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Der Pharmacia Lettre, 2010, 2(6): 302-315
(http://scholarsresearchlibrary.com/archive.html)

ISSN 0975-5071
USA CODEN: DPLEB4

Identification, evaluation and standardization of herbal drugs: A review

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ABSTRACT

After post General agreement on tariffs and trade (GATT) era there is big surge in herbal based medicines to find out their potential for treatment and cure of diseases and ailments which can or cannot by cured by well established allopathic formulations. For preparation of any herbal formulation identification, evaluation and standardization is rudimentary. Identification involves the morphology, microscopy parameter of plants, evaluation and standardization of herbal drugs includes physical, chemical and biological parameters. These parameters are crucial for preparation of accurate and potent formulation. Reason of these studies involve the safe and accurately selection and handling of crude materials, ensure efficacy and stability of finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion.

Key words: Herbal drugs, WHO guideline, standardization, evaluation.

INTRODUCTION

In recent era, 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. (1) There are around 6000 herbal manufacturers in India. More than 4000 units are producing Ayurveda medicines.(2) World health Organization(WHO) give guidelines for the herbal standardization and evaluation.

WHO Guidelines for Herbal Drug Standardization and Evaluation

The WHO guidelines for herbal drugs can be summarized as follows:-

- **Identity of the drug:** Botanical evaluation- sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements etc.

- **Physicochemical character of the drug:** Physical and chemical identity, chromatographic fingerprints, ash values, extractive values, moisture content, volatile oil and alkaloidal assays, quantitative estimation protocols etc.
- Pharmacological parameters, biological activity profiles, bitterness values, hemolytic index, astringency, swelling factor, foaming index etc.
- Toxicity details :- pesticide residues, heavy metals, microbial contamination like total viable count, pathogens like *E.coli, Salmonalla, P.aeroginosa, S. aureus, Enterobacteria* etc.
- Microbial contamination.
- Radioactive contamination.(3)

Herbal Drugs-: The herbal drugs define as whole or plants parts, algae, fungi in unprocessed state usually in dried form but sometimes fresh.(4)

Herbs and their parts used, activity, chemical constituents and examples (Table: 1)

Plants name	Biological name (family)	Part used	Chemical constituents	Biological activity
Nux-vomica	*Strychnos nux vomica* (Loganiaceae)	seeds	Strychnine Brucine	CNS stimulants, bitter stomachic and tonic
Opium	*Papaver somniferum* (Papaveraceae)	Dried latex from capsules	Narcotine Papaverine	Narcotic analgesic, diarrhoea
Ipecac	*Cephalelis ipecacuanha* (Rubiaceae)	Rhizomes and roots	Emetine Cephaeline	Antiamoebic, emetic And expectorant
Taxus	*Taxus brevifolia* (Taxaceae)	Stem bark	Taxol	Anticancer
Rauwolfia	*Rauwolfia serpentina* (Apocyanaceae)	Root	Reserpine	Antihypertensive

The various parameters for identification, evaluation and standardization (Table: 2)

METHODS	EVALUTION PARAMETERS
1. Authentication	A. Parts of plants collect like leaf, flower, root, stolen B. Regional status C. Family D. Biological source E. Chemical constituents
2. Marphology or Organoleptic evaluation	A. Odour B. Taste C. Size D. Shape E. Special feature
3. Microscopy evaluation	A. Leaf content B. Trichomes C. Stomata D. Quantitative microscopy
4. Chemical evaluation	A. Chemical test B. Chemical assay C. Phytochemical screening

5.	Physical evaluation	A. Moisture content B. Viscosity C. Melting point D. Solubility E. Optical rotation F. Refractive index G. Ash value H. Extractive value I. Volatile oil content J. Foreign matter etc.
6.	Biological evaluation	A. Microbial contamination B. Pesticides contamination C. Pharmacological activity of drugs

