IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, January 2023
Impact Factor: 7.301

Quality Aspects of Herbal Drugs and its Formulation

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Abstract: *To evaluate a high-quality medicine, herbal compositions must be standardised. The total of all aspects that directly or indirectly influence the safety, efficacy, and acceptance of a drug product is the quality of a herbal drug. The field of herbal drugs and formulations is developing quickly nowadays, and there is still much to learn about the standardisation of these products. However, the lack of a standardised parameter hurts herbal treatment. The primary constraints are the absence of standards for raw materials, processing techniques, and finished goods, product formulas, and absence of quality control standards. To assure the quality, safety, and effectiveness of herbal medicine using contemporary methods, it is required to measure the regulation of herbal medicine.*

Keywords: Herbal drugs

I. INTRODUCTION

Traditional medicine is frequently utilized to treat a variety of human illnesses. All plants on this world are significant because of Li, whose traditional system of medicine has gained enormous global popularity due to its ability to treat chronic illnesses with little to no toxicity. Since numerous factors affect biological efficacy and therapeutic effect repeatability, using herbal medicine is not an easy process. Standard herbal formulations are necessary to obtain high-quality medications based on the concentration of their active ingredients and other in-vitro, in-vivo, and phytochemical factors. The evaluation of herbal formulations' quality is of utmost significance in establishing their acceptability in the contemporary medical system. The absence of a strict quality control profile for herbal materials and their formulations is one of the key issues the herbal pharmaceutical sector faces. The term "herbal drug and product" should be used to describe the entire field of study, from the cultivation of medicinal plants to their use in clinical settings. Plant products and herbal medicines made from them make up a sizeable share of the worldwide market, so it is important to adhere to internationally accepted standards for their quality control.The World Health Organization has underlined the necessity to assure quality control of medicinal plant products by adopting appropriate parameters and standards together with current methodologies.

II. GENERAL INTRODUCTION TO QUALITY ASPECTS OF HERBALS

1.1 Herbal Medicine

These are made up of plants or parts of plants that have medical potential but are typically raw or untreated. It comprises various plant parts, such as the complete aerial portion, flowers, fruits, seeds, leaves, bark, and roots and rhizomes.

1.2 Raw Material

Excluding vegetables and other plants used for macronutrient consumption, herbs are generally defined as plants with properties used for flavouring and garnishing food, for medical purposes, or for fragrances.

1.3 Herbal Formulations

An herbal formulation is a physical form of a herbal product, such as a liquid, solid, or semisolid product, with or without excipients, in a specific formulation (such as decoction, tablets, ointment)

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III. MEANING OF QUALITY IN TERMS OF HERBAL DRUGS

The term "quality control" refers to the processes required to maintain the validity or quality of manufactured goods. Any herbal product should go through some type of quality control, regardless of how it is produced. There is no assurance that the herb within the container matches what is indicated on the label on the outside without effective quality control. The widespread disregard for quality control in the industry has tarnished the image of several important medicinal plants. Improvements in analytical techniques have undoubtedly resulted in advancements in harvesting schedules, cultivation methods, storage, activity, stability of active ingredients, and product purity. The quality of the current herbal goods has greatly improved as a result of all these successes. Manufacturers and suppliers of herbal goods must follow quality control guidelines and good manufacturing methods in order to address the quality control issue that exists in the US. The consumers should at least have the assurance that the proper plant is being utilised thanks to advancements in the identification of plants through laboratory examination. Only a few manufacturers currently follow thorough quality control and good manufacturing practises, which include microscopic, physical, chemical/physical, and biological tests. Currently, businesses who provide standardised medications and/or extracts offer the best prices.

IV. FACTORS AFFECTING QUALITY OF HERBAL

4.1 Pesticides

Insecticides, fungicides, and herbicides are examples of pesticides. Pesticide residues, including their metabolites and/or breakdown products, will continue to exist in soil, plants, and animals to some extent. Such remnants are now a significant source of contamination for herbal medications. Organizations like the WHO and others have imposed requirements reducing the impact of pesticide residues on herbal materials Organochloride pesticides (OCPs), such as benzene hexachlorides (BHC) and dichlorodiphenyl-trichloroethane (DDT), are frequently found in herbal medicines. DDT has been banned in many countries for about 30 years due to its negative effects.

