

Review on “Quality Aspects Of Herbal Drug and its Formulations”

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I. INTRODUCTION

1.1 Pharmacopoeia Definition

A. Herbal Drugs

The medicines are created from various plant parts that are known to have medicinal characteristics, such as roots, stems, leaves, bark, fruit, seeds, or flowers. Additionally, many common drugs are derived from plants. The word “drugs” actually derives from the French word “drogue,” which means “dry herbs”. [1]

B. Raw Material

Raw materials are called as materials or substances used in primary production or manufacturing of goods. [2]

C. Herbal Formulations

Herbal formulation is dosage form consisting of one or more herbs or processed herbs in particular quantities to provide specific nutritional, cosmetics benefits and are meant to diagnose, treat, alleviate, disease of human being or animal, alter the structure of human being or animals. [3]

1.2 Meaning of Quality in Terms of Herbal Drugs

Quality control for efficacy and safety of herbal products is of paramount importance. Quality can be defined as the status of a drug that is determined by identity, purity, content, physical or biological properties or by the manufacturing processes. Quality control is a term that refers to processes involved in maintaining the quality and validity of a manufactured product. For quality controls of traditional methods are procured and studied and documents and the traditional information about the identity and quality assessment are interpreted in terms of modern basements. [4]

Factors affecting quality of herbals:

1. Altitude.
2. Temperature and humidity
3. Rainfall.
4. Soil and soil erosion
5. Fertilizer
6. Plant hormone
7. Polyploidy
8. Hybridization
9. Greenhouse effect

A. Altitude

The most significant element affecting the cultivation of medicinal plants is altitude. While the wind speed, relative humidity, and light intensity rise as height, temperature, and atmospheric pressure decrease. Therefore, when the climate conditions change with height, the pattern of the vegetation likewise changes.

Senna may be grown at sea level, unlike tea, cinchona, and eucalyptus which prefer a height of 1000–2000 meters.

Example: 1) Clove up to 900.

2) Camphor 1500 – 2000.

B. Temperature and Humidity

Another important component for the cultivation of the medicinal plant is temperature and humidity. Plants eventually perish from dryness and desiccation as a result of the sudden drop in temperature that led to the production of ice crystals in their intercellular spaces. The rate of photosynthesis is influenced by temperature changes. As the temperature rises, the rate of respiration increases. Water vapors, which are a kind of humidity, are present. The term for this is atmospheric humidity. Humidity manifests itself visually as clouds and fog. Plant structure, form, and transpiration are all impacted by humidity.

C. Rainfall or Irrigation

Except for xerophytes, the majority of other plants require water, proper irrigation, and enough rainfall to grow. The most significant factor affecting the cultivation of medicinal plants is rainfall. Rainwater is the primary source of water for the soil. The amount of rain and snowfall greatly influences the weather. Rainfall water goes into rivers and lakes, percolates into the earth to create ground water, and then evaporates the remainder. Plants absorb the minerals from the soil once they have been dissolved in water. Water affects a plant's physiology and morphology. Example: continuous rain can lead to a loss of water – soluble substances from leaves and roots by leaching.

D. Soil and Soil Fertility

The growth of all plants is supported by soil, making it the most significant natural resource. In addition to providing necessary plant food elements, soil also offers mechanical strength and anchoring. The term “soil fertility” refers to a soil's ability to give plants with the necessary amounts and ratios of nutrients as well as a favorable environment for plant growth. The joint action of climatic elements like plants and microorganisms results in the formation of the soil. To guarantee maximum medicinal retention, fertility, and a pH range of 6.5 to 7.5, the soil should include the right number of nutrients, organic matter, and other factors. Alkaline soils can be reclaimed by gypsum, while acidic soils can be limed. Leguminous plants cannot grow in acidic soil because nodule bacteria cannot develop to their full potential.

E. Fertilizer

Any substance of natural or synthetic origin (apart from liming materials) applied to soil or plant tissue (often leaves) in order to supply one or more plants with nutrients necessary for their growth is referred to as a fertilizer or fertilizer. Fertilizers are nutrients that plants need in order to develop and flourish. The second way that certain fertilizers work is to improve the soil's efficiency by altering its water retention and aeration. For the purpose of preserving soil fertility, enhancing crop development, yield, and/or crop quality, fertilizers are either applied to the soil, directly to the plant (foliage), or mixed into an aqueous solution.

