

A review on Evaluation in research of herbal medicine

Prithvi Raj Chauhan¹, Prof. Dr. Mohd Wasiullah², Piyush Yadav³, Sushil Yadav⁴, Satish kumar yadav^{5*}

1. Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P., India.

2. Principal, Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P., India.

3. Principal, Department of Pharmacy, Prasad Polytechnic, Jaunpur (222001), U.P., India.

4. Assistance Professor, Department of Pharmacy, Prasad Institute of Technology Jaunpur (222001), U.P., India.

5. Assistance Professor, Department of Pharmacy, Prasad Institute of Technology Jaunpur (222001), U.P., India.

Submitted: 05-05-2023

Accepted: 15-05-2023

ABSTRACT:-

The term "herbal drugs" refers to plants or plant parts that have undergone simple processes, such as harvesting, drying, and storage, to become phytopharmaceuticals. Other crude products derived from plants, such as essential oils, fatty oils, resins, and gums, can also be included. Although the use of herbal drugs in medical practice is gaining acceptance, there is a growing concern about their abuse and adulteration, which can lead to adverse consequences. To ensure the safety of the global herbal market, it is essential to establish quality parameters using advanced analytical tools and standardized methods. This review highlights the importance of evaluating herbal drugs and implementing good quality assurance and standardization processes, which involve the use of spectroscopic, chromatographic, and electrophoretic methods. Quality control of herbal medicines requires an interdisciplinary approach that combines chemistry, pharmacology, medicine, and statistics to identify the novel therapeutics composed of multiple chemical compounds. The use of herbal medicine has been practiced for thousands of years, and it is still widely used today. However, the safety and efficacy of herbal medicine are often questioned due to the lack of rigorous scientific research. Recent research has focused on the evaluation of herbal medicine using modern scientific methods. This research includes laboratory studies, animal studies, clinical trials, and systematic reviews.

Key Word:-herbal medicine, Microscopic evaluation, efficacy, safety, evaluation, etc.

I. INTRODUCTION:-

The evaluation of herbal medicine is a complex and multidisciplinary field that involves

the application of scientific methods to study the safety, efficacy, and quality of herbal products. The use of herbal medicine has been increasing worldwide due to the perceived health benefits and the popularity of natural products. However, the lack of standardization, regulation, and quality control in the production and distribution of herbal medicine poses significant challenges in ensuring their safety and efficacy.

The evaluation of herbal medicine requires a comprehensive approach that involves the investigation of the chemical constituents, pharmacological properties, clinical effectiveness, adverse effects, and interactions with other medications. This involves the use of various research methods, such as laboratory experiments, animal studies, clinical trials, and systematic reviews.

The research in the evaluation of herbal medicine has several objectives, including the identification of active compounds, the determination of therapeutic doses, the investigation of the mechanism of action, the evaluation of the safety and efficacy in humans, and the development of standardized protocols for the production and quality control of herbal medicine.

The research in the evaluation of herbal medicine is important in providing scientific evidence for the use of herbal medicine and in ensuring their safety and efficacy. It also contributes to the development of new drugs and the improvement of healthcare services by providing alternative treatments for various diseases and health conditions.

The World Health Organization emphasizes the significance of both qualitative and quantitative methods for describing samples, determining the amount of bio-markers or chemical

markers, and creating a fingerprint profile. When the primary active component is identified, quantifying that compound is the most reasonable approach. If botanical preparations contain active ingredients that contribute to therapeutic effectiveness, they should be standardized based on their compounds. If the active ingredients are not yet identified, a marker substance specific to the botanical plant should be selected for analytical purposes.

Herbal drugs:-

Herbal drugs are of two types -

- Single/ crude drug
- Multiple herbal formulations

Single /crude drugs:-

- This category encompasses primarily intact, broken, or chopped plant material that is typically dried, though occasionally fresh.
- Additionally, it encompasses algae, fungi, and lichen.

Multiple herbal formulations:-

Herbal ingredients undergo several manufacturing processes such as extraction, distillation, expression, fractionation, partitioning, chromatography, and formulation to obtain different formulations.