4.2 Microbes and Mycotoxins

Microbes frequently contaminate medications, which is an issue. On herbal materials, pathogenic bacteria have been observed to grow, including enterobacter, enterococcus, shigella, and streptococcus. 33 Fusarial toxin, aflatoxins, ochratoxin, citreoviridin, penicillic acid, etc. are a few examples of mycotoxins. Aflatoxin is extremely lethal and widely disseminated. 6 More than 50% of the samples of medicinal herbs tested positive for bacteria, exceeding the US Pharmacopoeia's microbial count restrictions, according to a study of plants purchased from a Brazilian market. 34 Mycotoxins and microbial contamination were also discovered in subsequent research. In herbal treatments from South Africa, India, and Malaysia In 35 China, Indonesia, and 37, microorganisms could infect the production and distribution of herbal medicines at any time. The following conditions apply to processing and storing

4.3 Other Foreign Material

Ash, adjuvants, or organic solvents are examples of additional foreign substances that might cause herbal medicines to become contaminated externally. 6, 39 Reduce this issue as much as possible to guarantee the final product's high quality

4.4 Adulteration

Adulteration, which is defined as "to make impure by introducing additional, unsuitable, or inferior ingredients," is always fraudulent. There have been numerous reported cases of herbal medicine including contaminated orthodox medications and plant ingredients. Three types of adulterations can be distinguished: substitution (using phoney or subpar plant ingredients), adding of orthodox pharmaceuticals to herbal remedies, and addition of foreign elements (non-officinal herb parts, Sands, metals). Numerous drugs have been discovered in herbal medicines, and adulteration of commercially accessible herbal preparations has been reported to occur on average in California (7%), New York (5.5%), and Singapore (1.23%). 14 Sildenafil, the active ingredient in Viagra, has recently been discovered in various herbal items marketed as tonics. Typically, adding foreign substances and substitutes to herbal drugs is done to increase their effectiveness.

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V. NEED OF QUALITY EVALUATION OF HERBAL DRUGS AND IT'S FORMULATIONS

As the risks and shortcomings of modern medicine become increasingly obvious, there is a shift toward the use of herba l therapy on a global scale. The regulatory authorities' primary duty is to make sure that patients receive medication that is guaranteed to be pure, safe, potent, and effective. Through the statutory imposition of good Manufacturing practises, the regulatory authorities strictly adhere to the numerous criteria of quality set for raw materials and finished Products i n pharmacopoeias, formularies, and manufacturing operations. These steps should be followed for all pharmaceutical ty pes, whether they are part of a traditional or modern medical system. Despite the fact that herbal products have gained p opularity around the world, a barrier to their adoption is the lack of standards.profile for quality control. The effectiveness and safety of herbal medicine are impacted by the quality of the drug, or the composition of its elements in the finished product. However, it is challenging to define quality control parameters because of the complex nature and intrinsic unpredictability of the ingredients of plant-based drugs. Although it is anticipated that contemporary analytical techniques would aid in avoiding this issue. Furthermore, it is usually unknown or only partially understood what Constituents are behind the purported therapeutic Effects. The use of a combination of herbal compounds, as is done in traditional therapy, further complicates this. Up to five different botanical ingredients are frequently included in a single product. As a result, batch to batch variation begins with the actual acquisition of raw materials.an identifying standard. During storage and subsequent Processing, these variations increase in number. Therefore, standardisation should include the full field of study for herbal medications and goods, from the production of medicinal plants to their clinical application.

VI. CONSTRAINTS IN QUALITY DETERMINATION OF HERBAL DRUG

6.1 Reproducibility of Biological Activity of Herbal Extracts

One of the primary challenges to using plants in pharmaceutical development is the fact that more than 40% of plant extracts lack repeatable effect [46]. The biggest problem is repeatability because the activities seen in screens usually do not occur when plants are re-sampled and re-extracted. Changes in the biochemical profiles of plants collected at various times and locations, variations in plant species, and variations in extraction and biological activity assessment procedures are the main causes of this problem. Additionally, additive or synergistic interactions between the component parts might contribute to the activity and efficacy of plant extracts and pharmaceuticals.To assess changes in the concentration of bioactive phytochemicals in plant material, a procedure should be applied. Recognizing the numerous stress or agroclimatic locations,, Climate, microenvironments, physical, and chemical stimuli—often referred to as elicitors—that affect the quantity and quality of bioactive secondary metabolite content are crucial. The reliability and effectiveness of plant extracts in drug development should therefore be greatly increased as a result of elicitation-induced recurring increases that could otherwise be missed in screens. The manufacture of several herbal medications could be made economical and with strict quality control by standardisation, optimization, and thorough control of growth conditions.

