# Quality Aspects of Herbal Rug and Its Formulation

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**Abstract**

**The term 'herbal drugs 'denotes plant or parts that have been converted into phytopharmaceuticals by means of simple process involving harvesting, drying and storage. A practical addition to the definition is also includes other crude products derived from plant, which no longer show any organic structure, such as essential oils, fatty oils, resins and gums. There is increasing awareness and general acceptability of the use of herbal drugs in today's medical practice. Although most of these applications are unorthodox, it is however known fact that over 80 % of the worlds population depend on herbal medicine and product for healthy living. This rise in herbal products has also given rise to various forms of abuse and adultration of the product leading to consumers and manufacturers disappointment and in some intense fatal consequences. The challenge is innumerable and enormous, making the global herbal market unsafe. Evaluation of herbal drug is an important tool in the formulation of high-quality herbal product. This review seeks to enlighten stakeholders in herbal medicine on the need to establish quality parameters with the help of advanced analytical tools and well define standardization methods in ensuring the safety of global herbal market.**

**The process of good quality assurance and standardization of herbal medicine and product using various spectroscopic, chromatographic and electrophoretic methods were also discussed.**

**Kaywords: Herbal cosmetics, Herbal cream, Herbal plants, clove,cinnamon**

## Introduction:

### Module 1: General Introduction to Quality aspects of herbals

Herbal drugs - Herbal drug are made from the roots, stems, leaves, bark, fruit, seeds, or flowers of various plants known or believed to have medicinal properties. Many conventional drugs are also derived from plants.

In fact the word "drug" came from French word drogue, meaning "dried herb".

RAW MATERIAL:-

The raw material for the process are called materials Herbal materials are part of plants such as root, rhizomes, Bark, seed d leaves, flower and stem.

HERBAL FORMULATION

Herbal formulation mean a dosage form consisting of one or more herbs or processed herbs in specified quantities to provide specific nutritional, cosmatic benefits meant for used to diagnose, treat mitigate, disease of human beings or animals alter the structure or physiology of human beings or animals.

QUALITY TERMS IN HERBAL DRUGS

control in a term refers to process involved in maintaining the quality or validity of a manufactured product. Some degree of quality control should exist regardless off the from of herbal preparation.

**FACTOR AFFECNG QUALITY OF HERBS :-**

1. Altitude
2. Temperature and Humidity
3. Rainfall
4. Soil land and soil fertility
5. Fertiliser
6. Plant Hormone
7. Polyploidy
8. Hybridization
9. Green house effect

**1. Altitude :**

Altitude is a very important factor in cultivation of medicinal plants.

The increase the altitude, the temperature and atmospheric pressure decreases while the wind velocity, relative humidity and light intensity increases.

Thus, as the climatic conditions change with height, they also produce change in the vegetation pattern.

Examples: Tea- 9500-1500 meters; cinnamon- 300-1000 meters and saffron- up to 1250 meters

**2. Temperature and Humidity :**

Temperature is the major factor influencing the cultivation of the medicinal plant. The sudden decrease in temperature caused the formation of the ice crystals in intercellular spaces of the plant.

The rate of respiration increases with increase in temperature. Examples; Cinchona- 58-73°F; Tea- 75-90°F and coffee- 55-70°F

The major sources of water vapours in the atmosphere are evaporation of water from earth surface and transpiration from plants the major effect of humidity on plant life and climate. Evaporation of water, its condensation and precipitation depends upon relative humidity and humidity affects structure, form and transpiration in plants.

**3. Rainfall :**

The main source of water for the soil is rain water. Rainfall and snowfall have a large effect the climate condition. The water from rainfall flows into the rivers and lakes percolates into the soil to form ground water and remaining is evaporated. The minerals in the soil get dissolved in water and are then absorbed by plants. Water influences morphological and physiology of plant. Examples: continuous rain can lead to a loss of water- soluble substance from leaves and root by leaching; this is known to apply to some plants producing glycoside and alkaloids.

**4. Soil and Soil Fertility:-**

The soil provide mechanical strength, as well as essential plant food element of plant Acidic soils are not suitable for Leguminous plant due to poor development of nodule bacteria.

