

Review article

Indian Herbal Drug Industry: Prospects and Current Scenario

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Abstract

Plants are knowingly or unknowingly helping the living beings since the beginning of civilization. Although new and new diseases are getting discovered day by day, creator had provided us with most of the cure in the form of medicinal plants. Herbal drug Industry is undergoing a major change with respect to domestic and global requirements. Nutraceuticals is the fastest growing herbal components due to increase in day to day lifestyle concern among global population. Along with the increased global and domestic essentiality of evidence based reports on safety, efficacy and kinetics of herbal products, scientific technicality and involvement of trained human resource should be promoted in the site of herbal drug manufacturing. Efforts of government's ministry should be expanded in foreign and internal promotion of herbal formulation, exchange of foreign scholars and students in university providing AYUSH education. Harmonization of global regulatory requirements will provide a flawless dealing among manufacturing and exported countries regarding herbal products.

Keywords: Drug industry, Herbal drugs, AYUSH, Nutraceuticals

Introduction

Historically, Natural Products are the key subjects in drug discovery processes providing special interest towards cancer and infectious disease, also in other medical conditions including cardiovascular diseases and Multiple sclerosis. These NP's are optimized structurally with due course of time to regulate the Endogenous physiological defense system and exogenous interaction with harmful organisms resulting greater significance in treating cancer and other infectious disease. India's medicinal system comprises of Ayurveda, Siddha, Unani and Homeopathy consuming about 6000-7000 medicinal plant species, nearly about 35-40% of the total medicinal plant population. [1]

Uses of natural plant products, their extracts and extracted compounds in trading purposes are increasing at Industrial level in current time. This increased trend of

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trading has assisted in economical growth and poverty management in several developing countries [2]. In contrast, although richness in the biodiversity, areas like Hindu kush –Himalaya region, socio-economic growth is very poor due to several biophysical and demographical challenges [3]. Literature Review suggested regarding several plant extracts to be more effective than the synthetic one with limited or no side effect. Interestingly there is very little literature available regarding the cause validation and quantification of their biological activity [4].

In India, Around 270 million people extracts their livelihood though non timber plant products, medicinal and aromatic plants [5]. As a result the economic growth of these particular communities directly depends on available diversity of natural resources and their sustainable utilization through enterprise development and industrial procurement [6-8]. Natural plant products have a significant impact on countries foreign exchange earnings through export of raw material and Industrial herbal products, formulations etc. Several Plants and their formulated products has a tremendous demand in developed foreign market exempling Opium poppy, tropane alkaloid-bearing plants, sapogenin bearing yams, senna, cinchona etc. India estimated about 860 billion worth export of herbal raw material and formulated drugs to various developed countries [2].

Table 1:- Medicinal plants with prioritize commercial value [9]

Sl. No	Plant	Common Name
1	<i>Plantago ovata</i>	Isabgol
2	<i>Bacopa manner</i>	Brahmi
3	<i>Centella asiatica</i>	Mandukaparni
4	<i>Withania somnifera</i>	Ashwagandha
5	<i>Andrographis paniculata</i>	Kalmegh
6	<i>Swertia chirata</i>	Chirata
7	<i>Tinospora cordifolia</i>	Guduchi
8	<i>Emblica officinalis</i>	Amla
9	<i>Commiphora wightii</i>	Guggul
10	<i>Phyllanthus amarus</i>	Bhumyamalaki
11	<i>Podophyllum</i>	Papra
12	<i>Asparagus racemosus</i>	Shatavari
13	<i>Picrorhiza kurroa</i>	Kutki
14	<i>Streblus asper</i>	Shakhotaka

Methods

For the present review Herbal drug Industry, Commercialization, Controversies are the key words. Information's on current scenario of Indian herbal industry are compiled from Pubmed, Google Scholar, Library genesis, ABIM, AYUSH Ministry official portals etc. Discussions were divided into three main topics based on current Indian Industrial perspective on commercialization and regulations aspect.