F. Plant Hormone

It is an artificial organic molecule that resembles hormones. It influences growth and development in short doses by either encouraging or suppressing growth. General plant hormones are broadly divided into five classes, including auxin (cell elongation), which is the first class. (2) Gibberellins, which cause cell division

and elongation, which results in growth. (3) Cytokine's (cell division + senescence inhibition. Abscissic acid (4) (abscission leaves and fruits) (5) Ethylene (promotes senescence, epinasty and fruits ripening).

G. Polyploidy

Euploidy is a type of ploidy in which the genome contains the entire set of chromosomes, and it includes monoploidy, diploidy, and polyploidy. Polyploidy occurs when some plants have more than two genomes. Artificially induced methods/physical agents (a) Colchicine's (b) Veratrin (c) Sulphanilamide (d) Mercuric chloride cause polyploidy. Greater relevance of medicinal plants is a significant impact of polyploidy. It might lead to the emergence of new species. Mutation: Mutation is the name given to the sudden change in genotype that results in qualitative or quantitative alteration of genetic material. Mutagens are a class of agents that can artificially promote mutation. Varieties of mutagens (A) Physical mutagens include cosmic rays, gamma radiation, and ionizing radiation. UV radiation is a non-ionizing radiation. (B) Chemical Mutagens: Acridines: Acridines and profoavinea, Alkylating Agents: Nitrogen and Sulphur Mustard. Novolex acid.

H. Hybridization

In the process of hybridization, two genetically distinct individuals are crossed to produce a third person with a different, frequently desirable, set of qualities. Plants of the same species can easily hybridize and create viable offspring. Wide crossings are challenging to perform and typically result in sterile offspring due to problems with chromosomal matching during meiosis. Plant hybridization happens naturally through a variety of methods. Some plants are pollinated by insects, while others are pollinated by the wind. Cross-pollinated plants are those that have undergone this process. Natural hybridization, which is typical in cross-pollinated plants, has been crucial in creating novel genetic combinations. It is a typical method of producing genetic diversity. [5]

1.3 Constraints in quality determination of herbal Drugs

Symptoms connected to handling medicinal plants, indiscriminate harvesting, and subparts post-harvest care procedures. Lack of research into domestication, the creation of high- yielding cultivars, etc. inadequate farming and propagation practices. Inadequate processing methods resulting in low yields and subparts goods. Inadequate quality control methods.

Insufficient use of modern good manufacturing processes. Product and process development lacks research and development. Problems with marketing. Inadequate equipment and manpower. Lack of access to the most recent market and technological information. Complex mixes of organic compounds, such as fatty acids, sterols, alkaloids, flavonoids, glycosides, saponin, tannins, lignin, and terpenes, as well as other tiny molecules like peptide and oligosaccharides, are present in both the raw herbs and the extract. Finding an herb's component(s) that has biological activity in humans is frequently difficult. Additionally, heating or boiling herbs can change how quickly they dissolve or even change their organic elements' pharmacological activity. Similar to this, a wide range of environmental variables, such as, seed change in temperature, ambient humidity, duration of daylight, rainfall per day, dew, and frost condition, may influence the quantities of constituents in every one batch of an herb. Other elements, such as disease, insects, planning, density, rivalry with other plant species, growing period, and genetic elements, are also important. One of the concerns for quality is plant gathering for use in botanicals. Plants that have been harvested from the wild may contain non-targeted species, especially if they have been purposefully or accidentally adulterated. Herbal products can be tampered with in a number of ways, but the most common is to replace the intended

plant species with another that is more readily available or less expensive, or occasionally by adding synthetic ingredients to the product. [6]

II. QUALITY EVOLUTION OF HERBAL FORMULATION

2.1 Raw Material Quality Evolution

A. Microscopic Evolution

It involves detailed examination of the drugs and it can be used to identify the organized drugs by their known histological characters. It is mostly used for qualitative evolution of organized crude drugs in entire and power forms with help of microscope. Using microscope detecting various cellular tissues, trichome, stomata, starch, granules, calcium oxalate and aleuronic grains are some of the important parameters which play an important role in identification of certain crude drugs. Starch and hemicelluloses are identified by blue color with iodine solution, all lignified tissues give pink stain with phloroglucinol and HCl etc. Mucilage is stained pink with ruthenium red and can be used to distinguish cellular structure. Microscopic evolution also includes study of constituents in the powdered drug by the use of chemical reagents. Quantitative aspects of microscopy include study of stomata number and index, palisade ratio, vein isolate number, size of starch grains, length of fiber etc. which plays a very important role in identification of drug.

