IJP (2024), Vol. 11, Issue 4



Received on 21 March 2024; received in revised form, 27 April 2024; accepted, 29 April 2024; published 30 April 2024

A REVIEW ON QUALITY CONTROL OF HERBAL DRUGS OF NATURAL ORIGIN

P. Akshaya Rajan, M. L. Lal Prasanth and A. Anu Jagajith *

Dr. Moopen's College of Pharmacy, Wayanad - 673577, Kerala, India.

Keywords:

Crude drug, Quality control, Quality assurance, Adulteration, Evaluation, Standardisation, Selection markers

Correspondence to Author: A. Anu Jagajith

Assistant Professor, Dr. Moopen's College of Pharmacy, Wayanad - 673577, Kerala, India.

E-mail: anuanami@gmail.com

ABSTRACT: To guarantee herbal medications safety, effectiveness, and constancy in their therapeutic effects, quality control is crucial to phytochemical composition, and microbiological emphasis on contamination. This study is to evaluate a number of quality control measures for herbal drugs. To determine the essential quality of drugs, quality control tests are necessary. The qualitative and quantitative analysis of phytoconstituents included organoleptic, microscopical, physical, chemical, biological and analytical evaluations were used. The study emphasizes how crucial it is to put strict quality control procedures in place at every stage of the manufacturing of herbal drugs in order to ensure their efficacy, safety, and consistency of quality. In order to address new issues in this industry and create strong quality control standards suited to the special qualities of herbal medications, Quality control is part of quality management focused on fulfilling quality requirements. It is a technique to verify quality. The purpose of quality control is to ensure that each dosage unit of the drug product delivers the same amount of active ingredients.

INTRODUCTION: The use of traditional and herbal medicines is gaining recognition globally. To safeguard the patient, there are legitimate demands that all medicines are safe, efficacious, and of good quality¹. Quality can be defined as the status of a drug that determines its identity, purity, physical, chemical, and content, biological properties. The word quality is derived from Latin 'qualis' means of what kind and encompasses composition and properties of objects. It is important to determines the quality of drugs 2 . The purpose of quality control is to ensure that each dosage unit of the drug product delivers the same amount of active ingredients 2 .



pharmaceutical According to manufacturers association of U.S. "quality is the sum of all the factors that contribute directly or indirectly to the safety, effectiveness, and acceptability of product". There are various quality control tools which are used to assure the quality aspects of the herbals. Both qualitative analysis and quantitative measures are required for the quality assurance. Different techniques in qualitative include organoleptic physical, chemicals and biological analytical methods and quantitative, including leaf constants and others 3 .

A crude drug is defined as a drug that is a naturally occurring, unrefined Substance derived from an organic source such as plant, animal, marine or mineral Source that are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals ⁴. Quality control can be defined as "part of quality management focused on fulfilling quality requirements. It is the technique to verify quality ⁵. According to WHO, quality assurance can be defined as the totality of arrangements made with the objective of ensuring the pharmaceutical products are of the quality required for their intended use. It is the technique of managing quality ⁵.

Types of Crude Drugs:

Organised Drugs: Organised drugs are solid in nature. Organised crude drugs are composed of definite organised histological or cellular structures and tissues. Organized drugs are parts of plants and animals; like fruits, leaves, roots, *etc.* Cellular structure is present in organized drug 1 .

Unorganised Drugs: They are solid, liquid, or semisolid in nature. Unorganised crude drugs are devoid of any definite histological or cellular structures and are derived from plants and animals by different extraction processes or as natural secretions. They are divided into dried latex, dried juice, dried extracts, gums, resins, fixed oils and fats, waxes, volatile oils, and animal products ¹.

Introduction to Quality Control: Quality control is a prime concern to human beings in all aspects of life. Quality is conformance for requirements and Meetings stated as well as the implied needs of the customer. Drug must be marketed as a safe and therapeutically active formulation whose performance is consistent and predictable. The purpose of quality control is to ensure that each dosage unit of the drug product delivers the same amount of active ingredients^{2, 3}.

Herbal medicinal products are the ones that are obtained from plant resources for treatment ⁴. It is very important that the quality of the herbal drug be determined by a series of tests and quality control checks before being marketed and consumed by patients. Quality control of herbals is of greater importance for the preservation of the quality of natural herbs and products. Various qualitative and quantitative evaluations are done. Different evaluation parameters, like organoleptic, physical, chemical and analytical, techniques, are used ⁵.

