Ayurvedic Research and Formulations Development

Pharmaceuticals
Government of Gujarat
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The term “Ayurveda” combines the Sanskrit words ayur (life) and veda (science or knowledge). It is one of the traditional medicinal systems, with an established history of many centuries. It is based on the belief that health and wellness depend on a delicate balance between the mind, body, and spirit. The primary focus of Ayurvedic medicine is to promote good health and prevent illness, rather than fight disease. Other traditional systems include Siddha, Unani, Iranian, Islamic, Vietnamese, Chinese, Acupuncture, Muti, Ifá, African and other treatments all over the globe. When adopted outside of its traditional culture, traditional medicine is often called complementary and alternative medicine (CAM).

There are three kinds of ingredients used in Ayurvedic medicines:

- **Herbal**
- **Mineral**
- **Animal**

The herbal medicines dominate the practice of Ayurveda. The worldwide use of herbal products decreased in the 20th century as these were believed to be less profitable than synthetic drugs and medicines. Post 1960, increasing concerns over the side effects of the synthetic drugs and medicines led to an increase in the demand for traditional alternative medicines across the world. Herbal medicine is still the mainstay of about 60% of the world population, mainly in developing countries for their primary healthcare needs.


In India, alternate medicinal system, commonly referred to as “Indian system of Medicine and Homeopathy” (ISM&H) includes:

- **Ayurveda**
- **Siddha**
- **Unani**
- **Homeopathy**

ISM&H includes over the counter formulations, herbal remedies, and prescription drugs.

As of 2013, more than 1.5 m practitioners used traditional medicinal system for healthcare in India, with more than 7,800 manufacturing units involved in the production of natural health products and traditional-plant based formulations.

Source: CSIR-National Botanical Research Institute article, 3 June 2013
Proposed Facilities

- The proposed manufacturing facility for Ayurveda research and formulations would be a GMP certified facility, licensed by the State Drug controlling authority. The facility will focus on “new generation medicines” instead of classical Ayurvedic products. This will include patented and proprietary drugs such as range of active pharmaceutical ingredients for the Kashyas. In addition, it will also manufacture tablets, granules and gels.
- The unit will have multiple sections such as pre-processing and processing section and clean room. The unit will also grow its range of herbs and plants, which will make it self-contained. Following are the key proposed departments:

**Production area:**
- Adequate working and in-process space to provide proper positioning of equipments/materials and movement of personnel to avoid misapplication of any manufacturing and control measures.
- Pipe-work, electrical fittings, ventilation openings and similar services lines shall be designed, fixed and constructed for proper operations of the facility.

**Manufacturing operations and controls:**
- For manufacturing ayurvedic medicines, large quantity of steam is required. An Ayurvedic medicine facility generally includes large steam boilers and big extractors and jacketed vessels for processing.
- For removing steam from the process area, the facility includes big blowers with exhaust piping system.
- For powdering requirements, a big pulveriser is required.
- For filling automatic filling machines are included.

**Warehousing area:**
- Warehousing areas should maintain good storage conditions. They should maintain temperature limits where special storage conditions are required.
- Regular checks would be required to make sure spillage, breakage and leakage of containers don’t occur.

**Quality Control area:**
- A Quality Control laboratory to carry out quality check of Botanical, Chemical, Analytical and Microbiological parameters.
- A High Performance Thin Layer Chromatography (HPTLC) and a scanner to detect active ingredients in Medicinal herbs and formulations.
- An Atomic Absorption Spectrophotometer (AAS) to detect the presence of toxic heavy metals such as Lead, Cadmium, Mercuric and Arsenic.

**Testing:**
- Technology to carry out sterility tests of herbal products in microbiology laboratory and monitor the presence of microorganisms in the manufacturing areas.
- Technology to carry out Physio Chemical tests and Pharmacognosy tests of Medicinal herbs.

*Source: GMP and requirements of premises, plant and equipment for pharmaceutical products*
Market Potential

Global Herbal Market

- Total global herbal market size was USD 35.6b in 2015 and is expected to grow at a CAGR of 4% to reach USD 43.3b by 2020
- Herbal medicines market is growing steadily in both the US and Europe
- China is a major market for herbal products and medicines

![Herbal Market 2015 (by geography)](image)

![Global Herbal Market (USD b)](image)

Source: Euromonitor

Note: Global herbal market includes OTC and dietary supplements

Indian Herbal Market

- The Indian herbal market consists of herbal products such as herbal hair care, herbal skin care & other herbal personal care products, as well as herbal medicines
- The Indian herbal medicines market includes OTC, ethical and classical formulations and home remedies of Ayurveda, unani, homeopathy and siddha systems of medicines
- Over the period of 2008 and 2013, the herbal medicine market in the country grew at a CAGR of 26.7%. The growth of herbal medicines reflects the shifting trend of consumers from allopathic to herbal medicines

