ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Review Article

NEED OF STANDARDIZATION OF AYURVEDA FORMULATIONS

Jyothi Raga P M[1]*, Vivek P[2], Harinarayanan C M[3]

*[1]PG Scholar, [2]Professor, Dept. of Dravyaguna Vijnana, Vaidyaratnam P S Varier Ayurveda College, Kottakkal.
[3]Scientist (Botany), Pharmacognosy Division, Centre for Medicinal Plants Research, Arya Vaidya Sala, Kottakkal, Malappuram, Kerala, India.

Article info

Article History:
Received: 20-09-2023
Accepted: 11-10-2023
Published: 10-11-2023

KEYWORDS:
Standardization, Ayurveda formulations, Poly herbal formulations, Quality control.

ABSTRACT

Standardization of herbal formulations is a process of setting some standard parameters which are essential for assuring the quality of the herbal formulations and it should be reproducible at any time of stability period of that formulations. Today many people all over the world experiencing the side effects of Modern medicine are shifting towards the traditional medical systems, among them most widely accepted is Ayurveda. Increased demand of herbal medicines, along with disparity in demand and supply of raw materials and profit mindedness of pharmaceutical agencies, has resulted substandard and unsafe products. The adulteration and substitution of drugs, improper methods of collection, storage and preservation of raw drugs, controversial opinions regarding formulations in classical text books, addition of preservatives and improper purification of toxic herbal and mineral drugs are the main problems that leading to the production of substandard and unsafe products. Authorities like WHO and Govt. of India has taken steps to standardize the individual drugs and formulations. Ministry of AYUSH have given the standard parameters for different types of preparations and few of the individual formulations are standardized in Ayurvedic pharmacopoeia of India. As the general population uses Ayurvedic medicines mainly as polyherbal formulations, standardization of each formulation is a need of hour for ensuring the quality medicines that leading to the global acceptance of Ayurveda.

INTRODUCTION

Ayurveda one of the important traditional medicinal systems of India uses mainly polyherbal formulations for the management of diseases. The quality control of these polyherbal formulations is a very hot topic nowadays in the pharmaceutical industry as the use of these has been increased enormously. The regulatory authorities have paid special attention to this particular industry and developed many guidelines to ensure the quality of medicines prepared. Standardization is the key tool for ensuring the quality of a product. As far as medicines and formulations are concerned standardization means "it is a numerical value or specific property that quantifies the purity & quality of drug and formulated medicine. By standardizing the raw drugs, methods & formulations we can provide standard parameters to assess the quality, safety and efficacy of medicines.[1]

In India before the development of all other medical systems people used herbs for healing of various ailments. The practical experiences during that period were recorded and compiled as manuscripts. The Ayurveda medical system wherein the concepts of 'Holism' logically and intelligently implemented in healthy and unhealthy conditions of living beings, emerged at that time. In Ayurveda the raw drugs and their formulations were used according to the unique principles of Ayurveda pharmacology which can said to be based on 'Network pharmacology' (multi drug-multi target mode of action) due to the presence of several bioactive molecules, that is different from the single drug- single target action of molecular drugs (Lock and key hypothesis). [2]

In this medical system, during olden days the collection of raw drugs for the preparation of medicines was done by the *Vaidya* directly or by their helpers who have thorough knowledge about the drugs, and the medicines were prepared by the same or by the patient himself where optimum quality

