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REVIEW

Current Status of Herbal Drug Standards in the Indian Pharmacopoeia

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The benefits of herbal drugs were well understood way back. They have been used for the promotion of health and medical purposes – in disease conditions. It is a conventional belief that herbal drugs have no side effects, are cheaper and locally available. Among Indian systems of medicines, herbs/herbal formulations are used to a larger extent. The quality control of the marketed herbs/herbal formulations is important for acquiring optimum therapeutic benefit as well as for expanding global outreach. Therefore, herbal drug standards are important. Reference standards, the Indian Pharmacopoeia Reference Substances especially the botanical reference substances and the phytochemical reference substances are required for comparison of quality of herbal drugs. The Indian Pharmacopoeia Commission has initiated the process of providing Indian Pharmacopoeia Reference Substances to the stakeholders. Therefore, this article provides an overview of the history and the status of herbal drug standards in the current and forthcoming issues of Indian Pharmacopoeia. In Indian Pharmacopeia, efforts have been made for the harmonization of standards with international counterparts wherever possible.

Keywords: herbal drug standards; Indian Pharmacopoeia; BRS; PRS; harmonization; reference substances.

INTRODUCTION

Herbal medicines are considered as the preferred treatment option for various common ailments in almost all parts of India because of their traditional values, lesser known side effects, easy accessibility, affordability and so on. In spite of several advancements, modern medical science failed to cater to the needs of all people and deal with ever increasing diseases and disorders (Sen & Chakraborty, 2017). The people from the socio-economic weaker sections and those living in remote areas rely solely on herbal medicines for healthcare needs, which are the only accessible and affordable therapy [Hegde, 2003; World Health Organization (WHO), 2004]. In the past two decades, more emphasis has been laid on scientific evidence of safety, efficacy, identification of plant species, quantification of active constituents, methods of preparation, method validation and so on because of great economic and medicinal importance. The improvements in the methods of analysis and scientific advancements have led to the development of modern medicines from herbal sources. Worldwide almost 250 000 higher plant species exist (Christenhusz & Byng, 2016); many of these could be having their medicinal value and need science-based evidence for proving the same.

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Eighty per cent of the population in developing countries depends on traditional herbal medicines for primary healthcare solutions (Ekor, 2013; Sen, Chakraborty, De, *et al.,* 2010; WHO, 2003). Seventy per cent of the rural population in India is dependent on the traditional system of medicines (Mafuva & Marima-Matarira, 2014; Pan, Litscher, Gao, *et al.,* 2014; Pandey, Rastogi, & Rawat, 2013; Wahab, Hussain, Ahamd Md, *et al.,* 2013). India is known as the botanical garden of the world and is one of the largest producers of medicinal herbs (Seth & Sharma, 2004). As per recent literature, there is global resurgence in traditional and alternative healthcare systems resulting in world herbal trade that stands at $US120 billion and is expected to reach $US7 trillion by 2050; however, Indian share in the world trade, at present, is quite low (NMPB, 2017).

Plant-derived medicines are also important from the perspective of new drug development. Till 1970, around 100 plant-based new drugs were available in the international market and are widely used throughout the world, for example, reserpine, vinblastine, artemisinin, ginkgolides and etoposide. Herbal drugs provide major contribution to modern therapeutic drugs, for example, use of reserpine, serpentine isolated from *Rauwolfia serpentina* root in hypertension (Farnsworth & Bingel, 1977), vinblastine and vincristine, isolated from *Catharanthus roseus* for cancer treatment (Farnsworth, Blowster, Darmratoski, *et al.,* 1967), digitoxin from *Digitalis purpurea* as cardiotonic for congestive heart failure (Der Marderosian & Beutler, 2002) and quinine from cinchona bark as antimalarial (Butler, 2004). Pharmacologically proven

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constituents of *Withania somnifera, Aloe vera, Bacopa monnieri, Curcuma longa* and many more medicinal plants are being used globally. A few more examples of modern medicines obtained from herbal sources that are used in India are quinine, atropine, physostigmine, caffeine, digoxin, pilocarpine, artemisinin and so on.

