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Research Article

Quality Aspects of Herbal Drugs and It's Formulation

Vedika Thete*, Soham Purohit, Ankush Vadnere, Akshada Kale

Sandip Institute of Pharmaceutical Sciences, Nashik

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ABSTRACT

Herbal formulations have long been integral to traditional medical practices and are increasingly acknowledged in modern healthcare for their natural origins and therapeutic benefits. This review delves into the foundational aspects of herbal drug development, such as their historical context, essential quality determinants, and the ongoing issues related to maintaining product consistency. Key attention is given to regulatory standards, standardization approaches, and analytical methodologies designed to uphold product safety, efficacy, and reliability. Furthermore, the incorporation of cutting-edge technologies—including nanotechnology and biotechnology—demonstrates the progressive transformation of herbal medicine. The article also considers future directions, emphasizing the importance of regulatory alignment across countries, environmentally responsible practices, and the promise of tailored treatments. By addressing existing limitations and embracing technological innovations, herbal formulations can evolve into dependable and widely accepted therapeutic alternatives. The review highlights the importance of cross-disciplinary efforts to merge age-old traditional wisdom with scientific rigor, reinforcing the continued relevance of herbal medicines in modern clinical practice.

INTRODUCTION

Pharmacopeial Definitions :

Herbs : A plant or plant part utilized for flavour, aroma, or medicinal purposes is called an herb. Herbs are a flavourful and aromatic addition to a wide range of dishes. Herbs have therapeutic properties in addition to being utilized in food preparation. Diabetes, cancer, and heart disease are among the illnesses that herbal remedies are used to treat and prevent. The world will be covered in herb gardens.

Crude Drugs : Any naturally produced raw material obtained from organic or inorganic sources—plants, animals, microbes, organs, or entire organisms—that is meant to be used in the

***Corresponding Author:** Vedika Thete
Address: *Sandip Institute of Pharmaceutical Sciences, Nashik*
Email : vedika03thete@gmail.com
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identification, mitigation, treatment, or prevention of disease in humans or other animals is referred to as a crude medicine.

Processed Drugs : They are herbs in a processed form. They can be made into powders, extracts, tinctures, fixed oils, volatile oils, resins, gums, and other forms. They are made from herbal medications using a variety of processes, including extraction, fractionalization, purification, concentration, and fermentation. They are made up of a variety of ingredients.

Raw Material: In the context of herbal medicine, "raw materials" refers to plant material or plant components (leaf, root, seed, bark, or entire plant) that are used to make herbal formulations or medications. Usually, these ingredients are gathered, dried, and processed in order to make herbal medication. The safety and effectiveness of the finished product depend heavily on the standards and quality of the herbal raw components.

Herbal Formulation: Herbal formulations are defined as dosage forms that contain one or more herbs, or processed herbs, in specific amounts to offer particular nutritional or cosmetic benefits intended for use in diagnosing, treating, or lessening human or animal diseases, as well as changing the physiology or structure of the affected parties.

Meaning of quality in terms of herbal drugs :

When it comes to herbal drugs, quality refers to the features and qualities that establish its overall worth, safety, and effectiveness. It includes a variety of elements that guarantee herbal medications are dependable, consistent, and appropriate for the intended use. A key component of herbal medications' compliance with regulations and suitability for ingestion by humans is their quality. Here are some key components of quality in herbal drugs:

Identity: Plant species and parts utilized in high-quality herbal remedies must be accurately identified. This guarantees that the herbal product is real and has all of the elements that are supposed to be there.

Purity: Herbal medications should be devoid of impurities such as pesticides, heavy metals, and microbiological pollutants, as well as alien materials like soil or unrelated plant material. Testing for purity guarantees that the product is safe to eat.

Potency: Herbal medications concentration of potent ingredients, such phytochemicals, need to adhere to predetermined guidelines. By doing this, the product is guaranteed to have the intended therapeutic effects.

Authenticity: The labels on herbal products should correctly list all of the components and substance. The data that is offered need to be accurate and open.

Good Manufacturing Practices (GMP): To ensure that their products are constantly produced under monitored conditions to fulfil specific quality requirements, reputable herbal pharmaceutical manufacturers should adhere to GMP rules.

Quality Control: To ensure a constant level of quality in herbal medications and products, strict quality control procedures like testing, verification, and documentation are necessary.

Safety: Good herbal medications shouldn't put users' health at danger. It is essential for the safety of consumers to ensure that they are devoid of dangerous materials and impurities.

Efficacy: As high-quality medicinal products have the right quantity of active ingredients, they should provide the desired therapeutic effects. When it comes to medicinal products, overall quality includes a thorough examination of product efficacy, consistency, and safety. For herbal medications and goods, it is essential to protect consumer health and wellbeing as well as industrial and regulatory requirements.

SEVERAL FACTORS CAN AFFECT THE QUALITY OF HERBAL PRODUCTS:

Plant Species and Variety: The quality and effectiveness of herbal products can be affected by the particular species and variety of plant used.

Growing Conditions: The chemical composition and medicinal qualities of a plant can be affected by various factors, including climate, soil quality, and production techniques.

Harvesting Time: The concentration of active chemicals in the plant can be greatly affected by when it is harvested. The ideal time to harvest different plants is different.

Processing Methods: The quality of herbs can be affected by the methods used to dry, store, and prepare them. Insufficient processing may cause active chemicals to lose their effectiveness.