B. Chemical Evolution:

Most of drugs have definite constituents to which definite chemical constituents to which their biological or pharmacological activity is attributed. Qualitative chemical test is used to identify certain drugs or to test their purity. Isolation, identification of active constituents is based on chemical methods of evolution.

1. Evolution test of resins – acid value, sulphated ash.
2. Evolution test of balsams: acid values, saponification value, bester values
3. Evolution test of volatile oils: acetyl and ester value the identification.

C. Physical Evolution

Physical constants are sometimes taken into consideration to evaluate certain drugs. These include moisture content, specific gravity, optical rotation, refractive index, melting point, viscosity and solubility in different solvents. All these physical properties are useful in identification and detecting of constituent present in plants.

D. Biological Evolution:

Some drugs have specific biological and pharmacological activity which is utilized for their evaluation. Actually, this activity is due to specific type of constituents present in the plant extract. For evolution the experiments were carried out on both intact and isolated organs of living animals. With the help of bioassay, strength of drug in its preparation can be evaluated. [7]

The Process of Evolution and Quality Assurance:

WHO Guidelines for Good Manufacturing Practices:

The general principles of GMP are set out in the parents. Cultivation and collection of medicinal plants, as the starting materials for Herbal medicines, are covered by other guidelines. The first critical step of their production where the application of GMP starts should be clearly designated. This is of particular importance for those products which consist solely of comminuted or powdered herbal materials.

WHO Guidelines for Good Laboratory Practice:

The GLP Principles set out the requirements for the appropriate management of non-clinical safety studies. This helps this help the researcher to perform his /her work in compliance with his/ her own pre-establishment scientific design. GLP principles help to define and standardize the planning, performance, recording, reporting monitoring and archiving processes within Research Institution. The regulation is not concerned with the scientific or technical content of studies per se. The regulation does not aim to evaluate the scientific value of the studies: this task is reserved first for senior scientist working on the research programmed, then for the Registration Authority, and eventually for the international scientific community as a whole. The GLP requirements for proper planning, for controlled performance of techniques, for faithfully recording of all observation, for appropriate monitoring of activities and for complete archiving of all raw data obtained, serve to eliminate many source of error. Whatever the industry targeted, GLP stresses the importance of the following main point:

1. Resource: Organization, personnel, facilities and equipment;
2. Characterization: Test items and test system;
3. Rules: Protocols, standard operating procedures (SOPs)
4. Results: Raw data, final report and device;
5. Quality Assurance: Independent monitoring of research processes.

Organization and Personnel

GLP regulation required clear definitions of the structure of the research organization and theresponsibility of the research personnel. This means that that the organizational chart should reflect the reality of the institution and should be kept up to date. Organizational charts and job description give an immediate idea of the way in which the laboratory functions and the relationship between the different departments and posts. GLP also stresses that the number of personnel available must be sufficient to perform the tasks required in timely and GLP compliant way. The responsibility of all personnel should be defined and recorded in job description and their qualification and competence defined in education and training records. To maintain adequate levels of competence, GLP attaches considerable importance to the qualifications of control for the whole study. This person is appointed by the test facility management and will assume responsible for the GLP compliance of all activities within the study. He/ she are responsible for the adequacy of study protocol and for the GLP compliant conduct of the study. He /she will assert this at the end of the study in his / her dated and signed GLP compliance statement which is included in the study report. The study director must therefore be aware of all events that may influence the quality and integrity of the study, evaluate their impact and institute corrective actions as necessary. Even when certain phases or parts of the study are delegated to other test sites (as in the case of multisite studies), the study director retains overall responsibility for the entire study, including the parts delegated and for the global interpretation of the study data.

Facilities and equipment

The GLP principles emphasize that facilities and equipment must be sufficient and adequate to perform the studies. The facilities should be spacious enough to avoid problem such as overcrowding, cross contamination or confusion between projects. Utilities (water, electricity etc.). must is adequate and stable. All equipment must be in working order, programmed of validation/qualification, calibration and maintenance attains this, keeping records of use and maintenance is essential in order to know, at any point in time, the precise status of the equipment and its history.[7]

2.2 Quality Evolution of Finished products

Phytochemical Analysis of Finished Products Using Chromatography Techniques:

Photochemical studies are the amount of compound isolated and its purity. Both of these factors greatly affect the possibilities for structural elucidation and the use of a compound in bioassays – something that has become increasingly important in recent decades.

