www.ThePharmaJournal.com

The Pharma Innovation

ISSN: 2277- 7695
TPI 2015; 4(9): 100-104

www.thepharmajournal.com
Received: 06-02-2016
Accepted: 08-03-2016

Mr. Shailesh. L Patwekar
Assistant professor,
Department of Pharmaceutics,
School of Pharmacy,
Swami Ramanand Teerth
Marathwada University
(S.R.T.M.U) Nanded
(Maharashtra) India 431606

Suryawanshi Arvind B
Department of Quality
Assurance (M.Pharm), School of
Pharmacy, Swami Ramanand
Teerth Marathwada University
(S.R.T.M.U) Nanded
(Maharashtra) India 431606

Gaikwad Manoj S
Department of Pharmaceutics
(M. Pharm), School of
Pharmacy, Swami Ramanand
Teerth Marathwada University
(S.R.T.M.U) Nanded
(Maharashtra) India 431606

Pedewad Snehal R
Department of
Pharmaceutics (M.Pharm),
School of Pharmacy, Swami
Ramanand Teerth Marathwada
University (S.R.T.M.U) Nanded
(Maharashtra) India 431606

Potulwar Ashwini P
Department of Pharmaceutics
(M.Pharm), School of Pharmacy,
Swami Ramanand Teerth
Marathwada University
(S.R.T.M.U) Nanded
(Maharashtra) India 431606
.

Correspondence
Mr. Shailesh. L Patwekar
Assistant professor,
Department of Pharmaceutics,
School of Pharmacy,
Swami Ramanand Teerth
Marathwada University
(S.R.T.M.U) Nanded
(Maharashtra) India 431606.

Standardization of herbal drugs: An overview

Mr. Shailesh. L Patwekar, Suryawanshi Arvind B, Gaikwad Manoj S, Pedewad Snehal R, Potulwar Ashwini P

Abstract
The use of herbal drugs as medicine is the ancients form of health care known to delicacy and it is used in all cultures throughout history. The primeval persons learned by trial and error basis to identified beneficial plants. The identification of purely active moiety is an important requirement for Quality control and dose determination of plant related dugs. Standardization of herbal drugs means confirmation of its identity, Quality and purity. The present overview covers the standardization parameters with their standards value of the some herbal drugs.

Keywords: Herbal Drugs, Standardization, Quality Control

Introduction
The term "herbal drugs" denoted by means of plant or part of plants that have been converted into phytopharmaceuticals by simply means of processes involving collection or harvesting, drying and storage [1]. The use of herbal drugs as medicine is the ancients form of healthcare known to delicacy and it is used in all cultures throughout history. Ancient humans well-known their dependence on nature for a good healthy life and since that time humankind depended on the variety of plant resources for food, shelter, clothing and medicine to cure immensurable of diseases. The first written records explaining the use of plant in the healing of Mesopotamian clay tablet writing and Egyptian papyrus. Led by nature, taste and experience, primeval men and women cured illness by using plant parts, animal parts and minerals that were not a part of usual diet. Primeval persons learned by trial and error basis to identified beneficial plants with helpful effects from those that were inactive or toxic, and also which processing methods or mixtures had to be used to meet steady and ideal results. Even in a ancient cultures ethnic, ancestral or tribal people collect information related to herbal plant and developed which is defined herbal phrmacopeais [2, 6].

The active principal of identification and standardization:
The identification of purely active moiety is an important requirement for Quality control and dose determination of plant related dugs. A medicinal herbal plant can be checked as a artificial laboratory as it produces and contains a chemical moiety. That moiety, responsible for medicinal activity of the herbal plant, are secondary metabolites. for example, of Alkaloids are nitrogenous principle organic moiety combine with acid to form crystalline salt and also herbal plants contains Resin, Oleoresins, lactones, saponin and volatile oils. Complete phytochemical screening of most of the medicinally essential herbs not done in India. this would be helpful in standardization and dose determination of herbal drugs [7].
Medicinal plant have play an important role in world health. They are circulated world wide, but they are most rich in tropical countries. It is noted that about 25% of all modern medicines are indirectly or directly obtained from higher plants.
World Health Organization (WHO) has individual herbal drugs as whole, labeled medicinal products that have robust ingredients, aerial or secret parts of the whole plant or other plant material or mixture of them. World Health Organization (WHO) has a set of specific Guidelines for the evaluation of the safety, efficacy and Quality of herbal drugs or herbal medicines. WHO find out that 80% of the world people currently use herbal medicine or drugs for the most important health cares. Except in some countries herbal drugs may also used by traditional, natural or inorganic active constituents. which are the not plant source. Herbal drugs is a main constituent in usual medicine and a general ingredient in Homeopathic, Ayurvedic, Naturopathic and in other medicine system. Herbs are usually measured as safe toxicity, side effects of allopathic drugs, has led to more increased in number of herbal drugs manufacturers. For the past few years, herbal drugs have been mostly used by the people with

no prescription, Leaves, stem, bark, flower, seeds, roots and extract of all these have been used in herbal drugs over the thousands of their use [8, 9].