Storage Conditions: For herbal items to remain unchanged, proper storage is essential. Deterioration may result from exposure to air, light, and moisture.

Extraction Techniques: The process (water extraction, ethanol extraction, etc.) used to separate the active ingredients from herbs can affect the quality of the finished product.

Adulteration and Contamination: The quality of herbal products can be harmed by adulteration with other botanicals or contamination with pesticides, heavy metals, or other chemicals.

Storage and Transportation: It's essential to store herbal products properly while they're being transported to avoid exposing them to bad environments that might reduce their quality. To ensure the quality and safety of herbal goods, it is essential to purchase them from reliable suppliers who adhere to proper manufacturing and agricultural standards.

Need of quality control :

Good experimental data, toxicity investigations, and human clinical research form the foundation of the modern medical system. However, there are no pharmacopeial standards for raw materials or finished goods. The highest basic criteria for medical plant products are neither maintained nor regulated, nor are cGMP for the herbal business properly defined. Hepatotoxicity to death is just a few of the moderate to significant negative effects that have been caused by the lack of quality standards. As a result, instruments are needed to assess the identification, purity, and quality of herbal substances. These instruments also need to meet GMP regulations and be reliable, quick, and affordable. The World Health Organization has established precise rules for evaluating the quality, safety, and efficacy of herbal remedies. Maintaining the quality control of herbal drugs is a difficult task because a variety of factors impact their bio-efficacy and repeatable therapeutic effect. Care must be taken from the correct identification of plants, season, and collection area, through their extraction and purification of polyherbal medications, in order to achieve quality-oriented herbal products.

Evaluation Parameters : Pharmacognostic evaluation: It includes color, odour, taste, size,

shape, microscopical characters, and histological parameters.

Physico-chemical parameters : It includes foreign matter, total ash, acid-insoluble ash, swelling and foaming index, assay, extractive values, moisture content, viscosity, pH, Disintegration time, friability, hardness, sedimentation, alcohol content.

Chemical parameters: It includes limit tests, chemical tests etc. Chromatographic and Spectroscopic Analysis. It includes TLC, HPLC, HPTLC, GC, UV, IR, AAS, FT-IR, LC-MS, and GC-MS etc.

Microbiological Parameters: It contains all of the usable material as well as the overall number of mold and bacteria. To measure and regulate the quantity of impurities, such as chemicals used in the extraction of different herbs, contaminants sent straight from the manufacturing process, solvents, etc., limiters can be utilized as a quantitative or semi-quantitative approach.

WHO Guidelines for Quality Control of Herbal formulations :

- Quality control of crude drugs material, plant preparations and finished products.
- Stability assessment and shelf life.
- Documentation of safety based on experience or toxicological studies.
- Assessment of efficacy by medical information's and biological activity evaluations.
- The bioactive extract should be standardized on the basis of active principles or major compounds along with the chromatographic fingerprints (TLC, HPTLC, HPLC, and GC).

The Constraints in Herbal Medicines:

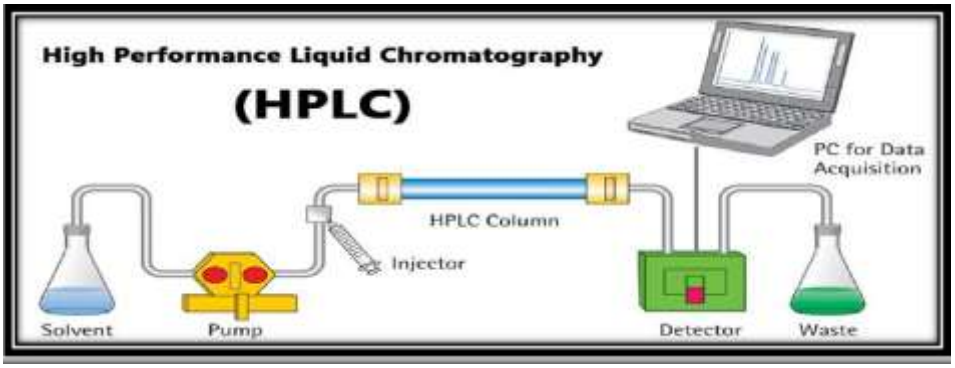
- Constraints associated with the handing of medicinal plants,
- Indiscriminate harvesting and poor post-harvest treatment practices.
- Lack of research on the development of high-yielding varieties, domestication etc.
- Poor agriculture and propagation methods.
- Inefficient processing techniques leading to low yields and poor-quality products.
- Poor quality control procedures.
- Lack of current good manufacturing practices.
- Lack of R & D on product and process development.
- Difficulties in marketing.
- Lack of trained personnel and equipment.
- Lack of facilities to fabricate equipment locally.
- Lack of access to latest technological and market Information.

Phytochemical analysis of finished products using chromatographic technique:

Phytochemical analysis of finished products using chromatographic techniques is a common and effective method in various industries, especially in pharmaceuticals, food and beverages, and herbal supplements. Chromatography is a powerful separation technique that can be used to identify and quantify individual components within a complex mixture.

High-Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) are two widely employed chromatographic methods for phytochemical analysis. Here's a basic overview of how these techniques are applied:

1. **High-Performance Liquid Chromatography (HPLC):**



Principle: HPLC separates components based on their interaction with a liquid mobile phase and a solid stationary phase. It is highly effective for the analysis of a wide range of compounds.