Chromatography has developed in similar way to spectroscopic techniques from early beginning to the present. Indeed, there is gap of several order orders of magnitude between early analytical tools such as Thin Layer Chromatography (TLC) on paper and silica gel to current chromatographic equipment. Advances such as GC, HPLC, chiral, affinity, exclusion, ion exchange and counter current (CCC) chromatography have widened the possibilities and lowered the quantities of compound required for analysis (e.g. Scherer et al. 1998; Hostettman et al. 1997). Besides the development of instrumental chromatographic techniques, the implementation of hyphenated tandem techniques that combine chromatographic separation separation with spectroscopic data collection and detection (first UV and MS, and later NMR) has again extended the possibilities for compound isolation, purification and structural elucidation (e.g. Zhang et al. 2006; Wolfenden et al., 2006). In addition, the implementation of fast and reliable methodologies for Analysis based on GC – MS, LC -UV – MS etc. Made possible the identification and qualifications of known compounds in plants and other organisms. The techniques described above are of particular importance since biosynthesis pathways could not be proposed without knowledge of the structures of minor secondary metabolites. Also, the study of role of secondary metabolites could not be properly addressed without techniques that allow the isolation of sufficient amounts of compounds with a high degree of purity to run the corresponding bioassays. In this sense, the technical advances achieved in chromatographic and spectroscopic technique have been a great influence in changing the Direction of phytochemical ecology from a descriptive approach of the structure to global vision of their role within the plant or in relation to environmental (biotic and abiotic) factors.[8]

Long Term and Short Term Stability Testing of Herbal Formulations Using ICH Guidelines:

Study is performed at 25/60% RH or 30°C/65%RH. Ideally 12 months' data is to be registration dossier, continued till end of shelf life for parental stability has to be carried out at 2-8°C – Liquid products packed in container with closure need to be stored in inverted position, to allow interactions with closure (Ex: sorption of preservative by rubber in vials).

Study storage conditions minimum time period covered by data at submission long term 25°C + 2°C / 60 % + 5% R.H or 30°C + 2°C / 65 % + 5 % R.H or 30 °C + 2°C / 75% + 5% R.H. 6 months' storage conditions Drugs products .[9]

Safety studies – Toxicological Data, Efficacy Studies – Clinical and Preclinical Data:

A. Safety

The safety of using most herbs with drugs is not well established. Some herbs are known to interact with. Pharmaceutical drugs, although most of this information comes from case reports rather than systematic investigation. St John's wort is the most notoriously interactive herbal product, and has been shown to interfere with numerous drugs metabolized by cytochrome P – 450 liver enzyme systems. Including protease inhibitors, chemotherapeutic agents and oral contraceptive. Some authorities note that many herbs, including kava, valerian, and St John's wort, have the potential to interact with aesthetic agents and other drugs given in the preoperative period.

B. Toxicological Data:

The potential for toxicity from certain herbs is compounded by the frequent use of misleading marketing information. For example, systematic review of citrus uranium for weight loss, identified only 1 methodology flawed study examining the effect of the herb, which incorrectly reported a statistically significant benefits for weight loss (the herb was no more effective than placebo). This misleading article is often cited as “published scientific evidence “of the efficacy of citrus uranium for weight loss, with no mention of possible side effects. Illegal and erroneous marketing claims for herbal products are common. In 1 study of interest marketing, more than half of herbal products illegally claimed to treat, prevent, diagnosis, or cure specific diseases.

C. Efficacy

A recent national survey identified the commonly used herbs in the United States and found that 18.9% of the adult population reported the use of herbs to treat a medical illness within the past year. The evidence for efficacy for the most common uses for each herb.

