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An Updated Review on Quality Aspects of Herbal Drug and its Formulation

Sarfaraz Kazi[1], Sanjay Bais[2], Kishori Parade[3]
Research Scholar, Shri Jagdishprasad Jhabarmal Tibrewala University, Jhunjhunu, Rajasthan, India[1]
Research Supervisor and Principal, Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India[2]
kishoriparade2013@gmail.com

Abstract: *Since a very long time ago, medicinal plants have been used to improve human health. Today, they are becoming more and more widely used as pharmaceuticals, supplementary and alternative therapies, food supplements, cosmetics, and, more surprising, medical gadgets. To assess a high-quality medicine, herbal formulations must be standardised. The total of all elements that directly or indirectly affect the safety, efficacy, and acceptability of the drug product makes up 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 major limitations are the lack of standardised raw materials, processing methods and of the final product , product formulation and lack of final products, product formulations, and lack of predetermined criteria for quality assurance. By applying current, suitable GMP standards, it is essential to evaluate the regulation of herbal medicine in order to ensure the quality, safety, and efficacy. The role of various spectroscopic, chromatographic, and electrophoretic methods in the standardisation and good quality assurance of herbal medicines and products was also discussed*

Keywords: Introduction to quality aspects of herbals, Factors affecting the quality of herbal, Need of quality evaluation of herbal Drugs and it's formulations , Constraints in quality determination of herbal drug ,Quality evaluation methods of Herbal crude drugs and formulations

I. INTRODUCTION

Traditional medicine is frequently utilised to treat a variety of human illnesses. All plants on this world are significant b ecause of their medical benefits. Traditional medicine, which uses plants to treat chronic illnesses in a less hazardous w ay, has gained enormous global popularity. Since numerous factorsaffect biological efficacy and therapeutic effect repe atability, using herbal medicine is not an easy process. The evaluation of herbal formulation quality is vital important in ensuring their acceptability in the current medical system. The lack of a strict quality control profile for herbal materials and their formulations is one of the key issues the herbal pharmaceutical field faces. 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.

1.1 General Introduction to Quality Aspect of Herbal

- **Herbal Drug:** These consist of plant or part of plant usually in unprocessed or crude form which have medicinal value. It includes different part of plant like entire aerial part, flower, fruit, seeds, bark, leave, root, and rhizome
- **Raw Material:** In general use, herb are plant with properties that are used for the flavoring and garnishing food, medical purpose or for fragrances; excluding Vegetable and other plant consumed for macronutrient.
- **Herbal Formulations:** Herbal formulations is a physical form like liquid, solid or Semisolid product from herb, with or without excipients, in a Particular formulations (such as decoction, tablets, ointment)

1.2 Meaning of Quality in Terms of Herbal Drugs

The phrase "quality control" describes the procedures used to preserve a manufactured good's quality or validity. Regardless of how a herbal concoction is made, there should be some sort of quality control. Without adequate quality

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control, there is no guarantee that the herb within the container corresponds to what is listed on the label on the outside. Many significant therapeutic plants have had their reputations soiled by the industry's pervasive disdain for quality control. Improvements in analytical techniques have unquestionably resulted in improvements in harvesting schedules, cultivation methods, storage, activity, stability of active substances, and product purity.
The quality of herbal products has significantly improved as a result of all these benefits.

1.3 Factor Affecting Quality of Herbal

The phrase "quality control" describes the procedures used to preserve a manufactured good's quality or validity. Regardless of how a herbal concoction is made, there should be some sort of quality control. Without adequate quality control, there is no guarantee that the herb within the container corresponds to what is listed on the label on the outside. Many significant therapeutic plants have had their reputations soiled by the industry's pervasive disdain for quality control. Improvements in analytical techniques have unquestionably resulted in improvements in harvesting schedules, cultivation methods, storage, activity, stability of active substances, and product purity. The quality of herbal products has significantly improved as a result of all these benefits.