6.2 Quality Evaluations of Herbal Formulations

A. Organoleptic or Macroscopic Evaluation

Drugs can be evaluated either organically using the sense organs (skin, eye, tongue, nose, and ear) or microscopically using elements like colour, odour, taste, size, form, and distinctive qualities like touch and texture. It is a technique for assessing a product's quality based on an examination of its morphological and sensory profile. The fractured surfaces seen in quassia wood, quillia, and cascara barks are significant characteristics. Licorice's sweet flavour and the aromatic perfume of umbelliferous fruits are two examples of this sort of evaluation, in which the presence of volatile oils impacts the odour of the drug.

B. Microscopic Evaluation

It requires a careful analysis of the ingredients and can be used to identify organised medicines based on recognised histological traits. It is mostly used to evaluate organised crude medications in their entire and concentrated forms at the microscopic level. Some of the important factors that are vital for the identification of particular crude pharmaceuticals [8–12] are trachomas, stomata, starch granules, calcium oxalate crystals, and aleuronic grains. Phloroglucinol and Hcl

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treatment causes all lignified tissues to emit a pink strain; starch and hemicelluloses can be distinguished by their blue colour in an iodine solution. Cellular structure can be seen when mucilage is dyed pink using ruthenium red. The microscopic analysis includes looking at the components of the powdered medication. using chemical techniques

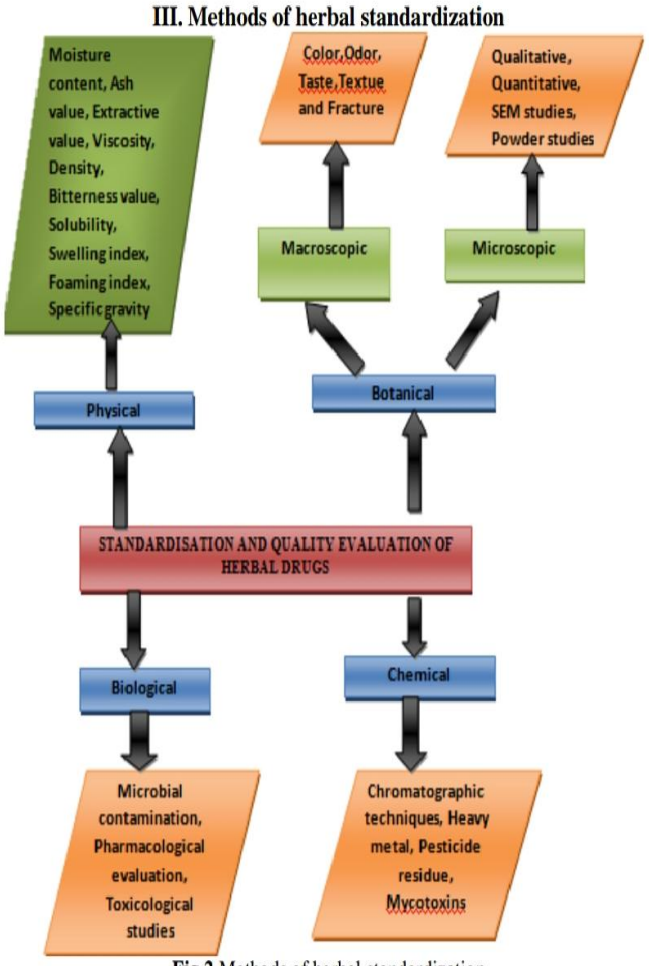

Fig.2 Methods of herbal standardization

C. Chemical Evaluation

The biological or pharmacological action of the majority of drugs is caused by distinct chemical components. Qualitative chemical tests are performed to identify certain medications or verify their purity. The separation, purification, and identification of active constituents are done using chemical assessment techniques. Using the acid value and sulphated ash to evaluate resins Balsams are assessed using their acid value, saponification value, and bester values. The qualitative chemical tests can be performed to locate adulterants and distinguish chemical constituents.