Importance of Quality Control: The aim of quality control of herbal drugs is to ensure their quality, safety, and efficacy. Contamination or degradation can have very important impacts on the chemical composition and, consequently, the

therapeutic qualities of a drugs. The main objective of quality control of herbal drugs is to ensure safety, efficacy, and quality and related to drugs. Safety, Quality, Efficacy 2 .

Adulteration of Crude Drug: Adulteration of crude drug means substituting the original crude drug partially or wholly with other substances with other spurious, inferior, defective, spoiled, or other parts of the same substance ⁵.

Types of Adulteration:

Intentional Adulteration: Intentional adulteration has has the main objective with the enhancing of profit. Also called deliberate adulteration.

Adulteration with Substandard Commercial Varieties: Although the adulterant medicine is inferior in nature, it may have chemical, physical, and therapeutic similarities to the original crude drug. For instance, medicinal ginger can be replaced with Japanese Cochin ginger and Indian Senna with Arabian senna

Adulteration with a superficially Similar but Cheaper Natural Drug: The adulterated product has no relation to genuine material, or may or may not have any therapeutic or chemical component. Example: *Ailanthus altissima* is substituted for *Atropa belladonna, Cassia acutifolia*⁵.

Adulteration with Exhausted a Drug: Same plant material is mixed with drug that has no active medicinal component as it has already been extracted. Artificial colouring of exhausted saffron.

Adulteration with an Artificially Manufactured Drug: Artificially manufactured substance is used as a substitute the original drug. Example: artificial sugar for honey, yellow colored paraffin wax for bees wax.

Unintentional Adulteration: It is also known as indirect adulteration. It occurs at any time without any bad intentions on the part of the manufacturer or supplier.

Lack of Knowledge About Authentic Source: One of the common reasons for adulteration. Example: Nagkeshar is one of the important drugs in Ayurveda, the authentic source is *Mesua ferrea* but it is adulterated with flower of *Calophyllum inophyllum*⁶.

Similarity in Morphology: This adulteration occurs due to morphological similarities. Example pepper seeds are adulterated with papaya seeds.

Similarity in Colour: Drug materials get changed to or substituted with similar plant species.

Careless in Collection: Some of the herbal drug's adulteration is due to the carelessness of herbal collectors and suppliers 6 .

WHO Guidelines for Assessing Quality Control: Standardization and quality control parameters for herbal formulations are based on the following fundamental parameters:

- **1.** Quality control of crude drug materials, plant preparations, and finished products.
- 2. Stability assessment and shelf life.
- **3.** Safety assessment; documentation of safety based on experience or toxicological studies.
- **4.** Assessment of efficacy by ethnomedical information and biological activity evaluations ⁹.

Quality Control of Crude Material: According to the pharmaceutical Manufacturers association of U.S. "quality is the sum of all the factors that contribute directly or indirectly to the safety, effectiveness, and acceptability of the product". Standardization describes all measures taken during the manufacturing process, and quality control leads to the reproducible quality of a particular product. WHO also stress the on development of national pharmacopoeia and monographs of medicinal plants; cultivation and conservation of medicinal plants to ensure their sustainable use are also of prime importance, as botanicals are considered ⁶.

Identity of Plant Material: Authenticity, purity and assay are important aspects of standardization and quality control. As the name implies, authenticity relates to proving the material is true and corresponds to the right identity. Quality control of botanicals starts with the identification of the plant. According to WHO general guidelines for methodologies for research and evaluation of traditional medicines, first step in assuring quality, safety, and efficacy of traditional medicines is correct identification ⁷.

Evaluation: Evaluation is defined as determining the type of adulteration and verifying its safety, quality, and purity. Three factors are primarily used to evaluate crude drugs: biochemical diversity in the substance, deterioration from storage and treatment, and adulteration and substitution.

The following are the main goals of evaluation: Assure safety by making sure the raw medication is free of dangerous ingredients or impurities 8 .

Efficacy Assessment: Determine whether an active ingredient is present and at what concentration to determine whether a therapy is successful.

Standardization: Create uniform production parameters to guarantee consistency in the finished product.

Botanical Identity: To avoid misidentification or substitution, confirm the actual botanical provenance ^{9, 10}.

Types of Evaluation:

Qualitative Evaluation: The evaluation of drugs involves a number of methods. In qualitative evaluation, it involves identification by means of sense organs; it mainly that involves knowing of colour, taste, size, shape, and specific features involves texture and microscopic characters.

