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THE QUALITY ASPECTS OF HERBAL DRUGS AND ITS FORMULATIONS: REVIEW

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ABSTRACT:
The quality characteristics of herbal medicines and herbal preparations are important factors to consider when evaluating the quality of medicinal products. All elements that either directly or indirectly impact the product's acceptability, efficacy, and safety contribute to its overall quality. However, naturopathy is challenging due to the absence of standards. There are no guidelines on the management and processing of raw materials and production of finished products. Appropriate GMP guidelines must be followed to ensure the effectiveness, safety and quality of herbal medicines for daily use.

Keywords: *Quality Control, Herbal Drug, Medicinal plant, GMP*

INTRODUCTION

A feature of traditional Chinese medicine is that all herbs, whether in the form of a single herb or a group of herbs, are extracted using hot water boiled in the method of decoction. The primary cause of Eastern plants' greater difficulty in management compared to Western ones is this. Its use has continued for centuries, and its acceptance and intensive use in traditional medicine has only occurred in the last decade. It is not yet recognized by many countries. As a result, research, guidance and training in this field are not properly monitored and supported. The amount and quality of information on the safety and effectiveness of traditional medicines does not meet the need to promote their use worldwide. The plant materials and medicinal herbs made from them are highly integrated in the international market and are therefore widely recognized. They need proper management. International health organizations emphasize the need for routine procedures to ensure the cleanliness, environmental handling and appropriate standards of medicinal products. [1]

Overview of the qualitative aspects of herbals

- **Herbal medicine:** There are herbs or plants that can be used as medicine, but most of them are raw or unprocessed. There are many types of plants such as finished upper parts of the plant, roots, bark, flowers, fruits, seeds, leaves and rhizomes.
- **Raw data:** Does not include vegetables and other plant macrophages used to produce food. As a purpose or seasoning.
- **Herbal preparations:** Herbal preparations are physical forms of herbal products, such as liquids, solids, or special-use semi products (Such as decoctions, tablets, ointments), with or without additives.

Definition of quality for herbal drug

The process required to check the originality or quality of the product is called "quality control". "But all herbal products have to go through some kind of quality control. There's no guarantee that the herbs in the box will be what it says on the outside label. There's no good guarantee." Lack of industrywide control has damaged the reputations of many important medicinal plants. There is no doubt that advances in screening technology have

led to improvements in harvest planning, product development, sanitation, processing, storage and stability of active ingredients. Thanks to all these achievements, the quality of available herbal products has greatly improved. [2] Manufacturers and other people. Because of progress in identifying herbs through laboratory testing, consumers need to at least be confident that the herbs are being used. Currently, only a few companies monitor quality control and production quality, which includes microscopic, physical, chemical/physical and chemical testing. Currently, the best prices are offered by companies that offer standard drugs and/or extracts.

Wild-collected vs. Cultivated material

The existence of many value chains and products depends on the quality of herbs and spices used in medicinal products. It is known that many rural and indigenous people, especially in Asia, base their livelihood on the collection of medicinal plants. The disadvantage of this natural collection method is that when the plant is collected from nature, its marketability decreases and its price increases. Single joint use of plant material may provide a better alternative to this model, but its main disadvantage is that the value of the final product of export increases significantly. Especially in Asian countries, air pollution is increasing due to pesticides, poisons and residues. Regions Large amounts of drugs in flavoured extracts. Controlling the plant crop will also save growers more time. Similarly, in many developing countries, farmed produce is sometimes more expensive than wild produce. [3]

Constraints in quality determination of flavouring medicine

Limitations in quality assessment of sweeteners. The activity of more than four percent of the plant extract is one of the most important problems in the use of plants in pharmacological development. The main disadvantage is reliability, as the activity recorded on the screen usually does not reappear when the plant is resampled and retracted. Most often, synergistic or additive are used to ensure the activities and effectiveness of herbal extracts and drugs. Effects of product interactions. As a result, a technique should be applied to ascertain the kind and extent of modifications in the literature's bioactive phytochemical content. Differences in agricultural climate or stress, climate, microenvironment, physical and chemical stimuli change the quantity and quality of secondary metabolites, often called elicitors, and therefore trigger induced replication.