D. Physical Evaluation

The evaluation of various medications occasionally includes consideration of physical constants. These include the amount of moisture present, specific gravity, rotational and refractive optical properties, melting point, viscosity, and solubility in various solvents. All of these physical characteristics are helpful in identifying and locating plant elements.

E. Biological Evaluation

Some medications have particular biological and pharmacological activity that is used to assess them. Actually, a particular type of ingredient found in the plant extract is what's causing this activity. The experiments were conducted on both entire and isolated organs of living animals for evaluation. Bioassays can be used to assess the drug's potency during preparation.

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VII. WHO GUIDELINE FOR GOOD MANUFACTURING PRACTICE

- Specific biological and pharmacological activity in some medications is used to assess them. Actually, a particular type of ingredient found in the plant extract is what's causing this activity. The experiments were conducted on both entire and isolated organs of living animals for evaluation. Bioassays can be used to assess the drug's potency during preparation.
- The United States complies with the current Good Manufacturing Practices for Finished Pharmaceuticals regulations.
- The European Union has access to the European Commission Guide to Good Manufacturing Practice for Medicinal Products.
- The ICH Q7 recommendations contain the Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.
- The Good Manufacturing Practices regulations are included in Schedule M of the 1945 Drugs and Cosmetics Act and Rules in India.

A. Documentation

GMP Compliance is based on documentation, which also guarantees the traceability of all testing, manufacturing, and development activities. Documentation gives auditors a way to evaluate the overall effectiveness of business activities and the end output. various GMP regulations are addressed

B. Environment

Is crucial to regulate a plant's lighting, ventilation, air, water, temperature, and humidity in order to prevent any negative effects on the quality of the final output. Facilities must be designed to minimise the danger of environmental contamination. It is necessary to have the proper lighting, temperature, humidity, and ventilation. Interior surfaces, including the walls, floors, and ceilings, are smooth, without cracks, and do not lose particles. Surfaces within are simple to clean. Drains are proportioned properly, have trapped gullies, and are easy to clean, as are the pipework, light fixtures, and ventilation points.

C. Equipment

Equipment Design and instal the equipment in a location that is suitable for its intended use and easy to clean. Equipment needs to be labelled clearly and calibrated at regular intervals.

D. Validate Processes

Every product's safety and efficacy must be maintained, and consistent performance improves a company's reputation for reliability and quality. Validation offers a high level of assurance that the things we are producing are of excellent quality. There are detailed documented protocols for every step in every stage. If there are any modifications to the production process, batch size, or new techniques, validation is necessary. All validation procedures should be carefully thought out and specified. Typically, a Validation Master Plan is used for this (VMP). Consider all the crucial criteria that could be impacted and have an impact on the quality of the final product before you reach this stage. Validation typically entails:

- Installation qualification testing, which verifies that the equipment is installed properly.
- Operational qualification testing, which determines whether the equipment operates properly.
- Performance Qualification, which involves testing to ensure that a product can be manufactured according to standards on a regular basis.

E. Change Control

When there is a process, method, or specification change, it is referred to as "change control" (Finished product and shelf life). Change control allows us to make any necessary corrections to procedures or incorrect writing. After change control has given its approval, we can go on to new techniques, protocols, and requirements. All modifications to facilities, equipment, or processes that can have an impact on product quality should be documented using a change control system.

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VIII. GUIDELINES FOR GLP

A. Test Facility Management

The term "test facility" refers to the people, places, and operational components required to carry out the non-clinical health and environmental safety investigation. The term "test facility" includes not only the buildings, rooms, and other premises but also the people who work there and are responsible for carrying out these studies. It may refer to several "test sites," at one or more geographical locations, where phases or components of a single overall study are conducted (Seiler, 2005). The test facility for multi-site studies takes into account the site where the study director is located as well as individual test sites, which can be regarded as test facilities either individually or collectively.