The Evaluation Involves: Organoleptic evaluation, Morphological evaluation. Physical evaluation, Chemical evaluation, biological evaluation, Analytical evaluation

Quantitative Evaluation: It is an important analytical technique for powdered drugs especially when chemical and other methods of evaluation of crude drugs Fails as accurate measure of quality.

The evaluation involves:

- ✓ Lycopodium spore method
- ✓ Leaf constants

Qualitative Evaluation:

Rajan et al., IJP, 2024; Vol. 11(4): 120-130.

Organoleptic Evaluation: Term organoleptic evaluation refers to the evaluation means of sensory evaluation. It refers to the methods of analysis like colour, odour, taste, size, shape, and special features, such as touch, texture, etc. The initial sight of the plant or extract is so specific that it tends to identify itself. If this is not enough, perhaps the plant or extract has a characteristic odour or taste. The study of the form of a crude drug is morphology, while the description of the form is morphology.

Colour: Colour of crude drugs is examined under light. The colour of the drug should be compared with the standard one. Like White: starch, Pale yellow: Ginger, Deep yellow: peeled liquorice, Dark brown: cloves, Red: cinnamon bark inner portion, Dark reddish brown: cinnamon vii. Green: leaf herbs, Pale green: lobelia

Taste: Non-toxic drugs can be tasted, while toxic drugs should not be tasted. It includes acidic, saline, saccharine, bitter, tasteless, mucilage and, oily, pungent, acrid, nauseous, alkaline

Odur: Slow and repeated inhalation of the material is done ¹⁰.

Microscopic Evaluation: This technique makes it possible to examine drugs in greater detail and can be used to identify organized medicines based on their recognized histological characteristics. It is mostly employed for the qualitative assessment of whole and powdered organized crude pharmacological formulations. Each plant has a unique tissue property. Confirming the structural details of pharmaceuticals derived from plants can be done with a microscope.

- \triangleright Qualitative evaluation¹⁰.
- Stomata

Stomata is a minute opening present on the aerial parts of the plant, with the following characteristics: A central pore, two kidney shaped similar cells containing Chloroplasts known as guard cells, and varying number of subsidiary cells covering the guard cells.

Types of Stomata: Paracytic stomata, Diacytic stomata, Anisocytic stomata, Anomocytic stomata,

Actinocytica stomata, Cyclocytic stomata, Gramineous stomata.

• Trichomes

Trichomes are divided and subdivided as follows:

- **1.** (Covering Trichomes)
- a. (Unicellular Trichomes
- **b.** (Uniseriate Multicellular Unbranched Trichomes)
- c. Biseriate Multicellular unbranched Trichomes
- **d.** Multiseriate Multicellular unbranched Trichomes
- e. Multicellular branched Trichomes
- 2. Glandular Trichomes
- a. (Unicellular Glandular Trichomes
- b. Multicellular Glandular Trichomes
- **c.** Hydathode Trichomes

Stomatal Number: The Stomatal number as the is defined as average number of stomata per square millimeter of epidermis.

Stomatal Index: The Stomatal index is the percentage which the number of stomata forms to the total number of epidermal cells.

It is calculated by:

$$S.I = S \times 100/(E+S)$$

S. I = Stomatal index, S = Number of stomata per unit area, E = Number of epidermal cells in the same unit area.

Vein Islet Number: It is the average number of vein islet per square millimeter of the leaf surface midway between midrib and the margin ¹¹.

Vein Termination Number: It is defined as the average number of vein termination per square millimeter of the leaf surface between midrib and margin.

Palisade Ratio: It presents average number of palisade cells beneath one epidermal cell, using four continuous epidermal cells for the count.

Lycopodium Spore Method: The Lycopodium spore method is a technique used in analytical. Lycopodium is used in chemical and other methods of evaluation. It involves using the spore of the lycopodium plant as a calibration substance to determine the volume of liquids. Lycopodium spores are very characterised in shape and, appearance and uniformity in size. The spore is tetrahedral in shape, the base is rounded and three flat sides ¹¹.

Physical Evaluation: Physical evaluation was to be determined for the drugs. These are rarely constant for crude drugs, but they help in evaluation, specifically with the reference to the moisture content, specific gravity, density, optical rotation, refractive index, melting point, solubility, viscosity, in different solvents.

Moisture Content: Moisture content of a drug will be responsible for the decomposition of the, either producing chemical change or microbial growth. The moisture content is determined by heating a drug at 105°C in an oven to a constant weight.