India has a diversified healthcare system like Allopathic, Homoeopathic, Ayurveda, Siddha and Unani systems of medicine in practice. Keeping in view the growing evidence of plant-derived drugs in improving human health, there is a need for quality control standards of these drugs. Quality is an important attribute for determining the safety of drugs. The traditional medicines of India are widely acknowledged around the globe, and demand is increasing continuously (Sen & Chakraborty, 2017; Singh, Pandey, Sharma, *et al.,* 2014). Many reviews in the area of research, development and standardization and regulation on herbal drugs are available (Dias, Urban, & Roessner, 2012; Gupta, Prakash, & Srivastava, 2002; Prakash & Gupta, 2000, 2004; Prakash, Gupta, & Dinda, 2002; Prakash, Gupta, Kochupillai, *et al.,* 2001; Prakash, Pandey, Nirmal, *et al.,* 2013; Rastogi, Bhatia, Kushwaha, *et al.,* 2014; Sahoo, Manchikanti, & Dey, 2010). The herbal medicines are included in various national pharmacopoeias and Essential Medicines List worldwide (Sahoo, Manchikanti, & Dey, *et al.,* 2010). However, a well-compiled information on the process of standards setting of herbal drugs with reference to Indian Pharmacopoeia (IP) is not yet available. In India, many organizations are working towards standardization, education, research and development of herbal drugs such as the Ministry of AYUSH, Central Council for Research in Ayurvedic Sciences (CCRAS), CSIR-Indian Institute of Integrative Medicine and Indian Pharmacopoeia Commission (IPC) as per their expertise and facilities available. However, IPC apart from setting the standards of modern medicines in IP is also involved in setting the standards of herbs and herbal products. Some of the herbs and herbal products mentioned in IP are also used for veterinary purpose (Rastogi, Pandey, Prakash, *et al.,* 2015). Detailed guidelines for the quality of herbal drugs and their products were published in 2012 by the IPC (Guidance Manual for Compliance of Indian Pharmacopoeia, 2012). Later on, specific guidelines for monograph development of herbs and herbal products including phytopharmaceutical drugs were brought out in 2016 (*Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs*, 2016). The polyherbal formulations are not yet included in IP.

Pharmacopoeial standards

The pharmacopoeial standards provide a reliable mechanism for independent assessment of the quality of medicines. In India, different pharmacopoeias such as the Ayurvedic Pharmacopoeia of India, Homoeopathic Pharmacopoeia of India, Unani Pharmacopoeia of India, Siddha Pharmacopoeia of India and IP are official as per the Drugs and Cosmetics Act 1940. The Pharmacopoeial standards are enforced by the central, state and union territory drug regulatory authorities of India in accordance with the Drugs and Cosmetics Act 1940 and Rules 1945 thereunder as amended from time to time (Garg, 2016).

In addition to the previous texts, Indian Herbal Pharmacopoeia published by Indian Drug Manufacturers Association in collaboration with Regional Research Laboratory, Jammu, presently known as Indian Institute of Integrative Medicine, and quality standards of Indian Medicinal Plants published by Indian Council of Medical Research, New Delhi, are also available (Kumar, 2015).

HISTORY OF HERBAL DRUGS STANDARDS IN THE INDIAN PHARMACOPOEIA

The IP is a legally recognized book of standards for drugs and their formulations in India. The standards of identity, purity and strength prescribed in IP are to ensure quality of the medicines (Garg, 2016). IP is published by the IPC, Ministry of Health and Family Welfare, Government of India. Addendum/Addenda to the main version of IP is/are published from time to time to take care of urgent requirements of changes in the existing monographs and for inclusion of new monographs. The Addendum has the same authority as IP.

The origin of IP goes back to the publication of the Bengal Pharmacopoeia and General Conspectus of Medicinal Plants 1844 generally known as Bengal Pharmacopoeia. The focus of this pharmacopoeia was on indigenous drugs although it included some products imported from Europe. The first pharmacopoeia of India was published in 1868, which contained drugs official in the British Pharmacopoeia 1867 and some indigenous drugs. The Indian Pharmacopoeial List 1946 was prepared to serve as an Indian supplement to the British Pharmacopoeia 1932.