Standardization of herbal medicines

In general, all drugs, whether synthetic or natural, must meet basic requirements for safety and effectiveness. The term "herb" refers to a plant or herb that has been transformed into a botanical medicine by a simple process including harvesting, drying, and storage. So they can change. This difference is also due to differences in growth, area and harvest time. Standardization of herbal medicines is a process or natural strength, constant, clear qualification and many important factors that guarantee quality, efficiency and safety. It is the process in which the construction process is approved. Specific methods are developed through experiments and observations that lead to a process of analysing the mechanisms offered by an individual plant. Therefore, design is a tool to solve some problems that do not apply to synthetic drugs and mostly affect the quality of plants. [4]

Example:

- Herbs are often a mixture of ingredients.
- In most cases the active ingredients are unknown.
- Select the analysis method or information regarding the use of the product will not be available for sale.
- Plant materials are chemical and have different properties.
- There are many different drugs and medicines.

• Source and quality of raw data vary. There are currently no official standards for herbal preparations. Companies now do some testing on their formulations and have their own parameters, many of which are very important. It is no longer easy to see the availability of all desired ingredients in the formula. The first important task is therefore to ameliorate inequality in terms of everything that can be detected. Various chromatographic and spectrophotometric methods as well as evaluation of physicochemical properties can be tested to create samples for product identification. Presence of different components. Where possible, this method can be used for the quantitative estimation of groups of bioactive substances such as alkaloids, flavonoids, polyphenolic compounds, or the estimation of specific elements.

The necessity of evaluating the quality of herbal drugs and their formulations

There is a global trend toward the use of herbal therapy as the risks and drawbacks of contemporary medicine become more widely recognized. Regulatory bodies' main duty is to guarantee that the medications patients are given are pure, safe, and effective. Regulatory agencies rigorously abide by a number of quality criteria for raw materials and completed goods in pharmacopoeias, designs, and production thanks to the good production Practices Act. These measures should be followed by all medical practitioners, whether they practice traditional or modern medicine. Despite their widespread popularity, herbal products have an uneven effect on uptake. The quality of the medication or the components of its completed goods have an impact on the safety and efficacy of herbal remedies. However, because botanical therapeutic compounds are scarce and complicated, it is challenging to define negative management. Despite the belief that contemporary scanning will assist in avoiding this issue. Furthermore, it is frequently unclear or only partially understood which components are responsible for the therapeutic advantages. This is made more difficult by the traditional therapy's use of a mix of herbal components. [5] A single product often contains up to five distinct botanical constituents. These variances multiply as they are stored and then processed. As a result, all research on medicinal plants and products from their production to their usage in medicine should be incorporated into the design.

Factors Affecting on the herbal quality

• **Pesticides:** Among them are insecticides, fungicides, and pesticides. There are several reasons why pesticide residues can be discovered in soil, plants, and animals, including metabolites and/or breakdown products. Currently, the primary cause of contamination in medicinal plants is these leftovers. Regulations have been released by the World Health Organization and other organizations to lessen the negative effects of pesticides on plant products. Plants frequently contain organochloride pesticides (OCPs), such as dichlorodiphenyltrichloroethane (DDT) and benzene hex chloride (BHC). Due of its detrimental consequences, DDT has been prohibited in several nations for almost 30 years.

• **Mycotoxins and microorganisms:** It is problematic when bacteria infect medication. Intestinal epithelial bacteria, enterococci, Scutellaria spp., and the development of dangerous bacteria like streptococci have all been found in herbal preparations. Aflatoxin, penicillin acid, fossil poisons, etc. Aflatoxin is a common and harmful substance. In a study of herbs bought from the Brazilian market, the USP microbial count limit was exceeded in more than 50% of the herbal samples that tested positive. In further investigations, mycotoxins and microbiological contamination were also found. Herbal remedies are used in China, Indonesia, Malaysia35, South Africa, India, and other countries. Illness can disperse and disseminate herbs at any moment. Regarding storage and transit, the following rules are applicable.