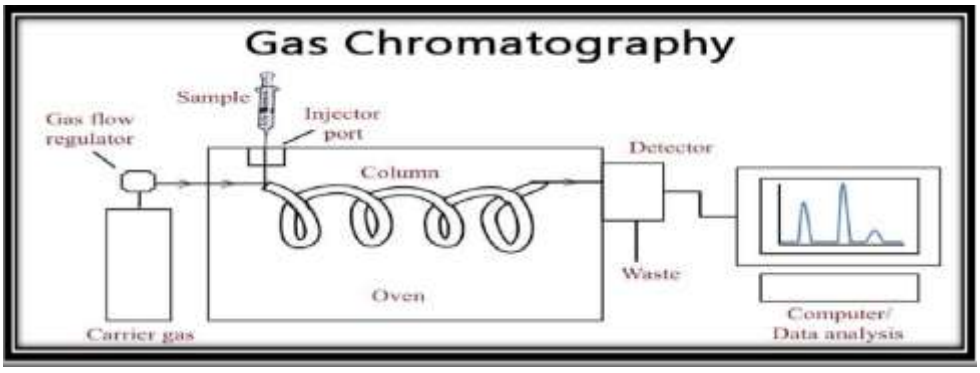
Application:

- **Identification and Quantification:** HPLC can be used to identify and quantify specific phytochemicals present in the finished product.
- **Purity Assessment:** It helps assess the purity of the product by separating individual compounds and detecting impurities.
- **Profile Analysis:** Provides a chromatographic profile that can be used for the fingerprinting of the product.

Procedure

- The sample is injected into the HPLC system.
- Compounds are separated as they pass through a column.
- Detection is typically done using UV-Visible spectrophotometry, and peaks are recorded on a chromatogram.

2. Gas Chromatography (GC):-



Principle: GC separates components based on their volatility. It is particularly useful for analyzing volatile and semi-volatile compounds.

Application:

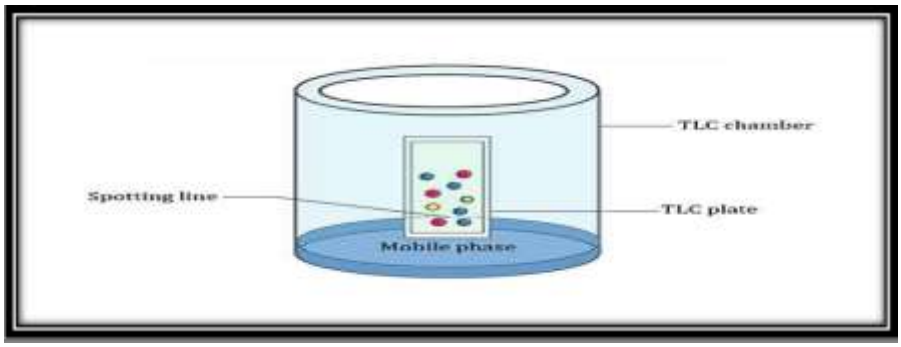
- **Analysis of Volatile Compounds:** GC is suitable for the analysis of volatile phytochemicals such as essential oils and certain terpenoids.
- **Fatty Acid Analysis:** It is commonly used for analysing fatty acids and triglycerides.

Procedure:

- The sample is vaporized and injected into the GC system.

- Compounds are separated as they move through a column.
- Detection is usually done using a detector like a Flame Ionization Detector (FID).

3. Thin Layer Chromatography (TLC):



Principle: TLC separates compounds based on their affinity for a stationary phase (thin layer of adsorbent material) and a mobile phase (solvent).

Application:

- **Compound Identification:** TLC is used to identify the number of compounds present in a mixture.
- **Purity Assessment:** It can indicate the purity of individual compounds by showing the separation of impurities.
- **Comparative Analysis:** TLC allows for the comparison of different samples and can be used for qualitative analysis.

Procedure:

- Apply a thin layer of adsorbent material (usually silica gel) on a glass or aluminium plate.
- Allow the layer to dry and activate if necessary.
- Spot the sample on the baseline of the TLC plate using a capillary tube or micropipette.
- Place the TLC plate in a developing chamber containing a solvent (mobile phase).
- The solvent moves up the plate by capillary action, carrying the sample with it.
- After development, remove the plate and allow it to dry.
- Visualize the separated compounds using UV light, iodine vapor, or specific staining reagents.
- Measure the distance travelled by each spot (Rf value) to identify and compare compounds.

LONG TERM & SHORT-TERM STABILITY TESTING OF HERBAL FORMULATIONS USING ICH GUIDELINES:

Stability testing of herbal formulations is crucial to ensure their quality, efficacy, and safety over time. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) provides guidelines for the stability testing of pharmaceutical products, including herbal formulations. These guidelines help in establishing the shelf-life and storage conditions for the products.

Long-Term Stability Testing:

- **Duration:** Typically conducted over 12 to 24 months or longer, depending on the intended shelf- life of the product.

- **Storage Conditions:** Products are stored under recommended conditions, which may include different temperatures and humidity levels.
- **Testing Intervals:** Samples are tested at specified intervals (e.g., 0, 3, 6, 9, 12, 18, and 24 months) for various parameters.
- **Parameters Tested**:
    - **Physical Characteristics:** Appearance, color, odor, and taste.
    - **Chemical Characteristics:** Content of active ingredients, degradation products, and impurities.
    - **Microbiological Stability**: Microbial load and preservative effectiveness.
    - **Container-Closure System Integrity:** Check for any issues with the packaging.
- **Documentation:-**Detailed documentation of the test results, including any observed changes or deviations.
- **Statistical Analysis:** Statistical analysis may be performed to predict the shelf-life of the product.