Result and discussion

Current Scenario of Herbal Industry

Herbal medicine trend in most of the European and non European countries became popular with WHO traditional medicine strategy 2002-05 and with the development of their own documentation format and their safety concerns. Indian herbal medicine market is 50 billion rupees with 14% annual growth. According to WHO financial report Global herbal market in 2050 will reach up to 5 trillion Indian rupees. Prior herbal market for Indian raw material and products are EU, USA, Canada, Australia, Singapore, and Japan while Brazil, Argentina, Mexico, China and Indonesia are the newly growing market with tremendous possibility[2]. With the increase in pollution and global warming, global population is bending towards the herbal medicine and cosmeceuticals. Simultaneously Global and domestic manufacturer's interest is also increasing against the bulky demands from the populations and also engaged themselves in exhaustive promotion and incremented supplement of the herbal products towards both developed and developing countries. [2]

EXIM study reveals contribution of total of 880 medicinal and aromatic plants in National trade, out of these 48 Med. Plants were exported and about 42 med. Species were imported. Ministry of Environment and forests, Government of India also reported about the availability of more than 8000 medicinal and aromatic plant, out of that 70% grows in the eastern and western Ghats. In 1997 The Export-Import Bank of India reported the trade of medicinal plant as about 5.5 billion and now it is growing sharp exponentially[2,3].

In recent report of World Bank, They complimented two Indian states Madhya Pradesh and Assam on appraisable marketing of medicinal plant related product within sustainability Limit [2]. It is of great worrying that, India is in the backyard regarding the patent on plant based extracts, formulations and other products. Although India is very rich in medico-diversity, its International export is comparatively very concentrated. Market Expansion is possible only through appropriate growing and development of medicinal species, standardization of extracts with high quality specification [2]. According to Indian Brand equity Foundation (IBEF) survey, estimated valuation of Indian domestic pharmaceutical

industry was \$26 billion which was expected to increase at a growing rate of 20% resulting in expected evaluation of \$50 billion in 2020. There are more than 200 manufacturing company in India serving about 130 billions of people. India’s participation in the global generic drug market was expected to be 36% in 2016-17[2]. Statistics from Pharmexcil suggests that, major portion of Indian medicinal export consists of bulk drugs and formulations to the developed countries. During the year 2013-14, Formulation alone contributed 72% to the total herbal export, which was merely about \$11 billion [2-3].

According to the Ministry of AYUSH, Exports of all AYUSH components and herbal Products has seen a 27% growth during 2021 as compared to the previous financial year. In contrast, Imports grew about 28% during the same financial year [9]. Ministry of AYUSH also informed about export of AYUSH and herbal products in the financial year 2020-21 to be as \$539.57million as compared to \$425.80 million in 2019-20. Among the states Gujarat came out as the highest exporter of AYUSH and herbal components in 2020-21 with a 32.3% growth than the 2019-20(\$189.59 million) resulting in an escalated exporting value of \$246.78 million. Maharashtra came second with \$71.82 million export growing at a 14.1% rate as compared to \$62.93 million in 2019-20. Rajasthan with third largest export of \$55.19 million with a growing rate of 61.5% as compared to the previous year’s export around \$34.17 million [10].

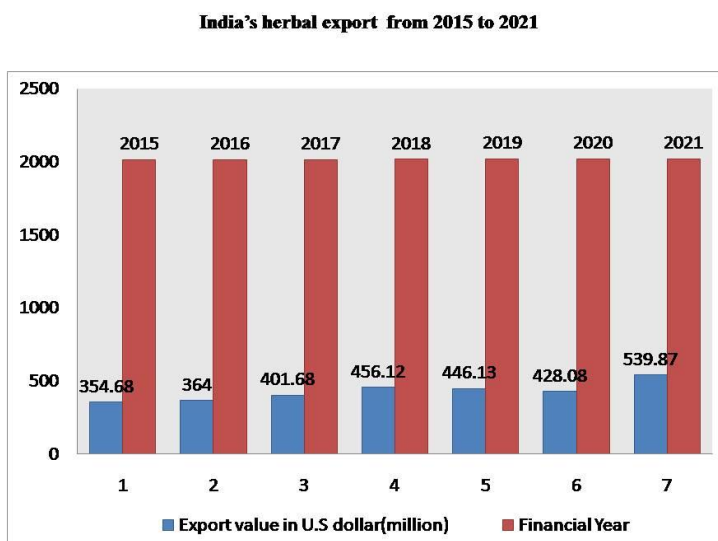


Figure 1 Herbal Export of India from 2015-21[11]

