

## STANDARDIZATION OF HERBAL DRUGS: AN OVERVIEW

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## ABSTRACT

Herbal drugs have been used since ancient times as medicines for the treatment of a range of diseases. Medicinal plants have played a key role in world health. There is a growing focus on the importance of medicinal plants in the traditional health care system (viz. Ayurveda, Unani, Homoeopathy, Yoga) in solving health care problems. Systematic approach and well-designed methodologies for the standardization of herbal raw materials and herbal formulations are developed. In view of the growing interest in herbal medicines, methods for standardization of herbal drugs are developed and used in different formulation.

**Keywords:** Herbal drugs, herbal raw material, herbal formulation, standardization.

## INTRODUCTION

Standardization of drugs means confirmation of its identity and determination of its quality and purity. Phytotherapeutic agents or phytomedicines are standardized herbal preparations consisting of complex mixtures of one or more plants which are used in most countries for the management of various diseases. According to the WHO definition, herbal drugs contain as active ingredients plant parts or plant materials in the crude or processed state plus certain excipients, i.e., solvents, diluents or preservatives.<sup>3</sup>

There are problems which may influence the quality of herbals

- Herbal drugs are usually mixtures of many constituents
- The active principles are, in most cases unknown
- Selective analytical methods or reference compounds may not be available commercially
- Plant materials are chemically and naturally variable
- The methods of harvesting, drying, storage, transportation, and processing have an effect

(ex. mode of extraction & polarity of the extracting solvent, instability of constituents, etc.)

Factors influencing phyto-chemical Profile of medicinal plants:

- Genetic variants (gene level) leading to the variability in the chemical composition.
- Geographical and nutritional factors-altitude, soil composition, microbial load, climate, temperature, etc.
- Seasonal changes (rainfall, drought, water stress, etc.)
- Seasonal variations alkaloid composition in the leaves of *Adhatoda vasica* is low in Feb and March and highest in Aug/September.
- Association patterns including animals and insects.

Need for standardization:

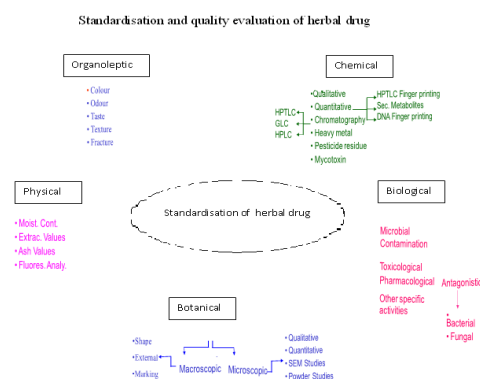
- Modern system of medicine is based on sound experimental data, toxicity studies and human clinical studies.
- But, pharmacopoeial standards on raw material/finished products are not available.
- cGMP for the herbal industry are not well defined nor the barest minimum standards of medicinal plant products are maintained or regulated.
- The lack of quality standards has resulted in mild to serious adverse effects ranging from hepatotoxicity to death. Hence, herbal ingredients require tools for determining identity, purity and quality and tools have to be technically sufficient, rapid and cost effective with GMP requirements.

World Health Organization has set specific guidelines for the assessment of the safety, efficacy, and quality of herbal medicines.

Standardization of herbal drugs is not an easy task as numerous factors influence the bio efficacy and reproducible therapeutic effect. In order to obtain quality oriented herbal products, care should be taken right from the proper identification of plants, season and area of collection and their extraction and purification process and rationalizing the combination in case of polyherbal drugs.<sup>7</sup>