After independence, an Indian Pharmacopoeia Committee was constituted in 1948, which prepared the Pharmacopoeia of India (The Indian Pharmacopoeia) in 1955. A supplement to it was published in 1960. This pharmacopoeia contained western and also traditional drugs, and the same policy continued while preparing the Pharmacopoeia of India: The Indian Pharmacopoeia, 1966 and its 1975 supplement. In the Pharmacopoeia of India, 1985, and its Addenda, 1989 and 1991, traditional drugs were not included, as publication of a pharmacopoeia of traditional system drugs was taken up separately, and only those herbal drugs were included that had supporting definitive quality control standards (Indian Pharmacopoeia, 1996a).

In IP 1966, an initial start regarding the vegetable drugs standards was made in respect of 10 drugs that were in wide use at that time. The authentic samples of these drugs were obtained and investigated at different laboratories in the country. On the basis of the results of these investigations, the Indian Medicinal Plants Sub-Committee drew up standards of the following three drugs: Jatamanshi (*Nardostachys jatamansi*), Rasna (*Alpinia officinarum*) and Vidang (*Embelia ribes*) that were then included as monographs. Preparations of these drugs, however, had not been included in this edition as standards because of non-availability of those preparations (Indian Pharmacopoeia, 1996a). Indian Pharmacopoeia, Addendum 2005 (1996b) introduced 10 new drugs including Ashwagandha, Bacopa, Bhuiamla, Centella, Garcinia, Ginger, Kalmegh, Sallaki, Turmeric and Vasaka.

Indian Pharmacopoeia (2007a) incorporated for the first time a chapter on the general requirements of herbs

and herbal products standards and a total of 58 specific monographs, including 23 new monographs. The new monographs included were Amalaki, Amra, Arjuna, Artemisia, Bhibhitaki, Bhringraj, Coleus, Gokhru, Gudmar, Guduchi, Haritaki, Kunduru, Kutki, Lasuna, Manjistha, Maricha, Pippali Large, Pippali Small, Punarnava, Sarpagandha, Shatavari, Shati and Tulasi. Indian Pharmacopoeia, Addendum 2008 (2007b) incorporated nine new monographs, namely, Ajwain, Anantmula, Daruharidra Roots, Daruharidra Stems, Kalmegh Dry Extract, Saunf, Senna Dry Extract, Senna Tablets and Yasti Dry Extract.

Indian Pharmacopoeia (2010a) contained 89 specific monographs of herbs and herbal products and its Addendum 2012 (Indian Pharmacopoeia, 2010b) incorporated four new monographs, namely, Bhuiamla Dry Extract, Gudmar Dry Extract, Kunduru Dry Extract and Mandukaparani Dry Extract with a total figure of 93 monographs.

CURRENT STATUS OF HERBAL DRUGS STANDARDS IN IP

The seventh edition of IP (2014a) containing four volumes came into effect from 1 April 2014. Herbal

Table 1. Herbals monographs in the Indian Pharmacopoeia 2014 and Addenda 2015 and 2016