Table 2:- Popular Herbal Industry in India

Sl.No	Name of Company
1	Ansar Drug Laboratories, Surat
2	Acis Laboratories
3	Amil Pharmaceuticals, New Delhi
4	Allen Laboratories, Kolkata
5	Bharti Rasanagar, Kolkata
6	Dabur India Limited, Ghaziabad
7	Dattatraya Krishan Sandu Bros, Mumbai
8	Herbals Pvt.Ltd, Patna
9	Herbo-med(P) Ltd.Kolkata
10	The Himalaya Drug Co,Bangalore
11	Indian Herb and research supply Co,Saharanpur
12	J&J Dechane Laboratories Pvt. Ltd, Hyderabad
13	Madona Pharmaceutical Research Pvt.Ltd., Kolkata
14	Kruzer Herbals, New Delhi
15	Silpachem, Indore
16	Hamdard (Wakf) Laboratories, New Delhi
17	Zandu Pharmaceutical Works Ltd., Mumbai
18	Badyanath Ayurveda Bhavan, Jhansi
19	Charak Pharmaceuticals, Mumbai
20	Patanjali Ayurved Ltd.,Uttarakhand

The Associated Chambers of Commerce and Industry of India (ASSOCHAM) estimated a probable market size of Herbal Industry to be of 15000 crores in 2015 and expected to grow at a annual growth rate of 20%. ASSOCHAM also estimated India's Potential to grow and collect raw stock of around \$300 billion and may collect around \$150 billion with herbal value added products [12].

Currently more than 3000 formulations and 1000 single herbal drugs are registered in the drug registry. India has more than 25 large scale manufacturers, but none of them follows the standardization program through bioactive marker to link and confirm the therapeutic activity of the formulized plant and plant materials. In India, Several Institutes in different demographic location are carrying out various researches concerning medicinal plants. Trending, authenticated and

commercializable outcomes are extracted by the industries with due permission of the researchers and manufactured and marketed by the Involving Industry [12-13].

Table 3:- Research and manufacturing organization related to Medicinal Plants in India [13]

Name	City
CCRAS(Central council for Research in ayurveda and Siddha	New Delhi
RRL(Regional Research Laboratory)(CSIR)	Jammu-Tawi
NBRI(National Botanical Research Instituite)(CSIR)	Lucknow
Bhavan;s SPARC	Mumbai
National Institute of Ayurveda	Jaipur
Banaras Hindu University	Varanasi
CIMAP(Central Institute for Medicinal and Aromatic Plants)	Lucknow
ICMR(Indian council of Medical research_)	New Delhi
PERDCentre(Pharmaceutical Education and research Development)	Ahmedabad
CCRUM(Central Council for Research in Unani medicine)	New Delhi
IHMMR(Indian Institute of History of Medicine and Medical Research)	New Delhi
Zandu Foundation	Mumbai
Pharmexcil	Hyderabad
Chemexcil	Mumbai
CDRI(Centrral Drug Research Instituite)(CSIR)	Lucknow
National Chemical laboratory	Pune
NPRC(Nicholas Piramal Research center)	Mumbai

Industrial Perspective of Herbal Drug's Commercialization and regulation

As previously discussed India's herbal export is primarily consists of formulated finished products along with plant extracts. Although rich in herbo-diversity global export of India is only about 1% [14]. Surveys accessed the reasons of being backbenchers in the herbal export as the constraints concerning regulation, production and commercialization of ethno medicinal or traditional drugs.

Sahoo Niharika et.al reported constraints concerning Indian Herbal Industries as-

i. Commercialization Constraints:-

The most common Constraints faced by the Indian herbal Industry is to achieve the the regulatory compliance of the exporting countries towards herbal materials. Individualized regional GMP standard, differential registration requirements are the most important hindrance for the Indian manufacturer and exporters [14-15].

ii. Country Specific Regulatory Requirements:-

Different approval requirements and unpleasant prolongation of application review processes are also one of the serious obstacles in the export of herbal drugs. Comparative analysis by Sahoo Niharika et.al revealed vast differences in country specific application requirements and approval procedures.

