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Distinct Role of Pharmacognostical Study in the Drug Development and Standardization.

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ABSTRACT

Since time immemorial *Ayurveda* is dealing with health and infirmities of human beings, animals and plants through its holistic approach in the prevention and cure of diseases. The basic source of medicine is fauna and fauna of the surrounding area and well utilized in the AYUSH system. India is the richest country well known for its plant and animal species diversity. In the ASU (*Ayurveda*, *Siddha*, *Unani* and *Amchi)* system of medicine, more than 2000 plant species have been mentioned. Moreover, in traditional local health practices, more than 8000 plant species have been reported. Apart from this, in the recent era, the scientists of the various fields are more interested to study the ethno-medicine or herbal medicines in the direction of new drug development. In this process, taxonomical and pharmacognostical study provides better confirmation for identification of plant specimen. Simultaneously, drug industries are growing up in India. Nowadays, GMP (Good Manufacturing Practices) and drug standardization are became strictly mandatory factors for drug preparation. The raw drug identity, purity, and content or assay is the utmost important components of drug preparation. In this whole process, the pharmacognostical study of a raw drug plays a major role through identification of plant material based on various micro-macroscopic characters. This paper highlights the role of pharmacognosy in the development of herbo-mineral medicines.

KEYWORDS

Ayurveda, Pharmacognosy, Drug Standardization

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INTRODUCTION

History depicts that plants are having a close relationship with human beings. They are basic tools to cure n number of aliments among many indigenous communities. Traditional medicine is based on hundreds of years of belief and observations, which predate the development and spread of modern medicine[1]. Today, there is widespread interest in herbal drugs and this interest is due to the belief that these are safer, inexpensive and have no adverse effects[2]. As result plants are upgraded from fringe to mainstream use with large population seeking herbal remedies for health consequences[3]. The maximum population of the world i.e. 1.42 billion are dependents on the traditional healthcare practices for the healthy; disease-free life[4]. But, in developed countries, one of the main obstacles in the acceptance of herbal medicines is the nonexistence of scientific documentation and stringent measures of quality control. It urges a need for documentation of herbal medicines with proper identification of herbs used in the therapeutic preparation by adopting the pharmacognostical and phytochemical studies. Then it will help in the authentication and standardization of the samples and it will ultimately ensure the reproducible quality of herbal medicine along with its safety and efficacy[5]. It will boost up the acceptance of herbal medicines in the developed world[6-8].

The term pharmacognosy is derived from two Greek words, "*pharmakon*" which means drug or medicine, and "*gnosis*" which means knowledge. Moreover, the American Society of Pharmacognosy elaborates the pharmacognosy as "the study of the physical, chemical, biochemical and biological properties of drugs/drug substances of natural origin". The study of drugs from plants means its study through botany, chemistry, and pharmacology. Where, botany focuses on plant identification (taxonomy), genetics, and cultivation methods. Chemistry highlights chemical characterization with the isolation, identification, and quantification of constituents in the herbal sample. And, Pharmacology indicates the biological effects of particular chemicals of plants on cell cultures, animals and humans. From a practical perspective, pharmacognostical study includes quality control (identity, purity, and consistency) and ultimately efficacy and safety of a drug.

Standardization of herbal drugs is an essential component for ensuring the quality control of the herbal drugs[9]. “Standardization” covers all the measures taken while manufacturing process and quality control leading to a reproducible

quality[10]. Herbal drugs standardization covers basic parameters like botanical evaluation, physicochemical evaluation, pharmacological evaluation along with toxicological parameters associated with the herbal drug[11].