## METHODOLOGY

In recent years, there has been great demand for plant derived products in developed countries. These products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics.<sup>9</sup> The Standardization of crude drug materials is done by authentication:-Stage of collection, parts of the plant collected, identity like phytomorphology, microscopical and histological analysis (characteristic of cell walls, cell contents, starch grains, calcium oxalate crystals, trichomes, fibers, vessels etc), Leaf constant: - palisade ratio, vein islet number, vein termination, stomatal number, and stomatal index .other histological test are trichomes, Stomata, quantitative microscopy, taxonomical identity, foreign matter, organoleptic evaluation, ash values and extractive values, moisture content determination, chromatographic and spectroscopic evaluation, heavy metal determination, pesticide residue, microbial contamination, radioactive contamination. The herbal formulation in general can be standardized schematically as to formulate the medicament using raw material collected from different localities and a comparative chemical efficacy of different batches of formulation are to be observed. The preparations with better clinical efficacy are to be selected. All the routine physical, chemical and pharmacological parameters are checked for all the batches in order to select the final finished product and to validate the whole manufacturing process.



Flow chart on standardization and evaluation of herbal drug<sup>6</sup>

The stability parameters for the herbal formulations which include physical, chemical and microbiological parameters are as follow:

Physical parameters include color, odor, appearance, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flow ability, flocculation, sedimentation, settling rate and ash values. Chemical parameters include limit tests, chemical tests, chemical assays etc. Chromatographic analysis of herbals can be done using TLC, HPLC, HPTLC, GC, UV, GC-MS, fluorimetry etc. Microbiological parameters include total viable content, total mold count, total enterobacterial and their count. Limiters can be utilized as a quantitative or semi quantitative tool to ascertain and control the amount of impurities like the reagents used during abstraction of various herbs, impurities coming directly from the manufacturing vessels and from the solvents etc.<sup>12</sup>

World Health Organization (WHO) stresses the importance of the qualitative and quantitative methods for characterizing the samples, quantification of the biomarkers and/ or chemical markers and the fingerprint profiles. The authenticity, quality and purity of herbal drugs are established by reference given in pharmacopoeia. The pharmacopoeia prescribes (numerical value) like structural, analytical, physical standards for the drugs. The important standards are mentioned in pharmacopoeia.<sup>6</sup>

Maintaining quality of herbal products is challenging and it includes a strict set of processes which help to maintain consistency within the specified limits. Standardization is a process which maintains consistency in the claimed efficacy of a product and its batch-to-batch reproducibility.

Standardization of herbal products can be divided into two categories, first, an active constituent extract, where biochemical principles are known and have therapeutic values, and second, a marker extract, where the active principle is not known and a characteristic compound is used as a marker to assess the presence of other therapeutic biochemical compounds.<sup>4</sup> Standardization has limitations because only isolated compounds are considered, ignoring the whole constituents of the herb, which may have synergistic or buffering activities to reduce the side effects.

In the marker extract, where the active principle is not known, partly known or the preparation contains many crude drugs or extracts, the whole formulation is considered active in the presence of all plant constituents. In this case, a single isolated compound would not be used as a marker because it is not unique to any one plant. With this in mind, it is fair to suggest that the standardization of herbal medicines is not merely an analytical operation which ends with the identification and assay of the active principle. Rather, it embodies the total information and controls which are necessary to ensure consistency in composition by employing relevant modern analytical tool.

Several pharmacopoeias like Chinese Herbal Pharmacopoeia, British Herbal Pharmacopoeia, British Herbal Compendium, Japanese Standards for Herbal Medicine and The Ayurvedic Pharmacopoeia of India. These pharmacopoeias lay down monographs for herbs and herbal products to maintain their quality in their respective nations. Government of India recommends quality parameters for various ayurvedic herbal drugs.

