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ADVANCED STANDARDIZATION OF HERBAL DRUG

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Abstract:

Plants have been used as medicine since prehistoric times. The increasing use of herbs and concerns about their safety and effectiveness have led to the need for the formulation of these herbs. The World Health Organization has developed guidelines for these drugs, which are used as models by many countries. Standardization includes external (naked/microscopic) as well as internal/ash analysis, extraction results and many other measures to identify, describe and study the chemical composition of the muscles.

Medicinal plants are important for drug production. Medicinal plants and herbs constitute a large part of the pharmaceutical market. Although most of the practices are not scientific, knowledge about the use of herbs in modern medicine is increasing and widely accepted. Herbal medicine is not an easy task because many factors affect its biological and therapeutic effects. Therefore, there is a need to improve the safety of herbal medicines by establishing some quality control measures and following the World Health Organization guidelines on herbal medicines. Methods of quality assurance and standardization of herbs and medicinal products using various spectroscopic, chromatographic and electrophoretic methods are also discussed.

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INTRODUCTION:

Although herbal drugs are generally considered safe and non-toxic, it has been determined that there are negative effects related to the product. This may be due to a variety of reasons, including but not limited to incorrect identification, poor manufacturing processes and registration. Meaning of Standardization: Standardization is created by comparing the product with the manufacturer to create a better medicine and defining the minimum amount of one or more compounds.

Design need:

As discussed earlier, the effective use of herbs depends on many factors that are difficult to control. Therefore, there needs to be a basis to help patients. As the previous discussion shows, the safety of using herbs depends on many factors that are difficult to control. Therefore, a system must be in place to persuade patients to achieve a minimum level of quality. In other words, there must be a standard system to ensure the quality of the product. This will include design for the quality of each step of the process, from product development to final check for accuracy. Using good agricultural practices and good harvesting practices in growing and harvesting plants is a starting point. Practice standards for the preservation of natural medicines should also be developed.

WHO Guidelines for Best Practices

•Quality assurance measures and shelf life of APIs, botanicals and finished products.
•Information on safety issues based on empirical or toxicological studies.
•Other benefits from ethnomedical data and bioactive evolution.

Standardization methods of Ayurvedic medicine:

•Raw material standardization
•Process standardization
•Finished product standardization

Raw material standardization:

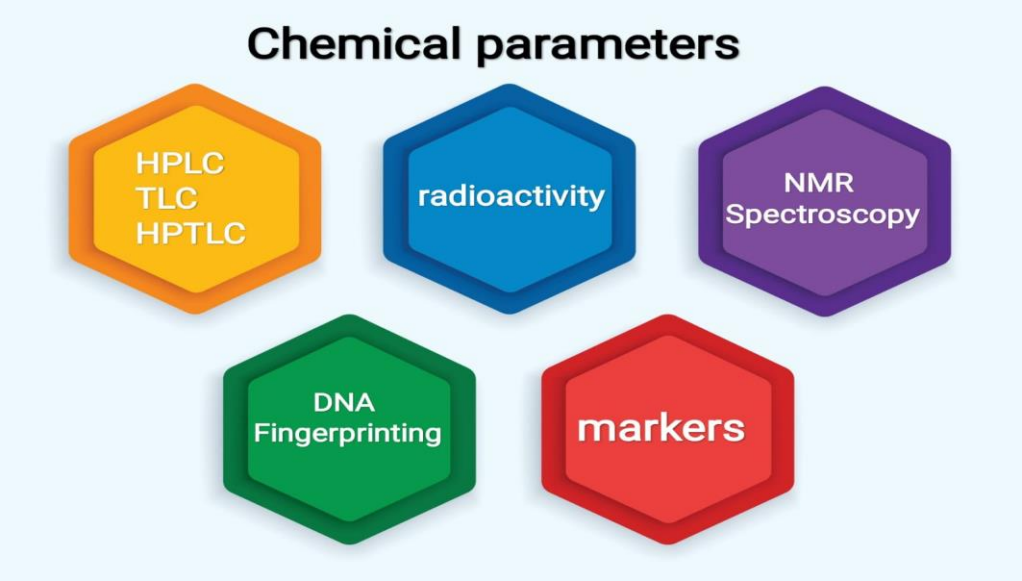
Spelling areas, plant residues, areas, plant characteristics, microscopic and histological analysis, distribution properties, foreign matter, weight loss during drying, expansion index, foaming index, ash and extraction values, chromatographic and spectral analysis, heavy metal analysis, pesticide residue, microbial contamination, radioactive contamination.