- **Inter- or intra-species variation:** The majority of the diversity in the constituents is genetically controlled, and it might be correlated with the nation of origin.
- **Environmental factors:** Climate, altitude, and other environmental factors, as well as the circumstances of the plant's cultivation, can all have an impact on the quality of a herbal ingredient.
- **Time of harvesting:** It is important to specify the best time to harvest particular herbs because it is well known that a plant's constituent concentrations can change throughout its growing cycle or even throughout a single day.
- **Plant part used:** Active ingredients in plants typically differ between plant parts, and it is not unusual for a herbal product to have plant portions that are not typically used. Additionally, in order to add to the weight of a batch of herbal ingredients, plant material that has previously undergone extraction and is subsequently "exhausted" is occasionally utilised as an adulterant.
- **Post-harvesting factors:** The quality of a herbal ingredient can be severely affected by storage conditions and treatment processes. After harvesting, improper storage can lead to microbial contamination, and drying techniques might cause the loss of thermo-labile active ingredients.

1.4 Need of Quality Evaluation of Herbal Drugs and it's Formulations

As the risks and limitations of modern medicine become more obvious, there is a global shift away from its use and toward the use of medications with herbal origins. Making sure that consumers receive medication that ensures purity, safety, potency, and effectiveness is the regulatory authorities' primary duty.
Constraints in quality determination of herbal drug

- Main dependence on wild sources
- Regulatory aspect
- Adulteration/ substitution
- No certification of raw material
- Lack of trained man power
- Poor investment in R&D of HMP
- Lack of safety evaluation facility

II. QUALITY EVALUATION METHOD OF HERBAL CRUE DRUG AND FORMULATION

2.1 Identification of herbal raw material by morphological and microscopical method

Morphological evaluation:- The sensory examination is referred to as morphological evaluation.
The qualities that are assessed using a sense organ, such as colour, smell, taste, size, form, and texture, etc.
Examples:

- Color :- (Cinnamon Bark -Brown)
- Odor :- (Jatamansi-Aromatic)

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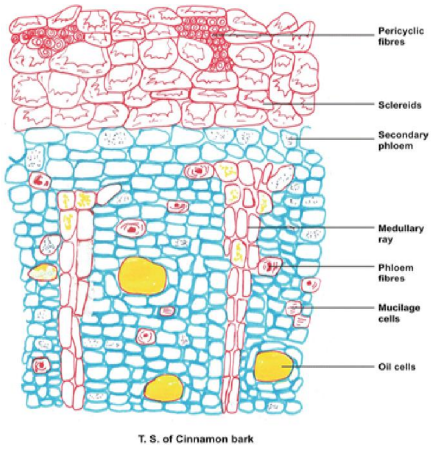
- Taste :- (Capsicum-Pungent)
- Size :- (Digitalis--10-30 cm long and 4-10 cm wide)
- Shape :- (Nux vomica-Disc shaped)
- Texture :- (Cascara barks- Fractured surface)

Microscopic evaluation:It entails a thorough analysis of the drugs and can be applied to the identification of organised medicines based on known histological characteristics. With the aid of microscopic analysis, it is mostly utilised for qualitative evaluation of whole and concentrated forms of organised crude medicines. Trichomes, stomata, starch granules, calcium oxalate crystals, and aleuronic grains are some of the crucial criteria that play a key part in the identification of specific crude pharmaceuticals [8-12] when using a microscope to detect distinct cellular tissues. the starch All lignified tissues give out a pink strain when treated with phloroglucinol and HCl, indicating the presence of hemicelluloses, by colour with iodine solution for example. To distinguish cellular structure, mucilage is tinted pink using ruthenium red. Utilizing chemical reagents, microscopic analysis also includes studying the components of the powdered medication. The quantitative features of microscopy include the examination of stomata number and index, palisade ratio, vein islet number, size of starch grains, length of fibres, etc., which is highly significant in the understanding of how microorganisms function. identification of drug.



T. S. of Cinnamon bark

Quantitative microscopy: This technique uses a transverse section (T.S.), longitudinal section (L.S.), radial longitudinal section (R.L.S.), or tangential longitudinal section to identify arranged drugs based on their established histological characteristics (T.L.S.).