Short-Term Stability Testing:

- **Purpose:** To provide preliminary information on the stability of the product in a shorter time frame.
- **Duration:** Conducted over a few weeks to a few months, depending on the study design.
- **Storage Conditions:** Usually includes accelerated conditions (elevated temperature and humidity) to induce rapid degradation.
- **Testing Intervals:** Frequent testing intervals to assess the stability under stress conditions.
- **Parameters Tested:** Similar parameters as in long-term stability testing but with a focus on detecting potential issues quickly.
- **Documentation:** Documentation of results, including any signs of instability or degradation.

Safety Studies – Toxicological data , efficacy studies- clinical & preclinical data Toxicological Data :-

- **Acute Toxicity:** Examines the immediate effects of a single exposure to the herbal formulation.
- **Chronic Toxicity:** Evaluates the effects of long-term exposure, often over a significant portion of the lifespan of the test subjects.
- **Genotoxicity:** Assesses whether the herbal formulation has the potential to cause genetic damage.
- **Carcinogenicity:** Examines the potential of the herbal formulation to induce cancer.
- **Reproductive and Developmental Toxicity:** Evaluates the impact on fertility, pregnancy, and development of offspring.
- **Mutagenicity: Assesses** whether the formulation has the potential to induce mutations.
- **Allergenicity:** Investigates the potential for allergic reactions in individuals.

Clinical & Pre-clinical Data:-

- **Preclinical Studies:** Preclinical efficacy studies involve laboratory and animal experiments to assess the product's effectiveness and safety before human trials.These studies help identify the product's potential mechanism of action and therapeutic benefits. There are two types ; In-vitro & In-vivo.

- **Phase I Clinical Trials:** Determine the safety and tolerability of the herbal formulation in humans.
- **Phase II Clinical Trials:** Evaluate the preliminary efficacy of the herbal formulation. Further assess safety.
- **Phase III Clinical Trials:** Confirm efficacy, monitor adverse events, and compare with standard treatments.
- **Post-Marketing Surveillance (Phase IV):** Monitor the herbal formulation's safety and efficacy in real-world settings.
- **Pharmacovigilance :** Continuously monitor and evaluate the safety of the herbal formulation after market approval.

FORMULATION SPECIFIC CHARACTERIZATION FOR HERBAL TABLETS, LIQUIDS AND TOPICAL FORMULATIONS:

1. Herbal Tablets:

Physical Characteristics:

- **Appearance:** Color, shape, size, and surface characteristics.
- **Hardness:** Measured using a hardness tester to ensure tablet integrity.
- **Friability:** Resistance to abrasion during handling and packaging.

Chemical Characteristics:

- **Active Ingredient Content:** Quantitative analysis to ensure the tablets amount of active herbal compounds.
- **Impurities:** Identification and quantification of impurities, including degradation products.

Biological Characteristics:

- **Dissolution Rate:** Assess how rapidly the tablet disintegrates and releases its active ingredients.
- **Bioavailability:** Evaluate the extent and rate at which the active ingredients are absorbed.

2. Herbal Liquids (Syrups, Tinctures, etc.):

Physical Characteristics:

- **Color and Clarity:** Evaluate the visual appearance of the liquid product.
- **Odor and Taste:** Subjective assessment of sensory characteristics.
- **pH Level:** Measure the acidity or alkalinity of the liquid.

Chemical Characteristics:

- **Active Ingredient Content:** Quantitative analysis to determine the concentration of active herbal compounds.
- **Preservative Efficacy:** Assess the effectiveness of preservatives in preventing microbial growth.

Biological Characteristics:

- **Stability:** Monitor changes in the active ingredient concentration over time.
- **Compatibility with Packaging:** Ensure the liquid is compatible with the packaging material.

3. Topical Formulations (Creams, Ointments, Gels):

Physical Characteristics:

- **Consistency:** Assess the texture and feel of the topical product.
- **Spreadability:** Evaluate how easily the product spreads on the skin.
- **Appearance:** Color, odor, and overall visual characteristics.

Chemical Characteristics:

- **Active Ingredient Content:** Quantitative analysis to ensure the formulation contains the intended concentration of herbal compounds.
- **Stability under Storage:** Monitor changes in the formulation's chemical composition over time.
- **Compatibility with Skin:** Evaluate skin irritation potential through patch testing.

Biological Characteristics:

- **Skin Permeation:** Assess the ability of the formulation to penetrate the skin.
- **Efficacy in Target Condition:** Evaluate the product's therapeutic effectiveness for the intended skin condition.

Chemical Tests:

A. **Phytochemical Tests**: To determine whether particular types of compounds—such as tannins, alkaloids, flavonoids, and essential oils—are present, perform simple chemical tests.

B. **Colour Reactions**: Use specific reagents to track color changes in plant extracts, which may provide information about the presence of particular chemicals.

Microscopic method of Identification:

1. **Epidermal Cells:**

- **Stomata**: Count and observe the type and distribution of stomata (pores) on the leaf surface.
- **Trichomes**: Examine the presence, type, and density of trichomes (hairs) on various plant parts.