Identification, evaluation and standardization

Identification of herb is based on macroscopical and microscopical features. Macroscopical feature involves odour, taste, color, size shape and special feature of plant and microscopically involves leaf content, trichome, stomata etc. Certain microscopical features and chemical test comes under evaluation and standardization of herbal drug. Evaluation of drugs means confirmation of its identity and determination of its quality and purity and detection of adulteration. (5)

Standardization expression is used to describe all measures which are taken during the manufacturing process and quality control leading to a reproducible quality. It's also involve the study from birth of plant to its clinical application. It's also include the herbal drugs preparation to a define content of a constituent or a group of substance with known therapeutic activity respectively by addition of excipients or by mixing herbal drugs preparation.(1) In other words it's ensuring that every packet of medicine has correct ingredient in correct amount and will induce intended therapeutic effect.

Example of macroscopy and microscopy for nux –vomica (Table: 3)

Macroscopy parameter	**Microscopy parameter**
Colour-greenish -brown	Epidermis-strongly thicked, pitted, lignified
Odour-none	Collapsed cells-present
Taste-intensely bitter	Endosperm-unlignifie, plasmodesma, aleurone graines
Size-10-30mm in dimeter 4-6mm in thickness	calcium oxlate crystalas-present

1. Authentication:

In India, two governments organizations first Central council for research in Unani medicine (CCRUM) and central council for research in ayurvedic medicine are working for quality control in authentication the plant material collect from an appropriate region of the country at an appropriate stage of its growth is well authentication by details taxonomical study and the correct botanical identity is established .(6) To ensure and enhance the quality of herbal medicines, the Government of India has notified Good Manufacturing Practices (GMP) under Schedule 'T' of the Drugs and Cosmetics Act 1940 which also ensures raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination. The guidelines for Good Agricultural Practices (GAP) seek to lay down a cultivation programmed designed to

ensure optimal yield in terms of both quality and quantity of any crop intended for health purposes.

Name of Institutes-

- Central Council for Research in Ayurveda and Siddha (CCRAS),
- Central Council for Research in Unani medicine (CCRUM),
- Central Council for Research in Homoeopathy (CCRH),
- Central Council for Research in Yoga and Naturopathy (CCRYN)
- Central Council for Indian Medicine (CCIM),
- Central Council for Homoeopathy (CCH)

Laboratories-

- Pharmacopoeial Laboratory for Indian Medicine (PLIM),
- Homoeopathy Pharmacopoeia Laboratory (HPL)

National Institutes-

- National institute of Homoeopathy (NIH),
- National Institute of Ayurveda (NIA),
- National Institute of Unani Medicine (NIUM),
- National Institute of Naturopathy (NIN),
- National Institute of Siddha (NIS),
- Institute of Post-Graduate Training and Research in Ayurveda (IPGTRA),
- Rashtriya Ayurved Vidyapeeth (RAV),
- Morarji Desai National Institute of Yoga (MDNIY)

2. Evaluation Parameters of herbal drugs

A. Macroscopic evaluation

In this methods, description, general condition of the drug size, shape outer surface inner surface are referred. A sensory or organoleptic character describes colour, odour taste, consistency.(7) The fractured surface in cinchona, quillia and cascara barks and quassia wood are important characteristics. Aromatic odour of umbellifrous fruits and sweet taste of liquric are the example of this evaluation. The ovoid tears of gum acacia ribbon shaped characterizes of tragacanth disc shaped structure of nux vomica concial shape of aconite quills of cinchona .(8)

B. Microscopic Evalution

The inner pseudoparenchyma cells are oval or rounded,the contain fixed oil & protein the whole tissue is devoid of cellulose and lignin.various parameter includes in microscopy(1)

A. Leaf content
B. Trichome
C. Stomata

a. Determination of leaf content

In this include parameter like stomatal number, stomatal index, vein islet number, vain termination number was determining by standard methods. For e.g- Digitalis purpurea (Table: 4) (1)

