



सत्यमेव जयते

GOVERNMENT OF GUJARAT

Pharmaceuticals Sector Profile

India Scenario

The image features a dark blue background with the text "India Scenario" centered in a white, serif font. Below the text, there is a large, abstract graphic composed of several overlapping, wavy bands of color. From left to right, the colors transition from yellow and orange to a deep purple. The bands are layered, creating a sense of depth and movement, and they curve upwards towards the right side of the frame.

Overview



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The Indian pharmaceutical sector ranks 3rd in the world in terms of volume (10 % of the global industry) and 14th in terms of value



Over 60,000 generic brands across 60 therapeutic categories and more than 500 different APIs are manufactured.



India contributes the 2nd largest share of pharmaceutical and biotech workforce in the world, after China. The other leading countries are USA & Brazil.



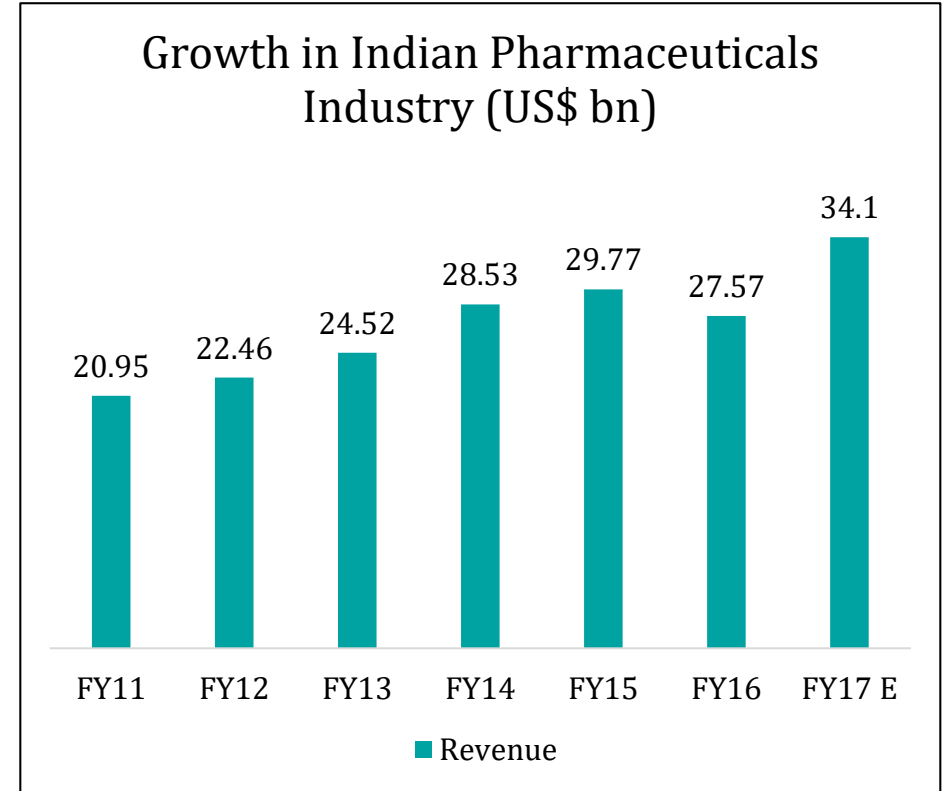
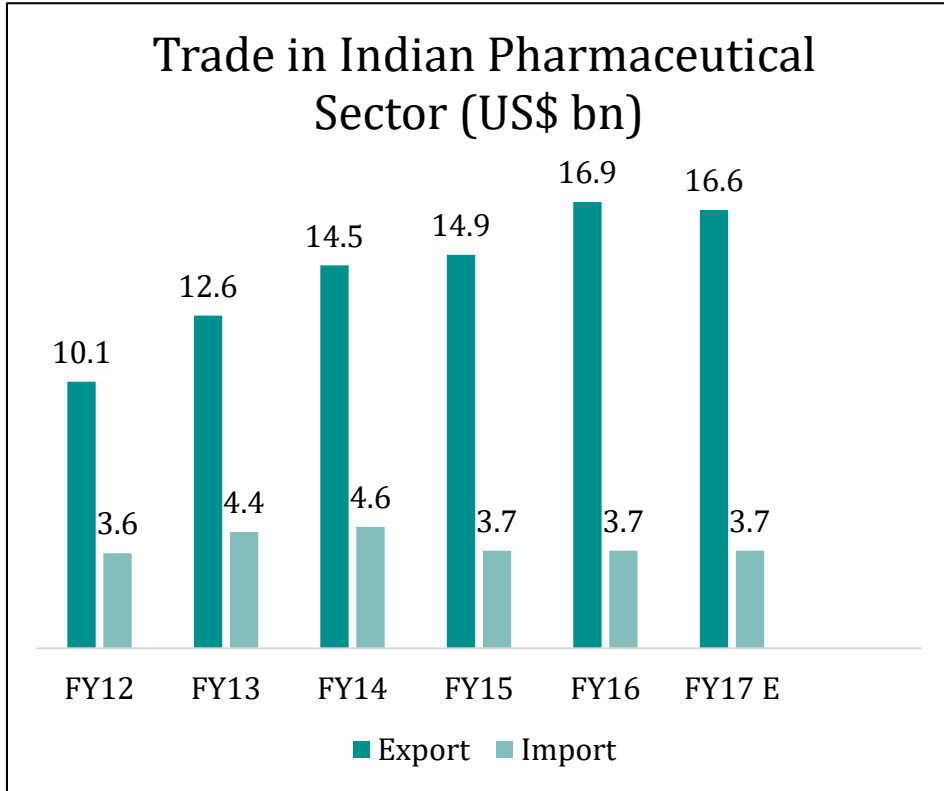
Per capita sales of pharmaceuticals expanded at a CAGR of 17.6 per cent during 2008 to 2016 to US\$ 33 in 2016 due to economic growth and increasing awareness of generics amongst the consumers. The total market size of the India Pharma Industry is expected to reach US \$ 100 Billion by 2025.



India's cost of production is nearly 33 per cent lower than that of the US with labour costs 50–55 per cent cheaper than in Western countries. The cost of setting up a production plant in India is 40 per cent lower than in Western countries.



Key Statistics-Pharmaceuticals



In FY17, India exported pharmaceutical products worth US\$ 16.8 billion, with the number expected to reach US\$ 40 billion by 2020. During April – November 2017, India exported products worth US\$ 8.49 billion.

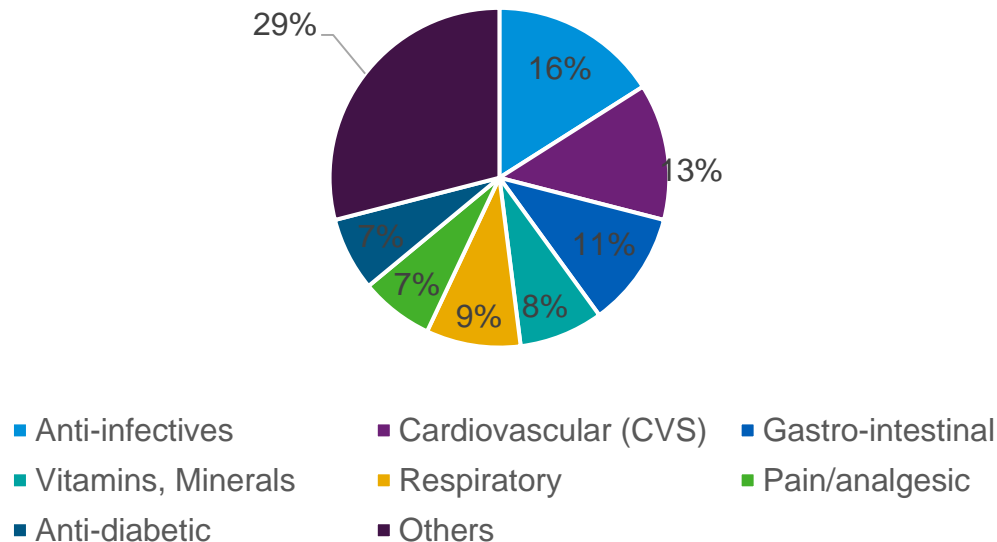
The market witnessed growth at a CAGR of 5.64 %, during FY11-16, with the market increasing from US\$ 20.95 billion in FY11 to US\$ 27.57 billion in FY16. The revenues is estimated to have grown by 7.4 % in FY17.