Classification of herbal drugs

Ayurvedic herbalism: It is derived from the from the Sanskrit word "*ayurveda" means "The science of life"*. Which is originated in India more than 4000 years ago.

Chinese herbalism: Which is a element of traditional related medicine.

African herbalism

Western herbalism: which is originated from Rome, Greece and then multiply to North, Europe and South America.

Ayurvedic and Chinese herbalism have produceded into extremely sophisticated system of diagnosis, identification and treatment over the centuries. It should have the long term and effective history of results. Western herbalism now a days is primary a system of people medicine. A European medicinal tradition, occasionally called the "wise women" also focuses primarily on herbal healing.

Advantages of herbal drugs

1. Low cost of production.
2. They may have fewer side effects.
3. Effective with chronic condition.
4. Wide spread availability.

Disadvantages of herbal drugs

1. Lack of dosage instruction.
2. Poison risk associated with wild herbs.
3. Can interact with other drugs.
4. Inappropriate for many condition.
5. Some are not safe to use.

Pharmacopoeial standards

The identification, purity and quality of herbal drugs are determined by reference given in a pharmacopoeia. Pharmacopoeia prescribes like Analytical, physical and structural standards for the herbal drugs. The essential standards are given in pharmacopoeia shown in figure 1.

A significant identification and examination of crude drugs is important in processes of herbal formulation because of more diversity and changes in their chemical nature or characters. To reduce this problem all pharmacopeias have certain standards. Specific test for specific plant material are given below. Alkaloids content dragendorff test, Fat content Acid value Iodine value, saponification value molish test carbohyadrates Millon tests Amino acid Volatile oil Hemolytic activity Assay for Phosphate/Aluminium/ Camphor /Potassium /Lead/Iron/Gold/Calcium [11, 15].

Parameters for standardization and Quality Control of herbal drugs

Morphological or Organoleptic evaluation

It includes the evaluation of herbal drugs by size, shape color, odor, taste and particular characteristics like touch, texture etc. This is a technique of qualitative evaluation related to the study of morphological and sensory report of whole drugs.eg. Fractured surfaces in cascara, cinchona, and quillia bark and quassia wood are essential characteristics. Umbelliferous fruits have aromatic odour and liquorice have sweet taste are the example of this type of evaluation. Shape of drug may be conical (aconite), subcylindrical (podophyllum), cylindrical (sarsapilla), fusiform (jalap).Size represents thickness, length, breadth and diameter. Color represents external color which various from white to brownish black are essential diagnostic features. Taste which is a specific type of sensation feel by epithelial layer of tongue. taste may be sweetish (saccharic),sour (acidic),salt like (saline),and bitter or tasteless [12, 16, 17].