**5. Fertiliser :**

Plant also needs food for their growth and development. What plants need basically for their growth are the carbon dioxide, sun-rays, water and mineral matter from the soil. Thus, it is seen that with limited number of chemical elements, plants build up fruits, grains, fibres, etc. and synthesize fixed and volatile oils, glycosides, alkaloids, sugar and many more chemicals.

**6. Plant Hormone :**

It is hormone like synthetic organic compound. The general plant hormone. These are group of five major classes.

1] Auxins (Cell elongation)

2] Gibberellins (Cell elongation cell division)

3] Cytokinin (Cell division inhibit substance)

4] Abscisic acid (Abscission of leaves and fruit)

5] Ethylene (Promotes substance and ripening)

**7. Polyploidy :**

Polyploidy is the heritable condition of possessing more than two complete sets of chromosomes. Polyploids are common among plants, as well as among certain groups of fish and amphibians. For instance, some salamanders, frogs, and leeches are polyploids.

**8. Hybridization :**

Hybridization is the process of crossing two genetically different individuals to result in third individual with different often prefer reset of traits plant of same species cross easily and produce fertile progeny.

**9. Green houseeffect :**

Greenhouses work well to promote plant growth because the energy from the visible rays of the sun can be used by plants in the greenhouse to fuel photosynthesis, and the greenhouse glass traps heat to keep the plants warm. Visible sunlight travels through the atmosphere and warms the earth.

**NEED OF QUALITY EVALUATION OF HERBAL DRUG AND FORMULATION:**

1. To maintain quality.

2. To maintain efficacy.

3. To maintain stability.

4. To maintain GMP standard

5. To maintain ISO standard

6. To achieve desire therapeutic action

7. Avoid error

8. Avoid loss of money, material, time.

**CONSTRAINTS IN QUALITY DETERMINATION ACTION OF HERBAL DRUG:-**

1. Constraints associated with handling of medicinal plant indiscriminate harvesting.

2. Lack of research on development of high yielding varieties, domestication, etc.

3. Poor agriculture propagation method.

4. Inefficient processing technique leading to low yields and poor quality products.

5. Poor quality control procedure.

6. Lack of current good manufacturing practice

7. Difficulty in marketing

8. Lack of trained personnel and equipment

**Module 2: Quality evaluation of Herbal formulations :**

**Raw material quality evaluation-**

**Clove (Syzygiumaromaticum) :**

Biological Source :Biological Source Clove consists of the **dried flower buds of Eugenia caryophyllus Thumb**., belonging to family Myrtaceae.

Geographical Source :Geographical Source Clove tree is a native of Indonesia. It is cultivated mainly in Islands of Zanzibar, Pemba, Brazil, Amboiana, and Sumatra. It is also found in Madagascar, Penang, Mauritius, West Indies, India, and Ceylon.

Characters : Clove is reddish-brown in colour, with an upper crown and a hypanthium. The hypanthium is sub-cylindrical and tapering at the end. The hypanthium is 10 to 13 mm long, 4 mm wide, and 2 mm thick and has schizolysigenous oil glands and an ovary which is bilocular.

Microscopy : Under a microscope, Powdered Clove reveals epidermal tis- sue with stomata, collenchyma, parenchyma with oil sacs, and spongy parenchyma or its fragments; furthermore, a few fusiform thick-walled fibres.

Chemical Constituents : Eugenol is the major compound, accounting for at least 50%. The remaining 10–40% consists of eugenyl acetate, β-caryophyllene, and α-humulene.

**Cinnamon (Cinnamomumverum)**

**Biological Source:** Cinnamon is the dried inner bark of the coppiced shoots of CinnamomumzeylanicumNees., belonging to family Lauraceae.

**Geographical Source:** Cinnamon is native to Sri Lanka (formerly Ceylon), the neighbouring Malabar Coast of India, and Myanmar (Burma) and is also cultivated in South America and the West Indies.

**Characters:** The spice, consisting of the dried inner bark, is brown in colour and has a delicately fragrant aroma and a warm sweet flavour. Cinnamon is used to flavour a variety of foods, from confections to curries to beverages

**Microscopy:** Under a microscope, Powdered Cinnamon Bark reveals starch grains, fragments of parenchyma cells containing them; fragments of fibres, oil cells containing yellow-brown oil droplets, stone cells, cork stone cells, cork tissue, and fine crystals of calcium oxalate.