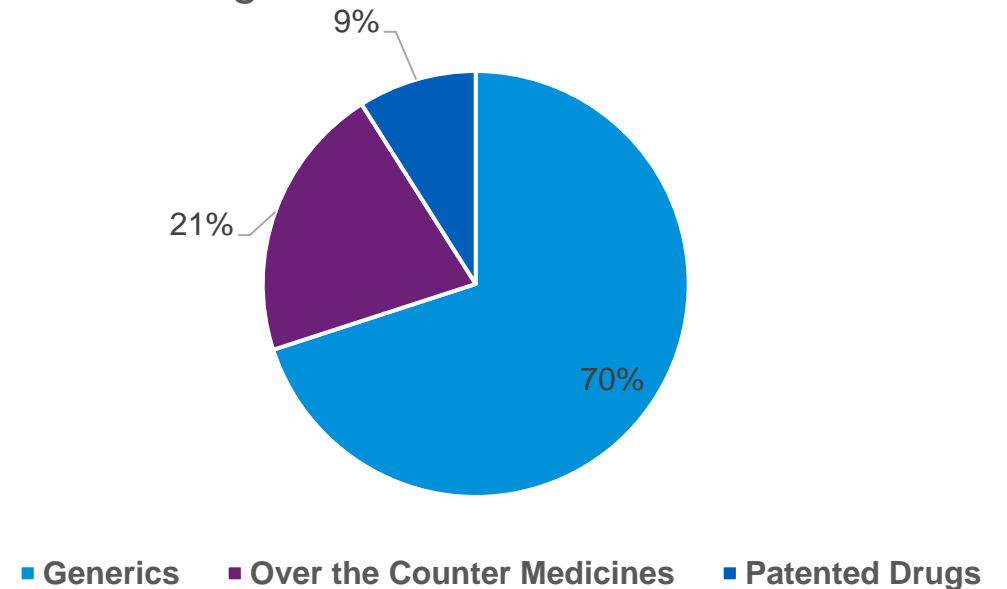
Key Statistics-Domestic market

- Indian domestic market was valued at US \$ 18.01 Bn in FY 17.
- Domestic demand has steadily increased over the years due to increase in household income, improvement of medical infrastructure & penetration in the country.
- In April 2018, a high-level task force was constituted to create a roadmap for increasing domestic production of APIs. Currently, India imports over 60 per cent of its APIs from other countries.

Segmentation of the Market



Segmentation of the Market

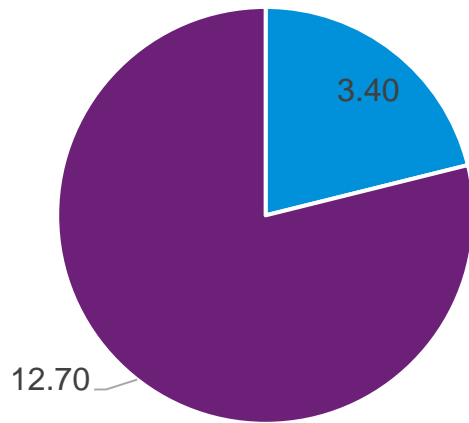




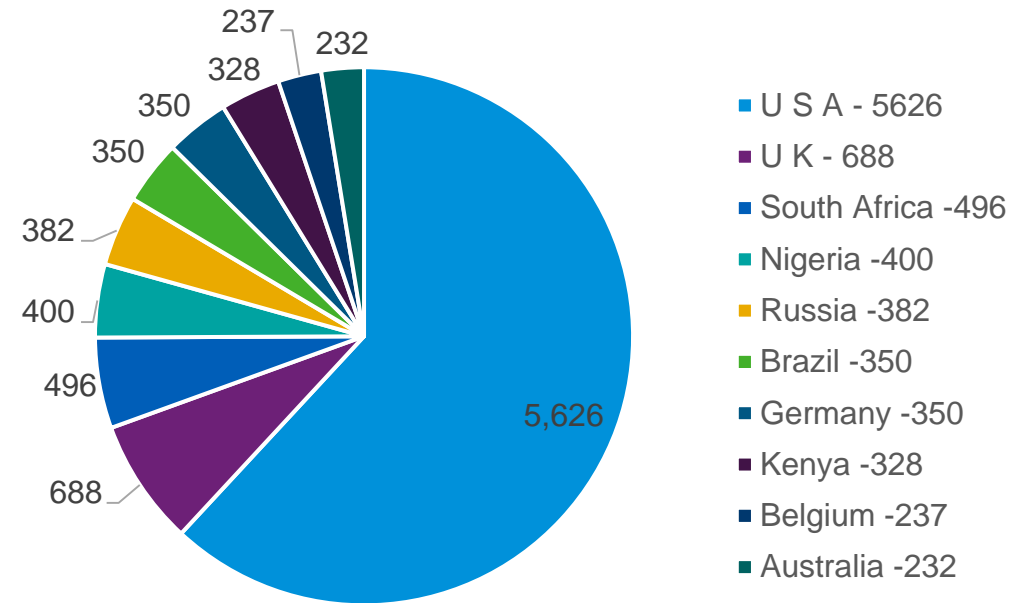
Key Statistics-Exports

- Biggest provider of generic medications which account for 20 percent of global exports concerning volume.
- India ranks among the top ten global exporters with exports totaling US \$ 16.1 Bn in FY 17.
- Indian drugs are exported to more than 220 countries across the globe
- India is also the largest vaccine producer in the world and supplies 80 per cent of the anti retroviral drugs to fight AIDS globally.

