

# The rise of phytopharmaceuticals in India: Opportunities and innovations



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## Abstract

Phytopharmaceuticals are pharmaceutical products that contain active ingredients derived from plants or parts of plants (e.g., leaves, roots, flowers, and seeds). They represent a category of medicinal products that stand between herbal medicines and chemically synthesized drugs. Phytopharmaceuticals undergo rigorous scientific evaluation, including clinical trials, and are required to meet the same standards of efficacy, safety, and quality as conventional pharmaceutical products. The history of phytopharmaceuticals in India is deeply rooted in the country's traditional medicinal systems, which have utilized plant-based remedies for thousands of years. India has a rich heritage of using plants for medicinal purposes, most notably through Ayurveda, Siddha, Unani, and Tibetan medicine. Over time, the traditional knowledge of herbal medicines has evolved into modern phytopharmaceuticals, where scientific validation, standardization, and regulatory oversight have become integral parts of drug development.

**Keywords:** Biodiversity, Standardization, Traditional medicine

## 1. Introduction

Phytopharmaceuticals, hold significant potential for India due to its rich biodiversity and long history of traditional medicine like Ayurveda, Unani, and Siddha. With the global shift toward natural and plant-based treatments, India is well-positioned to capitalize on this trend for various reasons including Rich Biodiversity and Traditional Medicine Systems. India is one of the world's most biodiverse countries, home to over 45,000 plant species, many of which have medicinal properties. This gives India a natural advantage in sourcing raw materials for phytopharmaceuticals. India's traditional medicine systems like Ayurveda and Unani already use plant-based ingredients. These systems offer a vast pool of knowledge that can be integrated into modern phytopharmaceutical research, creating products with both historical credibility and modern efficacy. These differ from Ayurvedic, Siddha or Unani (ASU) therapies, because phytopharmaceuticals, as defined under the Drugs and Cosmetics Act, 1940, must include a purified and standardized fraction with a defined minimum of four bio-active or phytochemical compounds of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder. These ASU therapies fall under the Ministry of AYUSH, whereas phytopharmaceuticals are regulated by the Central Drugs Standards Control Organization (CDSCO) (1).

## 2. Historical milestones in phytopharmaceutical development in India

### 2.1. Ancient and traditional medicine (3000 BCE onwards)

- **Ayurveda:** The roots of phytopharmaceuticals in India go back to the ancient Vedic texts (like the Rig Veda) and classical Ayurvedic texts such as the Charaka Samhita (circa 1000 BCE) and Sushruta Samhita (circa 600 BCE). Ayurveda emphasized the use of medicinal plants, minerals, and metals for treating various ailments (2).
- **Medicinal plants:** Common plants used in ancient Ayurvedic remedies include Ashwagandha (*Withania somnifera*), Neem (*Azadirachta indica*), Tulsi (*Ocimum sanctum*), Turmeric (*Curcuma longa*), Amla (*Phyllanthus emblica*), and Brahmi (*Bacopa monnieri*).
- **Polyherbal formulations:** Ayurveda often used combinations of plant extracts in polyherbal formulations like Triphala, Chyawanprash, and Dashmool, which are still used today for their therapeutic properties.
- **Siddha and Unani:** Both the Siddha (prevalent in Tamil Nadu) and Unani (introduced by Persian and Arab influences) systems of medicine in India also heavily relied on the medicinal properties of plants. Many of these plants are now being investigated for their potential in modern phytopharmaceuticals.

### 2.2. Colonial period (17<sup>th</sup> to 20<sup>th</sup> Century)

- During the British colonial period, India's traditional knowledge of herbal medicine began to be documented systematically. British botanists and scientists established herbariums, botanical gardens, and research institutes to catalog India's vast biodiversity of medicinal plants (3).
- British and European scientists also started researching and extracting active compounds from Indian medicinal plants. For example, quinine was isolated from Cinchona bark (used for treating malaria), and ephedrine was extracted from the plant Ephedra, long used in Indian and Chinese traditional medicine.

### 2.3. Post-independence era (1947–1980s)

- After India's independence in 1947, there was a renewed focus on the development of traditional medicine and herbal drugs. Research institutions like the Central Council for Research in Ayurvedic Sciences (CCRAS) and the Central Drug Research Institute (CDRI) were established to scientifically study and validate the efficacy of traditional herbal formulations (4).
- The Council of Scientific and Industrial Research (CSIR) played a significant role in the standardization, extraction, and study of bioactive compounds from medicinal plants. For example, ashwagandha, neem, brahmi, and tulsi were researched extensively during this period for their pharmacological potential.
- Indian pharmaceutical companies such as Dabur, Himalaya, Zandu, and Charak Pharma began focusing on modernizing and marketing traditional herbal medicines, which eventually became phytopharmaceuticals.