**Chemical Constituents:** Cinnamon consists of a variety of resinous compounds, including cinnamaldehyde, cinnamate, cinnamic acid, and numerous essential oils

INPROCESS QUALITY EVALUATION AND QUALITY ASSURANCE :

**WHO guidelines for Good Manufacturing Practices, Good laboratory practices:**
Good manufacturing practice (GMP) is that part of a quality management system to ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production; which may broadly be categorized into two groups:

(1) Cross-contamination/mix-ups.

(2) False labelling.

Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy. For this reason, risk assessment has come to play an important role in WH0 quality assurance guidelines.

**Quality assurance in the manufacture of herbal medicines:**

In addition to the use of modern analytical techniques (especially high performance thin-layer chromatography (HPTLC), gas chromatography, high performance liquíd chromatography (HPLC). Capillary electrophoresis, mass spectrometry (MS) and atomic absorption) to characterize herbal medicines, quality assurance requires the control of starting materials as well as of storage and processing. For this reason, an appropriate quality assurance system should be applied to the manufacture of herbal medicines.

**Personnel:**

General guidance in relation to personnel involved in the manufacture of medicinal products is given in the parent guide.

The release of herbal medicines should be authorized by a person who has been trained in the specific features of the processing and quality control of herbal materials, herbal preparations and finished herbal products.

Personnel dealing with the production and quality control of herbal medicines should have adequate training on the specific issues relevant to herbal medicines.

**Training:**

The personnel should have adequate training in appropriate fields such as pharmaceutical technology,taxonomic botany, phytochemistry, pharmacognosy, hygiene, microbiology and related subjects (such astraditional use of herbal medicines).

**QUALITY EVALUATION OF FINISHED PRODUCTS :**

**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 worth 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 worth, have the potential to interact with aesthetic agents and other drugs given in the preoperative period.

**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 I 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 ofpossible side effects. Illegal and erroneous marketing claims for herbalproducts are common. In 1 study of interest marketing, more than half of herbal products illegallyclaimed to tract, prevent, diagnosis, or cure specificdiseases.

**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.

**Clinical Data: -**

The clinical study on primary demostrate to comparatively examine the coded herbal drug formulations "Dysmo-off with authentic allopathic medicine “Diclofenac sodium “A ramdom controlled clinical trials was conducted. These evaluations were based on a verbal rating scale.

**Module 3: Applications of Chromatography for the quality evaluation of Herbal drugs and formulations.**

**Chromatography :**

Chromatography represents the most versatile separation technique and readily available. Plant materials are separated and purified by using various chromatographic techniques. Herbal medicine is a complicated system of mixtures. Thus, the methods of choice for identification of "botanical drug' are mainly intended to obtain a characteristic fingerprint of a specific plant that represent the presence of a particular quality defining chemical constituents. For such purposes, chromatographic techniques such as high-performance liquid chromatography (HPLC), gas mass spectrometry (GC-MS) and thin layer chromatography (TLC) were used widely as reported in numerous publications.

**Thin Layer Chromatography (TLC)** :

Thin layer chromatography is simply known as TLC. It is one of the most popular and simple chromatographic technique used of separation of compounds. In the phytochemical evaluation of herbal drugs, TLC is being employed extensively for the following reasons:

1. It enables rapid analysis of herbal extents with minimum sample clean-up requirement

2. It provides qualitative and semi quantitative information of the resolved compounds.

3. It enables the quantification of chemical constituents, finger printing using HPLC and GLC is also carried out in specific cases.

In TLC finger printing, the data that can be recorded using a high-performance TLC (HPTLC) scanner includes the chromatogram, retardation factor (R) values, the colour of the separated bands, their absorption spectra, Lambdamax and shoulder instructions of all the resolved bands.

All of these, together with the profiles on derivatization with different reagents, represent the TLCfingerprint profile of the sample. The information so generated as a potential application in theidentification of an authentic drug, in excluding the adulterants and in maintaining the quality andconsistency of the drug.

