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REVIEW ARTICLE: STANDARDIZATION AND EVALUATION OF HERBAL DRUGS IS NEED OF THE HOUR IN PRESENT ERA

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Abstract

The herbal preparations are being into used from the primordial time throughout the world. Now, maximum people are shifted towards the Ayurveda for the treatment of any affliction. Herbs are also used as side products in the preparation of synthetic medicine. Traditional system of medicine has taken over the place worldwide, hence majority of products are formulated. The increased use of herbal drug, now concerning with its purity and quality of herbal raw material as well as finished product. Purity of the herbal constituent is the main problem faced by the herbal industries. To overcome this issue, WHO has published the certain guidelines for the standardization of the herbal material. To ensure the efficacy, purity and quality control processes, the personnel should himself supervise the standardization processes with uniform rules. The review represents the standardization parameters with the standards value of quality, purity and efficacy.

Key words: Herbal drug, Purity, Medicine, Efficacy, WHO guidelines.

Introduction

The herbal drugs are in use from many centuries for treating numerous ailments. The medicinal plants have played a vital part in World health. There has been enormous increase in sales of herbal OTC (over the counter drugs). During the old times, the herbal drug is the primeval form which is consumed by medical management and humans (Capasso *et al.,* 2000). The trading and utilization of medicinal drug is growing globally to cure many diseases. From India, the shipping of medicinal stock and essential oils is more than Rs. 2 billion (Ahmad *et al.,* 2014). The artificial drugs does not have unique features but herbal drug comprise of unique appearances. Plants contain different active constituents which are important for its therapeutic effect. The different solvents are utilized for the segregation of active constituents by the help of extraction technique (Murali *et al.,* 2016). The ancestral or tribal people collect data which is associated with herbal plant and their development is defined in herbal pharmacopeia. By the extended ancient time, the protection and efficiency of the medicinal plant is well known.

"The Greatest thing about herbal drug is that its Treatment always yield side benefits, not side effects."

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In an extensive range, the acceptability of Ayurveda and its product is a major problem due to lack of standardization techniques. The significance of herbal medicine is to be strictly followed by the WHO guidelines to ensure the safety, efficacy and quality of drug. "Standardization" is a process of evaluation of the quality and purity of crude drugs by means of various factors like morphological, microscopical, physical, chemical and biological observations. This factor give us data related to the features of the plant which include active ingredients, bitterness value and DNA properties (Nikam *et al.,* 2012).

Need Of Stanadardisation

As we all know in current, herbal medicines are gaining their position in the Indian market as the synthetic one. People are now more fascinated about the herbal medication and diverted towards it, due its fewer side effects. Need of standardization of herbal drug is importance in accordance to achieve the possible quality and stability of the product (Mukesh *et al.*). If the quality and stability of the product is assured, the best quality of the active ingredient has been into usage. But, the principle of standardization is not stated in pharmacopoeia. The adverse effect due to absence of quality standards has been acknowledged which may also lead to death. For

example, in pregnancy, mothers are connected child with umbilical cord, thus noxious material ingested by the mother circulates to the fetus circulation as well, that produces acute intoxication to both and may also leads to death sometimes. To evaluate the parameters for the standardization, certain apparatus are required as per GMP acquirement (Cocka, 2015). Several factors such as bioefficacy, reproducible therapeutic effects influence the standardization of herbal drug. The major factor into consideration is the adulteration of herbal ingredient which can be carried out intentionally or non-intentionally such as lack of storage, blending of one ingredient with another, similar name of the herbs or replacement with dissipate material. In manufacturing of allopathy products, herbal extracts are used as excipients, standardization is the essential procedure should be followed to check their bioactivity (Sachan *et al.,* 2016).