### 2.4. Modern era (1990s–Present)

- **Phytopharmaceuticals as a recognized category:** In the late 20th and early 21st centuries, India began to align with international standards of drug development, including the phytopharmaceutical sector. The Government of India formally recognized phytopharmaceuticals as a distinct category under the Drugs and Cosmetics Act, 1940 in the 2015 Amendment (5).
- Phytopharmaceuticals are defined as plant-derived medicines with standardized bioactive compounds, undergoing rigorous clinical trials and quality control, much like allopathic drugs.
- **Ayurvedic and herbal drug market:** Indian companies started developing patented formulations derived from traditional knowledge but validated through modern scientific methods. For example:
  - **Himalaya's Liv.52** (a liver tonic) and **Dabur's Chyawanprash** are examples of traditional formulations that have undergone modern scientific validation.

- **Phytopharmaceutical Innovations:** In recent years, newer phytopharmaceuticals like BGR-34 (an antidiabetic drug derived from plant sources, developed by CSIR) have been launched, showcasing the merging of traditional knowledge with modern pharmacology.
- **Research and Development:** Indian institutes like the National Botanical Research Institute (NBRI), Indian Council of Medical Research (ICMR), and various pharmaceutical universities have been collaborating with the pharmaceutical industry to develop, standardize, and test phytopharmaceuticals through clinical trials. Indian pharmaceutical companies and research institutions are increasingly focusing on phytopharmaceuticals, with advancements in extraction, standardization, and clinical trials of plant-based products.

Collaborations between traditional healers and modern scientists can boost innovation and help in developing evidence-based phytopharmaceuticals that meet global regulatory standards. India is one of the largest exporters of herbal and plant-based products, with a significant focus on phytopharmaceuticals. The demand for plant-based medicines in Europe, North America, and South-east Asia has grown due to increasing interest in natural therapies.

## 2.5. Regulatory framework

- The Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy) was established in 2014 to promote traditional medicine and oversee the development of herbal drugs, including phytopharmaceuticals (6).
- The Indian government developed guidelines for the approval of phytopharmaceuticals, which included parameters for clinical trials, toxicity studies, and quality control.
- In 2015, the Drugs and Cosmetics Rules were amended to introduce the concept of phytopharmaceutical drugs. Under these guidelines, plant-based medicines that have undergone clinical trials and are proven to be effective can be marketed as phytopharmaceuticals, distinguishing them from traditional herbal remedies (7).
- GMP and Standardization: The government has made it mandatory for companies producing phytopharmaceuticals to follow Good Manufacturing Practices (GMP) which ensures that the drugs are safe, effective, and of high quality.

## 3. Government initiatives and support

The Indian government has launched several initiatives to promote the development of phytopharmaceuticals, recognizing their immense potential for healthcare and the pharmaceutical industry. Key initiatives and support mechanisms include:

### 3.1. AYUSH ministry

The Ministry of Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) plays a significant role in promoting traditional systems of medicine, including phytopharmaceuticals. Through this ministry, the government supports research, standardization, and the commercialization of plant-based medicines.

### 3.2. National Medicinal Plants Board (NMPB)

Established under the Ministry of AYUSH, the NMPB promotes the cultivation and sustainable use of medicinal plants. It provides financial assistance to farmers and entrepreneurs for the cultivation, conservation, and development of medicinal plants used in phytopharmaceuticals (8).

### 3.3. Phytopharmaceuticals guidelines (2015)

The Central Drugs Standard Control Organization (CDSCO) introduced specific guidelines for phytopharmaceutical drug development, making it easier for companies to bring plant-based medicines to the market (9). These guidelines streamline the process for conducting clinical trials and getting regulatory approvals.

### 3.4. Biotechnology Industry Research Assistance Council (BIRAC)

BIRAC, under the Department of Biotechnology, provides funding for research and innovation in phytopharmaceuticals. It supports startups and research organizations working on novel plant-based formulations (10).

These initiatives aim to boost research, cultivation, and commercialization of phytopharmaceuticals, positioning India as a global leader in the sector.

#### 4. Modern trends and global impact

Modern trends in phytopharmaceuticals, driven by advancements in technology and a growing preference for natural therapies, are significantly impacting global healthcare. India, with its rich biodiversity and traditional medicinal knowledge, stands to benefit immensely from these trends.

##### 4.1. Increasing research on bioactive compounds

India's focus on the scientific validation of traditional herbal medicines has led to the discovery of new bioactive compounds with potential therapeutic uses. This includes research into compounds like curcumin (from turmeric), withanolides (from ashwagandha), and bacosides (from brahmi), which have shown potential in treating conditions like cancer, Alzheimer's disease, and inflammation (11).

##### 4.2. Global interest

India's expertise in medicinal plants has attracted global interest in phytopharmaceutical R&D. Collaborations between Indian companies and international pharmaceutical giants have increased to explore plant-based therapies for chronic diseases (12).

##### 4.3. Growing global market

The global market for phytopharmaceuticals is expected to grow significantly, driven by increasing consumer preference for natural medicines. India can tap into this demand, particularly in areas such as chronic diseases, lifestyle disorders, and immune support.