Access this article online

Quick Response Code

https://doi.org/10.47070/ijapr.v11i10.2856

medicine was obtained as their only intention was to cure the disease. The *Vaidyas* used to treat patients on individual basis, and collected and prepared the medicine according to the requirement of the patient only. However by time the increasing population and the emerging diseases due to changing life style created more number of patients which caused increased need of herbs and herbal formulations. Also the decreased production of raw material due to the deforestation and urbanization of the land caused unavailability of herbal drugs. Due to these causes the above said tradition became impractical and declined. And nowadays the medicines are being manufactured on large scale in pharmaceutical units. Here the manufactures come across many problems such as non-availability of good quality raw material, authentication of raw material, non-availability of standards, improper standardization methodology of single drugs and formulation and quality control parameters. Another problem while manufacturing Ayurvedic formulations is the confusion among the identity of herbal drugs and different opinions in ingredients of formulations and group of drugs in classical texts. This results in herbal formulations with the same name but different ingredients. Subsequently the physicians are not aware that if the prescribed medicine contains the desired ingredients. These all problems reflected in the therapeutic results. Also there arises the blame that Ayurvedic medicines are causing organ failure due to the substandard and improperly purified drugs. However the present era population who understood the harmful side effects of modern medicine is switching once again towards alternative system of medicine. So it is essential to ensure that they get medicines which are genuine and having superior quality. Since the Ayurvedic medicines all are polyherbal formulations the standardization of these formulations is very much needed even though the standards of individual drugs are available.

Today the Ayurvedic medical science is a global science, many people all over the world are shifting towards the herbal medicines including Ayurvedic medicines. So currently WHO has focused on method of evaluation of medicinal plants to use them in healthcare system. Also special importance has been given to ensure quality control of medicinal preparation by using modern techniques and applying relevant standards. Even though in Ayurvedic pharmacopoeia of India, part 2, published by Govt. of India, standards of 202 formulations are available, a number of formulations available in the market are not having individual standards. To provide standard value, to generate faith, to provide quality control, safety and efficacy of Ayurvedic formulations standardization is an essential tool.

Need of Standardization

Nowadays people rely more on herbal drugs because of harmful side effects of synthetic drugs, and this trend is growing, not only in developing countries but in developed countries too. Unfortunately the number of reports of people experiencing side effects, caused by the use of herbal drugs, has also increased. There may be various reasons for such problems like one of the major causes of adverse effects is directly linked to the poor quality of herbal medicines. Ancient times the medicine preparation was carried out under the supervision of *Vaidyas* and they have developed some protocols for collection and storage of raw materials and manufacturing of medicines. They had developed guidelines based on the following factors:[3]

1. Place of origin and time of collection of raw material
2. Specific part and quality of raw material
3. Size and shape of furnaces
4. Type and quantity of fuel used in the preparation
5. Specification about the place of manufacturing
6. Time and duration of process
7. Characteristics of finished material
8. Shelf life

The medicines thus manufactured were directly given to the patients and there was no organized market structure for the sale of these formulations. But now the scenario has changed. Collection of drugs is now based on demands in huge quantities and storage, processing and preservation of these raw drugs in a proper way becomes a big challenge for the manufactures. Also there are many difficulties faced by the herbal pharmaceutical industries in large scale production of medicines which points to the need of standardization of herbal formulations.

1. Adulteration and Substitution

In the Text book of Pharmacognosy by C K Kokatte, it is defined as 'Adulteration is a practice of substituting original crude drug partially or fully with other substances which is either free from or inferior in therapeutic and chemical properties or addition of low grade or spoiled drugs or entirely different drug similar to that of original drug substituted with an intention of enhancement of profits'.[4] Normally adulteration is practiced by the unscrupulous dealers when a drug is scarce or when the price of a drug is high. Due to the commercialization of production of Ayurvedic formulations, increased demand of medicinal plants arose and to fill the gap between demand and supply adulteration came into practice. The profit making mentality of manufactures also increased the problem. Adulteration is a malpractice which affects the faith in Ayurveda drugs and also we don't get the desired therapeutic effect from these drugs.

Substitute is those drugs/materials having more or less similar medicinal properties of that of genuine one.[5] It is done due to non-availability of drugs, controversy of drug identity, confusion in nomenclature of different plants having similar name, regional availability, seasonal availability, shelf life, cost, similar *Rasapancaka* and morphological resemblance. Nowadays the concept of substitution is entirely converted into intentional and unintentional malpractices of adulteration. At present, for the purpose of benefits many inferior quality raw materials are mixed instead of original drug. This kind of substitution will lead to production of medicines which are of inferior quality.[6]