![Indian Herbal Market (USD b)](image)

![Indian Herbal Medicine Market Forecast (USD b)](image)

Source: Ken Research, Nov 2014

1 India Alternative Medicine and Herbal Products Market Outlook to 2018, Ken Research, Nov 2014
Growth Drivers

Key growth drivers of herbal products in India

**Product awareness**
Growing awareness regarding the side effects of chemical based products and medicines has shifted focus on the natural and herbal products.

**Rising income**
The growing economy has encouraged consumers to spend more on health and wellbeing. Rise in income has driven the demand for premium ayurvedic products priced relatively higher than chemical based products.

**Differentiating factor**
FMCG and pharma companies are looking at natural and herbal based products as a point of differentiation in the market.

**Changing lifestyle**
Rising stress levels among working population and changing lifestyle is leading to rise in skin and hair ailments and people are looking for natural treatments to cure such disorders.

**Online availability**
Easy availability of herbal products online has driven the demand of such products in the domestic marketplace.

**Large bio-diversity**
India is a megadiverse nation. There are ~45,000 plant species that include the Indian medicinal plants and Indian bulb plants. Abundance of raw material makes it easy for a company to venture into the industry.
Growth Drivers

Key Initiatives by Government of Gujarat\textsuperscript{2,3}

Academics

- The Gujarat Ayurvedic University has signed a Memorandum of Understanding (MoU) with nine Ayurvedic institutions functioning in Japan, Australia, the Netherlands, Italy, Argentina, and Germany to coordinate and facilitate the globalisation of ayurveda through academic collaboration.

Medicinal plant resources

- The drugs used in the Indian Systems of Medicine and Homeopathy (AYUSH), are mainly plant based, in addition to mineral and animal origins. The Government of India has set up a National Medicinal Plant Board (NMPB) for coordinating all matters related to medicinal plants.

Wellness tourism

- Health resorts offering Ayurvedic Treatments like the Panchkarma Therapy and other treatments would be developed and suitably incentivised through a separate Government resolution.
- Government plans to promote development of naturopathy and Ayurveda gardens at various locations in Gujarat.

Other Initiatives taken by the Indian Government\textsuperscript{4}

- Publication of Ayurvedic, Siddha, Unani and Homoeopathic (ASU&H) Pharmacopeias contains quality standards of 600 single drugs & 152 compound formulations of Ayurveda, 139 single drugs of Siddha, 298 single drugs and 100 compound formulations of Unani and 1016 Homoeopathic drugs respectively.
- 27 State Drug Testing Laboratories and 46 State Pharmacies have been provided financial assistance for strengthening of infrastructure and functional capacity and a component of Drugs Quality Control is provided in the National AYUSH Mission to support the state initiatives.
- 39 Drug Testing Laboratories are approved for testing of Ayurveda, Siddha, Unani and Homoeopathic drugs under the provisions of Drugs & Cosmetics Rules 1945.
- Provisions have been made in the International Cooperation scheme to support the manufacturers for promoting export by registration of AYUSH products in the foreign markets, development of drug dossiers and participation in international fairs & exhibitions.

\textsuperscript{2}“Ayurveda – A potential global medical system,” Financial Express, accessed 22 August 2016
\textsuperscript{3}Tourism Policy State of Gujarat (2015-2020)
\textsuperscript{4}Press Information Bureau, Govt. of India, AYUSH
**Gujarat - Competitive Advantage**

**Gujarat – a major pharma hub**

Gujarat is an established pharmaceutical manufacturing base for bulk drugs and formulations.

- **Pharma Manufacturing Licenses in Gujarat**
  - 2338 Allopathic
  - 390 Ayurvedic
  - 679 Cosmetics
  - 8 Homeopathic

- **Exports market is increasing for both pharma and Ayurveda sector**

- **Number of Ayurvedic licenses in Gujarat**
  - 619 (2012-13)
  - 643 (2013-14)
  - 659 (2014-15)
  - 676 (2015-16)

**Shift towards Ayurvedic Medicines**

- Ayurvedic medicines are gaining popularity in Gujarat. The state government aims to bring Ayurveda-based medical tourism in the state. A draft paper is being prepared in this regard.
- Gujarat is the first state in India to start Ayurveda university. Under National Ayush Mission (NAM), it has taken initiatives to start three new government Ayurveda colleges in Gandhinagar, Rajpiple and Dahod.
- The state government has allocated funds to improve the medicine distribution system. It plans to build 7 depots across in Bharuch, Vadodara, Rajkot, Bhuj, Himatnagar, Valsad and Dahot.
- As per Gujarat Food and Drug Control Administration (FDCA), the number of ayurvedic licenses have increased continuously over the past 4 years.