B. Equipment

Equipment, including validated computerised systems, used for data creation, analysis, and recovery as well as environmental factor control pertinent to the study should be appropriately positioned, of the right kind, and have enough capacity. The following information should be included in equipment records: the equipment's name, manufacturer, model or type for identification, serial number, and the date the equipment arrived in the lab, as well as a copy of the manufacturer's operating instructions (s). According to Standard Operating Procedures, all study-related equipment should undergo routine inspections, cleanings, upkeep, and calibrations. It is important to keep track of these actions. Calibration ought to be able to be linked to regional, global, or national standards of measurement. For any analytical laboratory, instrument validation is a process that is essential. Data generated by "faulty" instruments may give the impression of being accurate.

C. Receipt, Handling, Sampling and Storage

The way that laboratories track samples varies. Receiving, handling, sampling, and storing must be done properly. Records describing the characteristics of the test item and reference item, the date of receipt, the date of expiration, and the quantities received and used in research should be kept. Identification of handling, sampling, and storage techniques is necessary to prevent contamination and provide stability and homogeneity to the greatest extent possible (Seiler, 2005). They need to keep a clear link between a set of analytical results and the samples from which they were gathered.

D. Standard Operating Procedures (SOP)

The term "raw data" refers to any laboratory worksheets, records, memoranda, notes, or exact copies thereof that are the outcome of the initial observations and activities of a study and are required for the reconstruction and evaluation of the study's report, as defined by EPA (Environmental Protection Agency) GLP regulations. Raw data examples include logbooks for documenting temperatures or the operation, maintenance, and repair of equipment, field or laboratory notebooks, forms for field or laboratory observations, training reports, computer printouts, and data recorded from automated instruments. One of the purposes of the Standard Operating Procedures is to eliminate the need for anyone to recall all these specifics because it is so difficult to do so (SOPs).

E. Reporting of Study Results

Raw data, which are the first data obtained during the course of a Procedure, are produced by all studies. They are crucial for the reconstruction of studies and help to make a study's events traceable. The experimental results that will serve as the foundation for the study's conclusions are known as raw data. Some of the raw data may be used immediately, while others may undergo statistical processing. The study report's results and the scientist's interpretations of them must be a true and accurate depiction of the original data.

F. Storage and Retention of Records and Materials

Records and materials should be properly prepared for storage and retention. The study plan, raw data, samples of test and reference items, specimens, and other information shall be kept in the archives for the time frame specified by the relevant authorities. The final report of each study includes master schedules, records of personnel's qualifications, training, experience, and job descriptions; records and reports of the maintenance and calibration of apparatus; and

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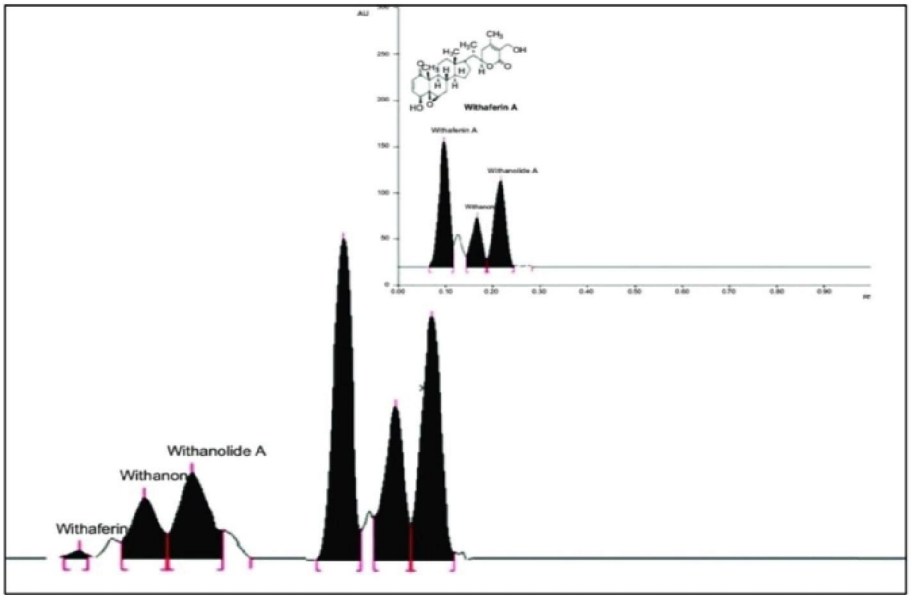
validation documentation for computerised systems. It also includes records of all inspections carried out by the Quality Assurance Programme. The final assembly of any study materials should be recorded even if there isn't a required retention period.