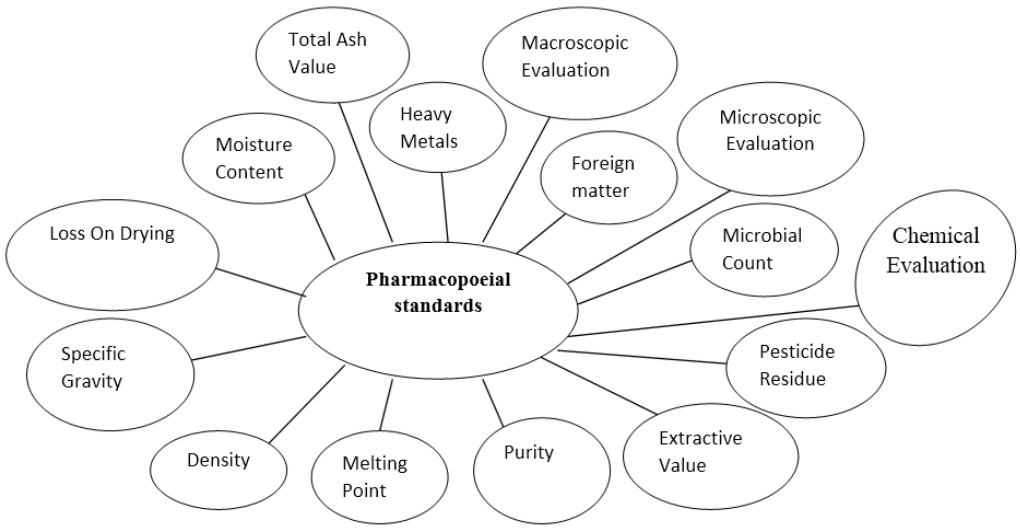

Fig 1: Standardization Parameters For herbal Drugs

Microscopic Evaluation

It involves the detailed assessment of the herbal drugs and it is used to recognize the organized drugs on the basis of their known histological characters. It is regularly used for qualitative analysis of organized crude drugs in total and powder form with the help of microscope. The inner pseudoparenchyma cells are round or oval shape. They contain protein and fixed oil. Crude drugs are microscopically identified by taking thin TS (Transverse section), LS (Longitudinal Section) in a bark, wood and leaf.

The various parameters included in microscopy are given bellow.

I. Stomata II. Trichomes III. Leaf Content IV. Quantitative Microscopy

Some Microscopic Identification test are given below [15, 18, 19].

Sr. No.	Name OF Constituents	Procedure For Test/Reagents	Result
1.	Starch, Hemicellulose	T.S. of Crude drug + 1 Drop of Iodine Solution	Blue color
2.	Mucilage	Ruthenium Red	Pink color
3.	Lignin	T.s. of crude drug + 1 drop of phloroglucinol + 1 drop of HCL	Pink color

Chemical Evaluation

The most of drug contain definite chemical constituents to which their pharmacological and Biological activity depended. Qualitative chemical test used to identify drug quality and purity. The identification, isolation and purification of active chemical constituents is depends chemical methods of evaluation. Preliminary phytochemical investigation is also a part of chemical evaluation. Some Qualitative chemical test for chemical evaluation crude drug are Saponification value and acid value etc [14, 15, 19].

Some important test used in chemical evaluation.

Sr. No.	Name of Constituents	Identification Test
1.	Volatile oil	1.Ester value 2. Acetyl value
2	Balsams	1.Acid value 2.Saponification value 3.bester value
3.	Resins	1.Sulphated Ash 2. Acid value
4.	Gums	1.methoxy determination 2.Volatile acidity

Determination of Foreign Matter

Herbal drugs should be prepared from the confirmed part of the plant. They should be totally free from insects or moulds, including visible and excreta contaminant such as stones, sand, harmful and poisonous foreign matter and chemical residues. Animal objects such as insects and invisible microbial contaminants, which produces toxins, as well as the potential contaminants of herbal medicines. Macroscopic evaluation can easily used to determine the presence of foreign matter, although microscopy is essential in certain special cases for example starch intentionally added to "dilute" the plant material [19, 22].

% of foreign Organic Matter = N × W × 94,100 × 100/S × M × P

Where; n = No. of chart particles in 25 field.
S = No. of spores in the same area of 25 fields.
W = Weight in mg of lycopodium taken.
M= weight in mg of the sample
P= number of characteristics particles per mg of the pure foreign matter.
94,000= number of spores per mg of lycopodium [19, 23].

Determination of Total Ash Value

The residue after incineration is the total ash content of the crude drug, which simply represents inorganic salts, naturally found in drug or adhering to it or deliberately added to it, in the form of adulteration.
Two types of total Ash value:

1. Water soluble Ash value
2. Acid insoluble Ash value.

Some examples of drug with their Total Ash Value [12].

Sr No.	Drugs	Total Ash (%w/w)	Acid Insoluble ash (%w/w)
1	Agar	-	1.00
2	Bael	3.50	-
3	Cannabis	15.00	5.00
4	Ginger	6.00	1.7(water soluble ash)

Determination of Extractive Values

The extract obtained by exhausting crude drugs are indicative of approximate measure of their chemical constituents. The various solvent are used for determination of extractives. These are classified as fallows.

1. Water Soluble extractives.
2. Alcohol Soluble extractives.
3. Ether Soluble extractives.

Some examples with their Extractive values [12, 19].

Sr No.	Drus	Water Soluble extractives (%w/w)	Alcohol Soluble extractives (%w/w)	Ether Soluble extractives (%w/w)
1	Aloe	NLT 25.00	NLT 10.00	-
2	Ginger	NLT 10.00	NLT 4.50	-
3	Capsicum	-	-	NLT 12.00
4	Nutmeg	-	-	NLT 25.00

NOTE: NLT means Not Less Than.