2. Methods of Collection, Storage and Preservation of Raw Drugs

Collection, storage and preservation methods play a very important role in the quality of the prepared medicines. The factors like time of collection, place of collection and botanical age of the plant will affect the chemical constituents of the plant. Even if good quality herbal raw drugs are collected the improper storing will lead to deterioration of its quality. Apart from deterioration in quality it can be contaminated with heavy metals or other inorganic substances or may be with macro or microorganisms like different kinds of fungus which will lead to substandard and unsafe products. To avoid these lot of guidelines are given by WHO and Govt. of India for collecting, storing and preserving the herbal and mineral raw drugs. Even though day by day these guidelines are becoming refined more and more, following these guidelines by large and small scale units are not sure. So by checking the quality parameters of prepared medicines and comparing it with the standards is necessary to avoid the blame that Ayurvedic medicines contains high level of heavy metals and aflatoxins and that may cause organ failure and diseases like cancer.

3. Different Opinions in Classical Textbooks

In Ayurvedic medical science so many classical books are available especially in *Dravyaguna vijnana, Rasasastra* and *Bhaishajya kalpana* and each author maintained their own way of identification features of raw materials, classification of drugs, different procedures to prepare formulations and a formulation with different ingredients. Different manufacturing companies follow different classical texts and due to this some marketed formulations are having different ingredients with the same name. Another problem is individual companies have their own pharmacopoeias and make their own medicines labelling the classical names.

Even though they have mentioned the reference in label, the customers buying the medicine are not aware of that. Even the physicians don't know if the desired contents of the prescribed medicine are present in it. For eg., in case of *Pancatikta gana* which is used in *Kwatha* form in market, more than one type of combinations of ingredients are available and also textual references are available about a number of different combinations as *Pancatikta*. Most of the manufactures mentioned reference as *Ashtanga Hrdaya*, but in this text there is no direct reference that it is *Pancatikta*. Also pharmacies make *Pancatikta kwatha* with different ingredients said in their own individual pharmacopoeia whose reference cannot be seen in classical textbooks. The non-uniformity of drugs in marketed formulations may not give an expected result in clinical practice.

4. Variation Among the Same Formulations

There are a number of different Ayurvedic formulations which is manufactured and marketed by many pharmaceutical companies. Even if it is said that they are following the same reference in the classical texts and also the regulatory standards, marked variations are observed among the same formulations manufactured by different companies. In a study an example of *Lodhrasavam* with 6 market samples manufactured by different companies were analysed and showed significant variations in their sensorial, physio-chemical, chromatographic as well as biological properties. This is a matter of serious concern and need to be addressed effectively to derive better standardization strategies for Ayurvedic formulations. Though there are several factors that make the standardization of Ayurveda formulation a great challenge, drastic variations within the same product will raise questions on the authenticity and credibility of the product.[2]

5. Preservatives

Preservative is a substance which is added to a formulation to prevent or inhibit the growth of microorganisms in the preparation.[7] Herbal drugs can be preserved for longer duration in different dosage forms like powder tablet, *Leha* etc . These formulations have less water content and the reduced water activity resists the growth of microorganisms. But liquid dosage forms cannot be preserved for longer duration because of growth of microorganisms. This is the very situation the role of preservatives come into the formulations.

The preparations like *Kwatha* definitely need preservatives for the longer shelf life. A study conducted on estimation of Sodium benzoate in Ayurvedic preparation *Kwatha* shows addition of preservatives 10-15 times more than the internationally accepted level for food. The maximum quantity of intake of paraben salt is 72mg for 60kg of body weight. The study conducted in market sample of *Nagaradhi kwatha* with preservatives showed that the paraben salt content is 176.01mg (if 30ml/day). The

reaction between the preservatives (Sodium benzoates and ascorbic acid) used in these formulations could generate benzene which is classified as class-I human carcinogen and responsible for various short and long term health effects.[8]

There is a need of research to study drug and preservative interaction for each Ayurvedic formulation. Addition of preservatives in increased quantity must be stopped to upgrade Ayurvedic products in the market. Standardization of formulations will be a solution for this.