• **Further Foreign Material:** Adjuvants, organic solvents, and ash are a few more examples of contaminants that might lead to further herbal medicine-related illnesses. Reduce this issue as much as you can to guarantee top-notch goods.

• **Adulteration:** Adulteration is a sort of deceit that is described as "contamination by the addition of unhealthy ingredients or unwholesome substances." Herbal medication frequently contains both traditional medicine and tainted herbal components. Adulteration may be classified into three categories: replacement (using phony or subpar botanical goods), adding of traditional medicines to herbs, and inclusion of foreign items (not sand, metal, or herbal medication). Numerous medications are found in plants, and reports indicate that the pollution caused by the herbal sector is average in California (7%), New York State (5.5%), and Singapore (1.23%) [6]

Herbal drugs and their preparations

Medicinal plants, called medicinal plants, include the above parts, flowers, fruits, leaves, seeds, stems and soil (such as roots, bulbs, tubers, rhizomes). Whole plants, whether raw, fresh or dried, extracted and sometimes even dried, are important to world trade. Whether true or not, their medical, commercial, health and medical values are increasing and their business is growing steadily. About the efficacy, safety, and quality of numerous plants as well as their preparations, extracts, and active substances, there is still a dearth of knowledge. To guarantee its efficacy and safety, it is critical to preserve its quality.

Herbal drug quality

Because even the same species might have quite different chemical compositions at different periods, quality control of medicinal plants cannot be limited to the plant level. In fact, expression of metabolites may have secondary biological activity in some plants. Special balsams for each taxon with animal (predators, parasitic competition between animals in one place) and genetics (various species, species, species). The phenological stage of the plant (starting of blooming, end of flowering, etc.), the harvest time (e.g., location...), and the interval between harvest and observation time should be provided. Make your worries clear. Drying is the simplest method of storage since fresh samples are not excellent or may not be suitable for maintaining the quality of microorganisms, storing secondary metabolites, and storing pharmaceuticals. Inadequate preservation and desiccation may result in food spoiling and toxicity, photolysis, or air oxidation. Additionally, contamination could happen during manufacture, which might have an impact on the final product's quality and composition. These illnesses or injuries may have an impact on the medicinal plant's chemical makeup and, consequently, its quality. [7]

Sampling and getting ready to analyse samples

Testing items other than flour presents a significant challenge; even when testing is conducted using various materials, test samples still need to be representative. For example, different origins of different lineages will produce different barks for different trees, but biomarkers can only be used in tissues, leading to different results; For example, here's the problem. Use radish root. This formulation is currently regulated by the European Pharmacopoeia, which recommends detailed procedures that often include homogenization and grinding. Recent developments have led to the development of the formulation's main idea, which demonstrates the necessity of considering a number of variables, including the target compound's solubility and the desired concentration (e.g., between ppm and 15%), heavy power, etc., which is weighted by model, time, temperature, pressure, and extraction type (static, dynamic, or ultrasonic maceration, percolation, Soxhlet extraction, etc.) [8] Properties like as toxicity and inertness, as well as physicochemical characteristics like polarity and selectivity, can be used to choose a solvent. In order to extract plant material in accordance with the "like dissolves like" rule, the solvent's polarity is crucial.

Evaluation of herbal formulations for quality

• **Macroscopic or organoleptic evaluation:** Drugs can be assessed macroscopically by utilizing materials like size, shape, touch, and texture, or organically by using the senses (skin, eyes, tongue, nose, and ears) and characteristics like color, smell, and taste. This tool evaluates an object's morphological and sensory attributes to establish its quality. The fractured bones seen in buckthorn bark, quartz, and quill aja are distinctive characteristics. The perfume had a strong scent and the liquorice tasted delicious.