In India, According to Drug and Cosmetic Act, 1940(DCA), Domestic manufacturers don't need to provide any safety and efficacy data in manufacturing traditional herbal medicines under traditional medicinal system of Ayurveda, Siddha and Unani [14].

In USA, majority of Indian exports are approved and marketed under dietary supplements following Health and Education Act of 1994. It does not require any safety and efficacy data prior to marketing approval [14]. In contrast, Herbal Marketing authorization in EU (European Union) requires traditional bibliographic proof and safety and efficacy data. Traditional Herbal Medicinal Product Directive (2004/ 24/EC) suggested the requirements of all the manufacturing process, pharmacological screening results in case of single and combinatorial herbal products [16]. According to Directive 2004/24/EC, market approval of herbal products in EU required a minimum of 15 years of marketing history in the non EU countries [14-15]. Vitamin and mineral combinational product with herbal preparation is allowed only if the supplements provide synergistic action towards the herbal therapeutics. Furthermore, specifications regarding preparation, quality control of herbal preparation and description of each and every vitamin and minerals are mandatory for marketing application in EU nations [14].

According to Indian industrial perspective, Herbal medicines are not getting proper appreciation due to their marketing status as supplements, not as herbal medicine. Also, Indian domestic herbal standards don't match with most of the exporting countries. Variation in the Pharmacopoeial standards such as different permissible limits for pesticides, heavy metals, microbial contamination for herbal medicine for different country and domestic level increases the cost of manufacturing and raises insecurity of the export process[14-15].

iii. Limited market

Survey suggested the limitation of global market as one of the major obstacle for Indian herbal Industrial exporters. Indian companies suggested an extensive

promotion of Indian herbal medicines in the foreign countries with the exhibition and trade fair arrangement [14-15].

Govt. of India has initiated foreign exhibition and exchange program for scholars and provisional technical and academical support to the foreign universities and colleges to boost the Ayush education in global platform [15]. Indo-US Collaborative Organization, Centre for Research on Indian systems of Medicine in Natural Centre for Natural Product Research, University of Mississippi was established to promote scientific validation and transmission of ASU medicine based information, which ultimately going to help in global acceptance of India based herbal medicines[17].

iv. Issues with standardization of raw materials

Authentication and standardization of raw material and formulated herbal products is one of the questionable aspects of concern towards Indian Herbal Industrial manufacturer. Department of Ayush informed regarding the use of about 600 medicinal plants, 50 animal derivatized products in ethnomedicinal ayurvedic preparations [14].

Sahoo Niharika *et.al* surveyed and reported that, about 50% of Indian herbal industries are facing problems regarding authentication and collection of raw materials. 36% of the companies consider qualitative effect of raw material adulteration as very common in herbal preparation. It also suggested adulteration, substitution, heavy metal, microbial and micotoxin contamination as major hindrance in standard quality maintenance of herbal drugs since collection to manufacturing. As, markers are very relevant mode of identification and standardization, only about 44% of the industries conducts chemical marker based identification and standardization in reputed laboratories[14,18-27].

Survey also suggested that only about 10% of the herbal Industry has its own research and development units as most of the Indian industries are small to medium scale enterprise. Due to lack of instrumentation and human resource facility they primarily based on traditional chemical and phytochemical standardization method for both formulation and raw materials [14].

There is also an urgent need of third party testing laboratories in or outside India for quality testing of both domestic and exported products [14-15].

v. Lack of regulatory guidelines

Regulation of quality is directly depends on quality control processes, good agricultural and collection practice and good storage practice. Although survey suggested the guidelines as impractical due to insufficient awareness and education among cultivators and associated high cost [14, 28-29]. Majority of the surveyed Industry suggested implementation of proper standard documentation process and guidelines regarding quality control and quality assurance process [14].As most of the herbal medicinal products are sold as Over the Counter drugs (OTC) Physician

influence is very less in promotion, rather than that advertisement and customer reach are the major conditions for fruitful market occupation [14].