Microscopic evaluations also include the use of staining agents to analyse various ingredients.

Name of the constituent Procedure for the Test Result

- Lignin :- T.S. of Crude Drug + 1 drop of Phloroglucinol + dil. hydrochloric acid Pink colour
- Starch:- T.S. of Crude Drug + 1 drop of Iodine solution Blue colour

Palisade Ratio: It is described as the typical quantity of palisade cells that lie beneath each epidermal cell.

Examples:

- Atropabelladona – 05-70.
- Digitalis lanata –2.5-6.5 .

Stomatal Number:

Stomatal number is the average number of stomata per square millimetre of the epidermis.

Examples:

- Atropa belladonna: upper epidermis---07-10 lower epidermis---77-115
- Daturametel: upper epidermis---147-160 lower epidermis---200-209.

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Stomatal Index

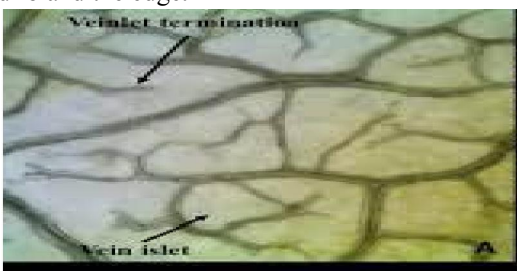
$$\text{Stomatal Index (S.I.)} = \frac{S}{E + S} \times 100$$

where, Stomatal index measures the proportion of stomata to the total number of epidermal cells, including the stomata, with each stoma being counted as one cell.
S = number of stomata per unit area.
E = number of epidermal cells in the same unit area.
Timmerman (1927) and Rowson (1943) were amongst the first few to investigate leaf drugs for stomatal number and stomatal index.

Vein-islet number: The number of vein islets per square millimetre of the leaf surface, halfway between the midrib and the margin, is what is used to describe it. It serves as a defining property for a certain plant species and is used to distinguish it from related species.

S.NO	NAME OF DRUG	Vein-islet Range
1	*Andrograohis paniculata*	9-12
2	*Bacopa monniera*	6-13
3	*Cannabis sativa*	18-24
4	*Digitalis purpurea*	2.5-3
5	*Eucalpytus globules*	8-13.5

Veinlet termination number:-It is determined by counting the veinlet terminations on each square millimetre of the leaf's surface halfway between the midrib and the edge**.**



Example: Atropa Belladonna: 6.3- 10.3

Stoma:

There are several types of stomata, distinguished by the forms and arrangement of the Surrounding cells
Example:-
(a) Anomocytic (Ranunculaceous) irregular-celled: Digitalis
(b)Diacytic (Caryophyllaceous) cross – celled: Mentha
(c) Paracytic (Rubiaceous) parallel celled: Senna

Trichomes:

Trichomes are divided and subdivided as follows-
(i) Covering Trichomes
(a) Unicellular Trichomes: Cannabis
(b) Uniseriate Multicellular Unbranched Trichomes: Datura
(c) Multiseriate Multicellular unbranched Trichomes: Male fern
(d) Multicellular branched Trichomes: Verbascum Thapsus
(ii) Glandular Trichomes

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(a) Unicellular Glandular Trichomes: Vasaka
(b) Multicellular Glandular Trichomes: Digitalis purpure

2.2 Determination of Moisture Content of Crude Drug

Procedure:

1. Weight accurately about 2 gm of triphala churna in porcelain dish.
2. Kept in hot air ovean for 2hours and cool.
3. Weight the triphala churna and calculate % of moisture content.

Sr.no	Drugs	Moisture content	w/w
1.	Aloes	Not more than	10
2.	Digitalis	Not more than	5
3.	Starch	Not more than	15

2.3 Determination of foreign matter of crude drug

The presence of moisture in the crude medication can cause it to degrade by either activating specific enzymes or promoting the growth of microorganisms.

By heating the medication at 150 C in an oven to a constant weight and calculating the weight loss, the moisture content can be identified.