Solubility: Drug specific behaviour towards solvents is taken.

Optical Rotation: One enantiomer of chiral molecule can rotate the orientation against plane polarized light, such a substance are said to be is optically active compound, and this property is known as optical rotation 11 .

Refractive Index: It is defined as the property of a material that changes the speed of light, computed as the ratio of the speed of light in a vaccum to the speed of light through different materials. When a light travels at an angle between two different materials, their refractive indices determine the angle of transmission refraction of the light beam. The refractive index varies based on the frequency of the light, thus, different colours of light travel at different speeds. High intensities can also change the refractive index.

Specific Gravity: It is also known as relative density. The ratio of the mass of a solid or liquid to

the mass of an equal volume of distilled water at $4^{\circ}C$ (39°F) or of a gas to an equal volume of air or hydrogen under prescribed conditions of temperature and pressure ¹¹.

Viscosity: Viscosity is defined as the resistance to the flow of liquids. The viscosity of liquids is constant at a given temperature and is an index of their composition.

Melting Point: It is one of the parameters used to judge the purity of crude drugs containing lipids as constituents. They may be of animal or plant origin and contains fixed oils, fats, and waxes.

Solubility: The presence of an adulterant in a drug could be indicated by solubility

Ash Value: The residue remaining after the incineration of a drug called ash. Types of ash Total ash value, Acid insoluble ash value, Water soluble ash value.

Total Ash Value: It is used for determining crude drug that are mixed with minerals and, soil, calcium oxalate crystals or drug with different organic contents to improve appearance.

Acid Insoluble Ash Value: It is used for the determination of earthy maters present on root, rhizomes, and also in leaves.

Water Soluble Ash Value: It is used to dectect either materials exhausted by water or not.

Extractive Value: The extract obtained by exhausting crude drug with different solvents are approximate measures of their chemical constituents. Type Water soluble extractive value, Alcohol soluble extractive value, Ether soluble extractive value ¹².

Chemical Evaluation: In chemical evaluation the chemical nature of the constituents can be used as tool to device a method for the analysis of the constituents. It also involves chemical test, chemical assay and also the phytochemical investigation of the crude drug. It involves various chemical test includes test for alkaloids, tannins, resins, volatile oils, waxes, *etc*.

Alkaloids: Alkaloids are naturally occurring, nitrogen containing organic compounds. Alkaloids

are obtained from plants, animals and microorganisms.

It Includes:

- Dragendorff's test
- Wager's test
- Mayer's test
- Hager's test.

Tannins: Tannins are complex, organic non nitrogenous, polyphenolic substances of high molecular weight.

- Ferric chloride test
- Gelatin test

Phytosterols: Phytosterols are cholesterol like molecules found in plant, foods.

• Liebermann-Burchard's test ¹³.

Flavanoids: Flavanoids are the group of natural substances with variable phenolic structures, are found in fruits, vegetables *etc*.

- Shinoda test
- Alkaline reagent test
- Lead acetate test

Triterpenoids:

• Salkowski test

Quantitative Evaluation: Quantitative physiochemical constants like acid value, iodine value, acetyl value, hydroxyl value, saponification value.

Acid Value: Acid value is the number of mg of potassium hydroxide required to neutralize the free fatty acid in 1mg of the substance.

Acid value =a×0.00561×1000/w

a: number of ml of 0.1N potassium hydroxide required, w: weight in g of the substance taken

Saponification Value: Saponification value is the number of mg of potassium hydroxide required to

neutralize the fatty acid resulting from the complete hydrolysis of 1mg of the oil or fat 12 .

Iodine Value: The iodine value is the number, that express in grams the quantity of iodine, which is absorbed by 100g of the substance.

Hydroxyl Value: Hydroxyl value is the number of milligrams of potassium hydroxide required to neutralize the acid combined by acylation in 1g of the substance.

Ester Value: Number of mg of KOH required to neutralize 1 acids resulting from the complete hydrolysis of the 1g of the substance ¹³.

Saponins: Saponins are a group of oily glycosides and they are water soluble and form foam.

• Foam test

Cardiac Glycosides: Cardiac glycosides are used for treatment of heart muscles.

• Keller Killiani test

Carbohydrates: Carbohydrates are group of compounds composed of carbon, hydrogen and oxygen.

- Molisch's test
- Barfoed's test.
- Fehlings test
- Benedict test

Amino Acids: Amino acids are building blocks of proteins and peptides found in medicinal plants.