India's Exports of Pharmaceuticals to World (US \$ Billion)



Top 10 Countries

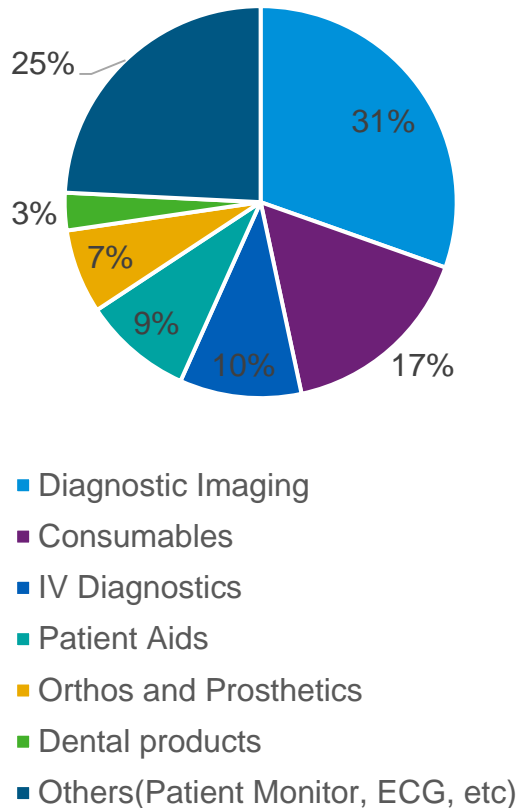


■ Bulk Drugs and Drug Intermediates ■ Drug Formulations and Biologicals



Medical Devices-India

India's Domestic Market
(US \$ 5.2 Billion)



Market Overview

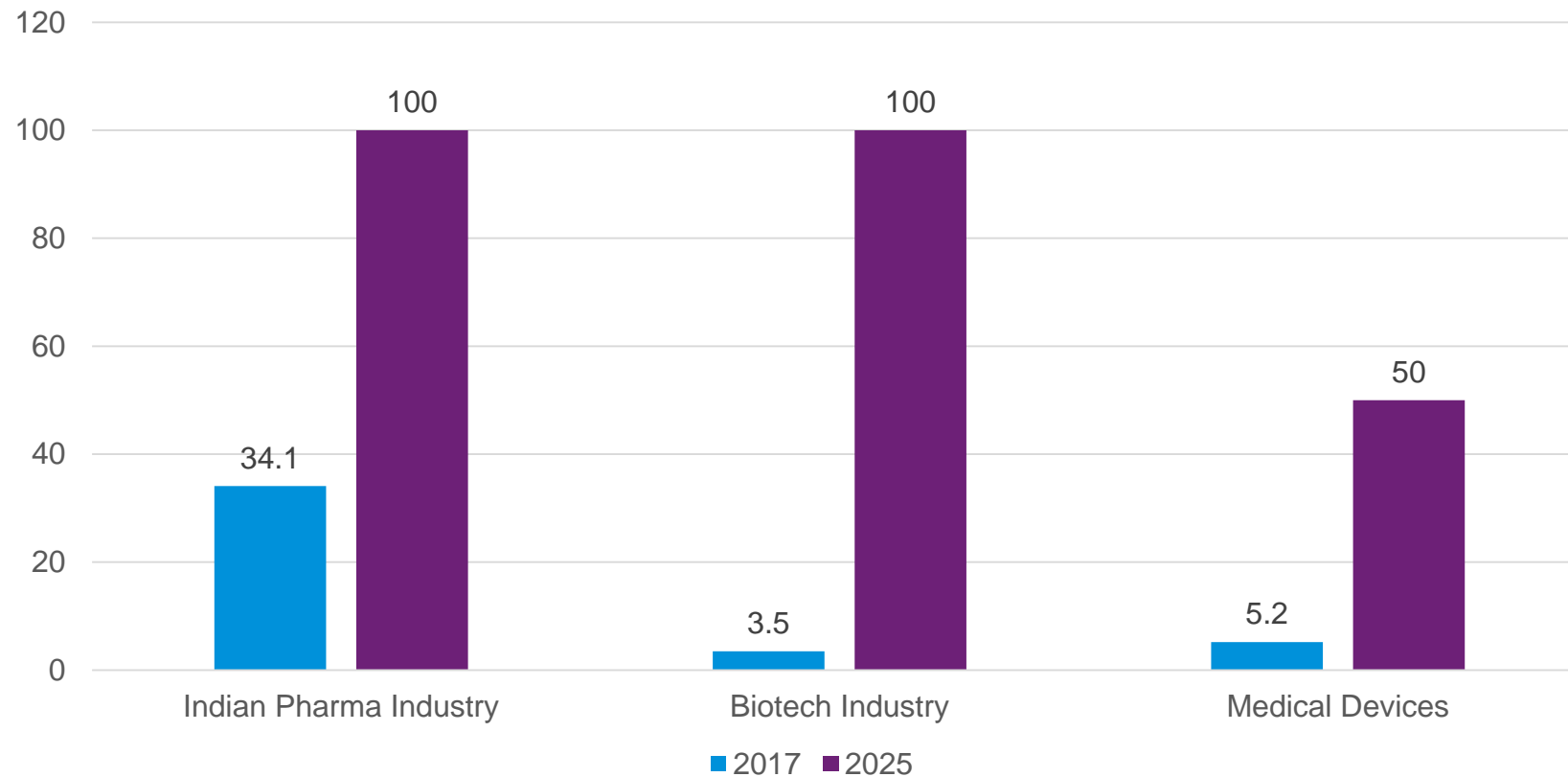
- India has about 750–800 medical device manufacturers in the country, with an average investment of Rs 170–200 million and an average turnover of Rs 450–500 million.
- Among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea

Growth Drivers & Government Support

- India's population has crossed 1.32 billion and with the ageing population to increase to 6% by 2021, there will be a greater demand for better health care facilities and medical devices.
- Periodic renewal of licenses for manufacturing and imports will not be required further.
- A single window mechanism for statutory clearances which need to be obtained for the manufacturing units has been developed.
- Interest subsidy for MSMEs, concession on power tariffs, seed capital and minimum or zero duty on raw materials have been proposed in the Draft National Medical Device Policy-2017.
- With the new Goods and Services Tax regime, the new tax rate is flat 12%. which earlier use to be more than 13%. It helps to achieve lower costs of manufacturing.

Growth Potential of Indian Market

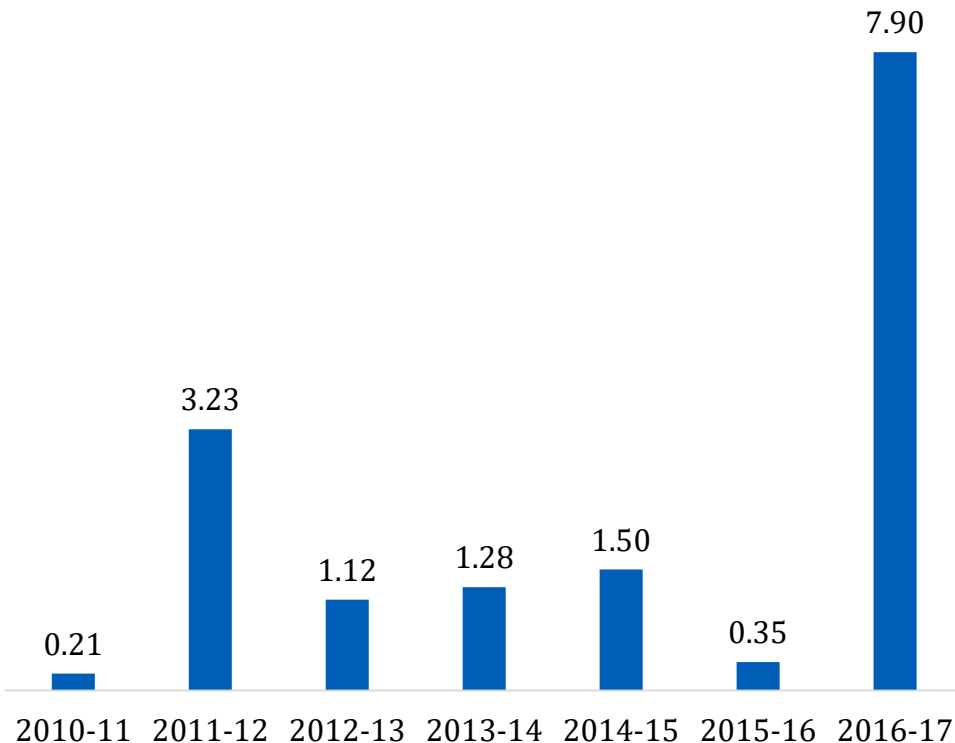
Estimated Growth projected in India by 2025 (US \$ Bn)



Key Statistics-FDI



FDI in Pharmaceutical Sector (US \$ Billion)



- There has been a tremendous increase in FDI in the FY 16-17 due to the liberalization from June 2016.
- Pharmaceutical companies can now invest 100% for greenfield & up to 74% for brownfield projects under automatic route.

