



सत्यमेव जयते

GOVERNMENT OF GUJARAT

Pharmaceuticals

Sector Profile



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GUJARAT 10-13 Jan
2017

Connecting India to the World | **8th Global Summit**

Pharmaceuticals

India Scenario



Overview

- Indian pharmaceutical sector accounts for about **2.4%** of the global pharmaceutical industry in value terms and **10%** in volume terms
- The sector increased at a CAGR of **~13%** over 10 year period and is expected to grow at a CAGR of **~22%** to reach USD 55 billion by 2020 (from 2015)
- By 2020, India is expected to be **6th largest market globally**
- Leader in exports: Exported products worth USD 15 billion in FY15 and exports are expected to reach USD 40 billion by 2020
- India accounts for **20%** of global exports in generics, largest provider of generic medicines globally
- Attracted FDI worth USD 13.5 billion during January 2000 to December 2015 (5% of total FDI)

	2010-11 (USD billion)	2015-16E (USD billion)	2020-21P (USD billion)	Past 5 year CAGR upto 2015-16	Future 5 year CAGR upto 2020-21
Domestic Formulation (E)	7.41	13.03	23.83 – 26.01	11.9%	13%-15%
Formulation Exports (E)	6.7	12.6-12.9	20.7-23.1	13.8%	10.5%-12.5%
Bulk Drugs Market (E)	11.3	13.9-14.2	23.9-26.7	4.4%	10%-12%
Total Pharmaceuticals	25.3	29.3-40.1	69.8-77.8	6.8%	12%-14%

Hub of the global pharma industry



75% of the world's vaccines are manufactured in India



India exports medicines to >220 countries



Every 3rd pill sold in USA is manufactured in India

Major stakeholders in India's pharmaceutical Industry



SERUM INSTITUTE OF INDIA LTD.



NOVARTIS



And many more...

India's Advantage in Pharmaceuticals



Cost leadership: Cost of production of pharmaceuticals in India is ~60% lower than that of US and almost half of that of Europe

Diverse range of products: Over 60,000 generic brands across 60 therapeutic categories are manufactured in India

Globally recognized capabilities: Out of all drug master filings from India, 49% are registered in the USA

Leader in Drug Applications: Indian pharmaceutical industry accounts for the 2nd largest number of Abbreviated New Drug Applications (ANDAs)

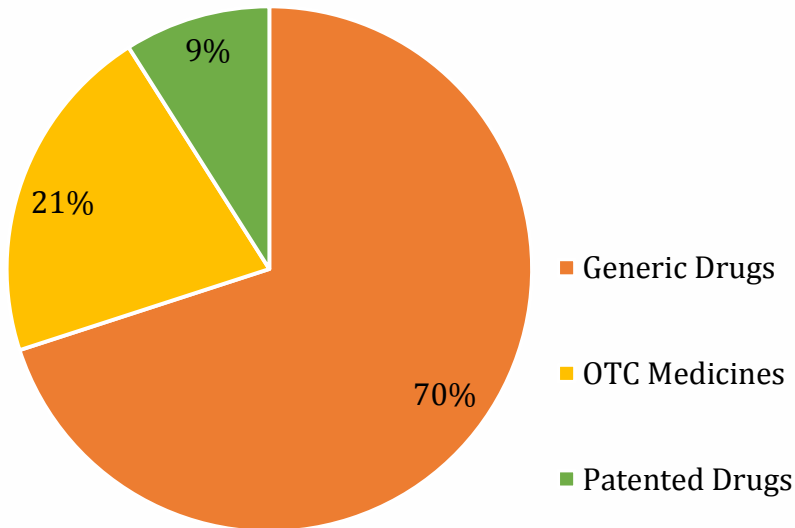
Rapidly expanding healthcare market: India's healthcare market expected to grow to USD 280 Billion by 2020, as compared to USD 83.36 Billion in 2014

Leader in Medical Tourism: Medical value travel market in India is expected to grow at a CAGR of approximately 30 per cent to 10.6 Billion in 2019 from USD 2.8 Billion in 2014

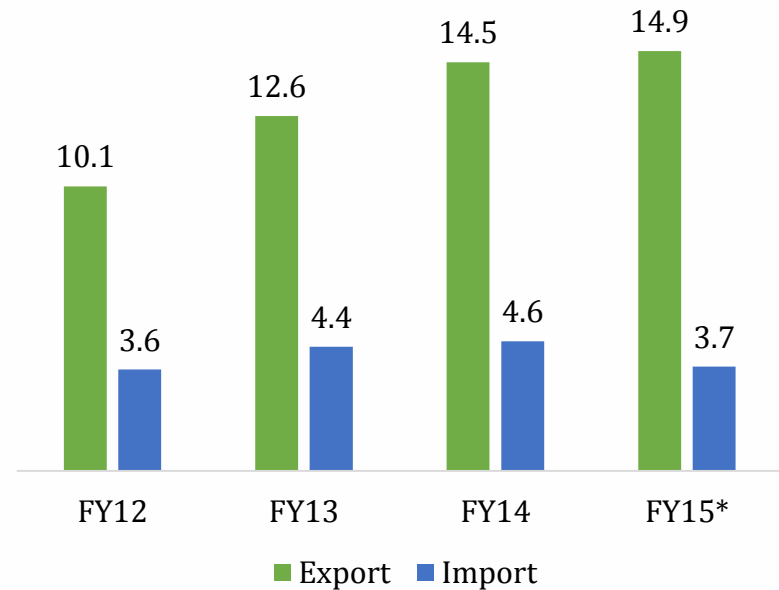
Segments with vast potential: Vaccines market expected to grow to USD 1700 Million by 2020, up from current USD 250 Million; Biologics market expected to grow to USD 3000 Million from current USD 300 Million