6. Drug Toxicity

It is an important matter that as Ayurvedic medicines are gaining popularity and global acceptability, the number of case reports pointing at an association between the toxicity and use of Ayurveda formulations is also increasing day by day. Most of the reports deal with drug toxicity due to the constituent heavy metals (such as lead and arsenic) and a few of them deal with toxicity due to herbal ingredients(like aconite).[9]

Aushadha vyapat is very well documented in many Ayurvedic literatures. *Acaryas* have noted many reasons for the adverse reactions of a drug. Administration of drugs causes complications due to the following reasons:[10]

1. *Akala* (Inappropriate time)
2. *Alpa matra* (In less dose)
3. *Ati matra* (In excess dose)
4. *Purana* (Very old/ expired medicine)
5. *Na Ca Bhavitam* (Improperly triturated)
6. *Asamyak Samskrtam* (Improperly purified/ processed)

But in the present scenario in the commercial production of medicines proper purification of drugs are not in a proper way as it is a time consuming process and needs a large labour work. The improperly purified drugs are the main cause for the blame that the use of Ayurvedic medicines may cause organ failure. In some market available mercury containing preparations we can see mercury as such by naked eyes. Lack of regulations regarding manufacturing of herbal formulations possesses a significant global public health problem. The eminent Ayurvedic scholars were very much aware about the effect of a medicine along with their side effects. In *Caraka Samhitha* it is said that if we are not following the proper guidelines in the preparation and usage of medicines it will act as *Visha*. In contrast a *Visha* will act as medicine if purified properly and administered in proper dose in appropriate condition.[11] So it is very important to confirm the proper purification and administration of toxic drugs both plant and mineral origin. Contamination of soil by heavy metals is another problem, which is caused by human agricultural and industrial activities. Among heavy metals lead is a potential pollutant that gets easily absorbed and accumulated in different plant parts even though it is not an essential element for plants. This results presence of heavy metals in increased amount in the herbal drugs which causes drug toxicity even if the drug is not toxic. So following the standard parameters is only the way to overcome these like problems.

Measures Taken for Quality Control on Ayurvedic Medicines

Internationally several pharmacopoeias are available which provide monographs that contains parameters and standards of many herbs and some of their formulations like

1. Indian Pharmacopoeia
2. Chinese Herbal Pharmacopoeia
3. United states Herbal Pharmacopoeia
4. British Herbal Pharmacopoeia
5. British Herbal compendium
6. Japanese standards for Herbal Medicine
7. Quality standards of Indian medicinal plants
8. The Ayurvedic Pharmacopoeia of India

In India, The Ayurvedic Pharmacopoeia of India and Indian Council of Medical Research has already made standards of most of the individual drugs. But the number of groups and formulations of drugs standardized are very less. Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Govt. of India, in General guidelines for drug development of Ayurvedic formulations, provided testing parameters for different types of formulations.

We know *Rasadi pancaka* of individual drugs. But when it combines and passes through various *Samskaras* or preparation methods to make a formulation, it will have another *Rasadi pancaka*. So making the standards of each and every individual formulation using Ayurvedic and modern parameters is an essential step to produce medicines of uniform characters and quality.

Steps for Standardization

For systematic study of standardization of Ayurvedic drugs and formulations, standardization in this context can be divided into 3 steps.[12]

1. Standardization of raw drugs
2. Standardization of process or procedures followed to prepare formulations
3. Standardization of finished products

Standards of individual drugs are now available in different Pharmacopoeias. But various processes used in the pharmacies are till to date not standardized. In *Rasasastra* and *Bhaishajya kalpana* classical texts we get many different references of preparation of medicines, *Sodhana*, *Marana* and other

procedures for a same drug or formulation and each book highlights its own different procedures to make a formulation, so that the students and physicians of Ayurveda are in big confusion that which particular method they has to be adopted and which method is effective in drug processing.