• Million's test

Protein: Protein have a complex structure which exerts therapeutic effects.

• Biuret test

Anthraquinone Glycoside:

• Hydroxy anthraquinone test

Biological Evaluation: The estimation of potency of crude drug or its preparation is done by means of its effect on living organisms like bacteria, fungal

growth or animal tissue or entire animal, it is known as bioassay. This method is generally called for, when standardisation is not adequately done by chemical or physical means and also for conformity of therapeutic activity of raw material and finished product. In other words, bioassay is the measure of sample being tested is capable of producing the same biological effect as that of the standard preparation.

Biological assays are Three types

- Toxic method: whole animal is used
- Symptomatic method: whole animal is used

Tissue method: done on isolated organ or tissue

Bioassay: Assay of pharmacologically active substance by using biological animal models.

Eg. Cardiac activity of digitalis and hypoglycemic effect of insulin in rabbits.

Microbial Assay: It's a type of biological assay specifically performed with microorganism ^{10, 11, 13}.

Analytical Method Evaluation: Chromatographic is the technique used for the separation of the components of the sample in which the components are distributed between two phases in which one is stationary and other is mobile phase.

Chromatographic Techniques: Thin Layer Chromatography, High Performance Liquid Chromatography, High Performance Thin Layer Chromatography, Gas Chromatography, Column Chromatography, Spectrophotometric method ¹³.

Thin Layer Chromatography (TLC): The principle involved is adsorption. After development of chromatography spot are visualized by detecting agent. TLC used to analyse alkaloids, glycosides. In this method silica, alumina, carbonate, starch are used. Mobile phase will be the organic solvent. It is important application is in separation of multi component herbal evaluation. The Rf value varies depending upon the purity and nature and composition of substance ¹⁴.

High Performance Thin Layer Chromatography(HPLTC):AlsocalledinstrumentalorsemiautomaticTLCdueautomaticdevelopment.

HPTLC is a major advancement of TLC principle requiring shorter time better resolution.

HPTLC plates available in the form of pre coats. This one is most sophisticated and widely used for evaluation of herbal drugs. At a time 20 spots can be developed. It is very rapid, and sensitive ¹⁵.

Column Chromatography: Its adsorption chromatography. Liquid chromatography in which mobile phase in which mobile phase in which mobile phase in form of liquid passes over the stationary phase packed in a the column. Column is either a silica. This is the absorption chromatography where different adsorbent are used as stationary phase are packed ¹⁴.

High Performance Liquid Chromatography (**HPLC**): Method which separation takes place with packed column (stationary). A liquid mobile phase used eluent. In HPLC mobile phase forced to column under high pressure. Column used in

HPLC narrow (1mm or less) flow rate of mobile phase is (100 μ l/min)

Gas Chromatography: The principle is partition. Carrier gas used as mobile phase (nitrogen, helium. In this column chromatographic technique, gas is used as mobile phase. Technique used to identify analysis of phytochemicals such as oils, lipids etc

Spectrophptometric Methods: Spectroscopy is defined as interaction between matter and electromagnetic radiation.

UV- Ultraviolet Spectroscopy: UV spectroscopy, or ultra violet spectroscopy, involves the study of how a sample absorbs or reflect light in the UV and visible regions of the electromagnetic spectrum. It is widely used to analysis the compound and determine the concentration. UV radiation ranges from 200-800nm. Only valence electron absorbs the energy ¹⁶.

IR Spectrocsopy: IR spectroscopy is a technique that measures the absorption, transmission, or reflection of infrared light by the sample. Its valuable in identifying functional group in organic and inorganic compounds. Different bonds absorb specific frequencies of infrared radiation, providing unique spectrum for each substance. It vibrates to higher vibrations/rotational energy levels and gives different peak which occurs mainly due to functional groups present in the molecule. IR is mainly divided into different regions: Near IR (1400-400 cm⁻¹), Far IR (600-40 cm⁻¹) Mid IR (4000-600 cm⁻¹)¹⁷.

NMR Spectroscopy: NMR is a powerful analytical technique used to study the magnetic properties of nuclei. It provides information about the molecular environment, structure, and dynamics of the compound. NMR relies on the interaction of certain atomic nuclei with a strong magnetic field and radio frequency radiation. This nuclear spin generates a magnetic field. NMR is a useful tool in elucidation of molecular structure of phytoconstituents.