Key Statistics

Revenue share of Indian pharmaceutical sub-segments in 2015 (%)



Trade data of Indian pharma sector (USD billion)



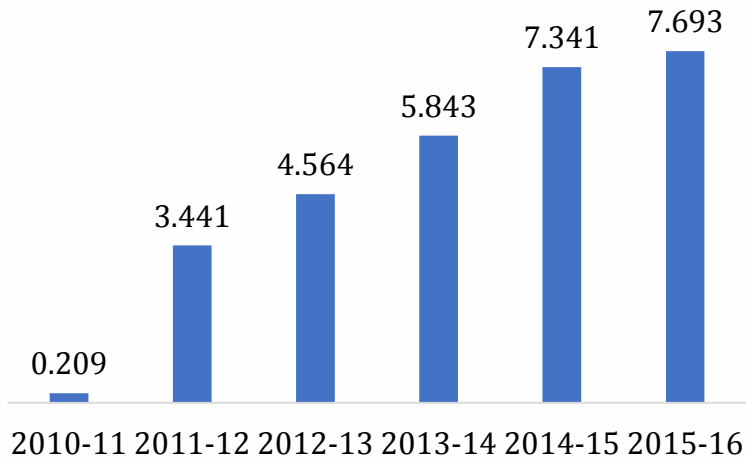
Foreign Investment in India



Key Growth Drivers

- Up to 100% FDI allowed for pharmaceuticals sector
- Up to 100% FDI allowed for manufacturing of medical devices/ equipment
- Conducive patent regime to attract foreign investors

Cumulative FDI in Pharmaceutical Sector (USD billion)



- 6th largest contributor in total FDI attracted during April 2000 – December 2015
- Cumulative FDI USD 13.4 billion during the period
- 4.8% of total FDI attracted in pharmaceuticals

Major Foreign Investors



Government of India Initiatives (1/2)



FDI

- Up to 100% FDI is allowed through automatic route for greenfield projects and through government route for brownfield project in the sector

Industry Infrastructure

- To boost drug discovery and strengthen pharma infrastructure, the Government plans to setup venture capital funds

Pharma Vision 2020

- Aims at making India a major hub for end to end drug discovery
- Provides support by way of world class infrastructure, internationally competitive scientific manpower for pharma R&D and venture fund for research in the public and private domain

Duty Exemptions

- Full exemption from excise duty 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)
- Customs duties on these drugs also exempted

Government of India Initiatives (2/2)



Export Incentive Schemes

- Focus product scheme
- Special focus product scheme
- Focus market scheme
- Export promotion capital goods scheme

Units in Clusters


- Scheme for the development of common facilities like effluent treatment, testing centres etc.

R&D benefits

- Industry/private sponsored research programmes
- Duty free import of Pharmaceuticals reference standards
- Weighted tax deduction for both capital and revenue expenditure incurred on scientific research and development

Pharmaceuticals

Gujarat Scenario

The background features a solid pink color. In the lower half, there are several overlapping, wavy, semi-transparent bands of color. From top to bottom, these bands are purple, orange, and yellow, creating a layered, flowing effect that moves from left to right across the page.

Leading the Way (1/2)



110

More than 110 years of excellence

33%

Of India's pharma sector turnover

40%

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

1

World's first biosimilar: Adalimumab manufactured in Gujarat

28%

Of India's pharma exports

35%

Of India's Diagnostic Reagent manufacturing

40%

Of CRAMS companies

1

Largest producer of contraceptive pills in the world

Leading the Way (2/2)



3574 *Manufacturing licenses in Gujarat*

1 *Only manufacturer of Dapsone in India*

78% *of India's cardiac stents are manufactured in Gujarat*

50% *of India's intraocular lenses are manufactured in Gujarat*

60% *India's orthopaedic implants are manufactured in Gujarat*

80% *World's Isoniazid is produced in Gujarat*

40% *CRO of India is based in Gujarat*

1st *Diagnostic reagent manufacturer in India to obtain product prequalification from WHO Geneva, is located in Gujarat*