WHO Guidelines for Standardization of Herbal Drugs

The goal of world health of organization (WHO) is to assess herbal drugs with their safety, stability, sterility and potency and therefore facilitate all organizations and authorities to analyze the certificates, acquaintance, dossiers and consents of the evaluated herbal medication (Shrikumar, 2007). There should be elucidation of each and every part of plant and from which part of plant herbal extract is extracted and the type of excipients are used that are satisfying all the general needs. The dossier also carries information about procedure mechanism followed in manufacturing. They also notifies the standardization of herbal medicine and their formulation

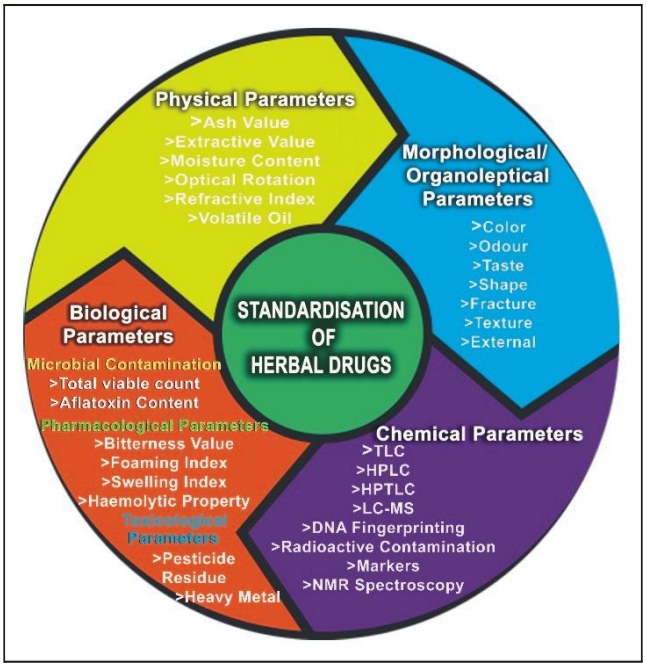

Fig. 1: Schematic Representation of Standardization and Evaluation of Herbal Drugs.

Table 1: Ash Value of Some Crude Drugs (Kokate *et al*., 2018).

S.No.	Drugs	Total Ash (%w/w)	Acid insoluble ash (%w/w)
1	Ashoka	11.0	-
2	Belladonna	-	3.00
3	Cardamom	0.60	3.50
4	Clove	0.70	0.75

and methodology are carried or not. The standardization method are identical for both synthesized and herbal medications. They also serve ministry of health to originate conventional medicine system in each sector, so that there is sufficient supply of herbals and safety is ensured. Herbal medication does not require animal testing, if the traditional method is composed during the manufacturing and all standardizations are obeyed in accordance to pharmacopoeia. Herbal drug and synthetic drug concurrently cannot be defined as the herbal medicine except some countries, in which it is acceptable (Mukherjee, 2019).

Various Stages of Standardization of Herbal Drugs

Standardization and Quality control of herbal drug have various stability parameters which include physical, chemical, biological, organoleptic and botanical evaluation.

Physical Assessment: It tell us about the identity of the material and as an initial screening test for impurities.

Chemical Assessment: It is used for identification of herb which is determined by various factors such as color reaction, principles and assay.

Biological Assessment: It is involved in determination of therapeutic activity by using bio-organism (Omprakash *et al.,*2019).

Physical Parameters

• Ash value: The remaining residue after furnacing of herbal drug known as ash value, which constitute naturally occurring minerals (Pradhan *et al.,* 2015). It is used to evaluate purity of raw material. It can be analyzed by determining various ash value. In herbal medicines, the more ash value expresses impurity (Kadam, 2011).

Table 2: Extractive Value of Some Crude Drugs (Kokate *et al*., 2018).

Sr no.	Drugs	Water-soluble extractive (%w/w)	Alcohol-soluble extractive (%w/w)	Ether-soluble extractive (%w/w)
1	Ginger	NLT 10.0	NLT 04.5	-
2	Linseed	NLT 15.0	-	NLT 25.0
3	Male fern	-	-	NLT 01.5
4	Capsicum	-	-	NLT 12.0
NOTE: NLT means Not less than				

Table 3: Moisture content of some Crude Drugs (Mukherjee *et al*., 2019).

S.No.	Drugs	Moisture content (%)	w/w
1.	Ajwain	Not more than	10
2.	Ashwagandha	Not more than	12
3.	Sunthi	Not more than	12
4.	Ergot	Not more than	08

The drug was taken in a tarred silica crucible and kept for burning in muffle furnace at 600-650°C for 6hours. After this, the drug is carbon free (Prakash *et al.,* 2017).

• Extractive Value: This method is used to evaluate the quantity of chemical constituents of herbal drug extracted with various solvents such as water soluble extractive, alcohol- soluble extractive and ether-soluble extractive (Dubey *et al.,* 2011).