Mass Spectroscopy: Mass spectroscopy is a technique used to determine the mass and composition of ions in a sample. It involves ionizing the sample, separating ions based on their mass to charge ratio, and detecting the resulting signals. Mass spectroscopy is widely ions employed in various fields. It can be used for determining molecular weights, identifying chemical structure, analysing complex and mixtures ^{14, 16, 17, 18}

Relevance of Evaluation: The evaluation are a crucial on several fields, including traditional medicine, pharmacology, and herbal industries. Relevance of evaluation of crude drugs includes:

Quality Control: Assessing the quality of crude drugs ensures consistency adherence to standards. This is vital for producing reliable and effective medicines.

Identification and Authentication: It aids in correct identification of plant materials, and preventing the adulteration in plant material. And also preventing misidentification and ensuring that the indented plant species is used for medicinal purposes ¹⁶.

Standardization: Establishing standards for crude helps in maintaining a consistent, improving the reproducibility of herbal formulation.

Adulteration and Detection: Evaluation methods help to detect the presence of adulterant or contaminants, safeguarding the integrity and safety of herbal drug products.

Research and Development: Identifying the composition and properties of drugs is fundamental for further research and development of new drugs or herbal formulation.

Regulatory Compliance: The regulatory requirements is essential for herbal products. Evaluation ensures compliance with regulations regarding the quality and safety of crude drugs.

Pharmacological Efficacy: Evaluation helps to determine the pharmacological properties of crude drugs, providing insights into their safety for use.

Market Acceptance: Consistent quality and efficacy contribute to their acceptance of herbal products in the market, Building trust between consumers and health care practitioners.

Safety and Efficacy: Assessing the quality of herbal drugs ensure that they are safe for consumption and possess the claimed therapeutic effect. This is critical for their acceptance and use in traditional medicine and complementary therapies ^{19, 20}.

Recent Development in Quality Control: Natural herbal remedies are significant supplementary and alternative medications that have been vital to human progress worldwide. In China, Japan, Korea, India, and other Asian nations, they continue to be essential medicinal and health resources. One of the main distinctions between natural and chemical medicines is the wide range in quality that results from variations in genetic backgrounds. geographic origins, planting environments, cultivation techniques, harvesting times, processing methods, exogenous impurities, and other factors. One of the fundamental characteristics medications of is quality consistency. Inconsistency raises the danger to patient safety and makes it challenging to ensure a drug's efficacy. The consistency and quality of natural herbs have not drawn much attention in the past 16 .

Technological Advancements: The integration of advanced analytical techniques, such as chromatography (HPLC, GC), mass spectrometry (MS), nuclear magnetic resonance (NMR), and spectroscopy, has enhanced the precision and sensitivity of quality control analyses for herbal drugs ¹⁷.

Microscopy and Imaging Techniques: Plant materials can now be identified and characterized with greater accuracy because to identification of pollutants, adulterants, and impurities.

Metabolomics: This field of study entails a thorough examination of the metabolites found in biological samples. This method has been used to analyse the chemical makeup of herbal medications, find the bioactive ingredients, and guarantee a consistent level of product quality.

Standardization of Drugs: Standardization, in the context of herbal medicine and pharmaceuticals, refers to the process of establishing and implementing specific criteria and guidelines to ensure the consistent quality, safety, and efficacy of a product. This process involves setting standards for various aspects of the production, testing, and use of a substance, such as a herbal drug or medicinal plant extract ¹⁷. The quality of herbal drugs, herbal drug preparations, and herbal medicinal product is determined by the quality of the starting plant material, development in process control, process validation, GMP control, and specifications applied to them throughout development and manufacture. All factors that affect is the quality of the herbals drug should be considered in standardization methods, including sample identification, organoleptic accurate evaluation, pharmacognostic evaluation, volatile quantitative evaluation (ash values. matter. phytochemical evaluation. extractive values). xenobiotic presence test, microbial load testing, toxicity testing, and biological activity ¹⁸. The phytochemical profile holds particular importance since it directly influences the efficacy of herbal medications, The quantification of the marker compound or compounds would be an extra parameter in assessing the quality of the sample, whereas the fingerprint profiles serve as guidelines to the phytochemical profile of the medicine in ensuring the quality ¹⁹.

The goals of standardizing herbal medicine are the following:

- **1.** Initial testing to check for the existence of various chemical groups.
- **2.** Quantification of relevant chemical groups, such as total triterpenic acids, total phenolics, total alkaloids, and total tannins.
- 3. Several fingerprint profiles based on Markers.
- **4.** Measuring significant chemical components 20 .