However, several pharmacopeia like Indian Pharmacopoeia, *The Ayurvedic Pharmacopoeia of India*, *The Unani Pharmacopoeia of India*, *The Siddha Pharmacopoeia of India*, *The Homoeopathy Pharmacopoeia of India*, *The British Pharmacopoeia*, *Chinese Herbal Pharmacopeia*, *British Herbal Pharmacopoeia*, *Japanese pharmacopeia*, *Japanese Standards for Herbal Medicine* and *United States Pharmacopoeia* has developed monographs on quality control tests for respective medicinal plants included among them[12-14]. Moreover, the Indian origin monographs like *Indian Pharmacopoeia*, *Ayurvedic Pharmacopoeia of India*, *Wealth of India* and *Ayurvedic Formulary of India* has provided the necessary information regarding various tests to be performed to determine the authenticity of the herbal crude drugs as per their standards[15]. Similarly, several international pharmacopeia have been also enlisted the monographs having quality parameters and standards of various herbs and herbal products.

The classification of herbal drugs

The herbal drugs can be defined as whole or plant parts, algae or fungi in an natural state usually in dried form but sometimes fresh and can be broadly classified as (a) Ayurveda herbal preparations: They are herbal preparations invented in India more than 4000 years ago[16-17]. (b) Chinese herbalism: It was originated in China which formed an extremely cultured system of diagnosis, identification, and treatment over the centuries. Chinese herbalism has an element of traditionally related medicine and (c) Western herbalism: The western herbalism created from Rome, Greece and then developed in North Europe along with South America. Western herbalism is considered primarily as a system of people's medicine in the existing world.

WHO guidelines for standardized herbal drugs

It is accepted worldwide that the standardization of herbal drug is wide and deep. According to WHO, the herbal drug standardization is the process involved in the Physico-chemical assessment of crude drugs that covers various aspects like selection and handling of crude drug material; safety, efficacy, and stability assessment of finished products; documentation of safety and risk of the product formulation to consumer and product promotion. This guideline for

herbal drug standardization can be stepwise summarized as primary botanical evaluation of herb which covers the sensory characters, foreign organic matter, microscopical, histological, histochemical evaluation, quantitative measurements, etc. Then Physicochemical parameters like physical and chemical identity, ash values, extractive values, moisture content, volatile oil content, quantitative estimation protocols, chromatographic fingerprints etc. Followed by various Pharmacological parameters like viz. biological activity profiles, bitterness values, swelling factor, foaming index, etc. Finally, the evaluation of toxicological parameters like pesticide residues, heavy metals etc.[18-20].

Evaluation tools for herbal drugs standardization

There are a number of tools for the standardization of herbal drugs and their formulations and they can be summarized as - (i) *Botanical evaluation***:** It includes different parameters like viz. family, biological source, chemical constituents and the various parts of plants collected like a leaf, flower, and root. This is the most important step in the development of standards for Herbal drugs. (ii) *Macroscopical evaluation***:** The colour, odour, taste, size, shape, along with some special features like touch and texture, etc. are covered under macroscopical evaluation and it is also called as morphological or organoleptic evaluation. It is a method of qualitative evaluation based on the morphological study and sensory profiles of whole drugs. Under the size, it covers length, width, and thickness of the crud material whereas, its odour and taste are sensitive criteria based on individuals' perceptions. The odour can be indistinct, distinct, aromatic, balsamic, spicy, fruity, musty, rancid, weak or strong. Whereas the taste of a raw drug can be of two types, i.e. a true taste which can be acidic, saline, bitter, alkaline or metallic; and false taste which can be categorized as mucilaginous, astringent, pungent, acrid or nauseous. (iii) *Microscopic evaluation***:** It is used for both powder and crude drugs and further categorized as qualitative and quantitative microscopy. The initial one is used to identify the prepared drug by their known histological characters through different section viz. transverse section (T.S.), longitudinal section (L.S.), radial longitudinal section (R.L.S.), or tangential longitudinal section (T.L.S.). The different staining reagents are also used to study the different constituents. However, different parameters like viz. Stomatal number (average number of stomata per sq. mm area of the epidermis); Stomatal Index (the percentage by which the number of stomata forms to the total number of epidermal