Safety in herbal drugs:-

Ensuring the quality, safety, and efficacy of herbal medicinal products is crucial for protecting consumers from potential risks. However, differences in how these aspects are assessed can create barriers to the free circulation of such products. Given the complexity of preparing herbal drugs and interpreting safety and efficacy data, it is important to involve experts with specific knowledge and experience.

The safety and efficacy of complex biological products, like herbal medicines, are closely tied to pharmaceutical factors, such as the manufacturing process and extract specifications. To properly assess the quality of herbal drugs, more detailed information may be needed regarding the agricultural aspects of production, such as seed selection, cultivation conditions, and harvesting practices. The ongoing discussions around good agriculture practices for medicinal plants should be regularly monitored to ensure that the resulting products are consistently high-quality and safe for consumers.

Toxicity in herbals and their interactions:-

The FDA is responsible not only for assessing the efficacy of drug products but also for ensuring their safety. It is crucial to recognize that not all botanicals and herbals are harmless, as exemplified by the 1991-1992 incident in Brussels, Belgium, in which 30 women died from renal failure caused by aristocholic acid in a Chinese herbal slimming preparation. One of the herbs in the mixture was mistakenly identified as non-toxic, underscoring the need for accurate plant identification from the outset. Furthermore, some combinations of herbs can be toxic, particularly when used improperly. Therefore, it is essential to maintain ongoing surveillance and actively request information, rather than just collecting reports. This could be achieved through a national program focused on monitoring the safety of herbal preparations.

Analytical evaluation technique in herbal drugs:-

Herbal drug quality control relies on three primary pharmacopoeias, with content being the most challenging aspect to evaluate due to the unknown active constituents in most herbal drugs. To address this, markers may be used as chemically-defined constituents for control purposes, regardless of their therapeutic activity.

Ensuring identity and purity requires assessing factors such as sensory properties, physical constants, adulteration, contaminants, moisture, ash content, and solvent residues. Establishing the botanical quality and verifying the correct identity of the cured herbal material are paramount to ensuring high-quality herbal drugs.

Organoleptic or macroscopic evaluation:-

Organoleptic evaluation refers to the sensory evaluation of herbal drugs using the human senses. This involves the evaluation of the appearance, taste, odor, texture, and color of the herbal drugs.

Macroscopic evaluation refers to the examination of the herbal drugs using the naked eye or a low-powered magnifying glass. This involves the evaluation of the size, shape, surface texture, and other physical characteristics of the herbal drugs.

Both organoleptic and macroscopic evaluations are important in the quality control of herbal drugs. These evaluations can provide valuable information about the identity, purity, and quality of the herbal drugs, and can help to ensure that they meet the

required standards for use in medicinal or other applications.

Microscopic evaluation:-

Microscopic evaluation is an essential quality control test for herbal drugs, as it allows for the identification and characterization of the plant material. Here are the general steps involved in microscopic evaluation of an herbal drug.

- Sample preparation: The herbal material should be collected and processed according to the official monograph or the established protocol. This may include grinding, sieving, or sectioning the material into thin slices.
- Microscopic examination: The prepared sample is then examined under a microscope, which may be either a simple microscope or a compound microscope. The aim of this examination is to identify the plant material, determine its anatomical features, and to identify any adulterants, contaminants, or foreign matter present.
- Staining: In some cases, staining may be necessary to highlight certain features of the plant material. For example, safranin may be used to stain lignified tissues, while iodine may be used to stain starch granules.
- Image analysis: After the microscopic examination, images of the plant material can be captured using a digital camera or a scanner. These images can then be analyzed using image processing software to quantify various features, such as the size and shape of cells, the thickness of cell walls, or the density of certain structures.
- Interpretation: The final step in microscopic evaluation is to interpret the results of the examination and analysis. This may involve comparing the observed features of the plant material with those described in reference texts or monographs, and making a determination as to the identity and quality of the herbal drug.

Chemical evaluation:-

Chemical methods are commonly used for the evaluation of drugs and their constituents. These methods are used for the isolation, purification, and identification of active constituents. Qualitative chemical tests are used to identify certain drugs or test their purity.

For example, resins can be evaluated using the acid value and sulphated ash tests. The acid value is a measure of the amount of free fatty

acids in a resin, and the sulphated ash test determines the inorganic content of the resin.