Regarding the clinical trials of herbal medicine, 4th amendment of Drug and cosmetic act and rule, 2008 classifies ASU medicine into 4 categories which suggests the extent of prescribed trials requirements for marketing approval [14, 22]. According to DCA section 3(a), records on safety and efficacy (clinical evidence) data is not required for aqueous extract based medicine in specific indications for domestic use. In contrast, For Proprietary Indian ethnomedinal based, ASU and hydroalcoholic extract based drugs, clinical safety and efficacy data is compulsory for marketing approval. Medication based on aqueous extract should also be studied clinically for new indications [14, 29].

Compliance towards GMP is also one of the major drawbacks in Indian Herbal Drug Manufacturer. A countable amount of Manufacturer/Exporter follows improper DCA based GMP guidelines which ultimately result in qualitative product deterioration[14]. Field Survey Reported regarding dissimilar interpretation of DCA by SFDA, which results in permission of manufacture/marketing of one formulation in one state which has a manufacturing prohibition in another state [14]. Thus, Industrial Survey suggested development of a universally accepted dossier submission and drug registration process for faster and smoother approval [14].

According to IP 2007, minimal mentioning of a herbal preparation doesn't specifies the formulation as a approved drug. To be manufactured or marketed as IP grade, a drug license is mandatory for herbal Industries. Specific IP graded equipment is required for the manufacture of an IP grade substance. In India, most of the herbal Industries are small or midsized manufactures, thus it is not economical for them to establish a dedicated infrastructure facility for country / Pharmacopoeia specific Herbal standards. So, Indian herbal Industries suggested harmonization among Pharmacopoeias to perform a universal manufacturing process, clinical trials for the same herbal preparation exporting to different countries [14, 29].

Controversies Concerning Drug Industries

Common synonyms

Common Homonyms creates confusion in Specific identification of medicinal Plants [30]. For Example:-

Synonym	Drug	Latin Name	Synonym in practice
Ananta	Sariba	<i>Hemidismus indicus</i>	Hemidismus indicus
	Ahnimanda	<i>Premma integrifolia</i>	
	Durva	<i>Cynadon dactylon</i>	
	Bahula	<i>Anthem sowa</i>	

Lack of correlated opinion

Ancient literature such as Samhita, Nighartus suggests opinions and commentaries on characteristics and properties of medicinal plants and formulations. They were generally described in Sanskrit. Due to language deviation, opinion correlation or extinction of plant, confusion arises among scientist and regionalist regarding the mentioned plant species [31, 32].

Rise up substitutes

Increase in the use of substitutes due to intentional or unavailability of the official drug results in quality degradation and improper authentication [33,34].

Rise up adulterations

Increase in the index of adulteration w.r.t. the morphological appearance (color, shape, size) but varies in their Pharmacological activity, causes confusions regarding the standard of herbal drugs. For Example:-

Sanskrit Name	Latin Name	Adultrant/Substitute
Krisnajeeraka	<i>Carum carvi</i>	<i>Nigella sativa</i>
Katuki	<i>Picrorrhiza kurrora</i>	<i>Getiana kuroo</i> [34]

Lack of quality control

Control of quality is one of the important measures to be taken to detect the presence of adultrants, substitutes and toxic compounds. Incomplete and country specific deviation of quality maintenance causes confusion among herbal industries [34].

Lack of standardization

General standardization methods can be followed in prescribing Metallic salts, fixed oils, volatile oil containing single or multi drug formulation. But this doesn't give information regarding standardization of vegetable drugs rising issues regarding identification of vegetable composition in the formulation [30].

Suggested Measures

Ancient literature suggests the necessacity of quality products for clinical application. So, quality aspect regarding nature, place of growth, Collection time of the year, mode of collection, method of preservation should be documented in a standard acceptable format [30-35].

Neutraceuticals are one of the rapid growing sectors of herbal drug industry. Neutraceutical Industries primarily manufacture the components under functional foods, dietary supplements and herbal/organic products [36]. Survey states the

CAGR of Functional food and beverages, Dietary supplements and herbal products/organic compounds are 18%, 19.5%, 11.6% in current circumstances [37]. Indian manufactured nutraceuticals are regulated under Indian Food safety standard Act, 2006. The main objectives of the Act are:-

- i) Introduction of a common statute relating to food components
- ii) Development of scientific method of food processing [37-38].