Major Companies

Company	Country
Johnson & Johnson	USA
GSK	United Kingdom
Pfizer	USA
P&G	USA
NIPRO	Japan
AstraZeneca	United Kingdom



Government of India Initiatives

Industry infrastructure	<ul style="list-style-type: none">• The government has planned to set up 6 pharma parks at an investment of about US\$ 27 million• Plans to set up mega bulk drug parks in order to reduce dependency on raw material imports.
Reduction in approval time	<ul style="list-style-type: none">• The Drug Controller General of India (DCGI) announced its plans to start a single-window facility to provide consents, approvals and other information.• NOC for export license is being given on a state level under ease of doing business for faster approval
Duty Exemptions	<ul style="list-style-type: none">• Full exemption from excise & custom duty is being provided for HIV/AIDS drugs and diagnostic kits supplied under National AIDS Control Programme funded by the Global Fund to fight AIDS, TB and Malaria (GFATM)
Union Budget 2018-19	<ul style="list-style-type: none">• The National Health Protection Scheme is largest government funded healthcare programme in the world, which is expected to benefit 100 million poor families by providing a cover of up to Rs 5 lakh (US\$ 7,723.2) per family per year for secondary & tertiary care hospitalisation.• The Government of India plans to set up a US\$ 640 million venture capital fund to boost drug discovery and strengthen pharmaceutical infrastructure.
Online Pharmacy Policy	<ul style="list-style-type: none">• Government plans to set up an electronic platform to regulate online pharmacies
National Intellectual Property Rights (IPR) Policy 2016	<ul style="list-style-type: none">• Legal and Legislative Framework for strong and effective IPR laws, which balance the interests of rights owners with larger public interest• Strengthens the enforcement and adjudicatory mechanisms for combating IPR infringements.

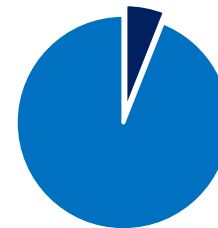
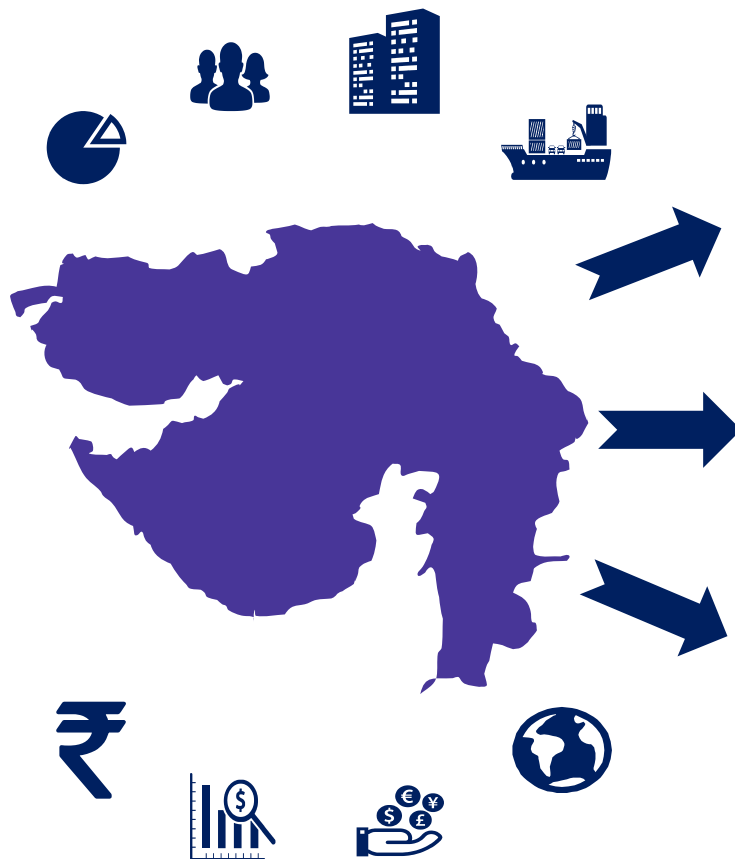
Gujarat Scenario

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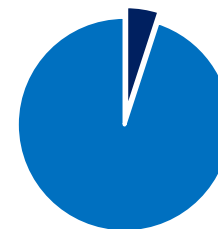
Key socio-economic indicators



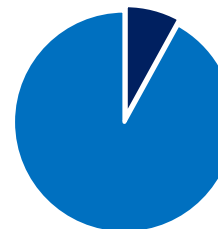
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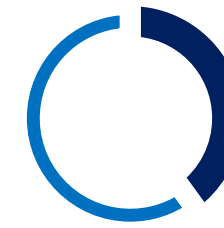
6% of India's Geographical Area
1,96,000 sq. km.



5% of India's population
60.4 million



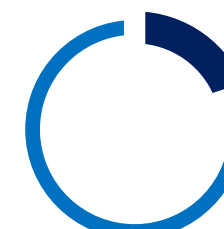
8% of India's GDP
INR 984,598 crore (~ USD 151 billion)
at Constant (2011-12) Prices



40% of India's Port Cargo
handled by Gujarat ports



43% population
lives in urban areas



More than 20%
of India's exports

Robust infrastructure facilitates



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Road

- 156,177 km of well-surfaced roads providing excellent connectivity across the State



Rail

- Railway route length 5259 km
- On-going Metro projects in Ahmedabad, Gandhinagar, Surat
- Upcoming HSR* between Ahmedabad & Mumbai
- 36% of DFC is in Gujarat



Airports

- 17 operational airports and airstrips with 2 International airports
- India's largest airport coming up in Dholera



Ports

- 48 large ports handling over 450 million tonnes cargo (2016-17)
- 40% of India's Port Cargo handled by Gujarat ports



Power

- > 30 GW installed power generation capacity providing 24x7 un-interrupted supply
- Peak demand of about 15 GW



Connectivity

- Tele-density ('00 popl.): 113.70 among the highest in India
- Internet subscribers: 27.3 million



Water Grid

- State-wide 120,769 km long water supply grid



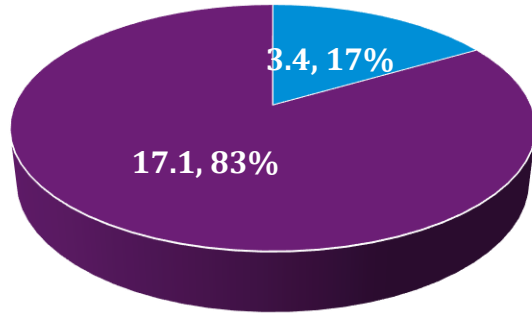
Natural Gas Grid

- 2600 km operational pipeline gas grid network passing through 25 districts
- 25 MMSCMD transmitted through grid