TLCwas the commonmethod of choice for herbalanalysis before instrumental chromatography method likeGC and HPLCwere established.

Even nowadays, TLC is stillfrequently used for the analysis herbal medicines since various pharmacopoeiasuch as American Herbal Pharmacopoeia (AHP).Chinese drug monographs and analysis, Pharmacopoeia ofthe People's Republic of Chinaetc. still use TLC toprovide first characteristic fingerprints of herbsRather, TLC is used as an easier method of initial screening with a semi quantitativeevaluation togetherwith other chromatographic techniques. As there is relatively less change in the simple TLC separation ofherbal medicines than with instrumental chromatography, only a brief summary is given here, and forfurther details about TLC the readers could consult references.

**HPTLC :**

Ayurvedic or Herbal medicines is the lack of standard quality control profiles. Duc to the complex nature and inherent variability of the chemical constituents of the plant-based drugs, it is difficult to establish quality control parameter. Quality assurance of herbal medicine is an important factor and basic requirement for herbal drug industry and other drug development organization. There are several problems which influence of the quality of herbal drugs.

**Module 4 : 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

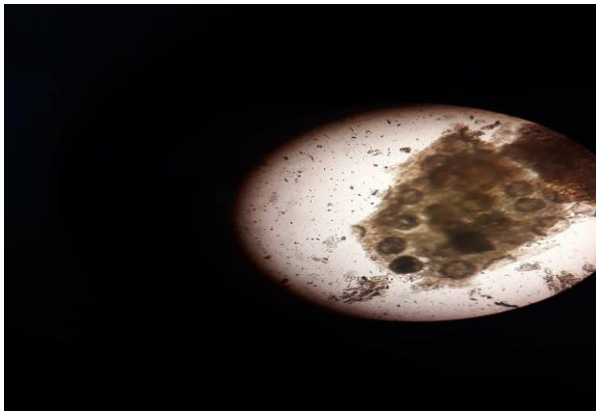
**Taste:** Pungent and aromatic followed by numbness.

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

**Shape:** Hypanthium is surrounded with 4 thick acute divergent sepels surrounded by done shaped corolla

**Microscopic Characteristics :**

The epidermis of clove is covered with thick cuticle. The epidermis itself consists of straight walled 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 crystal observed. | Eugenol is present |

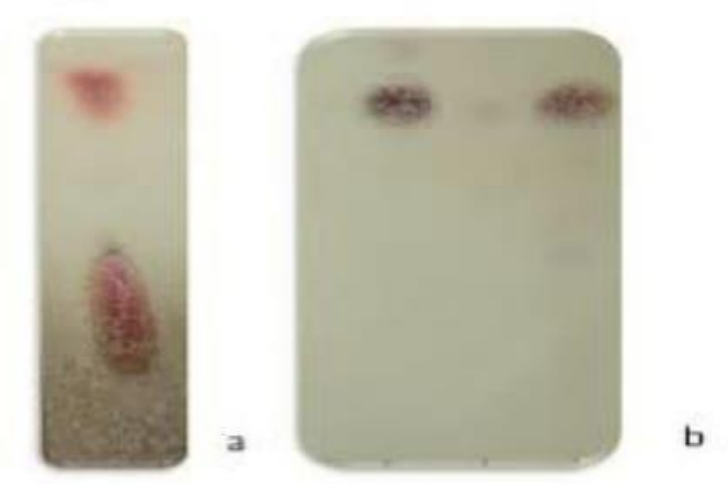
**Moisture content:**

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.

**Cinnamon**

**Synonyms:** Cinnamomumverum

**Biological Source:** Cinnamon is the dried inner bark of the coppiced shoots of CinnamomumzeylanicumNees., belonging to **family**Lauraceae.

**Morphological study:**

• **Colour**: Outer surface is dull yellowish brown, inner surface is dark yellowish-brown.