#### **Herbal medicine standardization**

In indigenous/traditional systems of medicine, the drugs are primarily dispensed as water decoction or ethanol extract. Fresh plant parts, juice or crude powder are a rarity rather than a rule. Thus medicinal plant parts should be authentic and free from harmful materials like pesticides, heavy metals, microbial, radioactive contamination, etc. The medicinal plant is subjected to a single solvent extraction once or repeatedly, or water decoction or as described in ancient texts. The extract should then be checked for indicated biological activity in an experimental animal model(s). The bioactive extract should be standardized on the basis of active

principle or major compound(s) along with fingerprints. The next important step is stabilization of the bioactive extract with a minimum shelf-life of over a year. The stabilized bioactive extract should undergo regulatory or limited safety studies. Determination of the probable mode of action will explain the therapeutic profile. The safe and stable herbal extract may be marketed if its therapeutic use is well documented in indigenous systems of medicine, as also viewed by WHO. A limited clinical trial to establish its therapeutic potential would promote clinical use. The herbal medicines developed in this mode should be dispensed as prescription drugs or even OTC products depending upon disease consideration.<sup>1, 11</sup>

The authenticity, quality and purity of herbal drugs are established by reference given in pharmacopoeia. The pharmacopoeia prescribes (numerical value) like structural, analytical, physical standards for the drugs<sup>8</sup>

A critical examination and identification of crude drugs is required in manufacturing of herbal formulation because of great diversity and variability in their chemical characters. To overcome this problem the pharmacopoeias have laid down certain standards<sup>5</sup>

#### **WHO Guidelines for Quality Standardized Herbal Formulations**

- Quality control of crude drugs material, plant preparations and finished products.
- Stability assessment and shelf life.
- Safety assessment; documentation of safety based on experience or toxicological studies.
- Assessment of efficacy by ethno medical informations and biological activity evaluations.

The bioactive extract should be standardized on the basis of active principles or major compounds along with the chromatographic fingerprints (TLC, HPTLC, HPLC and GC). The Standardization of crude drug materials includes the following steps:

1. Foreign matter (herbs collected should be free from soil, insect parts or animal excreta, etc.) Medicinal plant materials should be entirely free from visible signs of contamination by moulds or insects, and other animal contamination, including animal excreta.

No abnormal odour, discoloration, slime or signs of deterioration should be detected. It is seldom possible to obtain marketed plant materials that are entirely free from some form of innocuous foreign matter. However, no poisonous, dangerous or otherwise harmful foreign matter or residue should be allowed. During storage, products should be kept in a clean and hygienic place, so that no contamination occurs. Special care should be taken to avoid formation of moulds, since they may produce aflatoxins. Macroscopic examination can conveniently be employed to determine the presence of foreign matter in whole or cut plant materials. However, microscopy is indispensable for powdered materials. Any soil, stones, sand, dust and other foreign inorganic matter must be removed before medicinal plant materials are cut or ground for testing.

2. Macroscopic and microscopic examination: Medicinal plant materials are categorized according to sensory, macroscopic and microscopic characteristics. An examination to determine these characteristics is the first step towards establishing the identity and the degree of purity of such materials, and should be carried out before any further tests are undertaken. Wherever possible, authentic specimens of the material in question and samples of pharmacopoeial quality should be available to serve as a reference.

Visual inspection provides the simplest and quickest means to establish identity, purity and, possibly, quality. If a sample is found to be significantly different, in terms of colour, consistency, odour or taste, from the specifications, it is considered as not fulfilling the requirements. However, judgment must be exercised when considering odour and taste, owing to variability in assessment from person to person or by the same person at different times.

Macroscopic identity of medicinal plant materials is based on shape, size, color, surface characteristics, texture, fracture characteristics and appearance of the cut surface. However, since these characteristics are judged subjectively and substitutes or adulterants may closely resemble the genuine material. It is often necessary to substantiate the findings by microscopy and/or physicochemical analysis.

Microscopic inspection of medicinal plant materials is indispensable for the identification of broken or powdered materials; the specimen may have to be treated with chemical reagents. An examination by microscopy alone cannot always provide complete identification, though, when used in association with other analytical methods, it can frequently supply invaluable supporting evidence. Any additional useful information for preparation or analysis should also be included in the test procedures for individual plant materials, for example, the determination of vein islets and the palisade ratio.