IX. APPLICATION OF CHROMATOGRAPHY FOR THE QUALITY EVOLUTION OF HERBAL DRUGS AND FORMULATIONS

HPTLC analysis and case studies of some important herb and Formulations

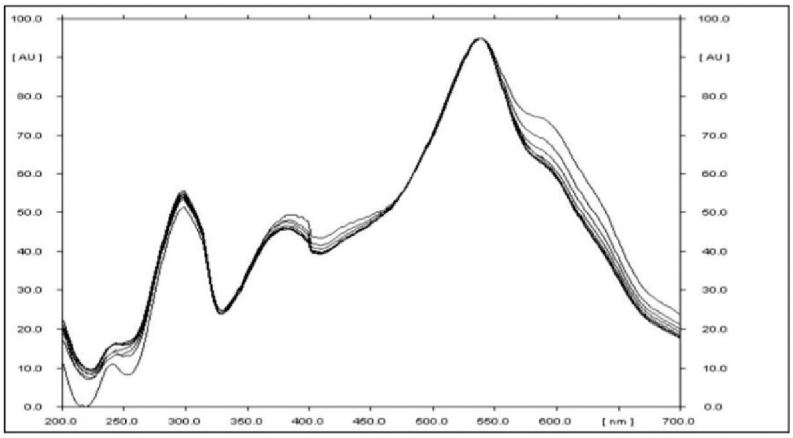
Withania somnifera (Ashwagandha)

Is a herb with "rasayana" (rejuvenator), "longevity" and "reviving" characteristics according to Ayurveda. The standardised aqueous extract of Withania somnifera's roots and leaves is known as Sensoril®. Examine the effects of Sensoril® supplements on the adaptations to strength training.



Creation of an HPTLC method for ursolic acid estimation: 1 gramme of aqueous 100 cc of methanol were used to dissolve an Ocimum sanctum extract before it was filtered through Whatman No. 1 filter paper. Libermann Burchard's reagent was used to derivatize 10 l of each extract collected from various geographic sources along with 3 l of standard solution chromato-Gram. Utilizing D2 and a tungsten light, a spectrum analysis was performed to determine the maximum amount of ursolic acid in the 200-700 nm range. The peak's maximum height and area were measured at the wavelength known as "max." Ursolic acid's maximum wavelength was discovered to be 550 nm. Using CAMAG Reprostar 3, the image of the derivatized plates was captured. HPTLC Method for Ursolic Acid Estimation

Ocimum Sanctum



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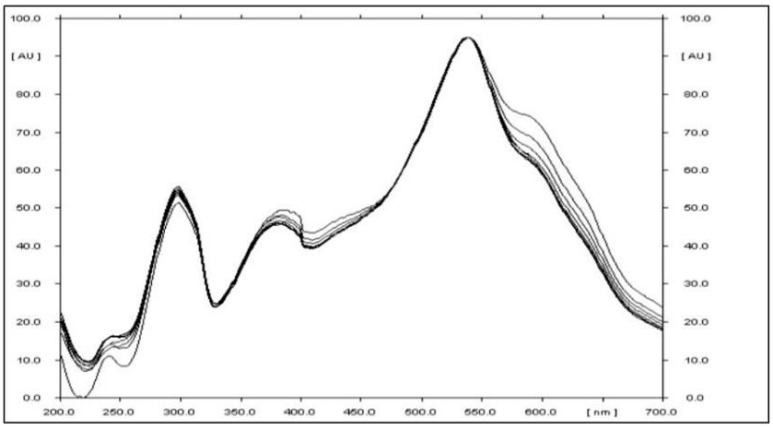
Background: Piper longum Linn. root, or pippalimula, is a well-known herb used as a single medication or in compound formulations for a variety of disorders. The study's goal was to analyse Pippalimula using physicochemical and HPTLC methods. Materials and Methods: Alcoholic extract and finely ground pippalimula powder were prepared and used in a chromatographic investigation and phytochemical analysis, respectively. The physical-chemical study of the root produced similar results to those reported for API standard limits. With toluene, ethyle acetate, and acetic acid (7:2:1) v/v, HPTLC analysis was carried out. which revealed three spots at 254 nm. The root of the Piper longum Linn. can be analysed using HPTLC to provide standard analysis with a chosen solvent system, which can be used as a reference for the drug's authentication and quality control.