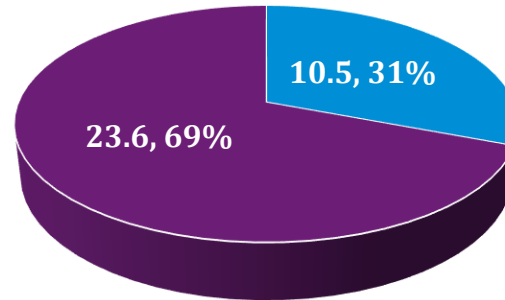
Gujarat: The market leader in India

Investment in US \$ Billion (2016-17)



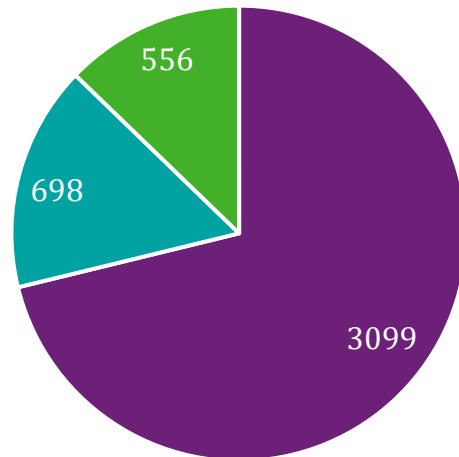
■ Gujarat ■ Rol

Total Output in US \$ Billion (2016-17)



■ Gujarat ■ Rol

Manufacturing Licenses in Gujarat



■ Allopathic

■ Ayurvedic

■ Cosmetics

1st

559 WHO GMP compliant manufacturing units

1st

Diagnostic reagent (Malaria) manufacturer to obtain product prequalification from WHO

1st

World's first biosimilar, 'Adalimumab' was manufactured in Gujarat

1st

Largest producer of contraceptive pills in the world

80%

World's Isoniazid (used for treatment of tuberculosis) is produced in Gujarat

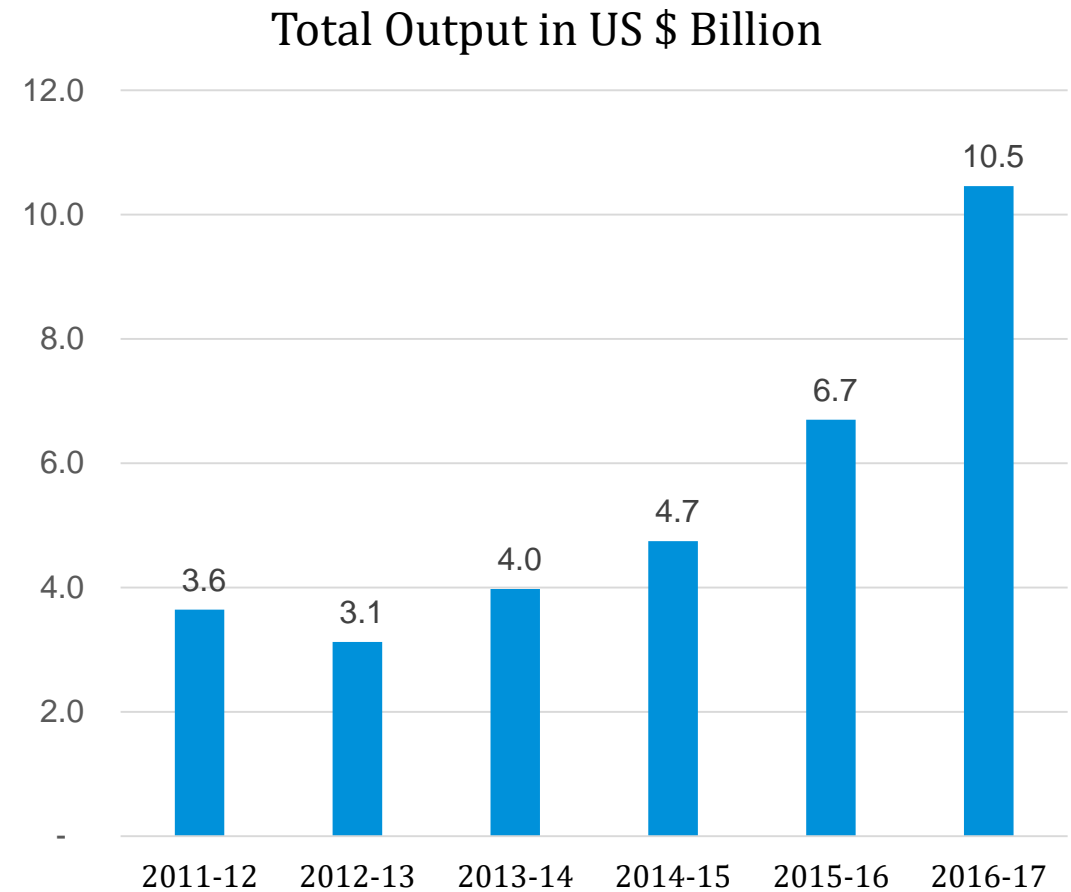
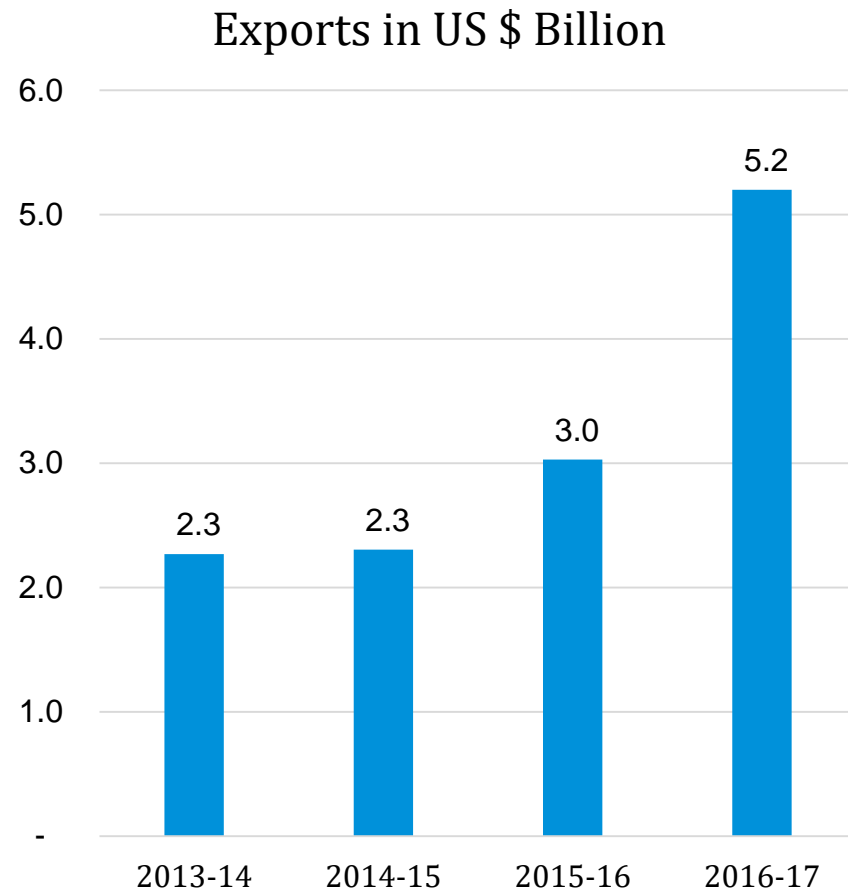
40%

of India's machinery for pharma sector is manufactured in Gujarat

Growth of Pharmaceuticals in Gujarat



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Growth Drivers for Gujarat's pharmaceutical industry



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Infrastructure: The growth of Gujarat's pharmaceuticals industry has been cluster-driven with 4 major clusters . There are 5 Special Economic Zones dedicated for Pharmaceutical exports from the state. 3 New Industrial parks are under development.