Similarly, balsams can be evaluated using the acid value, saponification value, and ester values. The acid value measures the amount of free fatty acids, while the saponification value is a measure of the total fatty acid content. The ester values are a measure of the amount of esters present in the balsam.

Volatile oils can also be evaluated using the acetyl and ester values. The acetyl value is a measure of the amount of acetyl groups present in the oil, while the ester value measures the total ester content.

The qualitative chemical tests are useful in identification of chemical constituents and detection of adulteration.

Physical evaluation:-

The physical evaluation of herbal drugs involves the use of various techniques to assess the quality and purity of the plant material. The following are some of the key aspects of physical evaluation of herbal drugs:

- Macroscopic examination: This involves the observation of the physical characteristics of the plant material, such as its color, odor, taste, texture, and size.
- Microscopic examination: This involves the use of a microscope to examine the plant material at the cellular level. This can help to identify the presence of particular structures or compounds, such as trichomes, starch granules, or crystals.
- Chemical analysis: This involves the use of various chemical tests to identify the presence of particular compounds, such as alkaloids, flavonoids, or tannins.
- Thin-layer chromatography (TLC): This is a technique used to separate and identify the different components of a plant extract. It involves applying the extract to a thin layer of a specific material, and then exposing it to a solvent that will cause the different compounds to separate and become visible.
- High-performance liquid chromatography (HPLC): This is a more advanced form of chromatography that can separate and identify even more complex mixtures of compounds. It involves the use of a liquid mobile phase and a stationary phase to separate the different components of the plant extract.

Biological evaluation:-

Biological Evaluation. Its a qualitative evaluation and drugs are evaluated by means of sensory features like colour, odour, taste, shape, size, texture, net content, volume. examination of organized crude drugs in their entire and powdered forms.

Evaluation in research of herbal medicine:-

Evaluation in the research of herbal medicine refers to the systematic process of assessing the safety, efficacy, and quality of herbal products or interventions. It involves the application of scientific methods to gather evidence regarding the potential benefits, risks, and mechanisms of action associated with the use of herbal remedies.

Here are some key aspects of evaluation in herbal medicine research:

- ❖ **Identification and collection of plant materials:** Researchers select and gather specific plant species or plant parts that have been traditionally used for medicinal purposes. Proper botanical identification is crucial to ensure consistency and accuracy in subsequent research.
- ❖ **Extraction and isolation of bioactive compounds:** The active constituents of the plants are extracted using appropriate techniques to obtain crude extracts. Further purification processes may be employed to isolate specific bioactive compounds responsible for the observed medicinal properties.
- ❖ **In vitro studies:** The isolated compounds or extracts are tested in laboratory settings to assess their biological activities, such as antimicrobial, antioxidant, anti-inflammatory, or anticancer properties. These studies often involve using cell cultures or isolated enzymes to evaluate the effects of the herbal preparations.
- ❖ **In vivo studies:** Promising compounds or extracts are further evaluated in animal models to determine their pharmacokinetics, toxicological profiles, and therapeutic effects in a more complex biological system. These studies help assess the safety and efficacy of the herbal preparations.
- ❖ **Clinical trials:** If the preclinical studies show positive results, controlled clinical trials are conducted to evaluate the effectiveness of the herbal medicine in humans. These trials follow rigorous protocols and involve a group of

participants who are monitored for specific health outcomes. The trials can be randomized, double-blinded, and placebo-controlled to ensure unbiased evaluation.

- ❖ **Safety assessments:** Research also focuses on evaluating the safety of herbal medicines by monitoring potential adverse effects, drug interactions, and long-term effects. This involves conducting toxicity studies and investigating the herb-drug interactions to ensure the safe use of these preparations.
- ❖ **Mechanism of action:** Understanding the mechanisms through which herbal medicines exert their therapeutic effects is an important aspect of research. This involves studying the molecular pathways, receptors, enzymes, and signaling mechanisms targeted by the bioactive compounds.
- ❖ **Standardization and quality control:** Research also includes efforts to standardize herbal preparations by establishing quality control parameters, including identification of active markers, standard extraction methods, and establishing quality assurance practices to ensure consistent and reliable herbal products.
- ❖ **Pharmacological Mechanisms:** Evaluation of herbal medicines involves studying their underlying mechanisms of action at a molecular, cellular, and physiological level. This includes exploring how specific bioactive compounds interact with biological targets, signaling pathways, or physiological processes to produce therapeutic effects.
- ❖ **Clinical Outcomes:** Assessing the impact of herbal interventions on patient outcomes is an essential aspect of evaluation. Clinical research may involve investigating the efficacy of herbal medicines in controlled trials, monitoring the long-term effects in observational studies, or analyzing real-world data from patient registries or electronic health records.
- ❖ **Systematic Reviews and Meta-Analyses:** These methods involve synthesizing existing research findings to provide a comprehensive overview of the evidence for herbal medicines. Systematic reviews assess the quality and validity of individual studies, while meta-analyses statistically combine data from multiple studies to generate more robust conclusions.
- ❖ **Traditional Knowledge and Ethnopharmacology:** Evaluation in herbal medicine research often incorporates