Determination Of heavy Metals

In general, quantitative and limit tests accurately determine the concentration of heay metals in the form of impurities and contaminants. The heavy metals like Arsenic, mercury, lead, thalium, cadmium have been shown to be contaminants of few herbal ingredients. A simple determination of heavy metals can be found ia many pharmacopieas and it is based on color reaction with special reagents such as diethyldithiocarbonate or thioacetamide and amount is determined by coparison with a standards. The methods commonly used for analysis are inductive coupled plasma (ICP), Netron activation analysis(NAA), Atomic Absorption Spectrophotometry(AAS).(25-27)
Examples of national limits for heavy metals in herbal medicine and products.

		Arsenic (As)	Lead (Pb)	Cadmium (Cd)	Chromium (Cr)	Mercury (Hz)	Copper (Cu)	Total Heavy metals as Lead
For Herbal Medicine								
Canada	Raw herbal material	5ppm	10 ppm	0.3ppm	2 ppm	0.2 ppm		
	Finished herbal products	0.01mg/day	0.02mg/day	0.006mg/day	0.02mg/day	0.02mg/day		
China	Herbal materials	2ppm	10ppm	1ppm		0.5ppm		20ppm
Malaysia	Finished herbal products	5mg/kg	10mg/kg			0.5mg/kg		
Republic of korea	Herbal materials							30ppm
Singapore	Finished herbal products	5ppm	20ppm			0.5ppm	150ppm	
Thailand	Herbal material, finished herbal products	4ppm	10ppm	0.3ppm				
WHO recommendation (2)			10mg/kg	0.3mg/kg				
For other herbal products								
National sanitation foundation draft proposal (Raw dietary supplement)		5ppm	10ppm	0.3ppm	2ppm			
National sanitation foundation draft proposal (finished dietary supplement)		0.01mg/day	0.02mg/day	0.006mg/day	0.02mg/day	0.02mg/day		

Radioactive contamination

The microbial growth in herbal drugs is usually avoided by irradiation. Dangerous contamination, may be the consequence of a nuclear accident. The WHO, in close co-operation with several other international organizations, has developed guidelines in the event of a wide spread contamination by radio nuclides resulting from major nuclear accidents. The nuclear accident in chernobyl and Fukushima may be serious and depend on the specific radionuclide, the stage of contamination and the quantity of the contaminant consumed. Examples of such radionuclides include long lived and short lived fission products, actinides and activation products. Theirfore, at current no limits are proposed for radioactive contamination. (28-31)

Pesticides Residue

Pesticides residue are any particular substance in food, agriculture commodities or animal feed resulting from the use of a pesticides. Herbal drugs are prone to contain pesticide residue, which gather from agricultural practices, such as Spraying, behavior of soil during cultivation and addition of fumigants during storage. The Pesticides contain chlorine in the molecules, which can be determined by analysis of chlorine, insecticides containing phosphate can be detected by measuring total organic phosphorus. The various methods are used to measure pesticides by GC, MS, OR GC-MS. Some simple methods are also published by the WHO and Europian pharmacopeia has in general limits for pesticides residue in medicine [32-34].

The list of approved pesticides for spices and their maximum residue limits (MRLs) (Codex Alimentarius Commission, 2005)

Pesticides (CCPR-number)	Group or sub group of spices	MRL (mg/kg)
Acephate (095)	Entire groug028[c]	0.2
Azinphos-methyl (002)	Entire groug028[c]	0.5
Chlorpyrifos (017)	Seeds	5
	Fruits or berries	1
	Roots or rhizomes	1
Chlorpyrifos-methyl (090)	Seeds	1
	Fruits or berries	0.3
	Roots or rhizomes	5
Diazinon (22)	Seeds	5
	Fruits or berries	0.1
	Roots or rhizomes	0.5
Dicofol (026)	Seeds	0.05
	Fruits or berries	0.1
	Roots or rhizomes	0.1

Determination of specific optical rotation [19]

Specific rotation determination formula -D25= 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.