D. Clinical Data

The clinical study on primary Dysmenorrhea to comparatively examine the coded herbal drug formulations “Dysmo – off” with authentic allopathic medicine “Diclofenac sodium “A random controlled clinical trials was conducted. These evaluations were based on a verbal rating scale so as to ascertain the rate of analgesic effects on dysmenorrhea pain. The patients were randomly allocated with the ratio of 1:2 for controlling treatment with (NSAIDS) (n=40) received Diclofenac sodium tablets twice daily for 4 days (50 mg one day prior to and three days after the menstruation) and test treatment with Dysmo – off (n=80) received powered Dysmo -off twice daily for 4 days (5g one day prior to and three days after the menstruation). Treatment lasted for 4 consecutive menstrual cycles. Hemoglobin, ESR, and ultrasound were measured at baseline during the study. All subjects were clinically studies. [10]

Formulation Specific Characteristics for Herbal Tablet, Liquid and Topical: Formulations:

Topical Formulation:

1. Physical Characterization:

| Sr. no | Parameter | Characterization |
|--------|---|---|
| 1 | Vehicle shape and surface morphology. | Transmission electron microscopy. Freeze –fracture electron microscopy. |
| 2 | Mean vehicle size and size distribution. | Dynamic light scattering, zeta size, photon correlation spectroscopy, laser light scattering, gel permeation and gel exclusion. |
| 3 | Surface drugs | Free flow electrophoresis. |
| 4 | Electrical surface potential and surface pH | Zeta potential and measurement and pH sensitive probes |
| 5 | Percent of free drugs /percent capture | Minicolumn centrifugation , ion – exchange chromatography , radiolabel ling |
| 6 | Drug release | Diffusion cell /dialysis |

2. Chemical characteristics:

| Sr .no | Parameter | Characterization |
|--------|------------------------------|------------------------------------|
| 1 | Phospholipids concentration | Barletta assay, Stewart assay HPLC |
| 2 | Cholesterol concentration | Cholesterol oxidase assay and HPLC |
| 3 | Phospholipids peroxidation . | UV absorbance , Iodometric and GLC |
| 4 | Phospholipids hydrolysis | HPLC and TLC |

3. Biological characteristics:

| Sr. no | Parameter | Characterization |
|--------|-----------------|---|
| 1 | Pyrogenicity | Limulus amoebocytes lysate , LAL test |
| 2 | Animal toxicity | Monitoring survival rates , histology and pathology |

Oral liquids:

1. Uniformity of content and mass.
2. PH (c)Microbial limits.
3. (d) Antimicrobial preservative content.(e)Antioxidant preservative content.
4. (f) Extractable from container / closure system.(g)Alcohol content.
5. Dissolution for suspensions and powders for suspensions.
6. Particle size distribution.
7. Re – dispensability for suspensions.
8. Viscosity for suspensions or viscous solutions.
9. Specific gravity for suspensions or viscous solutions. (m)Water content for powder for reconstitution.[11]

Topical Formulation:

Topical formulation is applied directly to the skin. Advantages of this include.

- An increased dose of medication is applied where it is needed.
- There are reduced side effects and toxicity to other organs compared systemicMedication.

Topical formulation is made up in a vehicle, or base, which may be optimized for a particular site of the body or type of skin condition. The products may be designed to be moisturizing or to maximize the penetration of an active ingredient, often a medicine, into orthrough skin.

The amount of the active ingredient which is absorbed through the skin depends on thefollowing factors:

- Thin skin absorbs more than thick skin – skin thickness varies with body site, age and thespecific skin disorder.
- Skin barrier function – this may be disrupted by dermatitis, ichthyosis, keratolytic agents(such as salicylic acid), so it may absorbs more medication than intact normal skin.
- Small molecules are more easily absorbed through the skin than large molecules.
- Lipophilic compounds are better absorbed than hydrophilic compounds

Higher concentrations of the active ingredient may penetrate more than lowerconcentration.[12]

Application of Chromatography for the Quality Evolution of Herbal andFormulations:

HPTLC Analysis and case studies of some important herbs and formulations:Case study:

Herbal medicine to treat the various ailments. Herbal medicine is available in three forms as raw plants material or medicinal herbal product but mixtures have several chemical components. Therefore, it is very

important to know the specific components having potential for treatment. For qualitative and quantitative analysis of the herbs and herbal drugs, high – performance thin layer chromatography (HPTLC) is one of the best techniques. Hence, a case study has performed to quantify vasicinone components from *Adhatoda zeylanica*.

Herbal drugs are an important system of medicine trusted worldwide than synthetic. Therefore, world's one – fourth population is depended on Ayurveda medicine to treat variety of disease. Herbal drugs have number of chemical components in complex form. Due to complex nature of such drugs, it is tedious to get quality control parameter.