• **Odour:** Fragrant

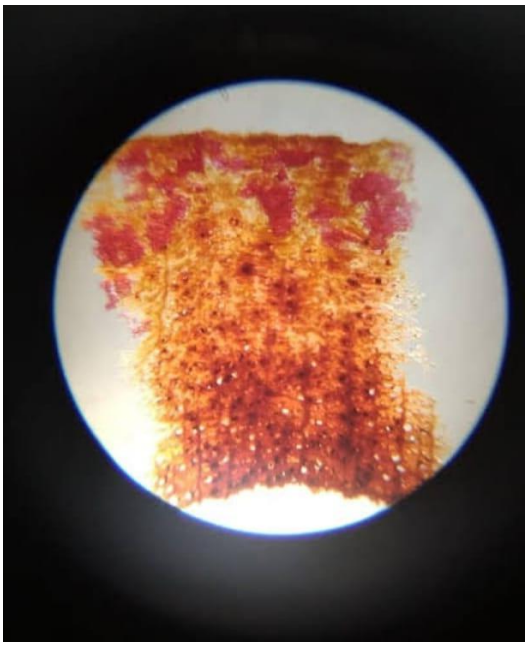
• **Shape:** compound quills

• **Size:** 1m in length and 1 cm in diameter

• **Taste:** Aromatic and sweet followed by warm sensation

• **Fracture:** splintery

**Microscopic Characters:**



The transverse section of cinnamon bark is is consist of 3- 4 layers of sclereids, it consisting of starch grains which is horse shoe shaped. Outer margin is containing pericyclic fibres (6-15).

**Chemical evolution:**

| Test | Observations | Result |
|---|---|---|
| Crude drug + water+amyl alcohol | Orange in alcohol layer | Flavonoids present |
| Crude drug + water take on filter paper | Filter paper turns red | Alkaloids present |
| Crude drug + water + reagent | Red colour | Quinines present |

**Moisture content: Moisture content:**


Moisture content of cinnamon is 32%

**Extractive values of crude drugs:**

Extractive value of cinchona is 47% w/w

**Uses of cinnamon:**

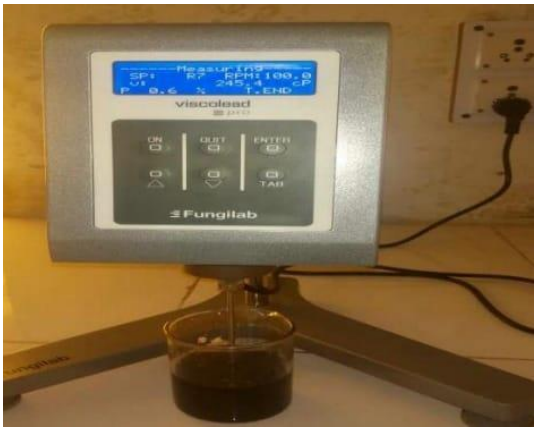
Possibly most the common baking spice, Cinnamon is used in cakes, cookies, and desserts throughout the world. It can boost antioxidant levels in your blood as well as lower inflammation markers.

**Evolution of Ayurveda Aristha:**

**Evolution test of Ashokaristha**

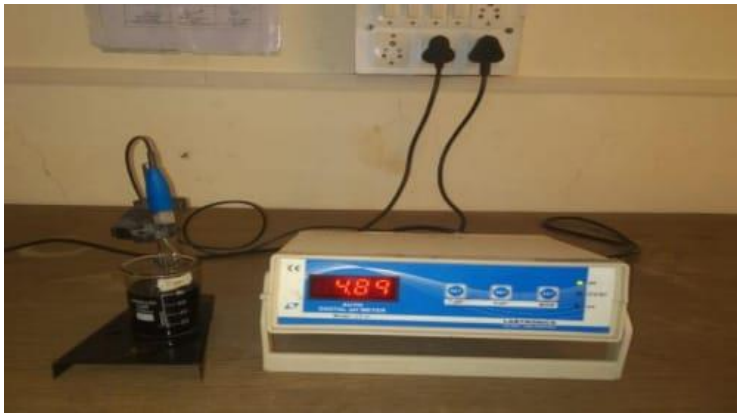

**Color:** Blue colourd liquid.

**Viscosity :**




245.4 Centripoise .
Ashokaristha is less viscous .

**PH:**




PH of Ashokaristha is 4.89.
The Ashokaristha is acidic in nature .

**Conclusion :-**

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 ulmost 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.

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