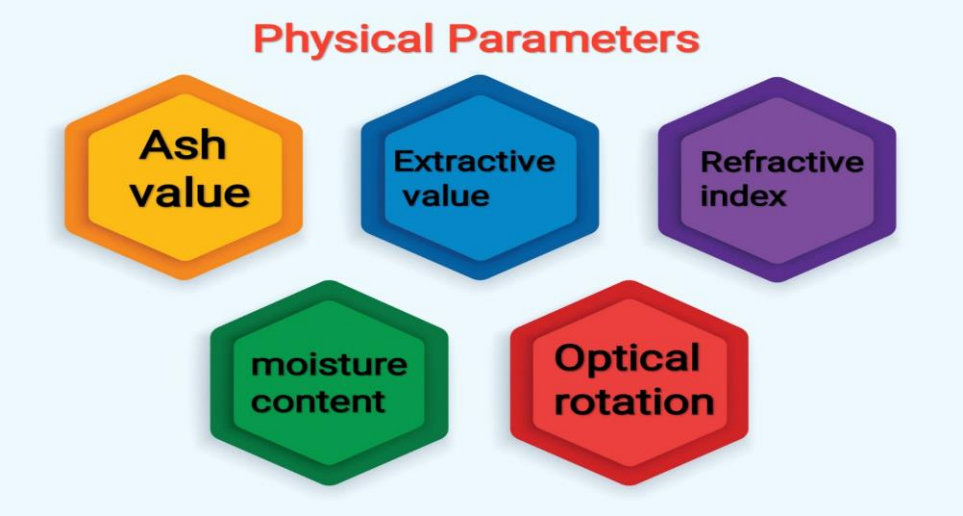
Process Standardization:

The process of preparation of Ayurvedic formula should have standard parameters. The production process should be clearly explained. If other chemicals are added during the manufacturing process to bring the botanical preparation to a particular active ingredient or characteristic, the chemical should be added to the chemical during the manufacturing process instead. Methods for the identification of botanical preparations should be included and evaluated whenever possible.

Standardization of the finished product:

Planning must complement the characteristics of the product. The manufacturing process and design should be described in detail, including the cost of additional equipment. The finished product must be described to ensure the quality of the product. The finished product must meet the general requirements of the specific recipe.





Standardization of Herbal Drug Parameters:
The World Health Organization's standards for medicinal plants include botanical, physicochemical, pharmacological and toxicological parameters.

•**Botanical Parameters:**
Sensory evaluation: visual inspection, touch, smell and taste Foreign matter – Microscopic testing of exotic plants, animals and minerals – Histological testing and measurement of pharmaceuticals.
Organoleptic Evolution: This It refers to the evaluation of substances according to special properties such as color, smell, size, shape, taste and touch, and texture. Analyzing these characteristics can provide valuable information about the identity, purity and quality of the product. Therefore, this step is the first step to compare the model with the model that meets the quality requirements. This is one of the easiest and fastest ways to determine identity and purity and therefore ensure the quality of the sample provided. Any sample that differs in sensory characteristics (such as colour, consistency and taste) is considered a non-standard sample.
Advantages:
•The advantage of this method is that initial treatment is often not required.
• Wrinkles on leaves and flowers should be stretched.
Disadvantages:
•One of the disadvantages of this method is that the feeling of desire varies from person to person.
•It is very difficult to specify characteristics in general, and characteristics such as taste and smell will only be labeled as characteristics.
Foreign body detection
Herbal formulation should be free of mold or insects, free of disease and free of disease such as stones, sand, problems or foreign chemical and chemical residues. Microbial diseases are another group of diseases that

can affect plants and are more dangerous for the following reasons. It can produce toxins. Macroscopic examination can help determine whether foreign matter is present. In general, microscopy is necessary for the identification of organisms. If the contamination is a chemical mixture, thin layer chromatography may be an option.

Microscopic examination

This is a simple and effective method of identifying plants. It can also help detect raw material or powder explosion. This is a great way to discover the availability of foreign products and add them to the mix. A microscope can help ensure that the plant is the real species and that the medicine contains the real plant. However, sometimes this may require microscopic examination. The presence of special microstructures, such as stomata, helps confirm that the plant was used.

Physicochemical Parameters

Many physicochemical parameters do not help identify medicinal herbs, These include:

TLC and HPTLC fingerprints

•Ash values - total ash, acid insolubility, water solubility

•Extraction values - hot water, cold water and ethanol Drying and agitation- Moisture content and volatile matter during boiling distillation Determination of essential oil by steam distillation.

Pharmacological Parameters:

addition to the usual drug tests, some herbal products need to be tested for certain qualities.

Contains: quinine solution

•Bitterness value-standard bitterness unit equivalent of hydrochloric acid

•Haemolytic power of bovine blood and standard saponins drug.

• swelling index - in water.