Raw herbs (A)		Herbal extracts (B)	Processed herbs/pharmaceutical aids/formulations (C)
1. Acacia	37. Ivy leaf	1. Amla juice powder	1. Arachis oil
2. Ajwain	38. Jangli haldi	2. Arjuna dry extract	2. Basil oil (Methyl Chavicol type)
3. Amalaki	39. Jatamansi	3. Ashwagandha dry extract	3. Belladonna Tincture
4. Amaltas	40. Kalmegh	4. Bassant dry extract	4. Black pepper oil
5. Amra	41. Kasni	5. Belladonna dry extract	5. Caraway oil
6. Anantmula	42. Kaunch	6. Belladonna soft extract	6. Cardamom oil
7. Arjuna	43. Kunduru	7. Bhibhitaki aqueous extract	7. Cassia oil
8. Artemisia	44. Kutki	8. Bhuiamla dry extract	8. Castor oil
9. Ashwagandha	45. Lasuna	9. Brahmi extract	9. Cinnamon Bark oil
10. Asoka	46. Lavang	10. Coleus dry extract	10. Cinnamon leaf oil
11. Asthisamhrta	47. Lodhra	11. Garcinia aqueous extract	11. Clove bud oil
12. Bakuci	48. Mandukaparni	12. Ginkgo dry extract	12. Clove leaf oil
13. Bala	49. Manjistha	13. Ginseng dry extract	13. Clove stem oil
14. Bassant	50. Maricha	14. Gudmar dry extract	14. Coconut oil
15. Belladona leaf	51. Methi	15. Gugulipid	15. Coriander oil
16. Bhibhitaki	52. Mirch	16. Haridra dry extract	16. Cumin oil
17. Bhringraj	53. Nagakesar	17. Haritaki aqueous extract	17. Dill seed oil
18. Bhuiamla	54. Neem	18. Haritaki extract	18. Eucalyptus oil
19. Birmi	55. Nirgundi	19. Ivy leaf dry extract	19. Ginkgo tablet
20. Brahmi	56. Noni	20. Kalmegh dry extract	20. Guar gum
21. Coleus	57. Pippali large	21. Kunduru dry extract	21. Gugulipid tablets
22. Daruharidra roots	58. Pippali small	22. Malt extract	22. Hydrogenated castor oil
23. Daruharidra stems	59. Punarnava	23. Mandukaparani dry extract	23. Ipecac Tincture
24. Draksha	60. Puskara	24. Opium	24. Lavender oil
25. Ergot	61. Sahajana leaf	25. Senna dry extract	25. Lemon grass oil
26. Garcinia	62. Sahajana stick	26. Sunthi extract	26. Lemon oil
27. Ginkgo leaf	63. Sarpagandha	27. Tulasi dry extract	27. Lime oil
28. Ginseng	64. Saunf	28. Valerian dry extract	28. Mentha oil
29. Gokhru	65. Senna leaf	29. Vasaka extract	29. *Mentha arvensis* oil
30. Gudmar	66. Senna pods	30. Yasti dry extract	30. Nutmeg oil
31. Guduchi	67. Shankhpushpi		31. Opium powder
32. Guggul resin	68. Shatavari		32. Papain
33. Haridra	69. Shati		33. Peppermint oil
34. Haritaki	70. Sunthi		34. Prepared ergot
35. Hingu	71. Tulasi		35. Rosemary oil
36. Ispaghula husk	72. Valerian root		36. Sarpagandha powder
	73. Vasaka		37. Sarpagandha tablets
	74. Vidanga		38. Senna tablets
	75. Vijayasara		39. Shellac
	76. Yasti		40. Starch
			41. Tea tree oil
			42. Thyme oil
			43. Tolu balsam
			44. Tragacanth

Total: 150 (A + B + C)

Source: *Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs*, 2016.

drugs standards are covered in Volume III. There is a separate chapter on general requirements – Herbs and Herbal Products. The specific monographs are mentioned in an alphabetical order. The important features with special reference to quality specifications of herbs and herbal products included a new general chapter on DNA-based authentication technique to rule out the adulterants. The general chapter on flash point determination of essential oils was also incorporated. The Addendum 2016 (Indian Pharmacopoeia, 2014c) incorporated a revised chapter on thin layer chromatography including high-performance thin layer chromatography. Some of the herbs and herbal products mentioned in IP are also used for veterinary purposes (Rastogi, Pandey, Prakash, *et al*., 2015).

Specific inclusion and exclusion criteria were observed while including the monographs of herbal drugs in IP (2014a, 2014b, 2014c; *Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs*, 2016). In brief, the herbs included should have therapeutic/prophylactic value with information of its safety profile through known history of use. They should be of public interest, commercially available with clear and defined botany apart from other inclusion criteria. Herbal drugs that are banned in India, obsolete and are not considered appropriate by the IPC and regulatory authority are excluded from IP. The status and future challenges for IP have been reviewed earlier (Prakash *et al.,* 2016). The list of monographs on herbs and herbal products in IP 2014 including its Addenda 2015 and 2016 are shown in the Table 1.