Table: 4

Parameter	Range
Stomatal index	1.3-3.5
Vein **i**slet number	2.5-3.0
Palisade ratios	3.7-4.2
Stomata number	25-50

b. Types of trichomes

Table: 5

Types of trichome	Subtype of trichome	Examples of plants
1 Covering trichomes	**a.** Unicellular tichomes	Nuxvomica,caanabis
	b. Multicellular-unbranched trichomes	
	(i) Uniseriate	Datura
	(ii) Biseriate	*Calendula officinalis*
	(iii)Multiseriate	Male fern
	c. Multicellular-branched ttichomes	*Verbascum thapsus*
2.Glandular trichome	**a.** Unicellular glandular trichome	Vasaka
	b. Multicellular glandular trichome	*Digitalis purpurea*
3.Hydathode trichome	-	Piper betal

c. Stomatal number and stomatal index study

There are several types of stomata, distinguished by the forms and arrangement of the surrounding cells.

- Anomocytic (irregular – celled)
- Anisoytic (unequal – celled)
- Diacytic (cross- celled)
- Paracytic (parallel celled)

Determination of stomatal index

The stomatal index is the percentage of the number of stomata formed by the total number of epidermal cells including the stoma being counted as one cell. Place leaf fragment of about 5x5mm in size in size in a test tube containing about 5ml chloral hydrate.

Stomatal index= S / E+S×100

Where: S= Total number of stomata in a given area of leaf
E= Number of epidermal cells (including trichomes) in the same area of leaf.

3. Physical Evaluation

a. Determination of foreign matter

Drugs should be free from moulds insects, animal, faecal matter and other contamination such as earth stones and extraneous matters.

Percentage of foreign organic matter = n × W × 94,100 × 100 / S × M × P

Where: n= number of chart particles in 25 fields.
S= number of spores in the same 25 field.
W= weight in mg of lycopodium taken.

M= weight in mg of the sample (calculation on the sample dried at 105.c
P= number of characteristics particles per mg of the pure foreign matter.
94,000= number of spores per mg of lycopodium.(1-2)

b. Determination of total ash

The residue remaining after incineration is the ash content of drugs ,which simply represents inorganic salts, naturally occurring in drugs or adhering added to it as form adulteration(1).
Two types ash determine-
(i) Acid insoluble ash value.
(ii) Determination of water soluble ash.

c. Determination of extractive value

(i) Determination of alcohol soluble extractive
(ii) Determination of water soluble extractive.

d. Determination of moisture content.-

Weighed 10 gm of drug and taken in a taken evaporating dish. Then it is dried 105°C for 3 hours and again weighed. Drying and weighing was continued at one hour interval until difference between two successive weighing corresponds to not more than 0.25 percent. The reading is taken after a constant weight is reached and the moisture content is determined.(2)

e. Determination of specific optical rotation (9)

Specific rotation formula -D_{25}= 100 × φlc

Where: φ = corrected observed rotation in drug at-25°
D = d line of sodium light
l = length of the polarimeter tube in done.
c = concentration of substance in percent w/v.

f. Determination of pH.

The pH value of an aqueous liquid may be defined as the common-logarithm of the hydrogen ion concentration expressed in grams. Potentiometrically pH value determine by a glass electrode and a suitable pH meter.(9)

g. Solubility

The presence of adulterant in a drug could be indicated by solubility studies identify by various solvents. (10)

i. Alcohol

5 gm of powdered material along with 100 ml of alcohol are shaken well occasionally for the first 6 hours and kept undisturbed for 18 hours. The liquefied extract thus obtained was concentrated in an vacuum oven and the percentage was calculated with the weight of the drug powder taken.

ii. Water

The procedure adopted for solubility percentage of alcohol is used with chloroform water instead of alcohol to get the water solubility.

h. Refractive index

When a ray passes from through a one medium to another of different density, it is bent from original path. Thus, the ratio of velocity of light in vacuum to its velocity in a substance is termed as refractive index of the second medium. Depending upon purity, it's constant for a liquid and can be consider as one of its standardization. Refractive index of a compound varies with the wave length of the incident light, temperature and pressure. Refractive indices of the following compound are for sodium light and a temperature 25°C **(Table: 6)** (1).