cells), Palisade Ratio (average number of palisade cells beneath each epidermal cell), Vein Islet Number (average number of vein islet per sq. mm of the leaf surface midway between the midrib and the margin), Vein Termination Number (average number of vein terminations per sq.mm of the leaf surface midway between the midrib and the margin), etc. comes under quantitative microscopy. (iv)*Chemical Evaluation***:** It is based on the chemical nature of the constituents and it involves the chemical Assays; the specific assays for different active principles were conducted by different chemical tests. And Chemical test is evaluation of specific chemical constituents which may be present in any drug to which its therapeutic activity is attributed. Whereas, Phytochemical Screening is extraction, screening, and identification of the medicinally active substances found in plants like flavonoids, alkaloids, carotenoids, tannins, antioxidants, and phenolic compounds. (v) *Physical Evaluation***:** It is an assessment of herbal drugs based on some important physical properties of active constituents. (vi)*Biological Evaluation***:** It includes the determination of the therapeutic activity of herbal drugs by using biological models of intact animals, animal preparation, microorganisms or isolated living tissue. The biological evaluation of the crude drugs can be done by bioassay; pharmacologically active substance by using biological animal models and microbial assay; especially performed with micro-organisms like bacteria and fungi for evaluation of the potency of antimicrobial, antibiotics, and antifungal drugs[21-24].

DISCUSSION

Day by day practices of substitution and adulteration are increasing due to high demand and less accessibility of natural sources in terms of unavailability of crude genuine drugs. The genuine plant material is adulterated or substituted to either increase the weight or potency of the production or to decrease its cost. Apart from this, few more reasons include poor appreciative nomenclature of plants; characteristic qualities of accent and dialects, and nonmedical literature describing the flora, etc.[25]. Adulteration and substitution of herbal drugs are becoming a major problem for the herbal drug industry. It is also creating health hazards or adverse events and leading to the declination of trust in herbal drugs. For effective quality control of herbal products modern analytical testing tools of various quality, parameters are very much essential from the very beginning i.e. the collection of raw material throughout the processing up to the

packaging of the finished product. It is a Standard Operative Procedure (SOP) of drug preparation. It has recommended that government agencies should follow a universal approach in quality herbal preparation by adopting the WHO guidelines. Thus, in the process of standardization and authentication of natural drugs pharmacognostic study is having a prime role. Most of the researches in this field have been carried out for the identification of controversial plant species and their authentication through morphological, phytochemical and physicochemical analysis. The plants mentioned in Ayurveda with unclear botanical description are generally considered as *Sandigdha Dravya* (Controversial drugs). The ancient Sanskrit *Ayurvedic* literature has described herb along with many synonyms. These synonyms more attribute to its properties and therapeutic utility rather than its morphology or botanical source. Thus, a single herb with various synonyms based on morphology, habitat, origin, and therapeutic uses, etc. by using different descriptions can attribute towards its controversy. Some of the controversial drugs are mentioned in table no.1[26,27].

Table 1 List of some controversial drugs.