• **Microscopic Evaluation:** This method may be used to detect joint chemistries based on established histological findings, but it needs meticulous product analysis. Its use is limited to microscopic analysis of weak materials and unprocessed compounds. The presence of trachoma, holes, starch granules, calcium oxalate crystals, and aleurone granules are a few key components in the identification of crude medicines. The entire tree tissue turned a vivid red color after being treated with phenolphthalein and hydrogen chloride; hemicellulose and starch may be identified by their blue color in an iodine solution. Sputum that has been stained red with ruthenium red can be examined for cellular structure. microscopic examination examining the powder's characteristics. use of chemical techniques.

• **Chemical Evaluation:** Many medications can have diverse chemical or pharmacological effects on one another. Tests for pharmaceutical quality are carried out to identify specific medications or verify their purity. Analytical methods are used in the isolation, purification, and identification of active substances. Resins are evaluated using acid and sulphated ash, Balsams are evaluated using acid, saponification number and positive results are obtained. A good drug test can be done to find people who are addicted to alcohol and different drugs.

• **Physical Evaluation:** Physical regularity is occasionally considered while comparing different drugs. These consist of the following: viscosity, melting point, specific gravity, rotational and optical characteristics, available moisture content, and solubility in different solvents. Plant identification and location are aided by all of these physical traits.

• **Biological Evaluation:** It is possible to measure some medications by looking for particular chemical reactions and activity. In fact, the person responsible for this is a special substance found in plant extracts. Animals' entire bodies as well as individual organs were used in experiments for assessment. Drug potency can be measured during preparation using bioassays. [9]

Key chemical identification using in-tube reactions

Today, blood vessels are still used to identify important drugs in laboratories with limited equipment and procedures. This reaction produces alkaloids, terpenoids, flavonoids, tannins, anthocyanins, coumarins, quinine, cyanogenic glycosides and others. It is produced by producing colored, precipitated and/or fluorescent derivatives. Plant knowledge. While there are some hurdles and options, this process, along with some training in evaluating the results, can help quickly answer “maybe yes/no” questions about the analysis. Tropane alkaloids (Vital Morin reagent), codeine (Marquis reagent), opioids (Froehde reagent), and other substances are treated with this technique. In contrast to the existing procedure, the testing equipment may be used to detect significant types of drugs after it has been certified by the United Nations Office on Security and Crime (UNODC). It is mostly employed in the field of border control of drugs.

- **Microscopy-based quantitative investigation:**

A number of features that may be seen under a microscope are referred to as microscopic metrics, including the fiber size, palisade ratio, stomata, vein terminations, and vein islet count. These studies help in the separation of closely related species.[10]

Determination of adulterants, impurities and trace contaminants

In certain other situations, problematic items can be advantageous to plants or storage facilities where antibiotics or contamination could occur. It is also feasible to replace less costly items with more costly ones, for as star anise torture with cinnamon. F or star anise berries and fruits, are a nice example. The first form is useful medically, particularly for treating infantile colic, whereas the second type is neurotoxic. When adulteration is known to occur, it may also be found by microscopic analysis of the powder using techniques including fluorescence microscopy, thin layer chromatography, gas chromatography, and DNA barcoding. The macroscopic inspection of the complete fruit can be used to detect adulteration. These might include pesticides used in agriculture, bacteria or other foreign materials found in plants, insects that feed on other plants, heavy metals, radioactive elements, and microbes or their byproducts. Since bacterium and foreign matter levels are often quite low in herbal goods, it is important to maintain both the quality of the products and the safety of consumers through excellent cultivation and collecting practices as well as the control of impurities or illnesses. Analysis ought to be useful. These include the DNA-based route, spectroscopy (MS, NMR, FTIR, ICP-AE, ICP MS, and ESR), chromatography (often paired with chemical processes), and microscopy (such as reflection, line, or object).