Vast Talent Pool: A skilled workforce with high managerial and technical competence is readily available in Gujarat with over 4,500 B Pharma & 10,000 MBA seats in Gujarat.



Generics Drugs Market: Wide spread awareness of generics among people and government increasing access to quality products through Jan Aushidhi stores which promotes generics to cater to masses. Approximately 500 such stores are operational in the state.



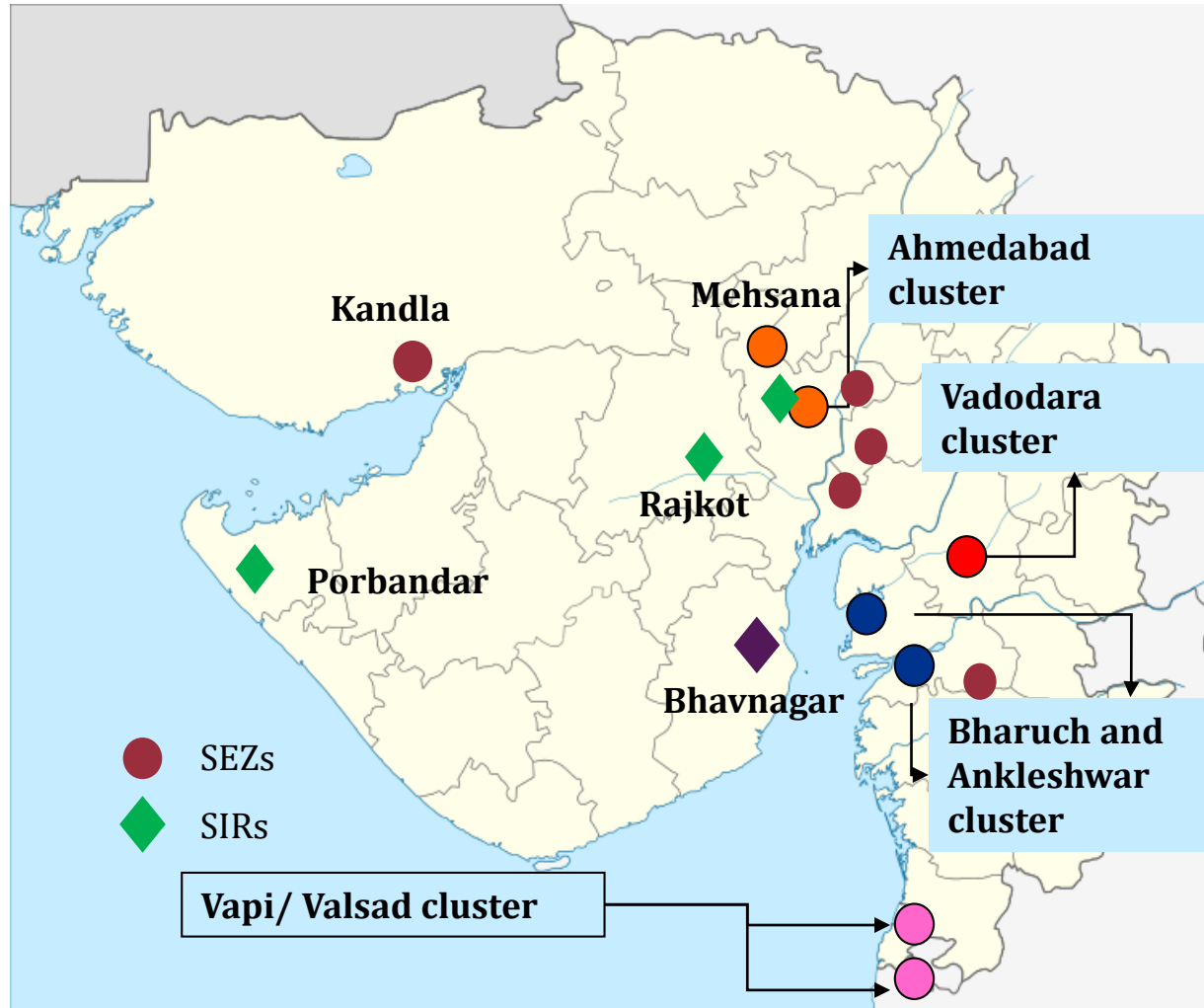
Government Policy: Several disease eradication programmes and a universal healthcare programme have fueled the demand for drugs. Penetration of pharmacies in rural areas has opened up a new market.



Availability of R&D Facilities: With the increasing investments in Research and Development (R&D) sector, introduction of new products and medicines development, has boosted research-based growth.



Pharma Clusters in Gujarat

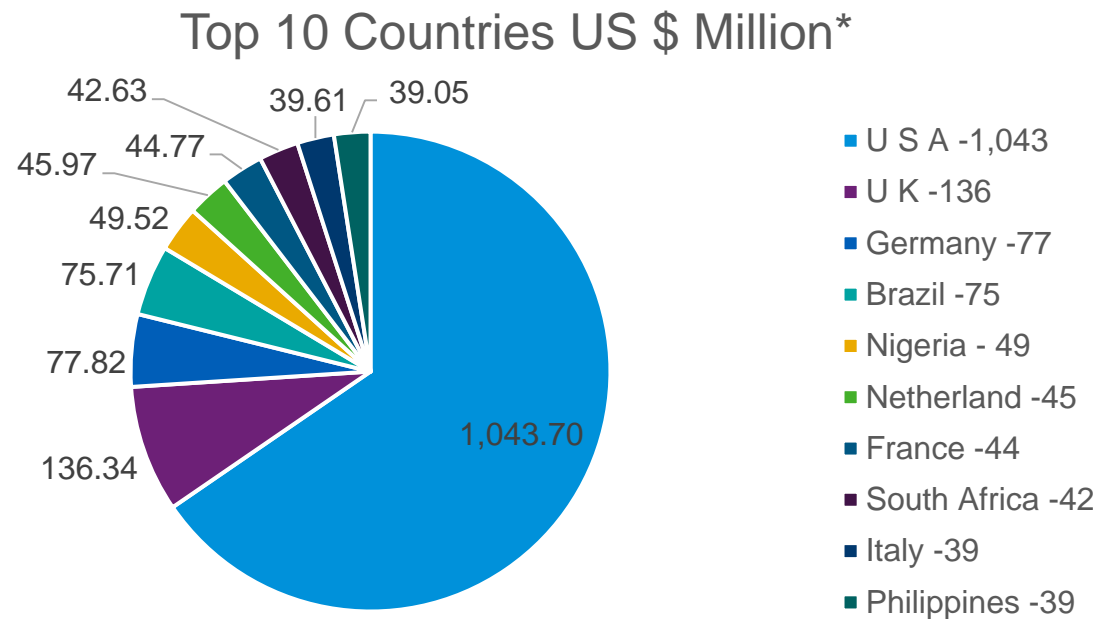


Products across the regions	
Ahmedabad <ul style="list-style-type: none"> • APIs • Formulations • Biological Products • Contract Manufacturing 	Vadodara <ul style="list-style-type: none"> • Formulations • Bio-generics
Bharuch & Ankleshwar <ul style="list-style-type: none"> • APIs • Formulations • Vaccines 	Vapi & Valsad <ul style="list-style-type: none"> • APIs • Formulations • Device and Diagnostic
Benefits in the Clusters apart from Common Infra	
Raw Material Availability <ul style="list-style-type: none"> • Bulk drugs, Excipients • Capsules, Preservatives • Ampules, Glass vials 	Support Institutions <ul style="list-style-type: none"> • Academic(Manpower) • Contract research • Laboratories
Financial Institutes <ul style="list-style-type: none"> • SIDBI • ICICI • SBI 	Industrial associations <ul style="list-style-type: none"> • IDMA-GSB • MDMA • ADMA