The global herbal medicine market size was valued at USD 216.40 billion in 2023 and is projected to grow from USD 233.08 billion in 2024 to USD 437 billion by 2032, exhibiting a CAGR of 8.17% during the forecast period.

Europe dominated the herbal medicine market with a market share of 44.82% in 2023. Moreover, the herbal medicine market size in the U.S. is projected to grow significantly, reaching an estimated value of USD 37.90 billion by 2032, driven by growing consumer awareness about health (13).

India contributes significantly to the global supply of medicinal plants and phytopharmaceutical products. Its herbal exports stood at USD 539.57 million in 2022, making it a key player in the global market.

Several well-known phytopharmaceutical products have gained international recognition for their therapeutic benefits. These products are derived from plant-based compounds and are used in various healthcare applications (Table 1).

**Table 1. Details of well-known phytopharmaceuticals in the market**

Marketed Product	Uses	Brand Name
Silymarin (Milk Thistle)	Primarily used for liver diseases, including cirrhosis, hepatitis, and liver damage from alcohol and toxins (14).	Legalon, Silibinin, Siliphos.
Curcumin (Turmeric)	Known for its anti-inflammatory, antioxidant, and potential anti-cancer properties (15).	Meriva, Curcumin C3 Complex.

Artemisinin (Sweet Wormwood)	The primary active component in the treatment of malaria. (16).	Coartem (artemether and lumefantrine combination), Riamet.
Vinpocetine	Used for improving cognitive functions and treating cerebrovascular disorders like stroke and memory issues (17).	Cavinton, Vinpo-10.
Forskolin ( <i>Coleus forskohlii</i> )	Popular in weight management supplements and as a treatment for glaucoma, asthma, and cardiovascular conditions (18).	ForsLean.
<i>Boswellia serrata</i> (Indian Frankincense)	Known for anti-inflammatory and anti-arthritis properties (19).	Shallaki, Boswellin.
Cannabidiol (CBD)	Widely marketed for treating epilepsy (e.g., Dravet syndrome), pain, anxiety, and other conditions (20).	Epidiolex (FDA-approved), Charlotte's Web.
<i>Andrographis paniculata</i> (Kalmegh)	Used in respiratory infections, liver issues, and immune system support. (21).	KalmCold, Kan Jang.
<i>Ginkgo biloba</i>	Mainly marketed for cognitive improvement, memory enhancement, and circulatory disorders (22).	Tebonin, Ginkgold.
Quinine (Derived from Cinchona Bark)	Traditionally used for treating malaria (23).	Quinate, Qalakin.
Resveratrol	Promoted for cardiovascular health, anti-aging, and antioxidant benefits (24)	Longevinex.
Ashwagandha ( <i>Withania somnifera</i> )	Adaptogen used for stress relief, cognitive function, and improving vitality (25).	Sensoril, KSM-66.
Picroliv ( <i>Picrorhiza kurroa</i> )	Used for liver protection and boosting immune responses (26).	Liv-52, Picroliv

## 5. Challenges

Phytopharmaceuticals hold immense potential for India's healthcare and pharmaceutical sectors, but several challenges hinder their growth. One of the key issues is standardization. Variability in the composition of plant-based medicines, influenced by factors like geographical location, season, and cultivation practices, leads to inconsistent therapeutic outcomes (27). This complicates product

approval, as regulatory bodies require strict adherence to quality standards, efficacy, and safety, comparable to synthetic drugs.

Another challenge is scientific validation. Unlike conventional pharmaceuticals, phytopharmaceuticals often lack extensive clinical data. The absence of robust clinical trials and comprehensive toxicological studies limits their acceptance among healthcare professionals and international markets (28).

Additionally, complex regulatory frameworks act as a barrier. India's regulations for phytopharmaceuticals, though evolving, remain less streamlined compared to Western countries. The regulatory landscape needs clearer guidelines to support product development and commercialization while ensuring quality and safety. Finally, intellectual property (IP) issues present challenges. Many phytopharmaceuticals are based on traditional knowledge, making patenting difficult under current legal frameworks. This restricts the development of proprietary formulations and investments in research.

Overcoming these challenges through better standardization, clinical validation, and supportive regulatory frameworks could help unlock the full potential of phytopharmaceuticals in India.

## 6. Conclusion

India's journey from traditional herbal remedies to modern phytopharmaceuticals reflects the country's ability to integrate ancient knowledge with modern science. Today, India is a leader in phytopharmaceutical production, with a robust regulatory framework that ensures the quality and efficacy of plant-based drugs. This sector holds great potential for addressing modern health challenges using natural resources. Phytopharmaceuticals offer immense potential for India in terms of healthcare solutions, economic growth, and exports. With a combination of its rich biodiversity, traditional knowledge, and increasing focus on R&D, India is well-positioned to become a global leader in the phytopharmaceutical industry.

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