traditional knowledge and ethnopharmacological studies to understand the historical use, traditional practices, and cultural perspectives associated with herbal remedies. This can provide insights into potential therapeutic applications, dosage recommendations, and safety precautions.

II. CONCLUSION:-

Evaluation of herbal medicine in research is an important process that helps to establish the efficacy, safety, and quality of herbal products. Proper evaluation involves conducting rigorous clinical trials, adhering to regulatory guidelines, and using validated scientific methods to measure the effects of herbal products. The evaluation process should also take into account the potential risks and benefits associated with the use of herbal medicines.

While there is increasing interest in the use of herbal medicines, it is important to recognize that not all products are safe or effective. Therefore, proper evaluation is essential to ensure that herbal medicines are of good quality and can be used safely in the treatment and management of various health conditions. The evaluation process also helps to build public trust in herbal medicine by providing evidence-based information to consumers, healthcare professionals, and regulatory agencies.

REFERENCE:-

- [1]. International Journal of Green Pharmacy. Quality control of herbal drugs: An overview. *Int J Green Pharm.* 2011;5(3):163-171.
- [2]. American Herbal Pharmacopoeia. (2019). Botanical pharmacognosy: Microscopic characterization of botanical medicines.
- [3]. Medicinal Plants and Herbal Medicines: Quality, Efficacy, and Safety. Mukherjee PK, editor. CRC Press, 2017.
- [4]. Quality Control and Evaluation of Herbal Drugs: Approaches and Techniques. Mukherjee PK, editor. CRC Press, 2019.
- [5]. Validation of analytical methods for pharmaceutical analysis" by C. M. Riley and R. D. Rosanske, *Pharmaceutical Research*, 2000.
- [6]. "Recent advances in analytical methods for the determination of drugs in biological samples" by Y. C. Wong and P. J. Worsfold, *TrAC Trends in Analytical Chemistry*, 2018.
- [7]. "Analytical Methods for Drug Analysis" by B. N. Patel and D. K. Patel, *Journal of Analytical & Bioanalytical Techniques*, 2015.
- [8]. Satheesh madavi NN, kumud upadya, asha bishti, phytochemical screening and standardization of poly herbal formulation for dyslipisemia. *Indian journal of physiology and pharmacology.* 2011.
- [9]. WHO. 1988. Quality Control Methods for Medicinal Plant Materials. World Health organisation, Geneva.
- [10]. WHO. 1992. Quality Control Methods for Medicinal Plant Materials. World organisation, Geneva.
- [11]. Eisenberg DM, kessler RC, Foster C, norlock FE, Calkins DR, Delbanco TL. Unconventional medicine in the United States. Prevalence, costs and patterns of use. 1993.
- [12]. Blumenthal M, Brusse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS, The complete german commission E monographs. Therapeutic guide to herbal medicines, the American botanical council, Austin, TX. 1998.
- [13]. Brain KR and Turner TD. Practical Evaluation of phytopharmaceuticals. Wright Scientecnica Bristol. 1975.
- [14]. Fahishi, A (1996) Complementary medicine. Vol.1. London: financial times and health care publishing. Future system for the free movement of medicinal products in the European community. the rules governing medicinal products in the European community volume3; guidelines on the quality safety and efficacy of medicinal products for human use. 1989.
- [15]. Gupta MK and Sharma PK. Test Book of Pharmacognosy, Ayurvedic formulations, Pragati Prakashan Meerut Vol II, 1st edition. 2007.