S. No.	*Sanskrit* Name	Botanical sources and family	
1.	*Brahmi*	i.	*Bacopa monnieri* (L.) Pennel (Scrophulariaceae)
		i.	*Centella asiatica* (L) urban (Apiaceae)
2.	*Jeevanti*	i.	*Leptadenia reticulata* Wight and Arn. (Asclepiadaceae)
		i.	*Desmotrichum fimbriatum* Bl. Bidr (Orchiaceae)
		i.	*Cimicifuga foetida* Linn (Ranunculaceae)
3.	*Shankhapushpi*	i.	*Convolvulus pluricaulis* Choisy (Convulvulaceae),
		i.	*Evolvulus alsinoides* (Convulvulaceae),
		i.	*Canscora decussate* Schult (Gentianaceae),
		v.	*Clitorea ternatea* Linn. (Papilonaceae).
4.	*Daruharidra*	i.	*Berberis aristata* DC (Berberidaceae),
		i.	*Coscinium fenestratum* (Gaertn.) Colebr. (Menispermaceae),
5.	*Rasana*	i.	*Vanda tessellata* Loud and Loud (Orchidaceae),
		i.	*Alpinia galanga* (L.) Willd (Scitaminaceae),
		i.	*Pleuchea lanceolata* C.B.Clarke. (Compositae)
		v.	*Viscum album* (Loranthaceae),
		v.	*Withania coagulens* (Stocks) Dunal (Solanaceae),
		i.	*Aristolochia indica* L.(Aristolochiaceae)
		i.	*Inula racemosa* Hook.f. (Asteraceae)
		i.	*Rauwolfia serpentine* (L.) Benth. ex Kurz (Apocynaceae),
		x.	*Lochnera rosea* (Apocynaceae)
		x.	*Enicostemma littorale* Blume (*E. littorale*) (Gentianaceae)
6.	*Nagakeshara*	i.	*Mesua ferrea* L.(Clusiaceae)
		i.	*Ochrocarpus longifolius* (Clusiaceae)
		i.	*Dillenia pentagyna* Roxb. (Dilleniaceae)
7.	*Twaka*	i.	*Cinnamomum tamala* Nees & Eberm (Lauraceae)
		i.	*Cinnamomum zeylanicum* Blume (Lauraceae)
		i.	*Cinnamomum cassia* Blume(Lauraceae)
8.	*Amaravela*	i.	*Cascutta reflexa* Roxb. (Convolvulaceae),
		i.	*Cassyatha filiformis* Linn. (Lauraceae).

9.	*Pashanabheda*	i.	*Aerva javanica* Juss. (Amarantaceae)
		i.	*Ammania baccifera* Linn. (Lythraceae)
		i.	*Bergenia ligulata* Wall (Saxifragaceae)
		v.	*Bryophyllum pinnatum* (Lam.)Kurz. (Crassulaceae)
		v.	*Coleus aromaticus* Benth. (Lamiaceae)
		i.	*Rotula aquatica* Lour.(Boraginaceae)
		i.	*Bridelia montana* (Roxb.) Willd. (Euphorbiaceae)
		i.	*Homania riparia* (Euphorbiaceae)
		x.	*Ocimum basillicum* L.(Lamiaceae)
10.	*Talishpatra*	i.	*Abies webbiana* Lindl.(Pinaceae)
		i.	*Taxus baccata* Linn.(Pinaceae)
		i.	*Rhododendron anthopogon* D. Don.(Ericaceae)

Apart from this, adulteration is another issue which can be resolved by cause of controversy pharmacognostical study. The practice of substituting original crude drugs partially or wholly with its replica is adulteration. However, adulterant is either devoid of or inferior in chemical and therapeutic properties as compared to the original drug. The adulteration is intentional, accidental and or indirect adulteration. Most of the time adulteration is done intentionally to achieve commercial benefits[28]. Few common adulterants are mentioned in table no. 2[29,30].

Table 2 Examples of few commonly used adulterants.

S. No.	*Sanskrit* Name	Scientific Name	Adulterants
1.	*Mussabara*	*Aloe barbadensis* Mill.	Black catechu (*Acacia catechu* (L.f.) Willd.)
2.	*Nagkeshara*	*Mesua ferrea* L.	Buds of *Mammea suriga* (Buch.- Ham. ex Roxb.) Kosterm. And *Calophyllum inophyllum* Linn.
3.	*Punarnava*	*Boerhavia diffusa* Linn.	*Trianthema portulachastrum* Linn.
4.	*Sthula Ela*	*Amomum subulatum* Roxb.	*Heracleum rigens* Wallichis
5.	*Vacha*	*Acorus calamus* Linn.	*Alpinia officinarum* Hance. *Alpinia galangal* (L.) Sw.
6.	*Vasa*	*Adhatoda vasica* Nees.	*Ailanthus excels* Linn.
7.	*Guggulu*	*Commiphora wightii* (Arnott) Bhandari	Gum resin of *Boswellia serrata* Triana & Planch., *Hymenodictyon excelsum* (Roxb.) Wall.
8.	*Bola*	*Commiphora myrrha* (Nees) Engl.	Gum of *Commiphora wightii* (Arnott) Bhandari
9.	*Kutaja*	*Holarrhena antidysenterica* Wall.	*Wrightia tinctoria* R.Br. *Wrightia tomentosa* Roem. & Schult.
10.	*Ashoka*	*Saraca asoca* (Roxb.)Willd.	*Polyalthia longifolia* (Sonn.) Thwaites