Procedure :-

- A 100g sample was taken and dispersed on a suitable platform. It was then examined in daylight with the unaided eye (or with a 6x or 10x magnification), the foreign matter was separated, and the sample was weighed.
- With reference to the drug sample, the percentage of foreign matter was computed.
- was then cooked for three hours in an oven at 105 °C.
- The drying and weighing were kept up at intervals of 30 minutes until the difference between two successive weigh-ins was no more than 0.25 percent.

2.4 Determination of extractive value of crude drug

Sometimes it is impossible to identify the active chemical component in a crude medication using any method.Inthese si tuations, the drug's extractive value that is soluble in water, alcohol, or ether is determined.

Type of extractive value:-

1. Water soluble extractive value
2. Alcohol soluble extractive value
3. Ether soluble extractive value

A. Water Soluble Extractive Value

1. In a 100 ml volumetric flask, macerate 5 gm of the precisely weighed coarse powder for 24 hours with 100 ml of chloroform water.
2. Shake continuously for the first six hours.
3. Evaporate 25ml of water extract to dryness in a shallow dish with a flat bottom by rapidly straining through filter paper.
4. Weigh and desiccate the residue after it has been dried at 105 ° c.
5. After drying the extract to a consistent weight, figure out the percentage of water-soluble extractive value using the air-dried pharmaceutical as a reference.
6. Senna leaves, for instance: not more than 30.0%W/W

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B. Alcohol Soluble Extractive Value

1. In a 100ml stoppered flask, macerate 5gm of the precisely weighed coarse powder with 100ml of 90% alcohol for 24 hours.
2. Shake constantly for the first six hours.
3. Evaporate 25ml of water extract to dryness in a shallow dish with a flat bottom by quickly filtering through filter paper.
4. Weigh and desiccate the residue after it has been dried at 105 degrees.
5. After drying the extract to a consistent weight, determine the percentage of water-soluble extractive value using the air-dried medication as a reference. [Ginger, for example: not more than 4 .0]

C. Ether Soluble Extractive Value

For the extraction of volatile oils, fixed oils, and resins, ether soluble extractive value is used.
[Example capsecum :- not more than 12.0

2.5 Determination of ash value of crude drugs

The ash content of the medicine is the residue that is left over after cremation.
Procedure:-

1. Accurately weigh 3 mg of drug powder within a silica crucible.
2. Burn drug powder by progressively raising the heat until it is carbon-free and cold.
3. Determine the total Ash value by weighing the ash.

2.6 Determination of bitterness value of crude drug

1. Therapeutic uses for medicinal plants with a potent bitter taste include appealing agents.
2. The threshold bitter concentration of an extract material is contrasted to the quinine hydrochloride threshold bitter concentration to assess the bitterness.
3. The measurement of bitterness in units equivalent to the bitterness of a 2000 ml solution containing 1 g of quinine hydrochloride.
4. The stock solution is made by mixing 0.1gm of quinine hydrochloride in 100ml of drinking water. The substance is then analyzed, diluted, and compared to a drug.

2.7 Determination of TLC profile of crude drug

1. Adsorption is the basic TLC driving principle.
2. G/C coated adsorbent silica gel that has been used.
3. After chromatography has formed, spots are revealed by misting with the appropriate detecting agent.
4. TLC is helpful for evaluating all bioconstituents, including alkaloids and glycosides.
5. The Rf value varies based on the purity, substance type, solvent composition, and impurities.
6. The micro analytical technique for determining a natural product is TLC/HPTLC.
7. Thin layer chromatography is widely used to assess medications both qualitatively and quantitatively.
8. The ratio of the solute's travel distance to the solvent's travel distance on thin layer adsorbent is referred to as t he Rf value

Rf = Distance travelled by the solute/ Distance travelled by the solvent

2.8 Chemical evaluation of crude drug

Chemical evaluation describes the process of identifying the drug's active ingredient by a chemical test.
The following are numerous techniques for evaluating chemicals.