WHO GOOD MANUFACTURING PRACTICE GUIDELINES:

- Specific activities of chemical and pharmaceutical products are used to evaluate them. In fact, the person responsible for this is a special substance found in plant extracts. Animals' entire bodies as well as individual organs were used in experiments for assessment. Drug potency can be measured throughout the preparation process using bioassays.
- The USA adheres to current Good Practices for finished pharmaceutical products.
- The EU has the right to appeal to the European Commission for guidance on the manufacturing quality of medicines.
- The Management of Quality Control Procedures Including Active Pharmaceutical Ingredients: ICH Q7 Recommendations.
- Good Manufacturing Practices are included in Annex M of Good Manufacturing Practices. Indian Drugs and Cosmetics Act, 1945 and Regulations.[11]

DIRECTIONS FOR GLP:

• **Test Facility Management**: A "testing facility" is any combination of staff, equipment, and activities needed to conduct environmental health and safety tests. In addition to rooms, buildings, and other spaces, the term "laboratory" also refers to the staff members who work there and are in charge of conducting these investigations. It might relate to different "experimental sites" at one or more places where certain stages or parts of a larger research project are carried out (Seiler, 2005). Various research domains consider personal labs, which may be classified as individual or group laboratories, in addition to the location of the researcher.[12]

• **Equipment:** Equipment, including computer systems used to generate, analyse and obtain data and manage environmental factors associated with the research, should be reasonably located, of the correct type and of sufficient capacity. The equipment file must contain the following information: equipment name, manufacturer, identifying model or make, serial number, date of arrival of the equipment at the laboratory, and a copy of the product manufacturer's instructions for use. All scientific research equipment should be regularly inspected, cleaned, maintained and calibrated according to standard operating procedures. It is important to follow these actions. National, international, or regional standards ought to be correlated with calibrations. Instrument

validation is an important process for any analytical laboratory. The information produced by a “negative” index can lead to incorrect assumptions.[13]

• **Standard Operating Procedures (SOP)**: The term "source document" means any working paper, document, record, memorandum, or actual copy thereof, which is the result of initial review and research activities and from which the work must be reconstructed and evaluated. The Environmental Protection Agency's (EPA) GLP guidelines serve as the foundation for this study report. A few types of raw data include computerized forms, training materials, written or laboratory data, written or field observations, hot data, or operational, maintenance, and repair data. Eliminating the need for someone to get all of these facts is one of the objectives of Standard Operating Procedure (SOP), as it would be challenging to do so.

• **Study Results Reporting:** The first data collected during an operation is known as raw data, and it is produced by every study. They support the scientific situation and are crucial for reconstruction study. Raw data are the experimental findings that serve as the foundation for research findings. While some of the raw data can be handled by code right away, some cannot. Both the study report's findings and the researcher's interpretation of them need to be precise and correctly documented in the primary source material.

• **Document and Material Storage and Retention:** Data and information must be properly prepared for storage and protection. Research plans, original documents, test samples, reference works, samples and other documents should be stored according to departmental deadlines. Each program's final report includes the entire program, information on qualified personnel, training, experience, and job descriptions; data and information regarding maintenance and measurement; and information accessible by computer systems. [14]

HPTLC study of some significant herbs and mixtures

According to Ayurveda, the plant Withania somnifera, sometimes known as ashwagandha, possesses "rasayana" (rejuvenating), "prolonging," and "rejuvenating" qualities. Sensorial is the name given to the aqueous extract of Withania somnifera leaves and roots. Analysis of the Effects of Sensorial Supplementation on Compliance with Strength Training. HPTLC method for ursolic acid estimation: Holy basil extract was dissolved in water using 1 g of 100 cc of methanol. Filter by Whatman No. 1 filter paper. Ten liters of each extract were collected from different areas and 3 liters of chromatogram standard solution were derived using Libermann Burchard reagent. Using D2 and tungsten lamps, spectroscopic analysis was used to find the greatest concentration of ursolic acid in the 200–700 nm region. The wavelength known as the "peak" is where the maximum and peak area are measured. Utilize CAMAG Reprostar 3 to take campaign pictures. Ursolic Acid Determination using HPTLC Method.[15]

TECHNIQUES FOR ASSESSING THE QUALITY OF HERBAL MIXTURES AND CRUDE DRUGS

1. Triphala churna:

• **Physico-chemical Evaluation:** The physical strength of all three samples, comprising foreign matter, moisture content (dry pH), pH, total ash, acid-insoluble ash, water-soluble extractable, and alcohol-soluble extractives, was evaluated using the following Design process.

