extraction efficiencies, and the effect of replicate extractions, and sonication on the isoflavone content of two soy products (high and low protein content) were evaluated. The later study was conducted to determine the effect of protein content on isoflavone extractability. Soy Isoflavones are reported to play a role in the prevention of osteoporosis, and several hormonally influenced cancers and to act as phytoestrogens in humans. Their ability to act as antioxidants may also serve to prevent oxidative damage in living tissue

Green tea is made from unfermented dried leaves from Camellia sinensis and has been consumed by humans for thousands of years. For nearly as long, it has been used as a folk remedy for a wide array of diseases. More recently, a large number of in-vitro and in-vivo scientific studies have supported this ancient contention that the polyphenols from green tea can provide a number of health benefits. Since these compounds are clearly safe for human consumption and ubiquitous in the food supply, they are highly attractive as lead compounds for drug discovery programs. However, as drugs, they are far from optimum. They are relatively unstable, poorly absorbed, and readily undergo a number of metabolic transformations by intestinal microbiota and human enzymes. Further, since these compounds target a wide array of biological systems, *in-vivo* testing is rather difficult since effects on alternative pathways need to be carefully eliminated. The purpose of this review is to discuss some of the challenges and benefits of pursuing this family of compounds for drug discovery.

References

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Lecture synopsis Sub: APET

Lecture No: 47

Name of topic/lesson – Current approaches in standardization

Subtopic: Biology approaches and DNA fingerprinting.
Objective: To Study Biology approaches and DNA fingerprinting.
Topic Outcomes: At the end of topic you will

able to explain DNA Finger priniting

DNA fingerprinting, also called DNA typing, DNA profiling, genetic fingerprinting, genotyping, or identity testing, in genetics, method of isolating and identifying variable elements within the base-pair sequence of DNA (deoxyribonucleic acid). The technique was developed in 1984 by British geneticist Alec Jeffreys, after he noticed that certain sequences of highly variable DNA (known as minisatellites), which do not contribute to the functions of genes, are repeated within genes. Jeffreys recognized that each individual has a unique pattern of minisatellites (the only exceptions being multiple individuals from a single zygote, such as identical twins).

Uses

Since it was invented in 1984, DNA fingerprinting most often has been used in court cases and legal matters.

It can: Physically connect a piece of evidence to a person or rule out someone as a suspect.

Show who your parents, siblings, and other relatives may be.

Identify a dead body that's too old or damaged to be recognizable.

DNA fingerprinting is extremely accurate. Most countries now keep DNA records on file in much the same way police keep copies of actual fingerprints.

References

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Lecture synopsis Sub: APET

Lecture No: 48

Name of topic/lesson – Current approaches in standardization

Subtopic: Biology approaches and DNA fingerprinting.
Objective: To Study Biology approaches and DNA fingerprinting.
Topic Outcomes: At the end of topic you will

able to explain DNA Finger priniting

DNA fingerprinting, one of the great discoveries of the late 20th century, has revolutionized forensic investigations. This review briefly recapitulates 30 years of progress in forensic DNA analysis which helps to convict criminals, exonerate the wrongly accused, and identify victims of crime, disasters, and war. Current standard methods based on short tandem repeats (STRs) as well as lineage markers (Y chromosome, mitochondrial DNA) are covered and applications are illustrated by casework examples. Benefits and risks of expanding forensic DNA databases are discussed and we ask what the future holds for forensic DNA fingerprinting. DNA Fingerprint DNA (deoxyribonucleic acid) represents the blueprint of the human genetic makeup. It exists in virtually every cell of the human body and differs in its sequence of nucleotides (molecules that make up DNA, also abbreviated by letters, A, T, G, C; or, adenine, thymine, guanine, and cytosine, respectively). The human genome is made up of 3 billion nucleotides, which are 99.9% identical from one person to the next. The 0.1% variation, therefore, can be used to distinguish one individual from another. It is this difference that can be used by forensic scientists to match specimens of blood , tissue, or hair follicles to an individual with a high level of certainty. The complete DNA of each individual is unique, with the exception of identical twins. A DNA fingerprint, therefore, is a DNA pattern that has a unique sequence such that it can be distinguished from the DNA patterns of other individuals. DNA fingerprinting **is also called DNA** typing.

References

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