**Gujarat for Pharma Manufacturing**

- **~40% of India’s machinery for pharma sector is from Gujarat**
- **40% of Contract Research and Manufacturing companies are from Gujarat**
- **It has granted 3,415 pharma manufacturing licenses**

**Pharma Exports from Gujarat (USD m)**

- **~445% increase in exports**
  - 562 (2006)
  - 3060 (2016)

**Source:** FDCA; IBEF
Gujarat - Competitive Advantage

Learning Infrastructure

Teaching institutes
- There are 11 AYUSH teaching institutions in the state where Graduate and Post-graduate courses of different AYUSH specialties are conducted

Operational Infrastructure\(^5\)

Healthcare practitioners:
- As of July 2016, there are more than 22,000 registered practitioners of Indian Systems of Medicine (Ayurveda) in Gujarat

Healthcare infrastructure:
- There are 33 speciality Ayurveda hospitals in different parts of Gujarat, with 1345 bed capacity available for patients
- There are 545 Ayurvedic dispensaries serving the health care of rural Gujarat people. Sixteen mobile dispensaries are on road to reach patients in remote villages of Gujarat

Pharmacies:
- Two Government Ayurveda pharmacy were established in 1982 at Rajpipala (Dist.Narmada) and Vadodara. These pharmacies serve 33 Ayurvedic hospitals and 545 dispensaries across the Gujarat

Regulatory and Industry Infrastructure

Indian Systems of Medicine & Homeopathy (AYUSH) is located in Gandhinagar
- The department of Ayurveda, under AYUSH, was started in Gujarat in 1960
- It manages all activities including inspection, maintenance, development, finance, administration and technical aspects related to Ayurvedic medicine

Gujarat Ayurved Aushadh Manufacturers’ Association (GAAMA) was established in Ahmedabad in 2001
- The association represents more than 500 owned and 160 loan licensed Ayurvedic medicine manufacturing units\(^6\)

\(^5\) AYUSH health & family welfare, Govt. of Gujarat website
\(^6\) GAAMA website
Following are the preferable locations for Ayurvedic research and formulations development unit. These locations are already established as pharma hubs and offer necessary infrastructure for Ayurvedic medicines.

**Possible Locations**

**Ahmedabad**
- Manufacturing Base:
  - Formulations
  - APIs
  - Biologicals
  - Contract manufacturing

**Vadodara**
- Manufacturing Base:
  - Formulations
  - Biogenerics

**Ahmedabad**
- Manufacturing Base:
  - Formulations
  - APIs
  - Vaccines

**Bharuch and Ankleshwar**
- Manufacturing Base:
  - Formulations
  - APIs
  - Vaccines

**Vapi/ Valsad**
- Manufacturing Base:
  - Formulations
  - APIs
  - Device and diagnostics

- Gujarat has five Special Economic Zones ("SEZ") and three Special Investment Regions ("SIR") for pharma sector
- There is a pharma industrial park in the state – Gujarat Pharma Techno Park (area: 17.07 hectare), which is located in Ahmedabad

<table>
<thead>
<tr>
<th>SEZs in Gujarat</th>
<th>Name</th>
<th>Area (hectare)</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zydus Infrastructure Pvt. Ltd</td>
<td>49</td>
<td>Ahmedabad</td>
<td></td>
</tr>
<tr>
<td>CPL Infrastructure Pvt. Ltd</td>
<td>122</td>
<td>Ahmedabad</td>
<td></td>
</tr>
<tr>
<td>Dishman Infrastructure Ltd.</td>
<td>106</td>
<td>Ahmedabad</td>
<td></td>
</tr>
<tr>
<td>HBS Pharmaceuticals SEZ</td>
<td>125</td>
<td>Bharuch</td>
<td></td>
</tr>
<tr>
<td>Dahej SEZ</td>
<td>1125</td>
<td>Dahej</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SIRs in Gujarat</th>
<th>Name</th>
<th>Area (sq. km)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changodar, Ahmedabad</td>
<td>319 sq. km</td>
<td></td>
</tr>
<tr>
<td>Viramgam, Ahmedabad</td>
<td>190 sq. km</td>
<td></td>
</tr>
<tr>
<td>Okha, Jamnagar</td>
<td>206 sq. km</td>
<td></td>
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</table>
Utility

Gujarat has a state-wide “water supply grid” spread across 1,20,769 km that aims to serve 75% of Gujarat’s population.

