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STANDARDIZATION OF HERBAL DRUG TECHNOLOGY

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ABSTRACT:

The term "herbal medicine" refers to plants or parts of plants that are transformed into phytomedicine by simple processes such as harvesting, drying and storage. Herbs also include other raw products derived from plants that no longer have an organic structure, such as essential oils, fatty oils, resins and gums. About 80% of the world's population depends on herbal medicines and products for a healthy lifestyle. Therefore, the use of herbal products also leads to various forms of product abuse and adulteration, leading to consumer and manufacturer disappointment. Standardization is therefore an important tool for quality herbal products, and standardization of herbal medicines means ensuring their identification, quality and purification. This overview describes the standardization of herbal medicines.

Keywords: -

Herbal drugs, standardization, chromatography, HP-LC, and GC-MS

INTRODUCTION: -

Herb is part of a plant that can be utilized for one or more medicinal purposes or as a precursor for pharmaceutics semi-synthesis. The largest global market for herbs is in INDIA, CHINA, the US, FRANCE, GERMANY, the UK, ITALY, JAPAN, and SPAIN.

INDIA is also gifted with a variety of herbal systems of medicine like AYURVEDA, SIDDHA, UNSNI & HOMEOPATHY. Which include a number of herbal preparations along with herbs. In the case of herbal preparation, it must be properly standardized for pure/ quality herbal drugs / medicinal product.

HERBAL DRUG STANDERDIZATION:-

Standardisation is a process that guarantees each dose of a chemical has a specific level of quality, quantity, and therapeutic efficacy. Herbal goods cannot be regarded as scientifically genuine if the medicine tested has not been verified & characterised in order to ensure repeatability in the production of the product. In addition, a number of deadly side effects, including as direct toxic effects, allergic response effects from contaminants, and interactions with herbal medications, have lately been recorded. A herbal formulation's medicinal effectiveness is influenced by its phytochemical components. Scientists have a significant difficulty in developing reliable analytical techniques that can quantitatively evaluate marker/bioactive chemicals and other important ingredients and correctly profile the phytochemical makeup. Given the foregoing, standardisation is a crucial step in creating uniform biological activity, a consistent chemical profile, and even just a quality assurance programme for the development and manufacturing of herbal medications. For pharmaceutical firms as well as the general public's health and to assure the repeatable quality of herbal medicine, it is crucial to authenticate herbal medications and identify adulterants made from real medicinal plants.

Standardization Of herbal drug: -

1. Biological: - microbial contamination, pharmacological evaluation, toxicological studies

2. BOTANICAL: - A)
Macroscopic: - color, odor, taste, texture & fractured SEM studies, powder studies

B)microscopical

3. PHYSICAL: - moisture content, extractive value, ash value

4. CHEMICAL: - chromatography techniques (TLC, HPTLC, HPLC. LC-MC, LC-NMR, GC-MS, GC-FID, SFC)

* **BIOLOGICAL EVALUATION**:

Each naturally occurring medication has pharmacological and biological characteristics that are used to assess them. Actually, the sort of elements found in the plant extracts primarily what are responsible for this action. Both whole and disassembled trials were run for assessment. The potency of the medicine in its formulation may be assessed with the use of bioassay. [8-10]

BOTANICAL EVALUATION: -

A] MACROSCOPIC EVALUATION

The term organic evaluation is also used to describe macroscopic evaluations. In which we detect evaluation with the help of sense organs (skin, eye, tongue, nose & ear.) microscopic evaluation include the evaluation of a drug by colour, odour, taste, size, shape & specific feature, like touch, texture, etc. it is the technique qualitative based on the study of morphology & sensory profile of whole drugs.

B] MICROSCOPICAL EVALUATION:-

It will involve thorough examination of the medicinal products and is capable of identifying organised medicinal products based on their known histologic characteristics. It's mainly used with microscopic help for qualitative evaluation of the organized chemical substances in their full and power forms.