2. **Leaf Anatomy:**

- **Leaf Epidermis:** Study the structure of the upper and lower epidermis, including the types of cells and their arrangements.
- **Vascular Bundles**: Examine the arrangement and characteristics of vascular bundles in the leaf.

3. **Powder Microscopy:**

- **Cellular Elements:** Analyse the size, shape, and arrangement of various cells in powdered plant material, including parenchyma cells, fibres, and sclereids.

- **Starch Grains:** Identify and measure the size, shape, and distinctive features of starch grains.
- **Calcium Oxalate Crystals:** Observe the presence and morphology of calcium oxalate crystals.
- **Oil Cells:** Detect the presence of oil cells and examine their characteristics.

4. Stem and Root Anatomy:

- **Vascular Tissues**: Examine the arrangement of xylem and phloem in stems and roots.
- **Cork Cells:** Study the cork cells in the outer bark of stems and roots.

5. Seed and Fruit Structures:

- **Seed Coat**: Analyse the structure of the seed coat, including its cells and any unique features.
- **Endosperm and Cotyledons**: Examine the characteristics of endosperm and cotyledons in seeds.
- **Fruit Anatomy:** Study the internal structures of fruits, such as the arrangement of seeds and other tissues.

6. Pollen Grains:

- **Pollen Morphology:** Observe the size, shape, and surface ornamentation of pollen grains.

7. Microchemical Tests:

- **Phytochemical Tests**: Perform tests to detect the presence of specific chemical compounds, such as lignin, tannins, and alkaloids.

1. Determination of moisture content of crude drugs

Determining the moisture level is important because, in addition to identifying excess water, it also helps determine the right temperature at which moisture will activate enzymes and provide an environment that is favorable for a drug's growth .

Procedure:

Measuring approximately 10g of powder, it was put in a moisture content device. After the temperature was changed to between 100 and 1100C, the weight was weighed and collected in a desiccator. According to IP, weight loss was taken into account when determining moisture content.

2. Determination of foreign matter of crude drugs.

A medicinal product has to be free of bacteria, insects, and other animal impurities as possible. The pharmacopoeia monograph states that each product's standard controlled amount of foreign materials shouldn't go above that amount.

Procedure:

The plant material undergoes this test in its entirety or in portions as directed. Take 100–500 g of the test substance, apply it thinly over a spotless surface, and examine it with a 6x lens microscope or your naked eyes. Sort, weigh, and determine the proportion of foreign material detected.

3. Determination of ash values of crude drug.

The ash determination method makes it possible to quickly and simply detect the vegetable's physiological and non-physiological components. The mineral components of the plant itself are the source of the physiological ash. However, the plant can have foreign objects stuck to it from the sand and dirt. We refer to this foreign substance as non-physiological ash. In most circumstances, an unsatisfactory collection and storage process is

indicated by an ash concentration higher than permitted .

Procedure:

In a platinum or silicon, the vessel, melt two to three grams of the drug at a temperature not to exceed 450-degree Celcius until it carbonizes, cools, and becomes weight less. If this procedure is unable to produce carbonized ash, combine the dough with hot water, gather the residue on ash residue filter paper, burn the residue and the paper, add the filtrate, evaporate it until it is completely dry, and heat it to a temperature not higher than 450 °. Determine what proportion of ashes are from drugs that have been air-dried.

Calculations:

Calculate the total ash as a percentage of the original weight of the drug.

Total Ash (%) = (Weight of Ash/Weight of Drug) × 100

0.062/2*100 = 3.1%

4. **Determination of extractive substance in crude drug.**

When suitable methods for identifying the active ingredients in medications by physical or physico-chemical procedures are unavailable, or when required by the Pharmacopoeia monograph, the extractable compounds are determined .

Procedure:

It generally uses ethanol, water, and infrequently ether to identify compounds that can be extracted. The technique relies on the active ingredients' solubility in a particular solvent and, in the event that the solubility is unknown, the pharmacological activity of the extract made using the solvent.

5. Determination of bitterness value of crude drugs.

Extremely bitter medicinal plant elements are known as bitters, and they are mostly used as flavoring agents in medical applications. Their bitterness stimulates the GIT to secrete more, particularly gastric juice. The primary physiological indicator for measuring overall bitterness is taste.

Procedure:

The threshold bitter concentration of an extract of the material is compared to that of a diluted solution of quinine HCl, as directed by the World Health Organization, to ascertain the bitter qualities of the plant material.

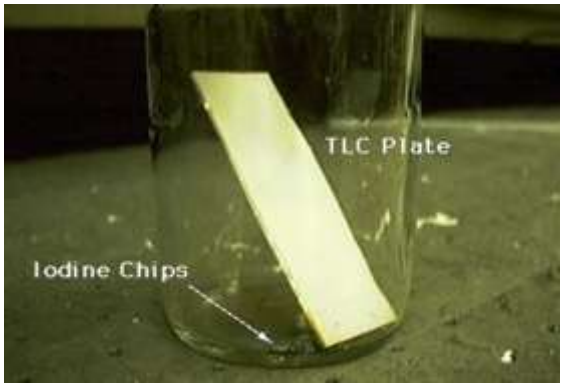
6. Determination of TLC profile of crude drugs

TLC, commonly referred to as thin layer chromatography, is a technique for analyzing mixtures by dividing the constituent substances. TLC is useful in identifying compounds, figuring out how many components are in a combination, and figuring out how pure a chemical is.

The three stages of TLC are spotting, development, and visualization. Initially, the sample to be examined is dissolved in a volatile solvent that evaporates readily, yielding a highly diluted solution (about 1%).