References

1. EMEA. Quality of Herbal Medicinal Products. Guidelines. European Agency for the Evaluation of Medicinal Products (EMEA), London, 1998.
2. Hong-Fang Ji, Xue-Juan Li. Hong-Yu Zhang, Natural products and drug discovery, European Molecular Biology Organization, 2009; 10(3)
3. Bensky D, Gamble A. Chinese Herbal Medicine: Materia Medica. Eastland Press, Seattle, 1993.
4. Sonali Patil, Sharique Zafar, Bapat US, Manisha Bhoir. Standardization and Stability Study of *Jawarish-e-Bisbasa*, a Unani Formulation, Biological Forum. An International Journal. 2011; 3(2):14-17.
5. Calixto JB. Efficacy, Safety, Quality Control, Marketing and Regulatory Guidelines for Herbal Medicines (Phytotherapeutic Agents), Bthraez Imliaend Ijcoiunranl Auls Oef Omf Hedericbaall Adnrudg Bsiological Research. 2000; 33:179-18.
6. Iqbal Ahemad, Farrukh Aqil, Mohammad Owais. (Ed), Modern Phytomedicine, wiley-VCH Verlag Gmbh &Co. KGa A. Weinheim, 2006.
7. Dubey NK, Rajesh Kumar, Pramila Tripathi. global promotion of herbal medicine: india's opportunity. current science, 2004; 86(1):10.
8. abhishek k. ashutosh m. sinha bn. herbal drugs- present status and efforts to promote and regulate cultivation, the pharma review, 2006; 6:73-77.
9. Bodhisattwa Maiti1, Nagori BP, Rambir Singh. Recent Trends in Herbal Drugs: A Review, al. International Journal of Drug Research and Technology. 2011; 1(1):17-25.
10. Quality Control Methods for Medicinal Plant Materials (WHO). Geneva, A.T.T.B.S. Publishers and Distributor Delhi, 2002.
11. Neeli Rose Ekka Standardization Strategies for Herbal Drugs-An Overview Research J. Pharm. and Tech. 2008; 1(4):310-312.
12. Kokate CK, Gokhale SB, Purohit AP. pharmacognosy, Nirali prakashan, Pune. 2010, I,II.
13. Sharma Pp. How to Practice Gmps Vandana, Publications, 6th edition, 2010.
14. Neeraj Choudhary, Bhupinder Singh Sekhon. An

overview of advances in the standardization of herbal drugs, J Pharm Educ Res. 2011; 2(2).
15. Swapnil G, Patil. Standard Tools For Evaluation Of Herbal Drugs: An Overview, The Pharma Innovation – Journal. 2013; 2(9):60.
16. Ansari SH. Essentials of Pharmacognosy, Birla Publications Pvt Ltd, 2011.
17. Gupta MK and Sharma PK.. Test Book of Pharmacognosy, Ayurvedic formulations, Pragati Prakashan Meerut Vol II, Ist edition. 2007.
18. WHO. 1988. Quality Control Methods for Medicinal Plant Materials. World Health
19. Organization, Geneva, Archana Gautam. Identification, evaluation and standardization of herbal drugs: A review, Der Pharmacia Lettre, 2010; 2(6):302-315.
20. Wickremasinghe M, Bandaranayake. Quality Control, Screening, Toxicity and Regulation of Herbal Drugs, 2006.
21. Kunle, Oluyemisi Folashade, Egharevba, Henry Omoregie, Ahmadu Peter Ochogu. Standardization of herbal medicines - A review. International Journal of Biodiversity and Conservation. 2012; 4(3)101-112.
22. WHO. WHO Guidelines on Good Agricultural and Collection Practices (GACP). World Health Organization, Geneva. 2003.
23. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.
24. Kirtikar KR, Basu BD. Indian medicinal plants, 1:503-507.
25. Watson DG. Pharmaceutical Analysis. Churchill Livingstone, Edinburgh, 1999.
26. Sarmani SB, Abugssa I, Hamzah A, Yahya MD. Biol. Trace Elem res. 1999; 71-72:365.
27. WHO. Guidelines for assessing quality of herbal medicines with reference to contaminants and residues. World Health Organization, 2007.
28. Derived intervention levels for radionuclides in food. Guidelines for application after wide spread radioactive contamination resulting from a major radiation accident. Geneva, World Health Organization, 1988.
29. Archana A, Bele Anubha Khle. Sytanderdization of herbal drugs A overview, international research journal of pharmacy. 2011; 2(12):56-60.
30. AOAC. Official Methods of Analysis of AOAC International, 18th edn. AOAC International, Gaithersburg, MD, 2005.
31. De Smet PAGM, Keller K, Hansel R, Chandler RF. Aristolochia species In: Adverse Effects of Herbal Drugs, Springer-Verlag, Heidelberg, 1992.
32. Patel pratik, Patel NM, Patel PM, WHO. Guidelines on Quality control of herbal medicine, IJRAP, 2011; 2(4):1148-1154.
33. Pesticides Residue in Food-Method of analysis and sampling codex Alimentarius. Part 1,2nd edition Rome, Joint FAO/WHO Food Standards Programme, 2000, 2.
34. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998a.