Using a microscope, record various cellular tissues, trachoma's, stomata, starch granules, calcium oxalate crystals and aleuronic granules. These are some of the key parameters that play an important role in identifying specific herbal medicines [2-6]

*** PHYSICAL EVALUATION:-**

Physical constants may be considered when evaluating certain drugs. These include water content, specific gravity, optical rotation, extraction value, ash content, melting point, viscosity, and solubility in various solvents. All of these physical properties help identify and recognize the constituents present in plants.

1) Moisture content –
Moisture content or moisture content is the quality of water in materials such as soil, rocks, pottery, crops, and wood. [22]
The formula for calculating moisture content is:

MC = w-t/w*100
was,
w = wet weight
d=weight after drying

2) Extractive value –
Extracted values are used to evaluate herbal medicines that cannot be estimated by other methods.
The formula for calculating the extracted value is

Extracted Value = Initial Weight – Extracted Weight / Initial Weight * 100

3) Ash value –
Ash usually represents inorganic residues such as phosphates, carbonates and silicates contained in herbal medicines.
% ash = weight after pain, tare weight. Crucible/original sample weight * 100

 # CHEMICAL EVALUATION:

Most drugs are composed of specific chemical constituents due to their biological or pharmacological activity. Qualitative chemical tests are used to identify a particular drug or to check its purity. The isolation, purification and identification of active ingredients are based on chemical assays.

CHROMATOGRAPHY: -

There are types of chromatography as below,

1) Fingerprinting & marker compound analysis

2) Thin layer chromatography (TLC)

3) High-performance liquid chromatography (HPLC)

4) High-performance thin liquid chromatography (HPTLC)

5) Liquid chromatography-mass spectroscopy (LC-MS)

6) Gas chromatography (GC-MS)

 # FINGERPRINTING & MARKER COMPOUND ANALYSIS:

An extract/herbal drug fingerprint is a chromatographic pattern of some common pharmacologically active botanical constituents and their chemical properties. This chromatographic analysis should be recommended by basic attribution of 'completeness', 'ambiguity', 'similarity' and 'dissimilarity' to chemically represent the crude drug profile.

Chromatographic fingerprints are recommended to be the real parameter (completeness) for authentication and identification that can be performed accurately, in addition to the small number of characteristic components (thus the 'ambiguity') present in various HM samples. Increase. Chromatographic fingerprinting can effectively reveal both 'similarities' and 'differences' between different samples. Therefore, a large number of components in the HM/extract can be considered and it is much better to consider components from 1-2 manufacturers individually for quality assessment. Fingerprint analysis is similarly useful for HM/extract identification and authentication, as human fingerprints are unique and reliable parameters for identifying individuals. However, HM/extracts consist of thousands of unknown ingredients, many of which are present in small amounts. Moreover, discrepancies often exist even within the same plant material. Therefore, it is very important to obtain accurate chromatographic fingerprints that also characterize the pharmacologically important and characteristic components of HM.

 # THIN LAYER CHROMATOGRAPHY (TLC) : -

It is the simplest and most accepted chromatographic technique for identifying and isolating plant components. TLC is widely used for phytochemical analysis of herbal medicines.

• This technique allows researchers to quickly analyse extracts with minimal clean-up.

• This technique provides qualitative and semi-quantitative information about dissolved compounds.

• Enables more accurate quantification of plant constituents by HPTLC.

Fingerprinting analysis along with HPLC and GLC can also be performed in some special cases. It includes a data recording system using an HPTLC scanner which includes:

- Chromatogram
- Retention factor (Rf)
- Divers band colours
- Absorption spectral analysis

This information provides a potential claim to identify the original drug product and helps remove contaminants and maintain drug quality and consistency.