1. A technical approach
2. Chemical test
3. Individual chemical testing of constituents
4. Micro chemical analysis

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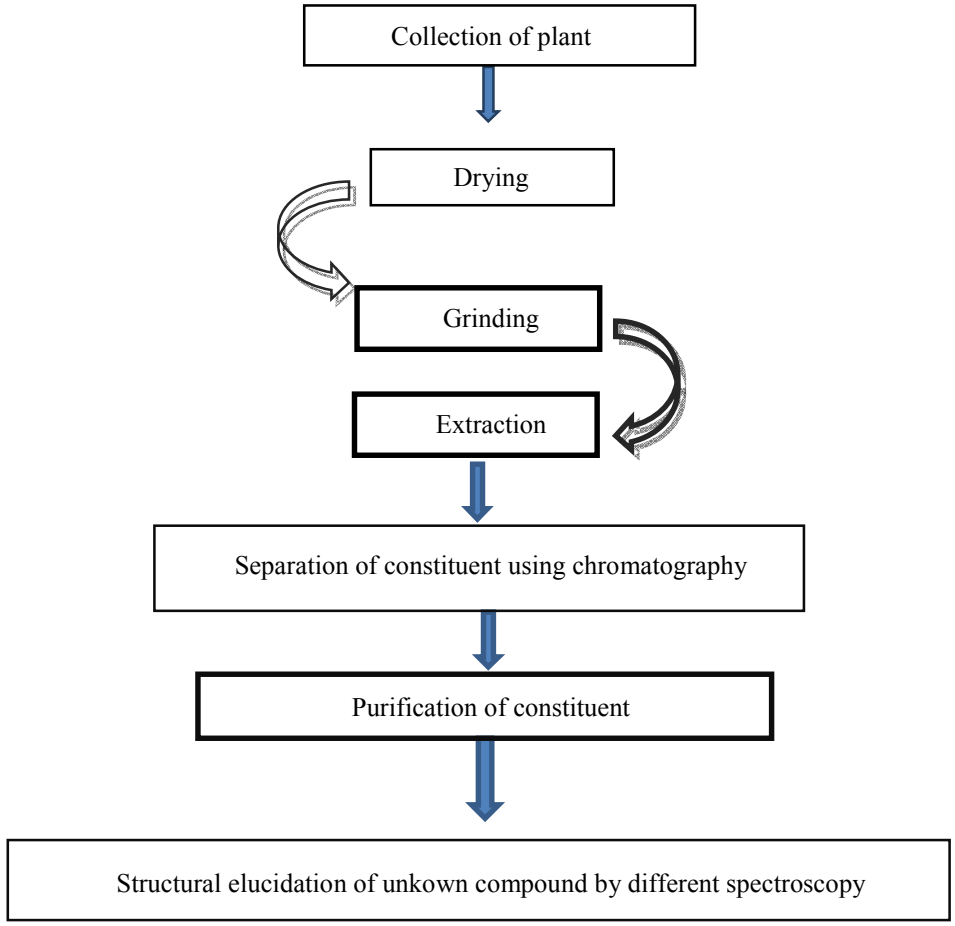
5. Instrumental method: They employ a variety of instruments for evaluation, such as spectrophotometry, colorim etry, and fluorimetry.
6. Chemical constant tests, such as those using the acid value, iodine value, ester value, and others, are used to identify fixed oils and fats.
7. Individual ingredient heme test: These tests are utilised to identify specific medications.
8. Slide-based microchemical tests: These tests are performed.

Example: Potassium euginate crystals are formed when euginol in clove oil precipitates.

2.9 Biological screening of crude drug extract



III. CONCLUSION

Plant materials account for a sizeable component of the global medicine market and are used all over the world, in both developed and developing countries as home remedies, in over-the-counter (OTC) medications, and as raw materials in the pharmaceutical businessThe need to assure the safety, quality, and efficacy of medical plants and herbal products is a severe issue. It is clear that with the cooperation of drug regulatory, scientists, and industries, the herbal industry can improve rapidly in India. To properly comprehend the usage of herbal medications, it is necessary to standardise methodologies and collect quality control data on safety and efficacy.

In order to evaluate their quality, it is crucial to create globally accepted norms.

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