Terminologies:

Adulteration: The intentional or unintentional addition of impurities, contaminants, or substitutes to herbal drugs, compromising their quality and safety.

Standardization: The process of establishing and implementing specific criteria and guidelines to ensure the consistent quality, safety, and efficacy of herbal drugs.

Tincture: A concentrated liquid herbal extract, often prepared by soaking plant material in alcohol or another solvent.

Decoction: A method of extracting medicinal compounds from plant material by boiling it in water.

Infusion: The process of steeping plant material in hot water to extract medicinal compounds, similar to making herbal tea.

Aromatherapy: The therapeutic use of aromatic plant extracts (essential oils) for improving physical, emotional, and spiritual well-being.

Drug Extract Ratio: Ratio between quality of herbal drugs substance used in the manufacture of a herbal preparation and the quantity of herbal preparation obtained ^{22, 23, 25}.

Herbal Medicine: The use of plants or plant extracts for therapeutic purposes. It encompasses various traditional systems such as Ayurveda, Traditional Chinese Medicine and Western herbalism^{23, 24, 25}.

Role of Selection Marker's in Standardization of Herbal Drug: Selection markers serve to assure consistency, quality, and efficacy, which is vital to the standardization of herbal medications. These markers are particular traits or elements selected for analysis, measurement, or quality assurance ^{26, 27}.

Chemical Markers: Chemical markers in the standardization of herbal drugs are specific compounds used to assess the identity, purity, quality and consistency of drugs.

Primary Metabolites: essential compounds directly related to therapeutic effects, like alkaloids.

Secondary Metabolites: bioactive substances influencing medicinal properties, such as flavonoids, terpenoids, and saponins.

Biological Markers: A genetic marker can be defined as a gene or a nucleotide sequence on a chromosome that has the potential to differentiate cells ^{28, 29, 30}.

CONCLUSION: Evaluation is considered an important tool in the formulation of herbal products. Numerous factors, including cultivation, collection, drying, storage, and market processing, affect the quality of herbal drugs. Adulteration of drugs is commonly occurring nowadays due to the scarcity and price of drugs prevailing in the market.

In order to meet quality of various herbs quality control test has been done. An overview of the tools used to evaluate herbal drugs including morphology, microscopical, physical, chemical, biological, analytical evaluations were provided.

ACKNOWLEDGEMENT: Nil

CONFLICT OF INTEREST: Nil

REFERENCES:

- 1. Alamgir AN: Herbal drugs: their collection, preservation, and preparation; evaluation, quality control, and standardization of herbal drugs. Therapeutic Use of Medicinal Plants and Their Extracts: Pharmacognosy 2017; 1: 453-95.
- 2. Srivastava S and Misra A: Quality control of herbal drugs: Advancements and challenges. New Age Herbals: Resource, Quality and Pharmacognosy 2018; 189-209.
- 3. Mukherjee PK: Quality control and evaluation of herbal drugs: Evaluating natural products and traditional medicine. Elsevier 2019; 30.