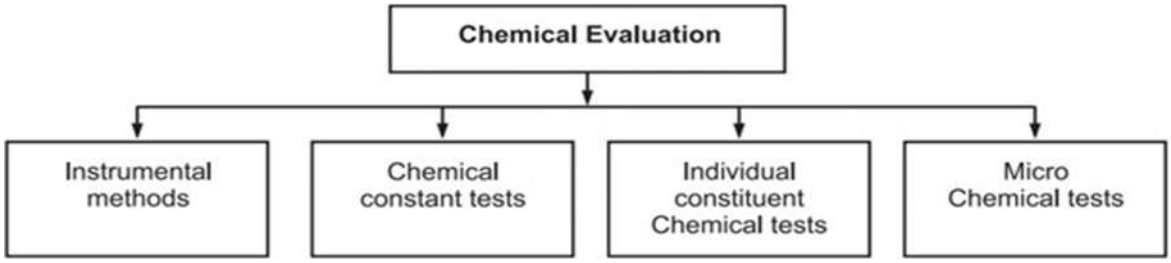
Spotting is the process of applying a little amount of this diluted solution—in this case, a thin film of powdered silica gel coated onto a plastic sheet—to one end of a TLC plate using a micro pipet. Only a little patch of the substance is left behind when the spotting solvent swiftly evaporates.

The process of development involves submerging the TLC plate's bottom into a small pool of a development solvent, which rises up the plate via capillary action. The solvent crosses the initial location as it advances up the plate. For the spotted material, a competition is set up between the development solvent and the silica gel plate.



7. Chemical evaluation of crude drugs.

Chemical assays, quantitative and qualitative chemical testing, and instrumental analysis are all included in the chemical evaluation. Chemical methods of evaluation include the separation, purification, and identification of active ingredients. Identification tests for different phytoconstituents, such as alkaloids, glycosides, tannins, etc., are included in qualitative chemical testing.



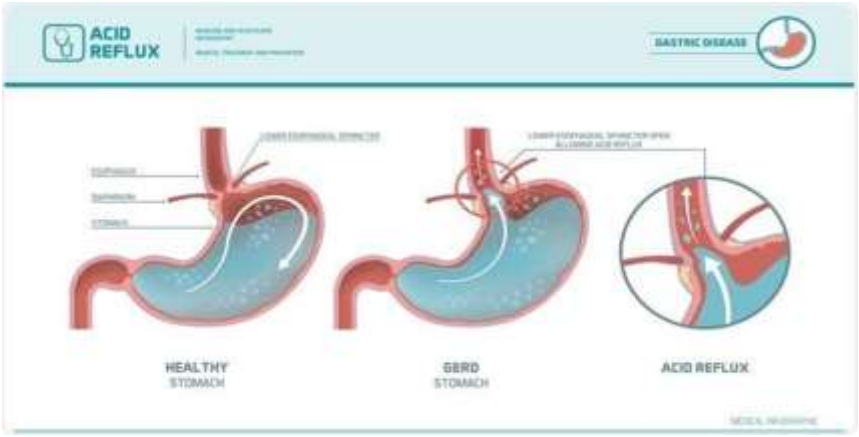
The chemical groups of phytoconstituents are analyzed instrumentally utilizing spectroscopic and chromatographic techniques. Paper chromatography, thin-layer chromatography, gas chromatography, high-performance liquid chromatography, and high-performance thin-layer chromatography are examples of chromatographic techniques. Nuclear magnetic spectroscopy, mass spectroscopy, infrared spectroscopy, and ultraviolet and visible spectroscopy are examples of spectroscopic techniques.

FORMULATION AND EVALUATION OF ANTI- ACIDIC ORAL DISSOLVING FILM (ODF)

ACIDITY:

Acidity is described as having happened when someone has heartburn and when gas builds up in the stomach. It happens because the stomach secretes too much HCL. When HCL levels rise above their normal range, the stomach's inner lining is affected, leading to an acidic stomach.

The condition known as acidity, also known as acid reflux or gastroesophageal reflux disease (GERD), is defined by the reflux of stomach acid backward into the oesophagus. Chest pain, regurgitation, heartburn, and difficulty in swallowing might result from this.



CAUSES :

Certain Foods and Beverages:–Spicy, fatty, or acidic foods can stimulate the production of stomach acid and relax the LES, leading to increased acidity. Common triggers include citrus fruits, tomatoes, chocolate, coffee, and spicy foods.

The following table enlists herbal ingredients and their mechanism of action that helps in reducing acidity:

Sr. No	Ingredients	Role Of Ingredeint
1.	Ajwain / Ova	Active Ingredient
2.	Coriander Powder	Active Ingredient
3.	Ginger Powder	Active Ingredient
4.	Piper Longum (Long Pepper)	Active Ingredient
5.	Cellulose, Glycerol	Plasticizer
6.	Gelatin	Polymer
7.	Mint	Flavouring Agent
8.	Sucrose	Sweetening Agent

Thin, water-soluble films known as mouth dissolving films (MDFs) dissolve rapidly in the oral cavity, releasing the active components for fast absorption. These films are useful for administering medication, particularly to those who might have trouble swallowing tablets or pills. Because they are usually 25 to 40 mm in length and 20 to 30 mm in width, ODFs have a larger overall surface area. This larger surface area, along with their thinness, allows ODFs to dissolve quickly. To create the perfect film characters, ODFs are made from mixtures of polymers. Water-soluble cellulose ethers, polysaccharides, polyvinyl alcohol, polyvinylpyrrolidone, polyethylene glycols, and other similar polymers are often the polymers. The plasticizer reduces the film's cracking and increases its flexibility. The term "blooming" or "blushing" refers to the white residue that forms on edible films when the concentration of plasticizer reaches its limit due to phase separation and physical exclusion of the plasticizer.