HPLC study involves

- The chromatograms

- Retention time
- The absorption spectra in different mobile phases

Similarly, gas-liquid chromatography can be used to examine the fingerprints of volatile and fixed oils derived from herbal medicines. In addition, other modern approaches include HPLC, HPLC diode array analysis (HPLC-DAD), gas chromatography-mass spectrometry (GC-MS), and capillary electrophoresis diode array. 5. Nuclear magnetic resonance modifications including liquid Chroma detection (CE-DAD), high performance liquid chromatography-mass spectrometry (HPLC-MS) and high performance liquid chromatography-spectroscopy (HPLC-NMR) provide additional information It is potentially important for providing unique qualitative results and elucidating online structures. [1]

 # HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) : -

It is an effective technique for the production and analysis of pharmaceuticals for the separation and purification of herbal ingredients in the pharmaceutical industry. This technique is mainly done by him in two ways. Preparative HPLC requires the use of low pressure HPLC (below 5 bar) and high pressure HPLC (above 20 bar). The key parameters considered in analytical HPLC are resolution, sensitivity, and fast analysis time, but both (preparative and analytical) are the purity of solutes and the number of components that can be recovered per unit of time. H. Throughput/Recovery in Preparative HPLC (Rae et al., 2009).

Preparative HPLC (pressure > 20 bar) uses large stainless steel columns and packing material (particle size 10-30 µm). A normal silica column, e.g. :

- Kromasil 10 µm,
- Chiralcel AS 20 mother for inversion stage
- chromasil C18 chromasil C8
- YMC C18.

The purpose of preparative HPLC is to separate/purify plant components and obtain information about samples for analytical work. These technologies are very important in the modern pharmaceutical industry as new products, whether natural or synthetic, need to be brought to market as quickly as possible. Using these powerful purification techniques saves various steps and time instead of synthesizing the drug [1].

 # HIGH - PERFORATED THIN LAYER CHROMATOGRAPHY (HPTLC) : -

It is a widely accepted and used technique for the development, identification and detection of contaminants and contaminants in pharmaceuticals, useful for pesticide level and mycotoxin detection, and quality control analysis of herbs and health foods. This technique uses less mobile phase than HPLC and analyzes multiple samples simultaneously. Mobile phases with a pH of 8 or higher can be used especially for HPTLC analysis. A further advantage of this technique is that the chromatograms can be repeatedly scanned under the same/different conditions. HPTLC has therefore been investigated for the simultaneous determination of various plant components in multicomponent formulations (Thoppil et al., 2001). The technology is also useful for certifying different plant species and assessing the stability and consistency of herbal formulations from different manufacturers. [1]

 # LIQUID CHROMATOGRAPHY – MASS SPECTROSCOPY (LC-MS) : -

This technique is preferred at many stages of drug development (Lee, 1999). Recent improvements include electrospray, ion-spray ionization techniques, and thermospray, which offer particular advantages of high sensitivity and specificity, and are two-pronged methods for accurately determining the molecular weight of proteins and peptides. It is equipped with secondary ion mass spectrometry and 600 MHz laser mass spectrometry. Isotopic patterns can also be detected using this method (Bhutan, 2000) [1]

 # GAS CHROMATOGRAPHY (GC-MS) : -

GC is a widely accepted method for the analysis of botanical constituents in herbal medicines due to its direct connection to mass spectrometry and its high sensitivity, stability and efficiency. These combined techniques provide consistent information for qualitative analysis of plant constituents. [20-21]

CONCLUSION: -

Herbal medicine is a very important medicine and plays an important role in maintaining good health. Kampo medicine accounts for about 80% of the world market, and India can boast to the world. There are thousands of plant species that are contaminated with one drug and another. Herbal medicine has excellent pharmacological effects. Contamination with impurities can have futile or harmful effects. Today, the field of herbal medicines and their formulations is advancing rapidly, and much remains to be done when it comes to standardization. Therefore, we need to know about its organoleptic properties, pharmacological activity, and standardization when developing herbal formulations. The quality assurance issues of herbal medicines have been largely resolved with the help of chromatographic DNA fingerprinting analysis.

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