The standardization of finished products includes both the classical and modern parameters which are adopted for confirming a quality of finished products. Here the basic tests mentioned in raw drug standardization shall be taken in to consideration for standardization of finished products. First classically mentioned *lakshanas* (morphology) of that finished product should be considered and confirmative test mentioned to assess quality of that particular formulation is also very essential to provide vital information in standardization of that formulation. Other modern parameters like organoleptic characters, physical constants as ash value, acid insoluble ash, water insoluble ash, specific gravity, moisture content etc. qualitative analysis and quantitative analysis by using sophisticated instruments like AAS, ICP-AES, ESCA etc., particle size assessment and structural cell shape study can be utilized for evaluation of finished products and the values are to be compared with the established standards.[13]

The following schematic diagrams (Fig.1 & Fig. 2) explain the standardization procedure followed for formulations:[14]

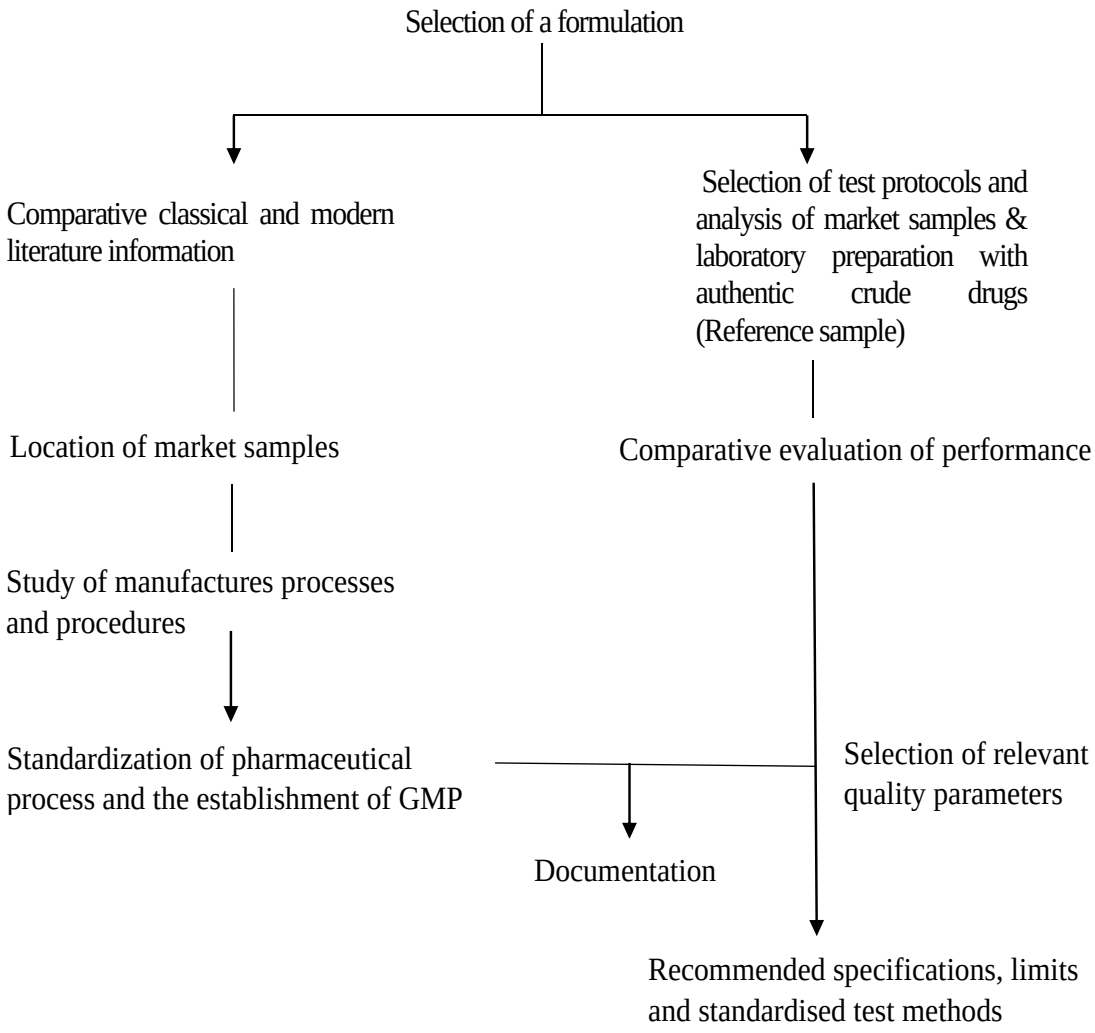

Figure 1: Steps of Standardization of herbal formulations

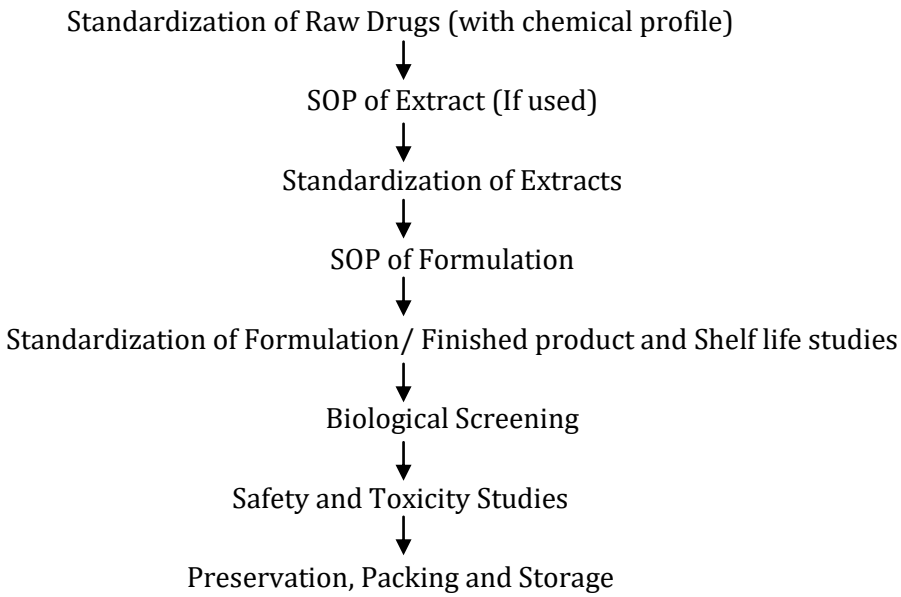

Figure 2: ASU Drug development, Standardization & Quality parameters[15]

DISCUSSION

Common people believe that Ayurvedic medicines are not having any side effects as these are made from natural raw materials especially from herbs. Any drugs modern or Ayurvedic having effects must have side effects. But following proper methods of collection, purification, preparation and storage of medicines will help to minimize these side effects in case of Ayurvedic drugs. In ancient days the processing, preparation and storage of medicines was done by the physicians and his helpers in a way which may appear quite crude in comparison to the modern age scientific