In the state budget for 2015-16, USD 83m was allocated for bulk water supply schemes and USD 574m was allocated for improving the infrastructure of existing water supply systems.

Power

Gujarat has 24-hour 3-phase uninterrupted power supply throughout the state, with installed power capacity of 29,293 MW (10.38% of India’s overall power capacity).

The state has surplus power to the tune of 2000 MW.

Logistics & Connectivity

Gujarat has an extensive outlay of robust physical, social and industrial infrastructure, which makes it an excellent investment destination.

Rail

- Gujarat has a total railway length of 5,257 km (8.25% of India)
- Mumbai-Ahmedabad bullet train project planned with an investment of USD 16.58b
- Government of Gujarat further plans to invest USD 1.65m in regional rail projects

Road

- Gujarat has a wide road network of around 77,030 km. Of these, 95% roads are surfaced, all-weather roads
- In 2015-16 budget, the state government further plans to invest USD 8.3m in a four-lane road joining Vadodara- Ankleshwar, USD 2.7m in construction of expressways and USD 81.4m in resurfacing roads

Air

- The state has 18 domestic airports (the highest in any state) and one international airport.
- During 2014-15, the Ahmedabad airport handled 59,313 thousand tonnes of freight. Freight traffic at Vadodara and Rajkot measured 966 tonnes and 79 tonnes respectively during April-September, 2015.

Port

- The state has one of the strongest port infrastructures in India, with 42 ports (21% of India’s ports are in Gujarat), including one major port at Kandla and 41 minor ports, along a 1,600 km coastline.
- It is the first state in India to take up port privatisation. Gujarat Maritime Board, has developed port privatisation models such as private/joint sector ports, private/captive jetties.
Sources of raw material

Key locations in Gujarat that offer high medicinal plant diversity:
- Dangs, Navsari, Narmada and Surat

Potential collaboration opportunities

Following collaboration opportunities exist for Ayurveda industry:
- **Medicinal herbs suppliers** – Ayurvedic manufacturers primarily rely on herbal plant suppliers who collect plants from the wild and supply to the industry, since herbal plant cultivation is costly and is not preferred.

> “The industry has been used to procuring medicinal plants through a network of traders who get their supply through collectors. The sector needs to develop an intellect for contract cultivation.” - Ranjit Puranik, CEO Shree Dhootapapeshwar

- **Government associations** – The companies may collaborate with government associations to seek guidance on science and technology, and to encourage, assist, extend, promote knowledge related to Ayurvedic medicines. Industry associations include Gujarat Ayurved Aushadh Manufacturers’ Association (GAAMA), Ayurvedic Drug Manufacturers Association (ADMA), Ayurveda Medical Association of India (AMAI), etc.

- **Food and drug laboratories** – Ayurvedic medicine manufacturers can collaborate with testing laboratories for conducting quality check. There are a number of laboratories located in Gujarat: Food and Drug Laboratories (FDL) in Vadodara and Patan, Regional Food Laboratories in Rajkot and Bhuj.
## Manpower requirement

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Number</th>
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<tbody>
<tr>
<td>Manager</td>
<td>1</td>
</tr>
<tr>
<td>Manufacturing Chemist</td>
<td>2</td>
</tr>
<tr>
<td>Analytical Chemist</td>
<td>4</td>
</tr>
<tr>
<td>Clerk cum Accountant</td>
<td>1</td>
</tr>
<tr>
<td>Skilled worker</td>
<td>10</td>
</tr>
<tr>
<td>Unskilled worker</td>
<td>15</td>
</tr>
<tr>
<td>Peon cum chowkidar</td>
<td>2</td>
</tr>
<tr>
<td>Sales representative</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
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## Leading Players

- **Emami**  
  (Navratna oil, Boroplus Antiseptic cream, Himani fast relief, Mentho plus, Sonachandi Chyawanprash, Baby massage oil)

- **Unjha Pharmacy**  
  (Immune system – Amiri Jivan; Digestive system – Niyam Churna; Joint disorder – Unjha pain balm; Infection – Panchun tablet; Nervous system; Child Care)

- **Vasu Healthcare**  
  (Men’s Health – Ural Capsule, Effectto capsule; Women’s Health – Meryton syrup; Children’s Health – Zeal kid drops; Skin care; Hair care; Liver care)

- **Teva**  
  (Daily foaming cleanser, Aloe eye serum, Aftershave balm, Body butter)
Ayurvedic Medicines Manufacturing Unit