Forthcoming edition: Indian Pharmacopoeia – 2018

The manuscript of IP 2018 is in press. IP 2018 will contain additional new monographs, namely, Amarbel, Anise Oil, Belladona Dry Extract Tablet, Citronella Oil (Geraniol type), Citronella Oil (Java type), Green Coffee Bean Extract, Horse Chestnut Dry Extract, Juniper Oil, Mandarin Oil, Milk Thistle, Milk Thistle Dry Extract, Schisandra Dry Extract, Schisandra Fruit, Sweet Orange Oil and Tvak. Thus, in aggregate specific herbal drugs monographs will be 165. IP 2018 is likely to be effective from 1 January 2018. The trend of inclusion of herbal drugs and herbal formulation monographs is shown in Fig. 1.

Content of individual herbal monograph

The details are covered in *Guidance Manual for Monographs Development of Herbs and Herbal Products including Phytopharmaceutical Drugs* (2016).

Briefly, each herbal monograph should contain the following:

(1) *A title with common name:* The title of the monograph should be written using Latin binomial nomenclature, a synonym or common name followed by the name of plant part(s)/product.
(2) *A grid picture of raw herb:* A photograph of the clean part of the herb placed on a standardized grid printed on a paper provides a clear visual depiction of the herb.
(3) *Definition:* A definition of the drug usually includes the state of the drug, complete scientific name, part of the plant and other related information and wherever possible the minimum content of quantifiable constituents.
(4) *Limits of active ingredient:* Percentage of quantifiable major active constituents should be provided.
(5) *Description:* The physical appearance of the drug should be specified.
(6) *Characters:* Organoleptic characters such as colour, odour and taste should be mentioned.
(7) *Category:* Therapeutic or prophylactic category of the drug should be mentioned.
(8) *Identification:* The important *Macroscopic* and *Microscopic* characteristics are specified so as to

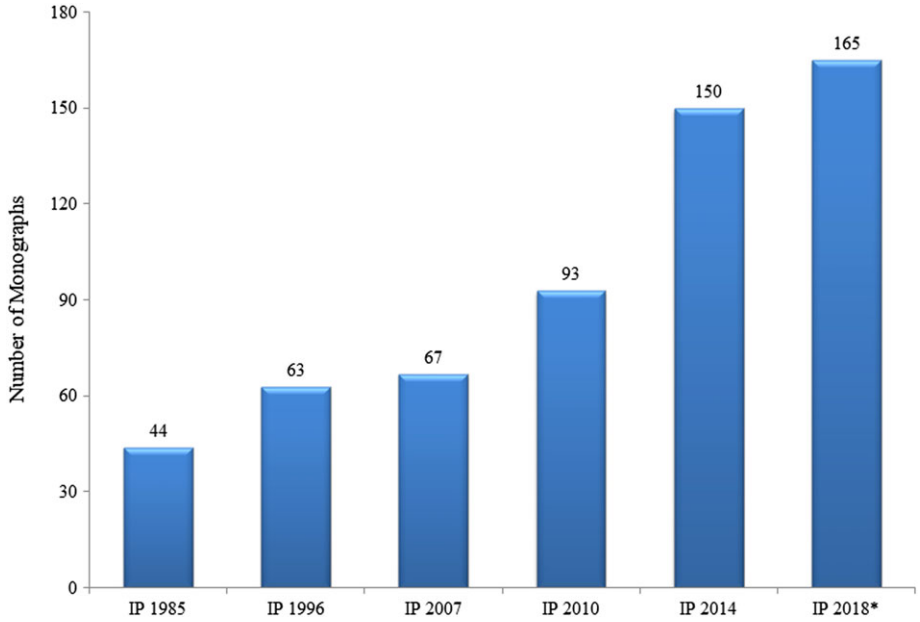

Figure 1. The trend of inclusion of herbal drugs and formulations monographs in the Indian Pharmacopoeia and its addenda. **In Press*. [Colour figure can be viewed at wileyonlinelibrary.com]

have a clear identification. Chromatographic or spectroscopic patterns referred to as 'fingerprints' may be used as standards for identification of the drugs

(9) *Chemical tests:* This serves as an important source of information and can be the appropriate standard to establish the quality of herbs.
(10) *Assay of the marker constituents:* An assay is carried out with appropriate instruments like UV–Visible spectrophotometer, liquid chromatography, gas chromatography, high performance liquid chromatography and high-performance thin layer chromatography.
(11) *Contaminants:* Some specifications peculiar to the monograph may be required. Limits of undesirable substances, occurring naturally or formed consequent to post harvest procedures, may be set and toxicity data must accompany.
(12) *Additional information*: Storage and labelling requirements need to be mentioned.