parameters. But it doesn't mean that ancient wisdom was unscientific. Nowadays in commercialized production of medicinal preparations there are a lot of things that affect the quality of formulations like methods of storage and preservation of raw drugs and formulations, adulteration and substitution, variation among same formulations manufactured by different companies, amount of preservatives and improper processing of poisonous drugs and heavy metals. Also following different text books having different opinions for a same formulation may affect the therapeutic efficacy of that formulation. These problems can be reduced to an extent by developing specific guidelines for collecting, storing and preserving individual herbal drugs and strictly adhering to these in all levels of raw drug industry; monitoring of malpractices of adulteration, substitution and improper usage of preservatives; and following principles of *Vrkshayurveda* for the cultivation of medicinal plants in order to avoid contamination of medicinal plants by heavy metals through chemical fertilizers and also to yield good quality raw materials.

For the global acceptance there should be some standard parameters that can be reproduced at any time. In case of Ayurvedic formulations it is not possible as no standard parameters are available for all formulations till date. So formulating the standard parameters for each formulations is a need of hour for the growth of Ayurveda which will ensure a safe, effective and quality product. Today there are lots of advanced technologies which are easily available for assessing the quality parameters. Ayurvedic drug manufactures should make use of these technologies for making the standard quality drugs and in the further development of the existing formulations. Also the authorities should make sure that the rules and regulations in this field are strictly following at all the levels of pharmaceutical industry.