Drugs	Refractive index
Arachis oil	1.4678-1.470
Caraway oil	1.4838-1-4858
Castor oil	1.4758-1.527
Clove oil	1.527-1.535

i. Volatile oil content-

Pharmaceutical significance of aromatic drugs is due to their odorous principal that is volatile oils such crude drugs are standardized on the basis of their volatile contain. **(Table:7)** (3)

Drugs	Volatile oil content (%w/w)
Caraway	Not less than 2.5
Lemon peel	Not less than 2.5
Clove	Not less than 15
Fennel	Not less than 1.4
Dill	Not less than 2.5
Cardamom seed	Not less than 4.0

j. Pesticide residue

WHO and FAO (Food and Agricultural Organization) set limits of pesticides, which are usually present in the herbs. These pesticides are mixed with the herbs during the time of cultivation. Mainly pesticides like DDT, BHC, toxaphene, aldrin cause serious side-effects in human beings if the crude drugs are mixed with these agents.(3)

k. Microbial contamination

Usually medicinal plants containing bacteria and molds are coming from soil and atmosphere. Analysis of the limits of *E. coli* and molds clearly throws light towards the harvesting and production practices. The substance known as afflatoxins will produce serious side-effects if consumed along with the crude drugs.(1)

Aflotoxins should be completely removed or should not be present.

l. 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.(3)

Table: 8: Limits for Microbial Contamination

Microorganism	Finished product	Raw materials
E. coli	10^1	10^4
Salmonella	-	-
Total aerobic bacteria	10^5	-
Enterobacteria	10^3	-

m. Viscosity

Viscosity of a liquid is constant at a given temperature and is an index of its composition. Hence it can be used as a means of standardizing liquid drugs.

The following are the suitable examples.

Liquid paraffin –kinematics viscosity not less than 64 centistokes at 37.8˚.

Pyroxylin- kinematic viscosity, 1100-2450 centistokes.(1)

n. Melting point

In case of pure chemicals or phytochemicals, melting points are very sharp and constant. Since the crude drugs from animal or plant origin contain the mixed chemicals, they are described with certain range of melting point.(1)

Table: 9: Melting point range for few crude drugs

Drugs	Melting Point (°C)
Colophony	75-85
Kokum butter	39-42
Coca butter	30-33
Bees wax	52-65
Whool fat	34-44

o. Chromatography –

1. Thin Layer Chromatography (TLC)

Thin layer chromatography is particularly valuable for the qualitative determination. TLC is a technique in which a solute undergoes distribution between two phase , a stationary phase acting through adsorption and a mobile phase in the form of liquid.(11)

The adsorbent is relatively thin uniform layer of dry finely powdered material, applied to a glass, plate are the most communally used. Separation may also be achived on the basis of partition or a combination of partition and adsorption depending on the particular types of support its preparation and its use with different solvent system**.**

Densitometry thin layer chromatographic determination of aescin in an herbal medicinal product containing Asculum and Vitis dry extract:-

A TLC method is developed to analyze the total saponin content, also referred to as the aescin content, in an herbal medicinal product containing two dry extract in capsules. After a

purification step using C18 solid phase extraction, the samples are analyzed on a silica gel HPTLC plate with the upper layer of a mixture of acetic acid/water/butanol (10/40/50v/v/v) as the mobile phase. Spots are visualized by spraying with anisaldehyde reagent and heating the plate for 5-10 min. (100-105°C) and measured at a wavelength of 535 nm.(12)