Quality evaluation methods of herbal crude drug and formulations

Triphala churna

Physico-Chemical Evaluation

The physical-chemical characteristics of all three samples, including foreign matter, moisture content (Loss on Drying), pH, total ash, acid-insoluble ash, water-soluble extractive, and alcohol-soluble extractive values, were assessed using established procedures. The following is a description of every procedure:

Determination of Foreign Matter

A 100g sample was spread out thinly on a suitable platform and inspected in the light without the help of glasses (or with a 6x or 10x magnifier), with the foreign matter being separated and the sample being weighed. Based on the drug sample, the percentage of foreign matter was computed. was then cooked for three hours in an oven at 105 °C. Until the difference between two subsequent weighs equated to no more than 0.25 percent, the drying and weighing were maintained at half-hour intervals.

Determination of Moisture Content

- Precisely weigh two grammes of triphala churna in a porcelain plate.
- Kept in cool air after 2 hours of heated air.
- Calculate the triphala churna's moisture content by weighing it**.**

Determination of total Ash value:-

- Accurately weigh 3 grammes of drug-infused silica crucible powder.
- Burn powdered drugs by gradually raising the temperature until they are carbon-free and cool.
- Determine the total Ash value by weighing the ash.

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Formulations and evaluation of herbal cream

Composition of cream

Sr. No	Name of Ingredients	Quantity given	Quantity Taken
1	White beeswax	5 gm	5 gm
2	Liquid paraffin	7 ml	7 ml
3	Borax	2 gm	2 gm
4	Perfume	2 drops	2 drops
5	Curcumin (Turmeric)	200 mg	200 mg
6	Aloe vera gel	1 gm	1 gm

Procedure:

1. Used a water bath set at a temperature of 700C to melt the bees wax and mineral oil.
2. Here, curcumin is not water soluble.
3. As a result, only a small amount of ethyl alcohol was added.
4. This was heated to the same temperature before being added to the borax water mixture.
5. After achieving both temperatures at a temperature of 700C, the aqueous phase was added and stirred quickly and continuously until it cooled.
6. Filtered it and put it in a container with a label.

Evaluation of Cream

Physical Characteristics

The cream's colour and smell were assessed.

- **Homogeneity**: The formulations' homogeneity was examined both visually and tactilely.
- **Appearance:** The cream's appearance was graded according to its colour, pearlescence, and roughness.
- **After feel:** After applying a certain amount of Cream, the emolliency, slipperiness, and amount of residue left were assessed.
- **Smear type:** Following application of the cream, the kind of film or smear that developed on the skin was examined.
- **Ease of Removal:** By rinsing the area where the cream had been applied with tap water, the cream's ease of removal was evaluated.
- **Thermal Stability Test:** A humidity chamber set at 60–70% relative humidity and 37–10°C was used to gauge the formulation's thermal stability.

X. CONCLUSION

Plant materials account for a sizeable share of the global medication market and are utilized all over the world, in both developed and developing nations, as OTC drug ingredients, home remedies, and pharmaceutical industry raw materials. A crucial issue that needs to be addressed is the assurance of the safety, quality, and efficacy of medicinal plants and herbal products. With the collaboration of drug regulatory agencies, scientists, and industries, it is obvious that the herbal business can advance significantly in India. To properly comprehend the utilisation of herbal medications, however, technique standardisation and quality control data on safety and efficacy are needed. Therefore, it is crucial to create widely accepted standards for evaluating their quality. Now that it's become clearthatA holistic approach to healthcare is required, and traditional medicines' untapped potential should be used. This won't be simple, though, as it calls for a thorough search for medicinal plants, accurate identification guidelines, validation of the scientific methods of active ingredient isolation, preclinical assessment of their pharmacological and toxicological profiles, and clinical proof of their efficacy. Clinical trials must to be carried out to identify details like the typical effective dose for any medication and any side effects a substance may have. In other words, these herbal medicines require the same type of analysis as any modern drug, i.e., randomised controlled clinical studies. This will raise the drug's quality and also

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