Interpretation of results must be based on the acceptance criteria for the monograph, general requirements and any other text applicable as per IP and relevant applicable rules. The decision regarding the quality of drugs can be taken based on acceptance criteria prescribed in IP.

Regulatory aspects

Standardization of herbal drugs and their formulations, stability and safety is a basic requirement for creating confidence in public about their therapeutic use. Globally, herbal drugs regulations exist in many developed countries like USA, Brazil, Australia, Canada, Germany and developing countries such as India, Indonesia and Bangladesh; however, many countries still lack a regulatory mechanism. However, the regulatory mechanisms for the manufacturing and marketing authorization are not uniform in different countries. In India, herbal medicines are regulated as per the first schedule to the Drugs and Cosmetics Act 1940 and Rules 1945 thereunder. Schedule T, Rule 157 under the Drugs and Cosmetics Rules, 1945 specifies the requirements about the good manufacturing practices for Ayurvedic, Siddha and Unani Medicines. The Central Drugs Standards Control Organization and IPC are making continuous efforts for approval and setting the standards of medicines, respectively (Kalaiselvan, Prakash, Kalaivani, *et al.,* 2014; Prakash, Pandey, Gupta *et al*., 2016).

The Central Government after consultation with the Drugs Technical Advisory Board has notified Drugs and Cosmetics Rules, 2015 to amend the Drugs and Cosmetics Rules, 1945 vide GSR 918(E) (2015) dated 30 November 2015. The rule describes the regulatory requirements for manufacturing/marketing of phytopharmaceutical drugs. The central and state drug regulatory authorities are entrusted to enforce these regulations.

National Policy on Indian Systems of Medicine and Homoeopathy – 2002 (2002) states … *a large number of units exist in large, medium, small and tiny sectors. The safety, efficacy, quality of drugs and their rational use have not been assured. Though enforcement mechanism has been envisaged in the Act, and is also in place in most of the States, implementation of the enforcement laws leaves much to be desired. There is reluctance on the part of a large number of manufacturers to adhere to good manufacturing practices. Preparation of formularies and pharmacopoeial standards have been speeded up but a lot is yet to be completed. There is no assurance whatsoever that Formularies and Pharmacopoeial standards are being followed by the Indian Systems of Medicine & Homoeopathy drug manufacturers*.

National Health Policy (2017) recognizes the need to standardize and validate Ayurvedic medicines and establish a robust and effective quality control mechanism for AYUSH drugs. The policy advocates strengthening and rationalizing the drug regulatory system, promotion of research and development in the pharmaceutical sector and building synergy and evolving a convergent approach with related sectors. The IP serves as a useful regulatory document for the Indian Drug Regulatory Authorities for the manufacture, marketing and inspection of quality of medicines including herbs and herbal products.

Stability testing of herbal drugs

Stability of herbal drugs and their formulations is an important criteria during their development process as well as after the marketing authorization. Critical systematic reviews and meta-analysis of available reports provide a reliable and rigorous method of assuring safety and efficacy of herbal drug/product. Similar to synthetic drugs in modern system of medicines, herbal products are also required to be subjected to comprehensive systematic testing in order to establish and ensure consistent therapeutic efficacy and safety throughout their shelf lives. The drug regulatory agencies across the globe such as European Medicines Agency, US Food and Drug Administration have recommended guidelines for conducting stability studies on herbal drugs and products and dossier requirement of stability data submission for product registration. The WHO (2006) has also recommended for stability studies on herbal drugs and finished herbal formulations. The stability testing of herbal drugs, challenges, regulatory compliance and perspectives has been recently reviewed (Bansal, Suthar, Kaur, *et al*., 2016). In India, for a phytopharmaceutical drug, there is a provision in Drugs and Cosmetics Rules, 1945 (notified vide GSR 918(E) (2015), Ministry of Health and Family Welfare) for requirement of stability data.