There is lot of factors affecting on quality of herbal drugs like time of collection, drying methods or most of the components are unknown etc. To overcome such problems, in recent year many advances in chromatographic Techniques came in focus for quality control of complex herbal medicines. High Performance Thin Layer Chromatography has advantages in quantification of analytes not only at micro and nanogram levels but also cost effectiveness. Thus, this technique can be used as a tool in the quality control for extraction of active compounds. The undertaken case study of *Adhatoda zeylanica* Medic deals with the quantification of vasicinone components by HPTLC High performance thin layer chromatography: It is very qualitative/ quantitative method for pharmaceutical analysis.

HPTLC plates available in the form of pre coats. Silica gel – Gel with very small particle size used as a stationary phase gives rapid separation with sensitivity. About 36 cm solvent front migration is sufficient to effect proper separation. Whatmann – HPTLC plates are produced from 4-5 μ m layer. About 7 cm distance achieved in 4 minutes.[13]

Quality evolution methods of herbal crude drugs and formulation :

Clove



Synonyms: Caryophyllum, clove flower, clove buds.

Biological source: clove consists of dried flower buds of *Eugenia caryophyllus* Linn.

Family: Myrtaceace

- Morphological study:

Color: Crimson to dark brown

Odor: Slightly aromatic

Taste: Pungent and aromatic followed by numbness.

Size: About 10 to 17.5 mm in length, 4 mm in width, 2mm thick.

Shape: Hypanthium is surrounded with 4 thick acute divergent sepals surrounded by donut shaped corolla

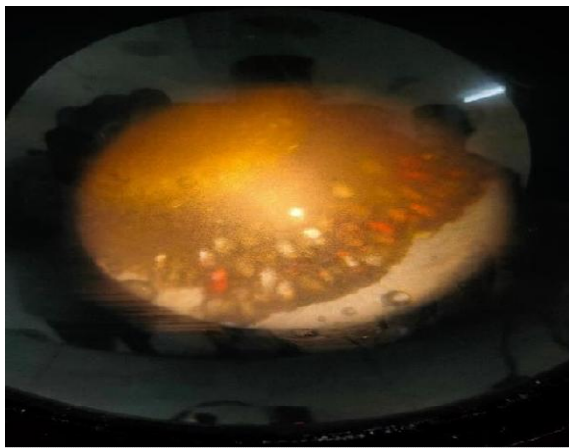
Microscopic Characteristics :

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The epidermis of clove is covered with thick cuticle. The epidermis itself consists of straightwalled cells and large normocytic stomata. The oil glands, which are ovoid and schizolysigenous are found in all parts of the drugs.

Chemical evolution:

| Test | Observation | Result |
|--|-----------------------------------|----------------------|
| Transverse section of clove is treated with strong potassium hydroxide . | Needle shaped crystals observed . | Eugenol is present . |

Moisture content of crude drugs:

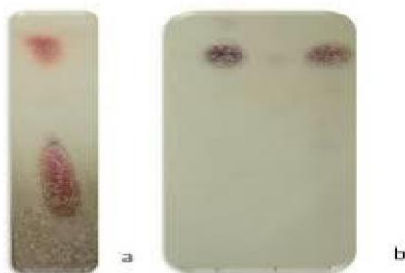


Moisture content of clove is 28%

Extractive values of crude drugs:

Extractive value of clove is 45% w/w.

Tlc profile of clove:



RF value of clove (Eugenol)= 0.42

- Uses of clove:

Clove is used as the dental analgesics.

Used as the carminative, stimulant, flavoring agent, an aromatic and antiseptic. It is also used in the preparation of cigarettes.

The oil is used in perfumery and also in the manufacture and also in the manufacture of vanillin.

- Storage:

Clove and its powder should be stored in air-tight containers in cool and dry places



Cinchona

Synonyms: Jesuit bark, Peruvian bark

Biological Source: dried bark of the cultivated tree of cinchona calisaya.