3. Thin layer chromatography: Thin layer chromatography is particularly valuable for the qualitative determination of small amounts of impurities. As it is effective and easy to perform, and the equipment required is inexpensive, the technique is frequently used for evaluating medicinal plant materials and their preparations.

The following parameters should be determined on the basis of published pharmacopoeial monographs or established experimentally for the analysis of each individual plant material by TLC.

- Type of adsorbent and method of activation; if no information on the latter can be obtained, by heating at 110°C for 30 minutes
- Method of preparation and concentration of the test and reference solutions
- Volume of the solutions to be applied on the plate
- Mobile phase and the distance of migration
- Drying conditions (including temperature) and method of detection

For the spots obtained the Rf values are calculated.

4. Determination of ash: The ash remaining following ignition of medicinal plant materials is determined by three different methods which measure total ash, acid-insoluble ash and water-soluble ash.

The total ash method is designed to measure the total amount of material remaining after ignition. This includes both "physiological ash", which is derived from the plant tissue itself, and "non-physiological" ash, which is the residue of the extraneous matter adhering to the plant surface.

Acid-insoluble ash is the residue obtained after boiling the total ash with dilute hydrochloric acid, and igniting the remaining insoluble matter. This measures the amount of silica present, especially as sand and siliceous earth.

Water soluble ash is the difference in weight between the total ash and the residue after treatment of the total ash with water.

5. Determination of extractable matter: This method determines amount of active constituents extracted with solvents from a given amount of medicinal plant material.<sup>2</sup>

6. Determination of water and volatile matter: An excess of water in medicinal plant materials will encourage microbial growth, the presence of fungi or insects, and deterioration following hydrolysis.

Limits for water content should therefore be set for every given plant material. This is especially important for material that absorbs moisture easily or deteriorates quickly in the presence of water.

The azeotropic method gives a direct measurement of the water present in the material being examined. When the sample is distilled together with an immiscible solvent, such as toluene or xylene, the water present in the sample is absorbed by the solvent. The water and the solvent are distilled together and separated in the receiving tube on cooling. If the solvent is anhydrous, water may remain absorbed in it leading to false results. It is therefore advisable to

saturate the solvent with water before use. The Dean-Stark apparatus in the laboratory typically consists of vertical cylindrical piece of glass (the trap), often with a volumetric graduation on its full length and a precision tap on the bottom very much like a burette. The top of the cylinder is fit with the bottom of the reflux condenser. Protruding from the top, the cylinder has a side-arm sloping towards the reaction flask. At the end the side-arm makes a sharp turn so that the end of the side arm is vertical as well. This end connects with the reactor. During the reaction vapors containing the reaction solvent and the component to be removed travel out of reaction flask up into the condenser, and then drip into the distilling trap. Here, immiscible liquids separate into layers. When the top (less dense) layer reaches the level of the side-arm it can flow back to the reactor, while the bottom layer remains in the trap. The trap is at full capacity when the lower level reaches the level of the side-arm—beyond this point, the lower layer would start to flow back into the reactor as well. It is therefore important to syphon or drain the lower layer from the Dean-Stark apparatus as much as needed. This type has a tube at the bottom of the side-arm to allow the organic solvent at the bottom to flow back into the reaction vessel. The water generated during the reaction floats on top of the organic phase. An azeotropic mixture of toluene and water distills out of the reaction, but only the toluene returns, since it floats on top of the water which collects in the trap.

The test for loss on drying determines both water and volatile matter. Drying can be carried out either by heating to 100-105° or in a desiccators over phosphorus pentoxide under atmospheric or reduced pressure at room temperature for a specified period of time.

The desiccation method is especially useful for materials that melt to a sticky mass at elevated temperatures.