• Moisture Content: The amount of water content present in herbal drug. It should be reduce to prevent decomposition of drug and the estimation of the actual weight of drug material. Method of determination can be achieved by weighing the tarred empty china dish, then transfer the suitable amount of drug into it. Now, place the china dish in a hot air oven for 5hours at 105°C until the constant weight is attained (Babu *et al.,* 2017).

• Melting Point: The melting point for phytochemicals and crude drugs varies. For phytochemicals, it is relatively constant and for crude drugs, it comprehend mixed chemicals (Kokate *et al.,* 2018).

• Optical Rotation: It is defined as the material which is optically active either rotate right (dextro) or left (Levo) when pass through the plane of polarized in the solution. It can consume by Na lamp and evaluated at 25°C (Verma *et al.,* 2017).

• Refractive Index: It can be determined by pureness and vital oil. If one or more mixed oil occurs in vital oil, its refractive index altered. It can be evaluated by fraction of velocity of light in atmosphere to velocity in material (oil) (Verma *et al.,* 2017).

• Volatile Oil: They are obtained from the aromas, vaporous principle of nature sources. They signify aura of plant and animal species. They are found in any portion of the plant. Various methods are used for extraction of volatile oil (Kokate *et al.,* 2018).

Table 4: Melting Point of Some Crude Drugs (Kokate *et al*., 2018).

Sr No.	Drugs	Melting Point (°C)
1.	Colophony	75-85
2.	Cocoa butter	30-33
3.	Bees wax	62-65
4.	Wool fat	34-44

Table 5: Optical Rotation of Some Crude Drugs (Kokate *et al*., 2018).

Sr No.	Drugs	Angle of Optical Rotation
1.	Caraway oil	+75° - +80°
2.	Clove oil	0° - +6.0°
3.	Honey	+3° - -15°
4.	Castor oil	3.5° - +6.0°

Morphological/ Organoleptic Parameters

The major parameters should be considered are sterility, quality and identity. Morphological denotes coloring, odour, taste buds, size, figure and distinctive features like touch, consistency etc. The characteristics of herbs such as cinchona, cascara barks and quaillia and quassia woods have fractured surfaces. The vital diagnostic characters are disc-shaped of nux vomica, conical shape of aconite, ovoid tears of gum, wavy shape of rauwolfia, pungent taste of capsicum and ginger, taste of spice drugs such as black pepper, cumin, caraway etc. and brown colour of cinnamon bark (Alamgir, 2017).

Chemical Parameters

Chromatography is a physical technique used for the separation of mixture which separate between two phases, the one (stationary phase), the other (the mobile phase) moving in a definite direction (Lalhriatpuii, T., 2019).

• Thin Layer Chromtography: It is a multipurpose technique for the analysis of herbal drugs and used for preliminary screening (Razmovski-Naumovski *et al.,* 2010). Their mechanism works on adsorption. An adsorbent material (silica gel) should be applied to glass metal sheet/plate, plastic which should have thin and uniform powdered drug layer. The most commonly used material is glass plates. The different solvents are used for the separation. By observing, spots on the glass plate under U.V chamber the Rf value is calculated. The unknown Rf value is than compared with standard sample (Mian *et al.,* 2019). There may be decrease or increase in number of spots due to mixed chemicals which leads to variation in Rf value. The resulting aims are:

♦ It enables rapid analysis of herbal extracts with minimum sample clean-up requirement.

♦ It provides qualitative and semi quantitative information of the resolved compounds.

♦ It enables the quantification of chemical

Table 6: Refractive Index of Some Crude Drugs (Kokate *et al*., 2018).

Sr No.	Drugs	Refractive index
1.	Caraway oil	1.4838- 1.470
2.	Clove oil	1.527- 1.535
3.	Arachis oil	1.4678- 1.470

constituents (Amponsah *et al.,* 2014).

• High-performance Liquid Chromatography: It is a qualitative way whose purpose is to segregate different constituents via decoction (Kustrin, A.S. and C.G. Hettiarachchi, 2014). It is a costly tool, which require bulky amount of solvent and in mobile phase, columns involve optimal pH. It is used for separation of phytochemical drugs in herbal industry. Ion exchange, partition and adsorption are the three forms which are widely used in hplc (Shulammithi *et al.,* 2016). This technique is useful to determine secondary metabolites. The main components to check the quality control of herbal drug are resolution, hypersensitivity and accuracy (Sharma *et al.,* 1992). It also aims for the distillation and refining of herbal medicine (Taleuzzaman *et al.,* 2016).