Family: Rubiaceae

Morphological study:

Stembark

Length: 30 cm Thickness: 2 to 6 mm

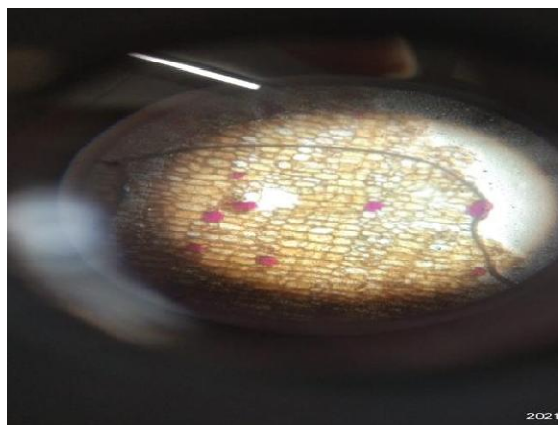
Color: outer surface brown grey, grey color

Root bark :

Length: 2 to 7 cm

Color: outer surface brown grey, grey color

Microscopic characters:



Cinchona exhibit the typical histological characters of the barks. The cork cells are thin walled, followed by phelloderm. The cortex consists of several secretory channel and phloemfibers. Medullary ray with radially arranged cells are present. Idioblast of calcium oxalate is the specific characteristics of cinchona bark. Starch grain are present in the parenchymatous tissues. Stone cells are rarely present in the structure. A few of the cork are cells are lignified. Medullary rays are 2 to 3 cells wide.

Chemical constituents: Quinine, quinidine, cinch nine, cinchonidine, caprine, hydroquinone.

Chemical test:

| Test | Observations | Result |
|--|----------------------|----------------------|
| Heat the powdered drug + glacial Acetic acid | Purple color vapors. | Quinine is present |
| Thalleoquin test: Drug powder + bromine water + dil. Ammoniacolor solution. | Emerald green color | Quinine is present |
| Drugs powder +silver nitrates solution | White precipitate | Quinidine is present |

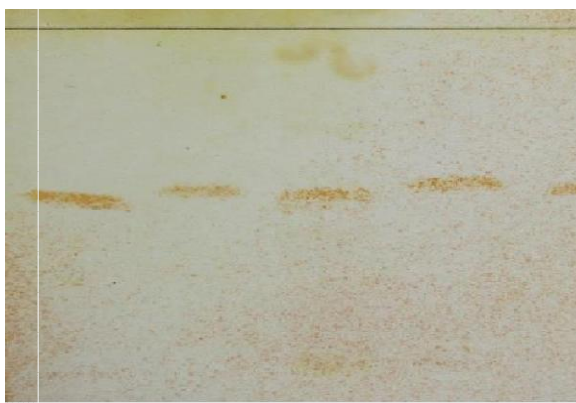
Moisture content of crude drugs:

Moisture content of cinchona drugs is 22%.

Extractive value crude drugs:

Extractive value of cinchona drug is 34%w/w.

Tlc profile of cinchona:



Rf values of cinchona (quinine) = 0.5

Uses:

- Cinchona bark is used as antimalarial plant.
- Quinine and its salt are used in treatment of malaria.
- Cinchona is used in eye lotions to numb pain, kill germs, and as an astringent.
- Cinchona extract is also applied to the skin for hemorrhoids, ulcers, stimulating hair growth, and managing varicose veins.

Formulation and evolution of Ayurveda Arishta

Ashokaristha



Evolution test of Ashokaristha Color: Blue colored liquid .

Viscosity : 0.34 centipoise .

Ashokaristha is less viscous .

PH:

PH of Ashokaristha is 4.89.

The Ashokaristha is acidic in nature



III. REPORT

The subject of herbal drug standardization is massively wide and deep. There is so much to know and so much seemingly contradictory theories on the subject of herbal medicines and its relationship with human physiology and mental function. For the purpose of research work on standardization of herbal formulations, a profound knowledge of the important herbs found in India and widely used in Ayurvedic formulation is of almost importance. Even when the chemical composition of a plant extract is known, the pharmacologically active moiety may not be. Environment, climate and growth conditions influence the composition, as does the specific part of the plant and its maturity. Monographs detailing standardization of active ingredients would improve the marketplace. Even if an herbal product is standardized to, for example, 4% of a constituent, the remaining 96% of ingredients is not standardized and may affect the product's solubility, bioavailability, stability, efficacy and toxicity. Just as controlled trials are necessary to establish safety and efficacy, manufacturing standards are required to ensure product quality. Nowadays newer and advanced methods are available for the standardization of herbal drugs like fluorescence quenching, the combination of chromatographic and spectrophotometric methods, biological assays, use of biomarkers in fingerprinting etc. Bioassay can play an important role in the standardization of herbal drugs and can also become an important quality control method as well as for proper stability testing of the product. India can emerge as the major country and play the lead role in the production of standardized, therapeutically effective Ayurvedic formulation. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization such as UV-visible, TLC, HPLC, HPTLC, GC-MS, spectrofluorimetric and other methods