2. High performance thin layer chromatography (HPLC):- (Recent Advancement)
HPTLC fingerprinting of marketed formulation containing herbal drugs:- Standardization of churnas was carried out by organoleptic study, phytochemical analysis; qualitative organic, inorganic analysis, thin layer chromatography, UV- visible spectrophotometer and HPLC fingerprint studies. Qualitative organic analysis the churnas showed the presence of alkaloids, steroids, phenols, tannins, glycosides, resins, saponins and flavonoids.(12,13)

3. Use of fingerprinting and marker compounds for identification and standardization of botanical drugs:- Chemical and chromatographic techniques may be used to aid in identification of an herbal material or extract. Chromatographic technique such as HPLC, TLC, GC and capillary electrophoresis and spectroscopic methods such as IR, NMR, and UV-may also is used for fingerprinting. DNA fingerprinting has been widely used in many species, e.g. DNA fingerprinting of *Panax* species and their adulterants. Marker compounds may be used to help identify herbal materials, set specifications for raw materials, standardize botanical preparations during all aspects of manufacturing processes and obtain stability profiles.(14)

4. Elemental analysis of herbal preparations for traditional medicines by neutron activation analysis with the potassium oxide standardization method: - In this method marketed herbal drugs were analysed by instrumental neutron activation analysis with potassium oxide standardization. Small amount of each sample (500-700 mg) was palletized under a pressure of six tones and irradiated together with monitors for alpha and neutron flux ratio determination for about 6h in a thermal flux of 2.29 × 10 n/cm2/s.(12,15)

5. Liquid chromatography UV-determination and liquid chromatography atmospheric pressure, chemical ionization mass spectrometric characterization of sitosterol and stigmasterol in soyabean oil:- A narrow bore HPLC-UV method was developed for the analysis of phytosterols in vegetable oils: sitosterol and stigmasterol.(16)

6. The recent use of GC in Simultaneous determination of cinnamaldehyde, eugenol and paeonol in traditional Chinese medicinal preparations by capillary GC-FID: - A capillary Gas chromatography method was developed for determination of cinnamaldehyde, eugenol and paeonol in two traditional Chinese herbal medicinal preparations, Weitongding tablet and Guifu Dihuang pill. The assays were based on a programmed temperature GC in a 30 m × 0.53 mm capillary column with nitrogen as carrier and FID detector. (17)

5. Chemical Evaluation-:
In this include chemical test, assay, isolation, purification and identification of active constituents are chemical methods of evaluation. It also includes phytochemical evaluation.(Table:10)

Tests	Reagents used	Colour formed	Sign
1.**Tests for alkaloids**			
a.mayer's tests	Potassium mercuric iodide solution	Cream precipitate	+
b.Wagner's tests	Iodine potassium solution	Brown precipitate	+
c.Hager's tests	Saturated solution of picric acid	Yellow colour	+
d.Dragendarff's tests	Potassium bismuth iodide solution	Raddish brown precipitate	+
2.Tests for amino acids			
a.Millon's tests	Millon reagents	White precipitate	+
b.Ninhydrine tests	Ninhydrin solution	Violet colour	+
3.Tests for carbohydrates			
a.Molisch's tests	Alcoholic a-naphthol+sulphuric acid	Purple to violet colour rings	+
b.Barfoed's tests	Barfoed reagents	Red colour(monosaccharide) after 10 min.colour form(disaccharide)	+
c.Selivanoff's tests	Selivanoff's reagents	Rose colour(keton)	+
d.Tests for pentoses	Hydrochloric acids + phloroglucinol	Red colour	+