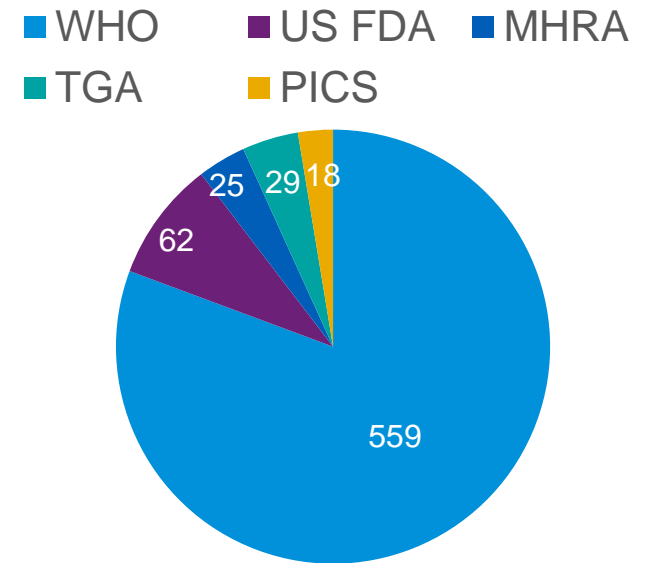


Export opportunities from Gujarat

- Gujarat exported pharmaceutical goods worth US \$ 5.2 Bn during 2016-2017 with USA being the major destination.
- The state has 559 WHO compliant manufacturing units out of the 1200 units across the country which is the highest amongst all states.



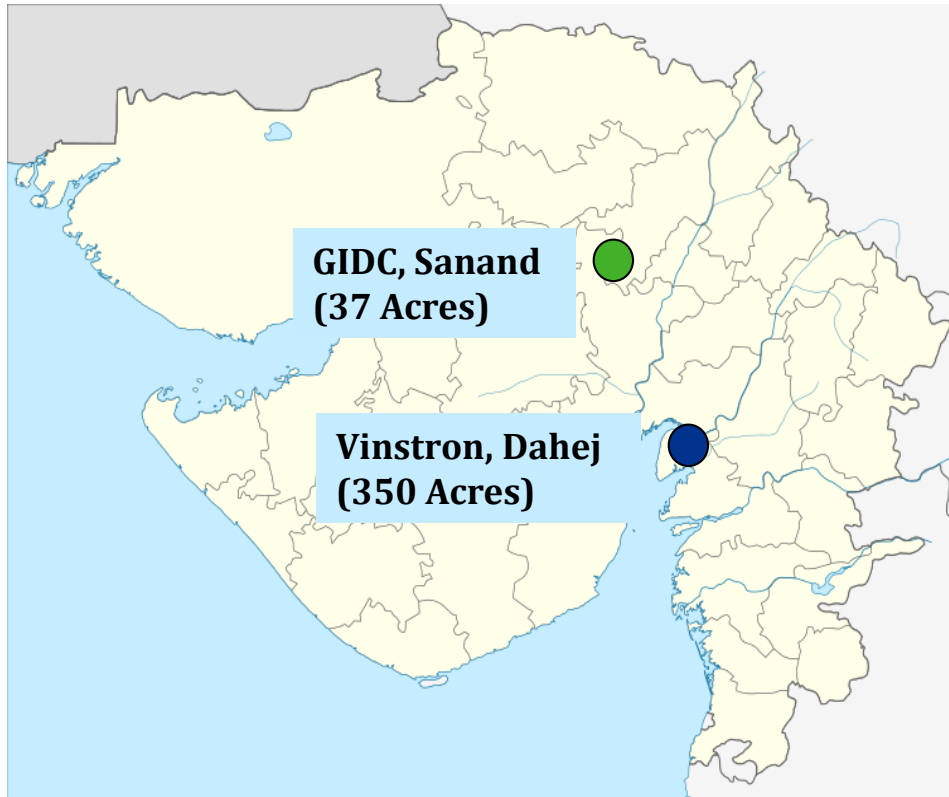
International Regulation Compliant Manufacturing units





Medical Devices-Gujarat

Upcoming Medical Device Parks in Gujarat



Setting up a unit in a medical device park with in-house high investment scientific facilities can help reduce the cost of manufacturing by 40- 50%.

Overview

- Gujarat as the state has the largest number of 146 licensed medical device companies as against 284 in the entire country
- NIPER Ahmedabad is being developed as a National Centre of Excellence for medical devices.
- The value of medical and scientific instruments exported from Gujarat crossed US\$ 100 million in 2017.

High market share of India with

- 78% of Cardiac stents
- 60% of Orthopedic implants
- 50% of Intraocular lenses

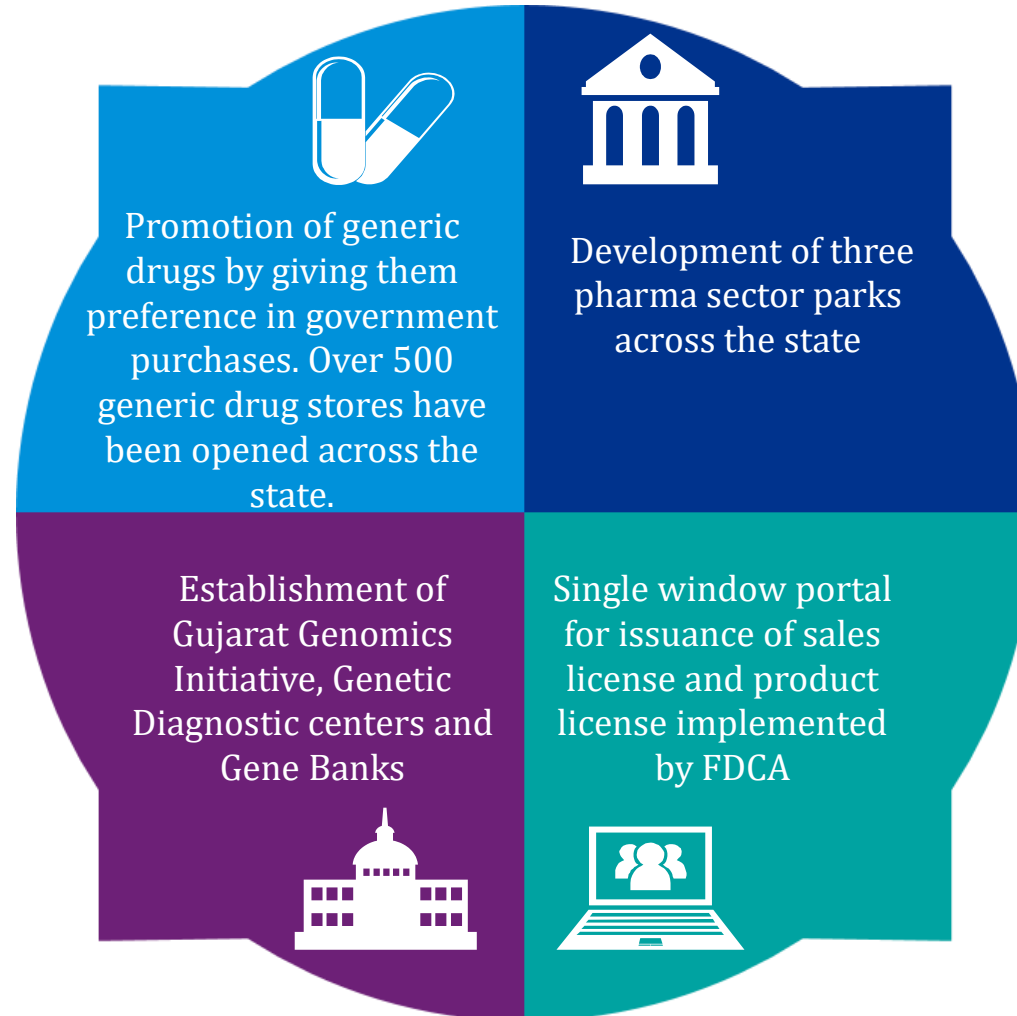
Major Companies with manufacturing facilities