REFERENCES

- [1] Sagar Bhanu , P.S. Zafar R. (2005). Herbal drug standardization . The Indian Pharmacist, 4 (35): 19 -22
- [2] Raw Materials: Definition, Accounting, and Direct vs. Indirect (investopedia.com)
- [3] Herbal formulation by Shagufta Farooqui. Herbal formulations (slideshare.net)
- [4] Modern Phytomedicine Book (turning meaning plant into Drugs) by Iqbal Ahmad , Farrukh Aqil and Mohammad Owais . Page no . 30 .
- [5] K.Sudheer Kumar, Assistant professor. Dept.of Pharmacognosy: Aug. 24, 2016, Dr. Basavaraj K. Nanjwade, Jan. 02, 2015 page no.19-36. <https://www.slideshare.net/SudheerKandibanda>.
- [6] [<https://www.longdom.org/proceedings/herbal-drugs-and-formulations-1801.html>].

- [7] Patel , P.M. Patel. , N.M. Goyal , R.K.(2006) Evolution of marketed polyherbal antidiabetic formulation uses biomarker charantin . The Pharma Review ,4(22) page no -113
- [8] Good manufacturing practice :Supplementary guidelines for the manufacture of herbal medicinal products In : WHO Expert committee on specifications for pharmaceutical preparations :Thirty four report Geneva . World Health Organization ; 1996 : Annex 8 (Who).
- [9] Revised Guidance for the Conduct of Laboratory Inspections an Study Audits. Environment Monograph No. 111. ENV/GD (95)67, OECD, Paris, 1995 (No.3 in OECD Series on Good Laboratory Practice Technical Repot.
- [10]Guidelines.html 2. Aulton's Pharmaceutics The Design & Manufacture of Medicines. Edited By Michael E. Aulton, Third Edition Patel, P.M., Patel N.M., Goyal, R.K. (2006).
- [11]Evaluation of marketed polyherbal antidiabetic formulations uses biomarker charantin.
- [12] The Pharma Review, 4(22): 113n. Published by Churchill Livingstone Elsevier. Page No. 661 to 665
3. Essentials of Physical Pharmacy By C. V. S. Subrahmanyam, Page no. 51-65
4. Futscher, N.: Schumacher P.: Pharm. Ind. 34, 479-483 (1972)
5. Grimm. W.: Krummen, K.: Stability Testing in the EC, Japan and the USA 6.
- [13] Wissenschaftliche Verlagsgesellschaft mbH. Stuttgart (1993)
7. Grimm, W.; Drugs made in Germany 28, 196-202 (1985) and 29, 39-47 (1986)
8. Dietz, R.; Feilner, K., Gerst, F.:
- [14]Grimm, W.: Drugs made in Germany 36, 99-103,9 (1993)
10 Hays 1D 1 PS 40 927-929 (1971)
12-11-2011 56.
- [15]Herbal Drug Foto and ration, Prof. Dr. Bava K. Napade J 2015 pg 29-49
- [16]Gong B.T. Wang, FT. Ch. YZ Liang Das processing for graph fingerprint of herbal medicine with chemometric appiches Analytic Letters, 2015, 38 .
- [17]Hosta, K. Marston, A Host, M. 1997 Preparative Chematography Techniques: Applications in Natural Pract biolations, conded Spring Berli.
- [18]Kadam P.V.. Yadav K.N., Shivatare R.S., Pande A.S., Patel A.N.. Patil M.J. Standardization of Gomutra Haritaki Vati: An Ayurvedic Formulation. Int. J. Pharm. Bio. Sci. 2012, 3(3). 181.
- [19]Kamboj, A., Saluja A.K. Developement of validated HPTLC method for quantification of stigmaterol from leaf and stem of Bryophylum pinnatum. Arabian journal of Chemistry 2017 10 (20) page number 2600 -2650.
- [20] Archana Gautam et.al.. "identification, evaluation & standardization of herbal drugs: a review". Pub in scholars research library, 2010, Vol 2(6), Page no. 302-315 .