• High- Performance Thin Liquid Chromatography: It is a quantitative way which is used as a separation technique (Shivatare *et al.,* 2013). It allows analysis of botanical materials and wide number of compounds both efficiently and cost effectively (Loescher *et al.,* 2014). The various samples can be run all together thereby reducing analytical time. It can be achieved by using smaller quantity of mobile phase whose pH should be above 8 than in HPLC (Folashade *et al.,* 2012). In HPTLC, the sample can be analyzed by passing different wavelengths of light which contributes complete profile of a plant. The HPTLC method have been developed for the herbal formulation from phtyoconstituents (Bijauliya *et al.,* 2017).

• Liquid Chromatography-mass Specroscopy: The evaluation of herbal constituents in biological fluids of LC-MS have provided tremendous tool with increased selectivity (Laua *et al.,* 2013). This method give data related to the molecular wt. It shows vital representation in description of biochemical and in lethal broadcast of herbaceous drug. LC-MS was accomplished for the segregation of natural goods and for the definite positive documentation of the crest (Marston, 2007).

• DNA Fingerprinting: DNA fingerprinting is a technique through which genetic information of the plant can obtained. In herbal drug standardization, DNA analysis showed a significant role (Tewfik, S., 2008). It is applicable in herbal ecosystem for shelter. The traits of assay depend on the traits of DNA due to which constancy and assurance of this technique is inferior (Dakup *et al.,* 2018). The bulky quantity of gDNA leads to the main drawback. It identify genetic alterations, cells, characters etc. Adulterants can be identified during processed samples and finished products (Choudhary and Sekhon, 2011).

Table 7: Volatile content of Some Crude Drugs (Kokate *et al*., 2018).

Sr No.	Drugs	Volatile oil content (%w/w)
1.	Fresh lemon peel	NLT 2.5
2.	Clove	NLT 15.0
3.	Dill	NLT 2.5
4.	Cardamom seed	NLT 4.0

Table 8: Bitterness value of some Medicinal Plants (Mukherjee *et al*., 2019).

Sr No.	Plant name	Bitterness value (Mean ± Standard deviation)
1.	Agathosma betulina	4859 ± 61
2.	Arctopus monacanthus	5407 ± 78
3.	Balanites maughamii	4211 ± 20
4.	Ziziphus mucronate	6410 ± 3

• Radioactive Contamination: In the process of growth/ cultivation of herbal drugs, the microbial growth of radioactive radiations has been used to prevent in the sterilization of herbal drug but the radioactivity threat should be taken into consideration (Patwekar *et al.,* 2015). According to guidelines, the radioactive sample of herbs should be inspected by International Atomic Energy (IAE) in Vienna and that of WHO. The synthetic drugs are analyzed by the chemical and instrumental analysis regularly to approve its authenticity whereas for polyherbal formulations biological-screening is widely accepted. To formulate the herbal formulation, the quality of raw material should be evaluated by phytochemical analysis and pharmacognostic identifications. The manufacturing process and the finished product for all batches should be validate (Gautam *et al.,* 2010).

• Markers: In the herbal drug, the ingredients are present inherently with or without medicinal property which is used for calibration and analysis. The quality of herbal drug is denoted by the amount of biochemical marker. It is used in herbal medicine equipment, chromosomal traits and identification and verification of mixed chemicals (Omprakash *et at.,* 2019).

• Nmr Spectroscopy: It is strong, consistent and non-damaging technique. For plant samples, this method delivers innovative prospects for QC evaluation (Heyman and Meyer, 2012). It is used in food validation and functional genetic variation. For numerous botanical tester, the standardization is beneficial. NMR fingerprinting and

Table 9: Foaming index of few Medicinal Plants (Mukherjee *et al*., 2019).

Sr No.	Plant name	Foaming index (U)
1.	Swertia chirata	190
2.	Hemidesmus indicus	220
3.	Trichodesma indicium	100

Table 10: Swelling Index of some Medicinal Plants (Mukherjee *et al*., 2019).

Sr No.	Plant name	Swelling index
1	Agar	10
2	Fucus sp.	6
3	Ispaghula seed (Plantago psyllium)	9
4	Trigonella foenum-graecum	6

QC fruit liquids in production is useful (Chauthe *et al.,* 2012).