Excipients used in the formulation of ODF play a very important role during the formulation. Following table shows the basic formulation of ODF:

Sr. No	Ingredient	Amount (W/W)
1	**Film-forming polymer**	40-50%
2	**Plasticizers**	0-20%
3	**Sweeteners**	3-6%
4	**Super disintegrant**	2-6%
5	**Active pharmaceutical ingredient (API)**	1-30%
6	**Surfactant**	q. s
7	**Saliva stimulating agent**	q. s
8	**Flavouring agent, colour**	q. s

1. **Film-Forming Agents:** Film-forming agents include hydroxypropyl methylcellulose

(HPMC), pullulan, and other polymers. They add to the film's flexibility and strength as well as its structural integrity.

2. **Plasticizers:** Glycerine, propylene glycol, and polyethylene glycol are examples of plasticizers that improve the film's elasticity and flexibility. They enhance the film's folding and bending properties and help keep it from breaking easily.

3. **Disintegrants:** Disintegrants, such as croscarmellose sodium or sodium starch glycolate, help the film break down quickly in the mouth. To get a rapid release of the active substance, this is essential.

4. **Sweeteners:** Sweeteners like sucrose, mannitol, or aspartame are added to mouth dissolving films to improve their palatability and increase user acceptance.

5. **Flavouring Agents:** To improve the overall taste of the film and hide the taste of the active substance, flavouring agents such menthol, peppermint, or fruit Flavors are added.

6. **Colorants:** Colorants can be added for decorative purposes, such as natural or artificial dyes. They improve in product identification and improve the film's appearance.

7. **Surfactants:** The addition of surfactants, like sodium lauryl sulfate or polysorbate 80, can enhance the film's spreading and wetting abilities. This could help the film's disintegration and dissolving in the mouth.

Here is a tabular form of synthetic excipients and their herbal alternatives used in the formulation of ODF :

Sr.no	Excipient	Synthetic drug	Herbal alternative
1.	Polymer	Hydroxypropyl methylcellulose, sodium carboxymethylcellulose, polyethylene oxide, hydroxypropyl cellulose, polyvinyl alcohol, ethyl cellulose.	Pullulan, Lignin, starch, Pectin, sodium alginate, Maltodextrins, Polymerized rosin.
2.	Plasticizer	Sulfonated melamine.	Glycerol, PEG
3.	Super disintegrant	Sodium starch glycolate (SSG), cellulose or croscarmellose sodium.	Banana powder, soy polysaccharide, gellan gum, locust been gum, fenugreek seed mucilage, mango peel pectin.
4.	Surfactant	Lucinactant,h beractant, calefacient	Lecithin, lanolin, alkyl glycoside, phytosterol
5.	Saliva stimulating agent		Citric acid
6.	Sweeteners	Neotame, saccharine, sucralose	Honey, dates, sucrose sorbitol, mannitol.
7	Flavours & colours	Artificial flavouring and colouring	Mint, cardamom, lemon.

METHODS OF PREPARATIONS :

There are some methods in which oral dissolving films can be prepared, each of the methods are described below

1. Preparation of film using, Solvent casting method

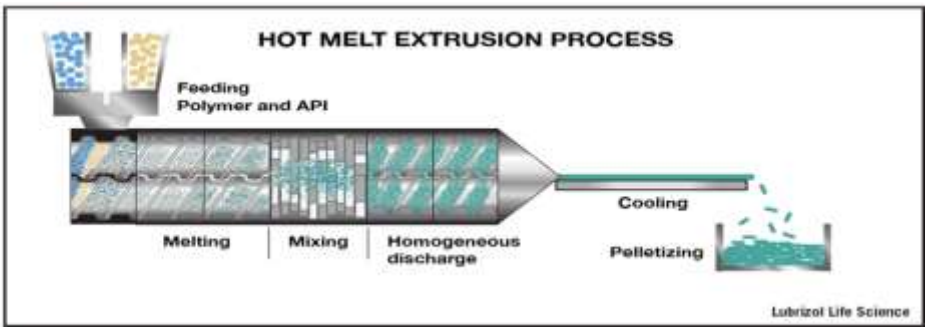
2. Semisolid casting

3. Hot melt extrusion

Hot Melt Extrusion :