Similarly, replacement of equivalent drugs instead of original drugs based on its similar pharmacological actions and therapeutic uses as a substitute is another major issue addressed through pharmacognostical study. Certainly, *Abhava Pratinidhi Dravya* has been already mentioned in Ayurveda for substitution and its few examples are mentioned in table no.3[31].

Table - 3: Examples of some substitute drugs (herbs) mentioned in *Bhavaprakasha Nighantu*.

S. No.	Main Drugs		Substitute drugs	
	***Sanskrit* Name**	**Botanical name**	***Sanskrit* name**	**Botanical name**
1.	*Chitraka*	*Plumbago zeylanicum* Linn.	*Danti*	*Baliospermum montanum* Muell
2.	*Dhanavyasa*	*Alhagi camerlorum* Fisch.	*Duralabha*	*Fagonia Arabica* Linn.
3.	*Tagara*	*Valeriana wallichii* DC.	*Kushtha*	*Saussurea lappa* C B Clarke
4.	*Murva*	*Marsedenia tenacissima* (Roxb.) Wight et Arn.	*Jhingini*	*Odina woodier* Roxb.
5.	*Himsra*	*Capparis sepiaria*	*Maankanda*	*Alocasia indica* (Roxb.) Schott
6.	*Lakshmana*	*Solanum xanthocarpum Schrad.* or *Ipomoea sepiara* Koenig	*Neelakanthashikha (Mayurshikha)*	*Adiantum caudatum* Linn. *or Celiosia cristata* Linn. ex Roxb
7.	*Bakula*	*Mimusops elengi* Linn.	*Kalhaar (Rakta Kumuda)*	*Nelumbo speciosum* Willd. / *Nelumbium rubra* Roxb.
8.	*Utpala*	*Nymphea pubescens* Willd. *Nymphea stellata* Will.	*Pankaja*	*Nelumbo speciosum* Willd/ *Nelumbo nucifera* Willd
9.	*Neel Utpala*	*Nymphea stellata* Willd/ *Nymphea Nouchali* Burm.f.	*Kumuda*	*Nymphea alba/ N.rubra* Roxb.ex Andrews */N.edulis*DC
10.	*Jati Pushpa*	*Myristica fragrans* Houtt.	*Lavanga*	*Syzygium aromaticum* (Linn) Merr. & L.M.Perry
11.	*Arka Payasa (Dugdha)*	*Calotropis gigantean* (Linn) R.Br. ex Ait	*Arka Patra Swarasa*	*Calotropis gigantean* (Linn) R.Br. ex Ait
12.	*Poushkara*	*Inula racemosa* Hook.f	*Kushtha*	*Saussurea lappa* C.B. Clarke
13.	*Langali*	*Gloriosa superb* Linn.	*Kushtha*	*Saussurea lappa* C.B. Clarke
14.	*Sthouneyaka*	*Clerodendron infortunatum* L	*Kushtha*	*Saussurea lappa* C.B. Clarke
15.	*Chavika*	*Piper chaba* Hunter	*Pippali Mula*	*Piper longum* Linn.
16.	*Gaja-Pippali*	*Scindapsus officinalis* Schott	*Pippali Mula*	*Piper longum* Linn.
17.	*Somraji (Bakuchi)*	*Psoralea corylifolia* Linn.	*Prapunnad Phala (Chakramarda)*	*Cassia tora* Linn.
18.	*Daru-nisha (Daruharidra)*	*Berberis aristata* DC	*Nisha (Haridra)*	*Curcuma longa* Linn.
19.	*Rasanjana*	*Berberis aristata* DC	*Darvi*	*Berberis aristata* D C
20.	*Talispatra*	*Abbies webbiana* Linn.	*Swarnataali*	Not yet identified
21.	*Bharangi*	*Clerodendrum serratum* Spreng	*Kantakari Mula*	*Solanum xanthocarpum* Schrad & Wendl
22.	*Madhuyashti*	*Glycrrhiza glabra* Linn.	*Dhataki*	*Woodfordia floribunda* Salisb
23.	*Meda*	*Polygonatum cirrifoluim* Linn.	*Vari (Shatavari)*	*Asparagus racemosus* Willd.
24.	*Mahameda*	*Polygonatum* verticillatum (Linn.) All.	*Vari (Shatavari)*	*Asparagus racemosus* Willd.
25.	*Jeevaka*	*Microstylis wallichi* Linn.	*Vidarikanda*	*Pueraria tuberosa*DC or *Ipomoea Digitata* Linn.
26.	*Rishabhaka*	*Microstylis muscifera* Ridley	*Vidarikanda*	*Pueraria tuberose* DC or *Ipomoea Digitata* Linn.
27.	*Kakoli*	*Fritillaria roylei* Hook.	*Ashwagandha*	*Withania somnifera* Dunal
28.	*Ksheerakakoli*	*Liluim polyphyllum* D.Don.	*Ashwagandha*	*Withania somnifera*
29.	*Riddhi*	*Habenaria edgeworthii* Hook.f. ex Collett	*Varahikanda*	*Dioscorea bulbifera* Linn.
30.	*Vriddhi*	*Habenaria latilabris* (Lindl.) Hook.f.	*Varahikanda*	*Dioscorea bulbifera* Linn.
31.	*Varahi kanda*	*Dioscorea bulbifera* Linn	*Charmakaralu*	*Tacca aspera* Roxb.
32.	*Bhallataka*	*Semecarpus anacarduim* Linn. f.	*Chitraka*	*Plumbago zeylanica* Linn.