Reference standards

The herbal drugs are complex in nature consisting of several bioactive constituents. In order to assure the amount of particular active constituents in these drugs and their formulations and for quality control, appropriate reference standards are needed. The use of reference substances and reference materials for the testing of a sample has been suggested as per WHO good practices for pharmaceutical quality control laboratories (WHO, 2011). Various pharmacopoeial bodies like the US Pharmacopoeia and European Pharmacopoeia are providing reference substances to the stakeholders

Table 2. Phytochemical reference substances (PRS) available at Indian Pharmacopoeia Commission

S. No.	PRS	S. No	PRS
1	Menthone	13.	Isovanillin
2	Eugenol	14.	*R* (+) limonene
3	Quercetin	15.	Bornyl acetate
4	Linalool	16.	*trans*-Ferulic acid
5	Camphor	17.	Catechin hydrate
6	Borneol	18.	L-Carvone
7	Thymol	19.	Cinnamic aldehyde
8	*S* (−) limonene	20.	Eucalyptol
9	Rutin hydrate	21.	Caryophyllene
10	α-Pinene	22.	Isomenthone
11	Cuminaldehyde	23.	D-Carvone
12	Gallic acid		

Table 3. Botanical reference substances (BRS) available at Indian Pharmacopoeia Commission

S. No.	BRS	S. No.	BRS
1.	Amaltas	11.	Gudmar
2.	Amra	12.	Guduchi
3.	Arjuna	13.	Haridra
4.	Asthisamhrta	14.	Kaunch
5.	Bakuci	15.	Lodhra
6.	Bala	16.	Mirch
7.	Birmi	17.	Nagkesar
8.	Bibhitaki	18.	Pippali small
9.	Bhringraj	19.	Punarnava
10.	Gokhru	20.	Shankhpushpi

(Zöllner and Schwarz, 2013). Reference substances (Indian Pharmacopoeia Reference Substances) are required to fulfil the requirement of the monograph in IP. The phytochemical reference substances (PRS) are highly characterized authentic biomarker compounds used wherever available and feasible for the purpose of quality control of herbal samples. Botanical reference substance (BRS) is an authentic standard whose botanical identity and genuineness has been well established to both genus and species level. When PRS is not available, BRS serves as standard for maintaining the quality of herbal samples under examination. IPC has initiated the work for providing BRS and PRS to the stakeholders. After acquisition, a candidate reference material is verified by the IPC or by an authorized laboratory and, if found suitable on the basis of the analytical tests, is containerized, labelled, stored and distributed to the stakeholders on demand. The list of these standards is available and updated on the website of IPC (www.ipc.gov.in) from time to time. Tables 2 and 3 depict the current list of PRS and BRS, respectively.

Harmonization of standards

The standards set out in IP are harmonized with prevailing international trend and keeping in mind the Indian context. The analytical methods feasibility, consensus of experts, inputs of stakeholders on the draft monographs and an all transparent approach is adopted during the process of standards setting. WHO has identified the need for harmonization of herbal monographs, and accordingly, necessary steps are underway for developing good pharmacopoeial practices guidelines for herbal monographs, and IP is the lead pharmacopoeia (WHO, 2015).

CONCLUSIONS

The quality of herbal drugs is as important as that of modern medicines, although the isolation of active ingredient in pure form and characterization is a challenging task. The IP has taken a lead in establishing the quality standards of herbal medicines – raw herbs, herbal extracts, processed herbs and so on – based on the well defined analytical parameters as evident from the content of this review. Many of the monographs that do not exist in other pharmacopoeias in the world find a place in IP. IPC encourages the stakeholders to use the monographs not only at the national level but also at international level. The approach of harmonization will help in uniform application of standards and the duplication of efforts can be minimized. The recently notified regulatory norms for phytopharmaceuticals by the Ministry of Health and Family Welfare, Government of India, in conjunction with IP standards will help in achieving better quality control of herbal drugs released in the market, consequently increasing the access and acceptance of Indian herbal medicines to the common man across the globe. This would ensure wider use of quality herbs and herbal products to larger population with the increasing trend of globalized use of herbal medicines from regional to diverse international markets and consumers through commonly accepted standards across the globe. This will also promote the Indian herbal drug industry.

Conflict of Interest

There is no conflict of interest among the authors.

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