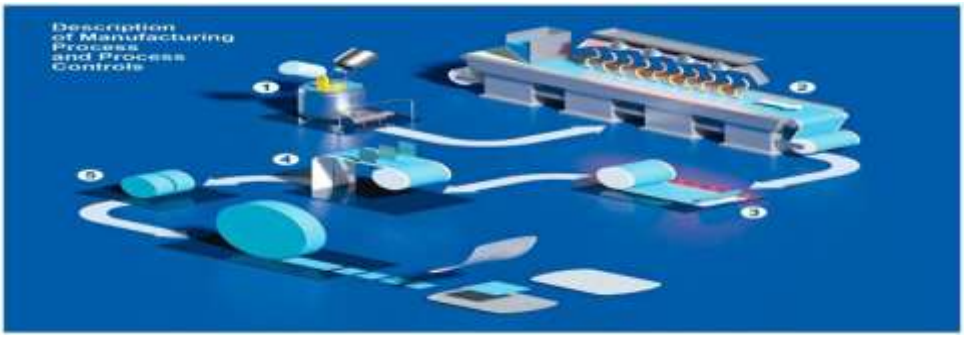
It's a procedure where pressure and heat are applied to cause polymer to melt. It is typically utilized in the granule and tablet preparation process for SR. This approach deviates from the traditional method of preparing ODF. This movie is heated in order to prepare it. After being heated, ingredients are combined while dry and removed while molten. Film is cast from the molten mass that is obtained. Films are then trimmed and chilled. The main disadvantage of this method is that the high temperature deactivates the active ingredients.

Figure 1



Semi Solid Casting Method :

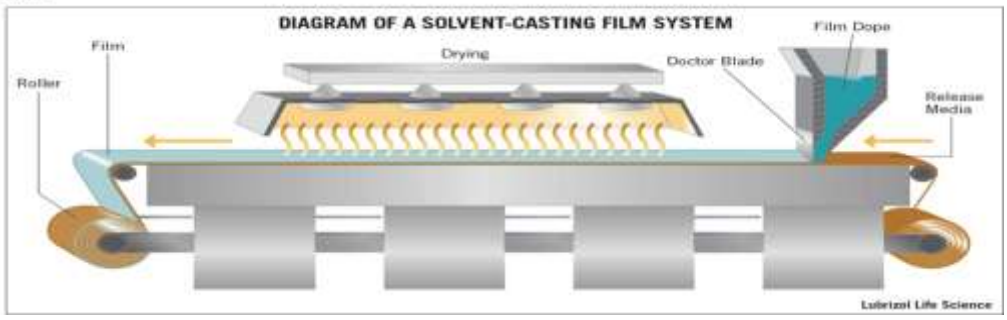
This approach involves first preparing a water-soluble polymeric film, and then adding the polymeric solution to an acid-insoluble polymeric solution. After adding enough plasticizers to create gel, the gel is cast into the necessary thickness on a plate. The water-soluble polymeric solution and acid- insoluble polymer should be mixed in a ratio of 1:1:4.



Solvent Casting Method :

It is among the most frequently used techniques for film formulation. Drug, excipients, and water-soluble polymers are used in its preparation. High shear force is applied, resulting in the formation of a homogeneous mixture. To achieve a consistent thickness, the solution is poured into foil and spread with a coating knife.

Figure 1



EVALUATION OF ORGANOLEPTIC EVALUATION:

The colour is the one of the important criteria as its acts as an identification of pharmaceutical product. The colour should be uniform and it should have consumer acceptance.

- **Odour**: A key factor that needs to be considered for the ODFs is odor. The smell in the dosage form frequently represents the smell of the excipient or API, and it can also occasionally represent the stability of the formulation.
- **Taste:** Consumer acceptability of a formulation is directly correlated with its flavor. These days, taste sensors intended for taste testing are used in a variety of in vitro procedures.
- **Thickness**: The micrometre screw gauge and calibrated vernier callipers were used to determine the film's thickness. Five points are used to measure the thickness of the film: the four corners and the center. The precision of dosage is directly correlated with the film's thickness.

Mechanical Properties :

- **Tensile strength**: It is described as the moment at when the greatest amount of force is applied to the film and it breaks. The purpose of this test is to evaluate the ODF's mechanical strength. The formula can be used to determine the tensile strength.
- **Tensile strength=** (failure load/strip thickness ×width of strip) ×100
- **Folding endurance:** In the folding endurance test, the strip is folded repeatedly until it breaks at the same spot. The total number of times a film can be folded without breaking is known as the folding endurance.
- **Young's modulus:** It is also known as the elastic modulus and is defined as the ratio of stress applied to create the elasticity of the film. It is a measure of the rigidity of the film.
- **Young's modulus**=Slope×100/ thickness of film × Crosshead speed
- **Tear resistance:** It is described as the most force required to break the film. The recruit is being loaded at a pace of two inches per minute in order to calculate the amount of force needed to cause the film specimen to tear.
- **Disintegration time:** Oral dissolving films have a disintegration time of five to thirty seconds. Generally speaking, though, there is not an accepted method for figuring out how oral dissolving films are disintegrating.

CONCLUSION:-

This report outlines the key components and learning outcomes of each module, emphasizing the interconnectedness of quality aspects in the herbal industry. The knowledge imparted in these modules collectively contributes to fostering a

culture of excellence and reliability in the realm of herbal products.

RESULTS

- **Metal contamination is widespread:** As noted earlier, 20–40% of surveyed Ayurvedic products exceed permissible levels of lead, mercury or arsenic.

- **High analytical variability:** Literature cites that HPLCs may differ by >10 % in marker quantification across suppliers due to batch variability—a challenge overcome by multivariate fingerprinting using UHPLC-QTOF coupled with chemometric analysis.

- **Chromatographic fingerprinting** enables differentiation between adulterated and genuine material, even where physical traits are similar—HPTLC has identified substitution in Asparagus racemosus and Withania somnifera batches in controlled studies.

- **Thermal analysis** detected moisture-induced degradation bands correlating with lower marker stability in samples stored beyond six months—even when visual inspection and HPTLC passed visual criteria

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