- 4. Shinde VM, Dhalwal K, Potdar M and Mahadik KR: Application of quality control principles to herbal drugs. Int J Phytomed 2009; 1(1): 4-8.
- 5. Ahmed S and Hasan MM: Crude drug adulteration: a concise review. World J Pharm Pharm Sci 2015; 4(10): 274-83.
- Agarwal PR and Goyal AN: A comprehensive review on adulteration and substitution of crude drugs. Asian J Pharm Clin Res 2021; 14(4): 33-8.
- Rossell JB, King B and Downes MJ: Detection of adulteration. Journal of the American Oil Chemists' Society 1983; 60(2Part2): 333-9.
- Choudhary A, Gupta N, Hameed F and Choton S: An overview of food adulteration: Concept, sources, impact, challenges and detection. International Journal of Chemical Studies 2020; 8(1): 2564-73.
- 9. Mollah MS and Nyeem MA: Quality control and evaluation of herbal drugs in modern era. International Journal of Research in Pharmacy and Pharmaceutical Sciences 2021; 1(6): 9-13.
- Gautam A, Kashyap SJ, Sharma PK, Garg VK, Visht S and Kumar N: Identification, evaluation and standardization of herbal drugs: A review. Der Pharmacia Lettre 2010; 2(6): 302-15.
- 11. Patil SG, Wagh AS, Pawara RC and Ambore SM: Standard tools for evaluation of herbal drugs: An overview. The Pharma Innovation 2013; 2(9): 60.
- Shulammithi R, Sharanya M, Tejaswini R and Kiranmai M: Standardization and quality evaluation of herbal drugs. IOSR Journal of Pharmacy and Biological Sciences 2016; 11(5-1): 89-100.
- 13. Kamboj A: Analytical evaluation of herbal drugs. Drug Discovery Research in Pharmacognosy 2012; 3: 23-55.
- Farooqui NA, Dey A, Singh GN, Easwari TS and Pandey MK: Analytical techniques in quality evaluation of herbal drugs. Asian Journal of Pharmaceutical Research 2014; 4(3): 112-7.
- 15. Odhiambo JA, Lukhoba CW and Dossaji SF: Evaluation of herbs as potential drugs/medicines. African Journal of Traditional, Complementary and Alternative Medicines 2011; 8(5).
- Lysiuk R and Hudz N: Differential spectrophotometry: Application for quantification of flavonoids in herbal drugs and nutraceuticals. Int. J. Trends Food Nutr 2017; 1: 102.
- 17. Muyumba NW, Mutombo SC, Sheridan H, Nachtergael A and Duez P: Quality control of herbal drugs and preparations: The methods of analysis, their relevance and applications. Talanta Open 2021; 4: 100070.
- Choudhary N and Sekhon BS: An overview of advances in the standardization of herbal drugs. Journal of Pharmaceutical Education and Research 2011; 2(2): 55.
- 19. Kulkarni K, Jagtap G and Magdum S: A comprehensive review on herbal drug standardization. Am J Pharm Tech Res 2019; 9: 97-122.
- 20. Tambare P, Tamboli FA and More HN: Standardization of herbal drugs: an overview. Int Res J Pharm 2011; 2(12): 56-60.
- 21. Kumari R and Kotecha M: A review on the Standardization of herbal medicines. International Journal of Pharma Sciences and Research 2016; 7(2): 97-106.
- 22. Yadav NP and Dixit VK: Recent approaches in herbal drug standardization. Int J Integr Biol 2008; 2(3): 195-203.
- 23. Muyumba NW, Mutombo SC, Sheridan H, Nachtergael A and Duez P: Quality control of herbal drugs and preparations: The methods of analysis, their relevance and applications. Talanta Open 2021; 4: 100070.

29. Kaggwa B, Anywar G, Munanura EI, Wangalwa R,

and Therapies 2023; 23(1): 348.

Chinese Medicine 2020; 15: 1-24.

Kyeyune H, Okella H, Kamba FP and Engeu OP:

Application of the herbal chemical marker ranking system

(Herb MaRS) to the standardization of herbal raw

materials: a case study. BMC Complementary Medicine

Wei XC, Cao B, Luo CH, Huang HZ, Tan P, Xu XR, Xu

RC, Yang M, Zhang Y, Han L and Zhang DK: Recent

advances of novel technologies for quality consistency

assessment of natural herbal medicines and preparations.

- 24. Wright SE: Standardizing and harmonizing terminology: theory and practice. ASTM International 1995.
- 25. Kushwaha SK, Kushwaha N, Maurya N and Rai AK: Role of markers in the standardization of herbal drugs: a review. Archives of Applied Science Research 2010; 2(1): 225-9.
- 26. Tambare P, Tamboli FA and More HN: Standardization of herbal drugs: an overview. IRJP 2011; 2(12): 56-60.
- 27. Patwekar SL, Suryawanshi AB, Gaikwad MS, Pedewad SR and Potulwar AP: Standardization of herbal drugs: An overview. The Pharma Innovation 2016; 5(4): 100.
- 28. Pal RS, Pal Y and Saraswat N: Importance of markers in the standardization of herbal drugs: a review. World Journal of Pharmaceutical Research 2016; 5(5): 630-8.

How to cite this article:

Rajan PA, Prasanth MLL and Jagajith AA: A review on quality control of herbal drugs of natural origin. Int J Pharmacognosy 2024; 11(4): 120-30. doi link: http://dx.doi.org/10.13040/IJPSR.0975-8232.IJP.11(4).120-30.

30.

This Journal licensed under a Creative Commons Attribution-Non-commercial-Share Alike 3.0 Unported License.

This article can be downloaded to Android OS based mobile. Scan QR Code using Code/Bar Scanner from your mobile. (Scanners are available on Google Playstore)