7. Determination of volatile oils: Volatile oils are characterized by their odour, oil like appearance and ability to volatilize at room temperature. Chemically they are usually composed of mixtures for example, monoterpenes, sesquiterpenes and their oxygenated derivative. Aromatic compounds predominate in certain volatile oils. Because they are considered to be the "essence" of the plant material and often biologically active, they are also known as "essential oils". Then term "volatile oil" is preferred because it is core specific and describes the physical properties. In order to determine the volume of oil, the plant material is distilled with water and the distillate is collected in a graduated tube. The aqueous portion separates automatically and is returned to the distillation flask. If the volatile oil posses a mass density higher than or near to that of water, or are difficult to separate from the aqueous phase owing to the formation of emulsions, a solvent with a low mass density and a suitable boiling point may be added to the measuring tube. The dissolved volatile oils will then float on top of the aqueous phase.

8. Determination of bitterness value: Medicinal plant materials that have a strong bitter taste are employed therapeutically, mostly as appetizing agents. Their bitterness stimulates secretions in the gastrointestinal tract, especially of gastric juice. Bitter substances can be determined by taste. However, since they are mostly composed of two or more constituents with various degrees of bitterness, it is first necessary to measure total bitterness by taste.

The bitter properties of plant material are determined by comparing the threshold bitter concentration of an extract of the materials with that of a dilute solution of quinine hydrochloride. The bitterness value is expressed in units equivalent to the bitterness of a solution containing 1 gm of quinine hydrochloride in 2000ml. Safe drinking water should be used as a vehicle for the extraction of plant materials and for the mouth wash after each tasting. Taste buds dull quickly if distilled water is used. The hardness of water rarely has any significant influence on bitterness.



9. Determination of haemolytic activity: Many medicinal plant materials, especially those derived from the families Caryophyllaceae, Araliaceae, Sapinaceae, Primulaceae, and Dioscoreaceae contain saponins. The haemolytic activity of plant materials, or a preparation containing saponins, is determined by comparison with that of a reference material, saponin, which has a haemolytic activity of 1000 units per gm. A suspension of erythrocytes is mixed with equal volumes of a serial haemolysis and is determined after allowing the mixtures to stand for a given period of time. A similar test is carried out simultaneously with saponin.

10. Determination of tannins: Tannins are substances capable of turning animal hides into leather by binding proteins to form water insoluble substance that resistant to proteolytic enzymes. This process, when applied to living tissue, is known as an "astringent" action and is the reason for the therapeutic application of tannins. Chemically, tannins are complex substances they usually occur as mixtures of polyphenols that are difficult to separate and crystallize. They are easily oxidized and polymerized in solution; if this happens they lose much of their astringent effect and are therefore of little therapeutic value.

Method-Fifty micro litre ( $\mu$ l) of tannins extract for each sample was taken in test tube and volume was made to 1.0 ml with distilled water. Then, 0.5 ml Folin Ciocalteu reagent was added and mixed properly. Then 2.5 ml 20 per cent sodium carbonate solution was added and mixed it and kept for 40 minutes at room temperature. Optical density was taken at 725 nm in spectrophotometer and concentration was estimated from the standard curve. Total phenol was estimated as tannic acid equivalent and expressed on dry matter basis. Non-tannins phenol was estimated by precipitating tannins with polyvinyl polypyrrolidone (PVPP), which binds tannins. 200 mg PVPP was taken in test tube and then 2.0 ml distilled water and 2.0 ml tannins extract was added. Vortex it and kept in refrigerator for 15 minutes at 40C. Then the mixture was again vortex and filtered through Whatman filter paper No. 1. Filtrate was taken for estimation of non tannin phenol. 150  $\mu$ l of filtrate was taken in test tube and volume was made to 1.0 ml with distilled water and then processed like that of total phenol estimation. Concentration of non tannin phenol was calculated from the standard curve and expressed on Dry Matter basis. Total tannins were calculated by subtracting non tannin phenol from total phenol.