Table:4 - Market approved nutraceutical product [39]

Product Name	Product Category	Composition	Manufacturer
Calciorol D-3	Calcium supplement	Calcium and vitamins	Cadilla healthcare limited, Ahmedabad, India
GRD[23-25]	Nutritional supplement	Proteins, vitamins, minerals and carbohydrates	Zybus Cadila Ltd. Ahmedabad, India
Proteinex®	Protein supplement	Predigested proteins, vitamins, minerals and carbohydrates	Pfizer Ltd., Mumbai, India
Coral calcium	Calcium supplement	Calcium and trace of minerals	Nature's answer, Hauppauge, NY, USA
Chyawanprash	Immune booster	Amla, ashwagandha, pippali	Daburindia ltd.
Omega woman	Immune supplement	Antioxidants, vitamins and phytochemicals (e.g. Lycopene and resveratrol)	Wassen, Surrey, U.K.
Celestial Healthtone	Immune booster	Dry fruit extract	Celestial Biolabs Limited
Amiriprash (Gold)	Good immunomodulator	Chyawanprash Avaleha, Swarnabhasma and RasSindur	UapPharma Pvt. Ltd.

Future Prospects

For a fruitful and productive future, guidelines, regulations, laws are to be developed regarding the unification of all states licensing requirements in the

country and also to develop an advisory authority to provide guidance regarding preparatory aspect, clinical trials and application procedures [14].

Several surveys suggested some major changes towards functioning of Indian herbal industries and Ayush ministry of India.

- Providing emphasis towards promotion of technical education under AYUSH Curriculum.
- Foreign promotion of Indian herbal medicine system.
- Universal and understandable quality control guideline.
- Monographs and reference standard development for marker based analysis and standardization of marketable herbal products.
- Identification of suitable habitat for sustainable cultivation of medicinal plants, flawless supply of certified raw materials.
- Promotion and awareness regarding Good Agricultural Practice, Good Agriculture and Cultural Practice, Good sustainable Practice among cultivators and Drug manufacturer.
- Building of Co-operation among the small and large companies for building of capacity and sharing of experience, knowledge with one another.
- Unification of protocols, timeline and guidelines regarding application procedure, report submission etc.
- Provision of Financial Assistance [14].

Indian herbal Industry is growing at an unexpectedly steady rate with comparison to the global demand. The main reasons of this slow evolution are – insufficient raw material and finished product standardization, inadequate importance towards research and development, insufficient marketing and promotion, inadequate importance regarding human resource development to be engaged in different heal sectors and ignorance towards modernization [21].

Current Administrations demands evidence of safety and efficacy of herbal products for both domestic and export approval. So, technological and methodological improvement should be prioritize for a fruitful development in the upcoming future. Indian Herbal Industry's perspective should be capitalized in scientific technological cultivation, harvesting, supply and manufacturing, research of herbal plant and products [15].

Administrative and Pharmacopoeial harmonization is essential for flawless and rapid commercialization across the globe. Due to demand of safe, effective and elucidated alternative medicine, Central AYUSH administration should look after to achieve a faster growth in education, research, clinical medicine and improvisation in regulatory affairs and other required services [14-15].

Neutraceuticals are the future of Indian herbal Industry. Neutraceutical industry is growing at an unbelievable rate, which is far far greater than the conventional

pharmaceutical industries. Thus, a proper regulatory authority should be constituted to inspect the Industry based standardization of these nutraceutical products [38-39]].

Survey suggests, to increase the export subsidy in the medicinal plant and products to motivate the growers and the industrialist. Proper financial assistance should be provided towards research and development on variety improvisation and availability enhancement etc. Emphasis towards zonal export promotion campaign should be increased. Transport linkage between cultivators and the manufacturing unit should be improved, demand –supply survey should be conducted and use of modern growth and pest controlling substances should be encouraged keeping an eye on the resource sustainability [14].

Recently, Steps are being taken towards promotion of standardization of herbal formulations. For example, CSIR's New Millennium Indian Technology Leadership Initiative filed for Investigational New Drug Application For a oral herbal formulation backed with documentations like finger printing study, activity guided fractionation, safety, efficacy and toxicological study along with pharmacokinetics and toxic kinetic evaluation [14].

Conflict of Interest

The authors declare no conflicting interests.

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