Biological Parameters

Microbial Contamination:

• Total Viable Count: is a quantitative estimate which represents the number of colony forming units per gram o by the different microorganisms such as yeast, bacteria or moulds etc. in a given sample (Jenkins and Maddocks, 2019).

• Aflatoxin Content: The occurrence of fungi should be monitored, to prevent the species mutagen (Aspergillus, Fusarium) which produce aflatoxins (Alhidary *et al.,* 2017). Absorption of minute amount of aflatoxin is hazardous to human. Many aflatoxins have been discovered whereas natural toxins are B1, B2, G1 and G2. The natural aflatoxins are categorized as oncogenic (Rossi *et al.,* 2017). The following methods are used for the detection of aflatoxins for example Thin layer chromatography (TLC), High Performance liquid Chromatography (HPLC), Mass spectroscopy, ELISA etc (Ezekwesili *et al.,* 2014).

Pharmacological Parameters

• Bitterness Value: The aqueous extract of the herbal plant is beneficial as an appetite tonic. It can be determined by adding 1g of herbal drug to the 100 ml of boiling water and kept overnight for the extraction of drug. The filtrate obtained is diluted 10,000 times. The value is compared with a quinine hydrochloride solution (standard) (Olivier and Vanwyk, 2013).

• Foaming Index: This method involve persistent foam by the aqueous decoction of the herbal material and their extract which helps in analyzing saponin content in the medication (Prasad *et al.,* 2012).

• Swelling Index: It is useful in the evaluation of crude drugs containing mucilage content. The swelling index can be evaluated by weighing 1gm of drug powder, dipped in water which is taken in measuring cylinder for 24hours at room temperature. The amount raised by the drug was estimated (Pradhan *et al.,* 2015).

• Haemolytic Property: Many medicinal plant materials, contain saponins produced haemolytic activity

Table 11: Haemolytic Property of some Medicinal Plants (Mukherjee *et al*., 2019).

Sr No.	Plant name	Hemolytic activity
1.	*Anagallis arvensis* L.	≥15 µg/mL
2.	Juniperus oxycedrus	2.5% - 4.4%
3.	Areca catechu	≤ 20%
4.	Smilax macrophylla	4.51% - 5.32%

which are obtained from different species (Azadbakhta *et al.,* 2019). Haemolysis is caused by the inherent property of saponins. They are added to blood suspension which alter erythrocyte membrane which leads to the diffusion of hemoglobin into the surrounding medium (Prasad *et al.,* 2012).

Toxicological Parameters

• Determination of Pesticide Residue: Pesticide residue refer to the pesticide that may persist in food crop that are bid during cultivation. One of the most natural occurring pesticide is the pyrethrins, obtained from plants which work as insecticide. It is not that harmful to human health as it eliminated from the human body through the excretory system (Meihua, Y. and W. linan, 2008). Due to this property of pyrethrins, organo-chloro and phosphorus are losing their rate. The pesticide that contain chloro and phosphorus molecule can be identified and measure by the total organic chlorine and phosphorus count respectively. GC, MS or GC-MS are used to identify individual pesticide. The homogeneity of a plant extract can be quantify by TLC, HPLC, quantitative TLC (QTLC) and high performance TLC (HPTLC) (Chirag *et al.,* 2019).

• Determination Of Heavy Metal: The heavy metals can cause contamination which is expected to cause destruction of habitat and also hazardous to health of user. The toxicological effect produced by metals may vary metal to metal (Chirag *et al.,* 2014). The concentration of heavy metals can be determined by the quantitative and limit test. The heavy metals can be evaluated on the groundwork of color reaction with indicators like diethyldithiocarbonate/ thioacetamide. The result obtained is compared with a specifications which are recorded in pharmacopoeias (Shaban *et al.,* 2016).

Conclusion

In herbal Indian industry, the purity and efficacy of drug is dependent on the standardization of herbal drug. The dispute which is generally faced by the industries are the identification, actual availability of drug and adulteration in finished product. To ensure the safety, efficacy and purity of the raw material for herbal drug, WHO has proposed the standardization guidelines. Some parameters which are followed by WHO are physical,

chemical, biological, botanical and etc. It is important to regulate these standardization parameters with uniform rules. This will help to reduce adulteration and the efficient product will be produced.

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