<table>
<thead>
<tr>
<th>Project components &amp; specifications</th>
<th>Cost (INR Crore)</th>
</tr>
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<tbody>
<tr>
<td>Site development (site levelling, internal roads, sewage lines, water supply, drainage, landscaping, street lighting) (Area: 33,800 square meter, Average rate: INR 1,200 per sq meter)</td>
<td>4.1</td>
</tr>
<tr>
<td>Building and construction (includes warehouse, research centre, administrative building etc) (Built-up area: 4,000 sq meter, Average rate: INR 25,000 per sq meter)</td>
<td>10.0</td>
</tr>
<tr>
<td>Machinery and equipment</td>
<td>7.7</td>
</tr>
<tr>
<td>Miscellaneous fixed assets (Furniture and fixtures)</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Indicative Project Cost</strong></td>
<td><strong>22.4</strong></td>
</tr>
</tbody>
</table>

Assumptions:

- Benchmark project: Ayurvedic manufacturing unit of Arya Vaidya Sala Kottakkal based in Nanjangud, Karnataka (INR15 crore facility set up in 33,800 square meters of land in 2010).

**Note:** The proposed machinery and equipment include SS.Vat 1500 Kg capacity, SS.Vat 750 Kg capacity, fermenter, sintered glass crucible, disintegrator, micro-pulverizer, tablet making machine, bottle filling and sealing machines, SS Pestle and mortar, mixing vessel, filtering unit, furnace, weighing scale, glass jars, vessels, air oven, bottle washing machine, bottle dryer, aluminium container, testing equipments and generator.
Approvals Required

Manufacturing approvals:

AYUSH

- To manufacture Ayurvedic / Herbal products in India, a license from the State Licensing Authority is required.
- There are 2 types of manufacturing licenses issued by AYUSH – Complete Manufacturing License, and Loan License.
- Good Manufacturing Practices (GMP) are mandatory for licensing of Ayurveda, Siddha, Unani and Homeopathic drugs.
- Pharmacopoeia Commission for Indian Medicine & Homoeopathy has been established to address quality concerns and accelerate the work of development of quality standards of Ayurveda, Siddha, Unani and Homoeopathic medicines.

Other pertinent laws and regulations:

- Manufacturing of ayurvedic medicines is governed by state FDCA body through enforcement of the Drugs and Cosmetic Act (1940) and Rules (1945).

Research and development approvals:

- The Central Council for Research in Ayurveda and Siddha (CCRAS) is an apex body for the formation, coordination, development, and promotion of research on scientific lines in Ayurveda and in the Siddha system of medicine.

Other approvals:

- Registration of business organization (Local body clearances)
- Acquisition of land from concerned office / owner
- Arrangement of power with zonal distribution company
- Arrangement of water with concerned municipal corporations
- Any other clearances required
- A private investor would be able to avail Government schemes subject to approval by the concerned Ministries / Departments.
<table>
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<th>Scheme for Assistance to Research &amp; Development Activities</th>
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<tr>
<td><strong>Operative Period</strong></td>
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<tr>
<td>From 01/01/2015 to 31/12/2019</td>
</tr>
<tr>
<td><strong>Eligibility of institutions</strong></td>
</tr>
<tr>
<td>All Research &amp; Development Institutions recognized by CSIR set up by GoG / GoI / Industrial Association</td>
</tr>
<tr>
<td><strong>Assistance available</strong></td>
</tr>
<tr>
<td>Assistance for Contract/Sponsored research work from any industrial enterprise/Industrial association to recognized R&amp;D institution / technical collages approved by AICTE, will be considered @ 50% of project cost, excluding cost of land and building, subject to maximum INR 50 lakh</td>
</tr>
</tbody>
</table>
AYUSH, Indian Systems of Medicine & Homeopathy

https://ayush.gujarat.gov.in/

GAAMA, Gujarat Ayurved Aushadh Manufacturers’ Association

http://gaama.co.in/

AMAI, Ayurveda Medical Association of India

http://www.ayurveda-amai.org/

Food and Drugs Control Administration


ADMA, Ayurvedic Drug Manufacturers Association

http://admaindia.com/index.php

AMAM, Association of Manufacturers of Ayurvedic Medicines

http://amam-ayurveda.org/default.htm

Indian Council for Medical Research

www.icmr.nic.in

Central Drugs Standard Control Organization

www.cdsco.nic.in

Note: This project profile is based on preliminary study to facilitate prospective entrepreneurs to assess a prima facie scope. It is, however, advisable to get a detailed feasibility study prepared before taking a final investment decision.