11. Determination of swelling index: The swelling index is the volume in ml taken up by the swelling of 1 gm of plant material under specified conditions. Its determination is based on the addition of water or a swelling agent as specified in the test procedure for each individual plant material. Using a glass stoppered measuring cylinder, the material is shaken repeatedly for 1 hour and then allowed to stand for a required period of time. The volume of the mixture is then read. The mixing of whole plant material with the swelling agent is easy to achieve, but cut or pulverized material requires vigorous shaking at specified intervals to ensure even distribution of the material in the swelling agent.

12. Determination of foaming index: Many medicinal plant materials contain saponins that can cause persistent foam when an aqueous decoction is shaken. The foaming ability of an aqueous decoction of plant materials and their extracts is measured in terms of a foaming index.

13. Determination of pesticide residues: Limits for pesticide residues should be established following the recommendations of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) which have already been established for food and animal feed. These recommendations include the analytical methodology for the assessment of specific pesticide residues.

14. Determination of arsenic and heavy metals<sup>2</sup>: Contamination of medicinal plant materials with arsenic and heavy metals can be

attributed to many causes including environment pollution and traces of pesticides.

Method for determination of arsenic by Gutzeit Apparatus : The solution of the substances to be examined is prepared as specified and transferred to the wide mouthed bottle. To this add 1 g of potassium iodide (5 ml of 1M KI), 5 ml of stannated hydrochloric acid solution and 10 g of zinc. Immediately place the glass tube in position and immerse the bottle in a water-bath at a temperature such that a uniform evolution of gas is maintained. The most suitable temperature for the test is about 40°C. The reaction is allowed to continue for 40 minutes. After 40 minutes, the yellow stain produced on the HgCl paper compared with the standard stain produced by treating 1.0 ml of the arsenic standard solution (10 ppm As) diluted to 50 ml with water in the same manner. If the intensity of the yellow stain produced in the test solution is less than that of standard stain, the sample passes the limit test for arsenic and vice-versa. The stain produced on paper fades on keeping and therefore the stains should be compared immediately.

Method for determination of heavy metal

Standard solution: Pipette 1.0 ml of standard lead solution (20 ppm Pb) into a Nessler cylinder labeled as "Standard" and dilute to 25 ml with water. Adjust the pH between 3.0 and 4.0 with dilute acetic acid or dilute ammonia solutions, dilute to 35 ml with water and mix.

Test solution:

Take 25 ml of the solution prepared as directed in the individual monograph into a Nessler cylinder labeled as "Test" or dissolve the specified quantity of the substance in water to produce 25 ml. Adjust the pH between 3.0 and 4.0 with dilute acetic acid or dilute ammonia solution, dilute to 35 ml with water and mix.

Procedure:

Add 10 ml of freshly prepared hydrogen sulphide to each of the Nessler cylinder containing test solution and standard solution respectively. Mix, dilute to 50 ml with water and allow to stand for 5 minutes. Compare the colour by viewing vertically downwards over a white surface. The colour produced with the test solution in not more intense than that produced with the standard solution.

15. Determination of microorganism: Methods for decontamination are restricted. For example, the use of ethylene oxide has been forbidden within countries of the European Union. Treatment with ionizing irradiation is also forbidden or requires a special registration procedure in some countries. In addition, the presence of aflatoxins in plant material can be hazardous to health if absorbed even in very small amounts. They should therefore be determined after using a suitable clean up procedure e.g. liquid chromatography (LC). Aflatoxins are extracted from a ground sample with methanol-water (80 + 20, v/v), and after a single cleanup step on a mini column packed with basic aluminum oxide, they are quantitated by LC equipped with a C18 column, photochemical reactor, and fluorescence detector.

16. Radioactive contamination: Microbial growth in herbals is usually avoided by irradiation. This process may sterilize the plant material but the radioactivity hazard should be taken into account. The radioactivity of the plant samples should be checked accordingly to the guidelines of International Atomic Energy (IAE) in Vienna and that of WHO.<sup>10</sup>

In order to obtain quality oriented herbal products care should be taken right from the proper identification of plants; season and area of collection, extraction, isolation and verification process.