Biological Evaluation-

1. Biological parameter (bioassay):- Bioassay is the determination of the biological potency of the herbal constituents. Marketed preparation contain mixture of bioactive plant constituents and the relative properties of a single bioactive compound can vary from batch to batch while the biological activity remains within the desirable limits. Some of the examples are:

a. Evaluation of adaptogenic activity profile of herbal preparation

Adaptogens help the body to come up with stress and enhance general health and performance. AVM- is an herbal formulation containing *Emblica officinalis, Withania somnifera, Asparagus racemosus*, *Ocimum sanctum, Tribulus terrestris* and *Piper longum.* This shows significant antistress, immunomodulatory and anabolic activities in different animal models. (18)

b. Evaluation of antioxidant activity of herbal products

A new test method for measuring the antioxidant power of herbal products, based on solid phase spectrophotometry using tetrabenzo-b, f, j, n, l, 5, 9, 13- tetraazacy- clohexadecin- Cu (II) complex immobilized on silica gel is proposed. The method was approved in the analysis of the most popular herbal beverages and drugs Echinacea determined spectrophotometrically.(19)

c. Evaluation of microbial contamination reduction on plants through technological process of decoction and spray dry

The aim of this work was to verify the microbial contamination, such as extractive solution (SE) and spray dried extract (PSA) with the purpose of evaluating the decrease of contamination after the decoction and the spray dry. The microbiological analysis of various marketed products was performed by total plate count and most probable number of total coliform. (18)

d. Evaluation of nitric oxide scavenging activity of selected medicinal plants used in inflammatory diseases

Various traditional medicinal plants like *Rubia cordifolia* Linn., *Lanatana camara* Linn. And *Morinda citrifolia* Linn. were selected for a study on the inhibition of nitric oxide (NO), which is a key mediator in the phenomenon of inflammation, signifying the presence of effective anti-inflammatory constituents of the plants. Plant samples were extracted with different solvents for

evaluation of their inhibitory activity on nitric oxide produced *in vitro* from sodium nitroprusside, and in lipopolysaccharide- activated murine peritoneal macrophages, *ex-vivo*.(19)

2. Evaluation of marketed polyherbal antidiabetic formulatios using biomarker charantin

Plant *Momordica charantia* contain Charantin, having antihyperglycaemia, anticholesterol, immunosuppressive, antiulcerogenic, antispermatogenic and androgenic activities. With the help of HPTLC method standardized polyherbal formulations. The recovery values of charantin were found to be about 98.89%.

3. *In vivo* and *in vitro* evaluation of hair growth potential of Shoe flower

The leaves and flowers of *Hibiscus rosa-sinensis* are used as promoters of hair growth and as an aid in healing of ulcers. Petroleum ether extract of leaves and flowers of the plant was evaluated for the potential hair growth *in vivo* and *in vitro*. *In vivo*, 1% extract of leaves and flowers in liquid was applied topically over the shaved skin of albino rats and monitored and assessed for 30 days. The length of hair and different cyclic phases of hair follicles, like anagen and telogen phases were determined at different time periods. *In vitro*, the hair follicles from albino rat neonates were isolated and cultured in Dulbecco's modified Eagle's medium supplemented with 0.01 mg/ml petroleum ether extract of leaves and flowers. It is concluded that the leaf extract, when compared to flower extract, exhibits more potency on hair growth. (21,22)

4. Clinical evaluation to assess the safety and efficacy of coded herbal medicine "Dysmo-off" versus allopathic medicine "Diclofenac sodium" for the treatment of primary dysmenorrhoea

These evaluations were based on verbal rating scale so as to ascertain the rate of analgesic effects on dysmenorrhoeic pain. The patients were randomly allocated with the ratio of 1:2 for controlled treatment with (NSAIDS) (n=40) received Diclofenac sodium tablets twice daily for 4 days (50 mg one day prior to and three days after the menstruation), and test treatment with Dysmo-off(a herbal drug formulation)(n=80) received powdered Dysmo-off twice daily for 4 days (5 g one day prior to and three days after the menstruation). Treatment lasted for 4 consecutive menstrual cycles. Haemoglobin, ESR and ultrasound were measured at baseline during study. (23)