• **Determination of Foreign Matter**: Spread 100 g of the thin sample on a suitable platform, examine under light without glasses (or use a 6x or 10x magnifying glass), separate the sample and weigh it. Calculate the percentage of foreign products according to the chemical formula. Then bake it in the oven at 105°C for three hours. Drying and weighing are done every half hour so that the difference between the two measurements does not exceed 0.25%.

• Determination of Moisture Content:

a) Weigh two grams of jam accurately and place it on a porcelain plate.
b) Heat it for 2 hours and put it in the refrigerator.
c) Determine the moisture content of our jams by weighing them.

• Determination of total Ash value:

a) Actual weight is 3 grams of silicon dioxide crucible powder.
b) Gradually increase the temperature to burn the powder until it is free of carbon and cools.
c) Define total cash value by ash weight.

2. Preparations and assessment of herbal cream:

Table No.1: Cream's composition

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

• Procedure:

1. Dry the wax and mineral oil using a water bath at 700C.
2. Here curcumin is insoluble in water.
3. Therefore only a small amount of ethanol was added.
4. Add to the borax-water mixture after heating to the same temperature.
5. After reaching two temperature of 7000C, add the water level and continue to cool, stirring rapidly.
6. Filter and put in a paper box.

3. Evaluation of cream

- Uniformity: Check the uniformity of the formula visually and tactilely.
- Appearance: Please rate the candy's look based on its color, pearlescence, and roughness.
- Feelings afteruse: After using some cream, measure its softening, smoothness and residue. Type of contamination: The type of film or stain formed on the skin after the application of the cream is examined.
- Ease of removal: Ease of removal of the cream was evaluated by rinsing the painted area with tap water.
- Thermal Stability Test: The humidity chamber was calibrated to 37–10°C and 60–70% relative humidity in order to assess the formulation's thermal stability.

FLAVONOIDS FROM SENNA ALATA FLOWER

Fig.1: Senna alata flower

Plant secondary metabolites having a diphenyl propane structure (C6-C3-C6) are referred to be flavonoids. Many preclinical and some clinical studies have shown that flavonoids have the ability to prevent and treat many diseases. The preventive effect of a diet high in foods high in flavonoids in lowering the risk of heart disease and cancer is supported by certain epidemiological research. Possible paths of interaction for flavonoids have been demonstrated by preclinical in vitro and in vivo studies. Preclinical studies conducted in vivo and in vitro have shown possible flavonoid interaction routes. Apply 1µl of the sample solution and 5 and 10µl of the test solution, respectively, using the standard applicator onto a 0.2 mm thick percolated silica 60F254 thin layer chromatography plate. On the weight system, open the plate to a distance of 8 cm. Using a TLC scanner, densitometric scans of the plates were carried out at 254 nm. The preventive effect of a diet high in foods high in flavonoids in lowering the risk of heart disease and cancer is supported by certain epidemiological research. Possible paths of interaction for flavonoids have been demonstrated by preclinical in vitro and in vivo studies.[16]

CONCLUSION

Plant materials form a significant portion of the global pharmaceutical market and are used as ingredients in retail stores, home remedies and raw materials for the pharmaceutical industry in both built and constructed countries around the world. The main issues to be addressed are the safety, quality and effectiveness of herbs and herbs. It is clear that with the collaboration of drug regulators, scientists and industry, the herbal medicine industry in India can grow well. However, design and administration data on safety and effectiveness are needed to better understand the use of herbs. Therefore, it is important to establish acceptable standards to measure their quality. It is now clear that there must be a good way to treat and the untapped resources of traditional medicine must be used. However, this is not easy, because definitive research on medicinal plants needs to be clearly defined, the research process determines the classification of active ingredients, and preclinical evaluation of their pharmacology and toxicology is needed. . And it has been clinically proven to be good. A drug review should be performed to determine factors such as appropriate dosage and side effects.In other words, these herbs. The kind of examination required by modern medicine is a randomized controlled trial.

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