Chemical and instrumental analysis is routinely used for analyzing synthetic drugs to confirm its authenticity. In the case of herbal drugs, however the scene is different, especially for polyherbal formulation, as there are no chemical or analytical methods available. Therefore biological-screening methods can be adopted

for routine checkup of herbal drugs and formulations. In case of herbal drugs, the quality of raw materials and products can be furnished by regular pharmacognostic identifications and photochemical analysis. The herbal formulations in general can be standardized schematically as to formulate the medicament using raw materials collected from different localities and a comparative chemical efficacy of different batches of formulation are to be observed. The preparations with better clinical efficacy are to be selected. All the routine physical, chemical parameters are to be checked for all the batches.

The stability parameters for the herbal formulations which includes physical parameters, chemical parameters, and microbiological parameters.

Physical parameters include color, appearance, odor, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flow ability, flocculation, sedimentation, settling rate and ash values.

Chemical parameters include limit tests, extractive values, chemical assays, etc.

Chromatographic analysis of herbals can be done using TLC, HPLC, HPTLC and GC, UV, Fluorimetry, GC-MS, etc.

Microbiological parameters include total viable content, total mold count, total enterobacterial and their count. Limits given in official books can be utilized as a quantitative or semi quantitative tool to ascertain and control the amount of impurities coming from the reagents used during abstraction of various herbs, impurities coming directly from the manufacturing vessels, impurities from the solvents, etc.

Chemical decomposition of substances present in the formulation also produces several toxic or impure compounds during storage in undesirable conditions. Contaminants may come directly from the atmosphere also. This includes mainly dust, sulfur dioxide, H<sub>2</sub>S, CO<sub>2</sub>, Arsenic, moisture, etc. The guidelines set by WHO can be summarized as follows:

A. Reference to the identity of the drug. Botanical evaluation – sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements, etc.

B. Reference to the physiochemical character of the drug. Chromatographic profiles, ash values, extractive values, refractive index, polarimetric readings, moisture content, volatile oil content, etc.

C. Reference to the pharmacological parameters. Biological activity profiles, bitterness values, haemolytic index, astringency, swelling factor, foaming index, etc.

D. Toxicity details – heavy metals like cadmium, lead, arsenic, mercury, etc. Pesticide residues.

E. Microbial contamination – Total viable aerobic count, pathogenic bacteria like enterobacteria, E. coli, salmonella, Pseudomonas aeruginosa, Staphylococcus aureus, etc. and presence of aflatoxins etc.

F. Radioactive contamination<sup>10</sup>.

## CONCLUSION

Standardization is the code of conduct in order to ensure the consistent efficacy that manufacturers should use to ensure batch-to-batch consistency of their products. The quality of herbal drugs is the sum of all factors which contribute directly or indirectly to the safety, effectiveness and acceptability of the product. Due to advancement in the chemical knowledge of crude drugs various methods like botanical, chemical, spectroscopic and biological methods are used for estimating active constituents present in the crude drugs. Standardization methods should take into consideration all aspects contributing to the quality of the herbal drugs. Standardization is important in various fields such as

**Pharmaceuticals:** QC, Identity-Purity checks, Stability

**Food and Feedstuff:** QC, Additives (Vitamins), Pesticides, Mycotoxins and Stability tests (expiration)

**Herbals:** Identification, Detection of adulteration, Assay of markers and Stability tests.

**Cosmetics:** Identity of raw material, Preservatives & colouring materials, Screening for unapproved substances.

**Industrial:** Process development.

**Clinical:** Lipids, metabolism studies and drug screening.

**Forensic:** Investigation of poisons and Dyestuffs.

**Environment:** Water, soil and residue analysis.

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