• Foaming index - the height of the foam produced by the Ig product under certain conditions

Toxicological parameters:

• Arsenic in stains causing mercury bromide test results Pesticide residues,

•organic phosphors and all organic chlorides

•heavy metals - lead and cadmium

•Radioactive Contamination

EVALUATION OF HERBAL EXTRACTS:

Herbal extracts are prepared by the interaction of water, alcohol, vegetable oil, propylene glycol and other solvents with raw materials. The concentration of active ingredients in the solvent and extraction properties are important factors in the final herbal extract. Water-soluble components such as amino acids.

Vitamins and terpenes are best extracted with water, alcohol, and propylene glycol, alone or in combination. Fatty acids and carotenoids can be extracted using oil as a solvent. All herbs must be pure liquid without foreign matter. Long-term storage should not affect this product in any way.

•Colour:

The extract has different colours depending on the characteristics of the plant. Carotenoid extracts from carrots are red, and spirulina extracts are blue. Brown extract may indicate inappropriate or chemical reactions such as oxidation and polymerization of sugar derivatives. This may also signal the beginning of the degradation process in the extract. •Smell

Smell, like colour, depends on the nature of the plant. Inconsistency between the taste of the herb and the extract usually indicates a problem with the extract.

•Microbial-free:

Although it does not have sterilization ability, the number of non-microbial bacteria in the extract should not exceed 100 species per gram. Antibiotics can be used to protect products from microbial spoilage. However, care should be taken to keep its concentration low.

•Dry Residue:

Dry residue is obtained from the soluble material of the plant extracted in a solvent. The larger the API threshold, the greater the dry residue rate. The chemical composition of the plant determines the amount of dry residue. As a rule, the maximum extractable fraction of the dry herb is usually around 10-20%. The dry fraction was estimated by placing 1 g of sample in an oven at 118°C for two hours. At the end of this period, it should be of constant size. Refractive Index: The refractive index depends on the percentage of residue present in the solution.

This relates to the results from the dry residue test: the greater the residue in solution, the higher the refractive index. The nature of the solvent is also something to consider.

•PH:

The pH range of extracts is generally 5-7 and can be considered one of the good indicators.

•UV-Visible Spectrophotometry:

Many plant compounds absorb wavelengths of UV rays that are characteristic of plants. UV-visible spectrophotometry is one of the simplest methods with high throughput and can also help quantify the stored product.

•Thin Layer Chromatography:

This is a physicochemical separation method sufficient to characterize plant extracts.

•Optical Densitometry:

Measures the optical density of light-emitting materials; It controls the concentration of active ingredients contained in TLC plates. It can be adjusted according to both the quantity and quality of the plate.

The only limitation is that the results depend on the quality of the chromatography plate.

•HPLC:

Helps determine very low content at ppm level. It is used only to control the quality of raw materials or spray-dried extracts.

RECENT APPROACHES IN HERBAL DRUG STANDARDIZATION:

DNA fingerprinting:

Correct identification and quality assurance of herbal products is an important issue; First of all, it is to make sure that the medicine is more effective. contributes to safety. and eefficiency

•Chromatographic fingerprint:

Chromatographic fingerprint has long been used for single drug APIs. Recently it has become one of the best ways to manage the quality of plants. The use of plant chromatographic fingerprints focuses mainly on the chromatographic identification and evaluation of the stability of the chemical reaction. Chemical and chromatographic methods can also be used to assist in the identification of herbal products or extracts. Chromatographic methods such as HPLC, thin layer chromatography (TLC), gas chromatography (GC), and capillary electrophoresis were used for self-diagnosis. Many examples have been found in the literature where inscribed compounds and chromatograms ("fingerprints") were used to help identify medicinal herbs and study their potency and stability.

•Advantages of plants:

Low production cost.
They will have fewer side effects.
Can be used in chronic diseases.
Available in a wide range.

•Disadvantages of herbs:

No dosage instructions.
Risks of poisoning with plants.
May interact with other medications.
Not suitable for many situations.
Some things are not good to use.

CONCLUSION:

Herbal drug technology is used for converting botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. The routine methods of herbal drug standardization address quality related issue using botanical and organoleptic parameters of crude drugs, and chemoprofiling assisted characterization with spectroscopic techniques but the new era of herbal drug standardization includes pharmacognostical, chemical, biological, biopharmaceutical and molecular approaches For standardization and quality assurance purposes, following three attributes are desirable i) Authenticity, ii) Purity and iii) Assay. Authenticity as the name suggests relates to proving that the material is true, i.e. it corresponds to the right identity. Authentication in itself involves many parameters including gross morphology, microscopy, chemical analysis and DNA fingerprinting

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