5. Thermographic evaluation

In this study thermography were used to evaluate the effects of herbal formulations based on "Sho" scientifically. In the cases that were suitable for Keishibukuryogan, the so called Keishibukuryogan Sho, a significant skin temperature rise was observed in the upper half of the body after the intake of Keishibukuryogan. In a case that was suitable for Hochuekkito, a marked elevation of skin temperature spread through the upper trunk. It suggested that thermography is useful for an objective evaluation of Sho in Kampo medicines, and for identification of the action site of the herbal formulation.(23, 24)

6. Biochemical evaluation

Muthu Marunthu is an herbal formulation comprising of eight various plant ingredients, and has been claimed to possess anticancer effect. It was observed that the growth rate in rats was normal and there was no change in blood parameters such as glucose, urea, proteins, cholesterol and also in the activities of pathophysiological enzymes such as lactate dehydrogenase (LDH), gluconate

oxaloacetate transaminase (GOT), glutamate pyruvate transaminase (GPT), alkaline and acid phosphatase after Muthu Marunthu administration. The tumor weight was found to be reduced in methylcholanthrene induced fibrosarcoma rats after Muthu Marunthu treatment. (25)

7. Evaluation of Kutaj-Ghanavati for alkaloidal principles

Kutaj-Ghanavati is a reputed Ayurvedic preparation used in dysentery and diarrhea. It contains water extract of Kurchi bark and fine powder of aconite roots. It was evaluated quantitatively and qualitatively employing TLC and titrimetric method. In TLC study no interference of Kurchi and Aconite alkaloids with one another in their respective solvent systems. The formulation was found to contain all alkaloids of Kurchi and Aconite. (26)

8. Organoleptic evaluation

Organoleptic evaluation of food products plays an important role in judging the censoring acceptability or rejection of food items in the market. Effect of various treatments (blanching, pricking, and lye treatment), sugar concentration (50%, 60%, 70%) and storage on the color scores; flavor scores; texture scores of intermediate moisture apricots. The overall acceptability of the products was significantly higher in 70% sugar syrup but these scores decreased as the storage period advanced. (27)

9. Clinical Evaluation

Even if an herbal product is standardized to, for example, 4% of a constituent, the remaining 96% of ingredients is not standardized and may affect the product's solubility, bioavailability, stability, efficacy and toxicity. Controlled trials are necessary to establish safety and efficacy, manufacturing standards are required to ensure product quality. (28)

The consumers – doctors and patients- expect innovation and effective options for chronic diseases. The industry has to:

1) Become creative in designing clinical trials,
2) Developing consumer friendly products
3) Effective marketing communication.

The future belongs to an herbal company that is research-focused, quality, regulatory-compliant, consumer-friendly and market-surveys. (29)

CONCLUSION

The field of the herbal drugs and formulations is very vast and there is still lot to explore on the subject of standardization of these. So, while developing an herbal drug formulation it is must to have all the related knowledge of that particular drug including all its organoleptic characters to phytoconstituents to pharmacological action to its standardization in respect to various parameters via various techniques.

Monographs as compiled in the standard books like Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, Wealth of India and Ayurvedic formulary, provide all the details for the various tests to be performed in order to determine the conformity of the crude or formulated herbal drug with the standards lay. It is also important to study the influence of the various

factors like effect of the environment, climate, growth conditions and condition of the storage on the potency of a crude drug or the formulation prepared using it as a whole or as extract or the constituent isolated. It is also important to standardize, not only the main drug constituent but also the other excipients and additives incorporated.

Future aspects

There have been various guidelines issued on the standards of the herbal drugs by the concerned governing bodies like CDSCO, US-FDA etc., along with the standard testing procedures to ascertain the conformity of the drug with prescribed standards. There is still a lot of drug which are not included in these official guidelines and books, but still used in the formulation of the herbal medicines. And lot to explore in regards to the standardization of these crude drugs or generated products. Every day a new chemical entity is being identified and isolated from the existed or newly identified crude drugs, so a need of the stringent regulation has arise to determine the conformity of these new chemicals to assess their physicochemical, pharmacological, clinical activities along with their safety and efficacy.

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