Furthermore, controversy about any plant is mainly due to its polynomial system of classification in classical texts. The nomenclature and morphology (*Naama-Roopa*) of drugs are very clearly mentioned in *Samhita* and controversy mainly found due to basonyms (*Nirukti*) and synonyms (*Paryaya*) given by other *Nighantu to a particular plant*. No doubt, the use of substitute herbs is the need of time as more than 300 medicinal plants becoming red-listed and in that case, substitution is based on pharmacological activity rather than morphology or Phyto-constituents. The adulteration is malpractice but it is not merely done intentionally but sometimes it happens accidentally during collection and trade of plant material. Though, as per the classical text of *Ayurveda*, it is quite difficult to trace out the authentic botanical source of medicinal plant hence it can be fixed by adopting integrated research on its pharmacognostical study, phytochemical analysis, and pharmacological study so that plants having optimum potency for described activities can be used in drug preparation.

CONCLUSION

The field of herbal drug formulations are vast and deep. However, standardization of herbal medicines is an essential measure to ascertain their quality and purity through active principles. While developing an herbal drug formulation, one must have a crucial knowledge about standardized parameters based on organoleptic characters, Phyto-constituents and pharmacological action. In this process, Pharmacognostical studies play a very important role by ensuring the proper identification of raw drug/ drug material derived from specific plant species as per the laydown standardization parameters. It aids in anticipation of controversy, adulteration, and substitution of the desired herb. Thus, it ensures the reproducible quality of herbal products along with the safety and efficacy of herbal therapeutic preparations.

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