CONCLUSION

As Ayurveda medical science is getting more global attention in the present era it is necessary to maintain the reliability of this science. For this first of all the medicines should be of good quality. To provide an authentic Ayurvedic preparation in the present science age, developing pharmacopoeia standards is the only way. Through this not only we can assess the safety, efficacy and quality of the formulations but also check the malpractices by the suppliers and manufacturing units. Standardization of Ayurvedic formulations is a big challenge as clear cut guidelines have not been developed so far. Requirements and methods for quality control of finished herbal products, particularly for mixture herbal products, are far more complex than for other pharmaceuticals. The quality of such products is influenced by the quality of the raw material used. As the scientific community is concerned about the quality, clinical safety and

efficacy of herbal remedies; for availability of uniform products all over the world and also for the public health, it is necessary to make standard quality control parameters for the Ayurvedic formulations with utmost importance.

REFERENCES

1. Honwad SV. A hand book of standardization of Ayurvedic formulations. Varanasi: Chaukhambha orientalia; 2012.1p.
2. Vaidya VN, Tatiya AU, Elango A, Kukkupuni SK, Vishnuprasad CN. Need for comprehensive standardization strategies for marketed Ayurveda formulations. Journal of Ayurveda and Integrative Medicine. 2018 Oct 1; 9(4): 312-5.
3. Joshi D, Joshi G. Quality control and standardization of Ayurvedic medicines. Varanasi: Chaukhamba orientalia; 2011. 14p.
4. Kokate C K, Purohit A P, Gokhale S B. Pharmacognosy. 48th edn. Pune: Nirali Prakashan; 2013. 71p.
5. Joshi D, Joshi G. Quality control and standardization of Ayurvedic medicines. Varanasi: Chaukhamba orientalia; 2011. 7p.
6. Shinde A, Gahunge P, Rath S. The real concept of substitution in Ayurveda literature and adulteration the misleading concept of modern era. Journal of Ayurveda and Integrated Medical Sciences. 2018 Jun 30; 3(03): 149-58.
7. Reddy RC. Bhaishajya Kalpana Vijnanam. 1st ed. Varanasi, Chaukhambha Sanskrit Samsthan; 1998. 85p.
8. Reddy SM. Regulatory Perspectives of preservatives in Ayurvedic kwatha formulations. Journal of Ayurveda medical sciences. 2018 Apr-Jun; 3(2): 344-6
9. Patwardhan K, Acharya R.Ayurveda formulations: A road map to address the safety concerns. Journal of Ayurveda and integrative medicine. 2017; 8(4): 279-282
10. Caraka samhitha of Agnivesa. (Sastri K and Chaturvedi G. Comme., Hindi). Siddhi Stana. 22nd edn. Varanasi: Chaukhambha Bharati Academy; 1996.1023p.
11. Sharma R K, Bhagwan Dash. Editor. Agnivesa. Caraka Samhita Suthra stana, Vol. 1. Reprint. Varanasi: Chowkhamba Sanskrit Series Office; 2005.60p.
12. Honwad SV. A hand book of standardization of Ayurvedic formulations. Varanasi: Chaukhambha orientalia; 2012. 3p.
13. Honwad SV. A hand book of standardization of Ayurvedic formulations. Varanasi: Chaukhambha orientalia; 2012.7p.
14. Agrawal S S, Paridhavi M. Herbal drug technology. Hyderabad: Universities Press (India) Private Limited; 2007. 629p.
15. Anonymous. General guidelines for drug development of Ayurvedic formulations. Vol.1. New Delhi: Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India; 2018.8p.

Cite this article as:
Jyothi Raga P M, Vivek P, Harinarayanan C M. Need of Standardization of Ayurveda Formulations. International Journal of Ayurveda and Pharma Research. 2023;11(10):40-45.
https://doi.org/10.47070/ijapr.v11i10.2856
Source of support: Nil, Conflict of interest: None Declared

***Address for Correspondence**
Dr. Jyothi Raga P M
PG Scholar,
Department of Dravyaguna Vijnana,
Vaidyaratnam P S Varier Ayurveda College, Kottakkal.
Email: jyothiragapm@gmail.com