- Siemens
- Meril Life Sciences
- Bayer AG
- Invent Bio-Med
- Contacare
- Sahajanand Technologies

State Government Initiatives



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Educational Infrastructure

Provisional Intake Capacity of Pharmacy Colleges in Gujarat was approximately 4530 seats in 2017

Leading Institutes	Location
L M College of Pharmacy	Ahmedabad
Institute of Pharmacy - Nirma University	Ahmedabad
Anand Pharmacy College	Anand
Faculty of Pharmacy, MS University	Vadodara
B. K. Modi Government Pharmacy College	Rajkot
National Institute for Pharmaceutical Education & Research	Gandhinagar
B.V. Patel Perd Center	Ahmedabad,



Research organizations



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40% of India's Contract research organizations are based in Gujarat

Company	Services Offered
Piramal Pharma Solutions	Early stage drug discovery services for Synthetic Chemistry, Medicinal Chemistry, In-vitro Screening and ADME Services, Analytical Support Services, Chiral Purification & Scale up
Fisher Clinical Services	EU GMP certified facilities for clinical trial packaging from blinding to primary and secondary packaging, comparator sourcing, labeling, storage and distribution of clinical supplies
Synchron Research Services	Bioavailability/bioequivalence, Pharmacokinetic/Pharmacodynamic studies, Dermatopharmacokinetics, Bioanalysis Statistical analysis & Data Management, Pharmacovigilance
Cliantha Research Limited	Integrated clinical offerings in Early Phase (Phase I/IIa), Late Phase (Phase II-IV), Bioequivalence (BA/BE), Clinical Endpoint Trials, Bioanalytical, Biosimilars, Dermatology, Respiratory, Allergy, Biometrics, and Personal Healthcare service
Lambda Therapeutic Research Limited	Bioanalytical, BA/BE, (Phase I), Late Phase (Phase II-IV), Biometrics and Data Management, Pharmacovigilance, Medical Imaging, Bio-similar, Medical & scientific writing and Quality assurance
FTF Pharma	Identification of new products, Regulatory, Non infringing & IP strategy, Bioequivalence & clinical trials
Accuprec Research Labs	Analytical Testing, Biotechnological, Microbiological, Biocompatibility Study Of Medical Device, Preclinical & Toxicological, Phytochemical, Food Testing, Formulation & Development, Dyes & Pigment Testing, Herbal Formulation Development, Stability Testing, Clinical Regulatory Dossier Preparation & Ipr Management

8 BA/BE centers have been approved in the state.

State Government Incentives



State Government Assistance for Micro, Small and Medium Enterprises



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Incentives under the Industrial Policy 2015

Assistance of Capital Investment Subsidy

@ **10%** and @ **15%** on loan amount in Municipal Corporation areas and in areas other than Municipal Corporation areas respectively

Assistance for Interest Subsidy

@ **5%** and @ **7%** for period of 5 years in Municipal Corporation areas and in areas other than Municipal Corporation areas respectively

Assistance for Venture Capital

Assistance to **raise promoter contribution** in the form of equity or loan through GVFL

Assistance for Quality Certification

50% of capital cost for installing Enterprise Resource Planning (ERP) system, for obtaining ISO certification, for obtaining WHO GMP, for testing equipment and machinery required

Assistance for Technology Acquisition

Grant at the rate of **50%** of cost of technology acquisition

Assistance for Patent Registration

75% of expenditure incurred for obtaining patents

Assistance for Saving in Consumption of Energy & Water

75% cost of energy/water audit conducted in a unit & **25%** of cost of equipment



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Partners in our success





Investment Opportunities

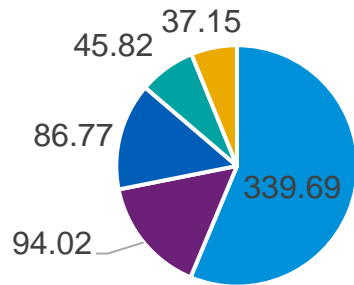
1	APIs 	Currently India imports over 60 per cent of its APIs from other countries. The government aims to produce 100% of the bulk drugs domestically and hence offers multiple incentives & support for the same. The state is coming up with a mega park for API manufacturers.
2	Formulations 	Increased demand for generics due to public healthcare reforms in US and Latin countries has led to a huge demand supply gap. Gujarat's expertise in manufacturing of low cost generics & well channeled export infrastructure can be leveraged here to the fullest.
3	Medical Devices 	Rising income levels, ageing population, increased prevalence of lifestyle-related diseases, and the government's commitment to provide universal healthcare services at a reasonable cost to both rural and urban population has led to a steep demand for medical devices within the country. There are 2 medical device parks in Gujarat which are under development.
4	Contract Research Organizations 	Globally, contract research is a high growth segment led by increasing outsourcing activities of pharma MNCs. There are high opportunities opening up for bio-informatics and clinical data management centers which can boost R &D.
5	Pharmaceutical Machinery 	Gujarat's strong and well established engineering sector can be leveraged to produce pharmaceutical machinery, whose demand is being fueled by strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market.



Export Opportunities to USA Market

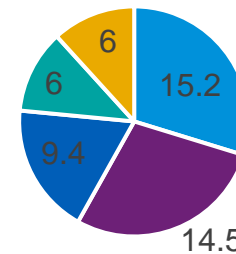
- USA is by far the largest pharmaceutical market in the world with a value of approximately 339 Bn with 25% of it being imports.
- India ranks 5th amongst the top 5 countries to export pharmaceuticals to the USA.
- India has 2nd largest number of USFDA-approved manufacturing plants outside the US with 546 sites & 2,633 FDA-approved drug products. Gujarat has 62 USFDA-approved manufacturing sites.
- India supplies generics at lower prices. Though generics are estimated to make up to 80% of U.S. prescriptions, they only contribute 22% of total U.S. spending on pharmaceuticals. The generics market is US\$ 70-80 billion.
- Indian companies received 304 Abbreviated New Drug Application (ANDA) approvals from USFDA in 2017.
- Exports to USA shall get a boost as branded drugs worth US\$ 55 billion will become off-patent during 2017-2019.

Top 5 Pharmaceutical Markets of the World (US \$ Billion)



■ USA ■ Japan ■ China ■ Germany ■ France

Top 5 Pharmaceutical Exporters (Total Market US \$ 92.5 Billion)



■ Ireland ■ Germany ■ Switzerland ■ Israel ■ India

Thank you