Overview



- Turnover of Gujarat Pharmaceutical industry was worth **~USD 6.7 Billion** in 2015-16; while exports was worth **~USD 3.06 Billion**
- Provides employment to around **85,000** people
- **More than 255** WHO-GMP compliant manufacturing facilities in India are from Gujarat
- Accounts for **53%** of the total medical devices manufacturers in the country
- World's **leading** companies entrust contract manufacturing work to Gujarat



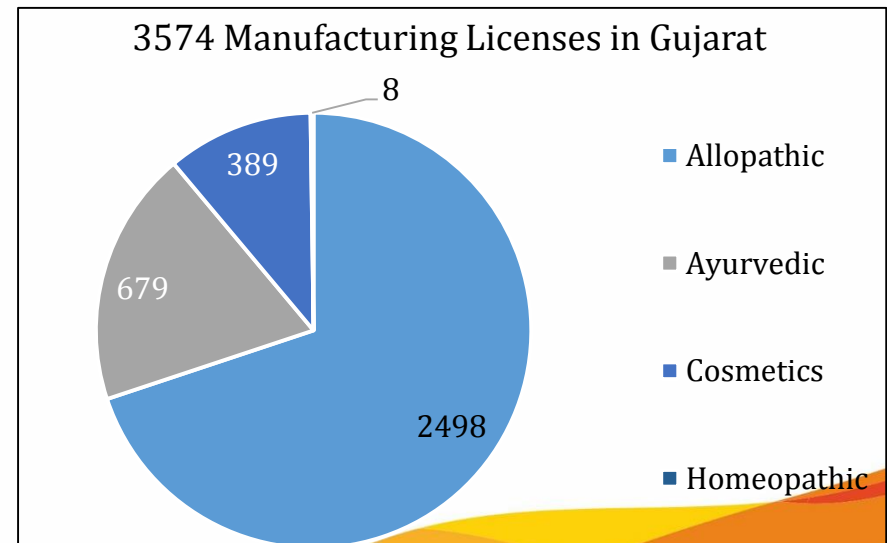
Leader in pharmaceuticals manufacturing in India



The State manufactures and exports different dosage forms including:
Generic drugs, intricate vaccines, r-DNA products, cytotoxic drugs, small and large volume parenterals, biosimilars, sex hormones, APIs, hi-tech cardiac stents, bio-pharma products, external preparations etc.

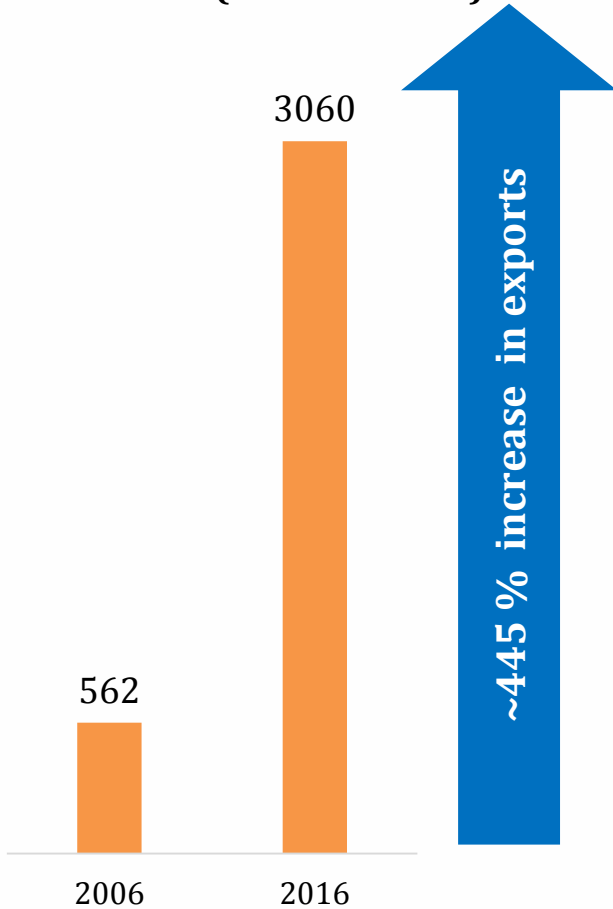
Major Export Destinations:

USA, European Union, UK, Russia, Australia, African Countries, Far East



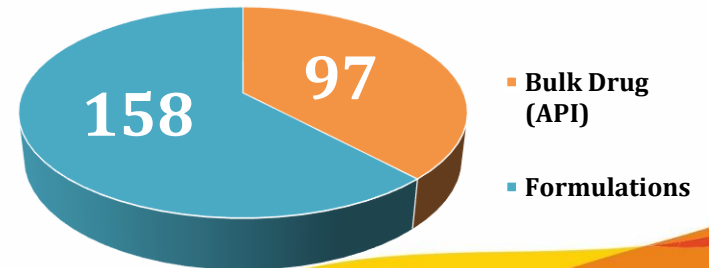
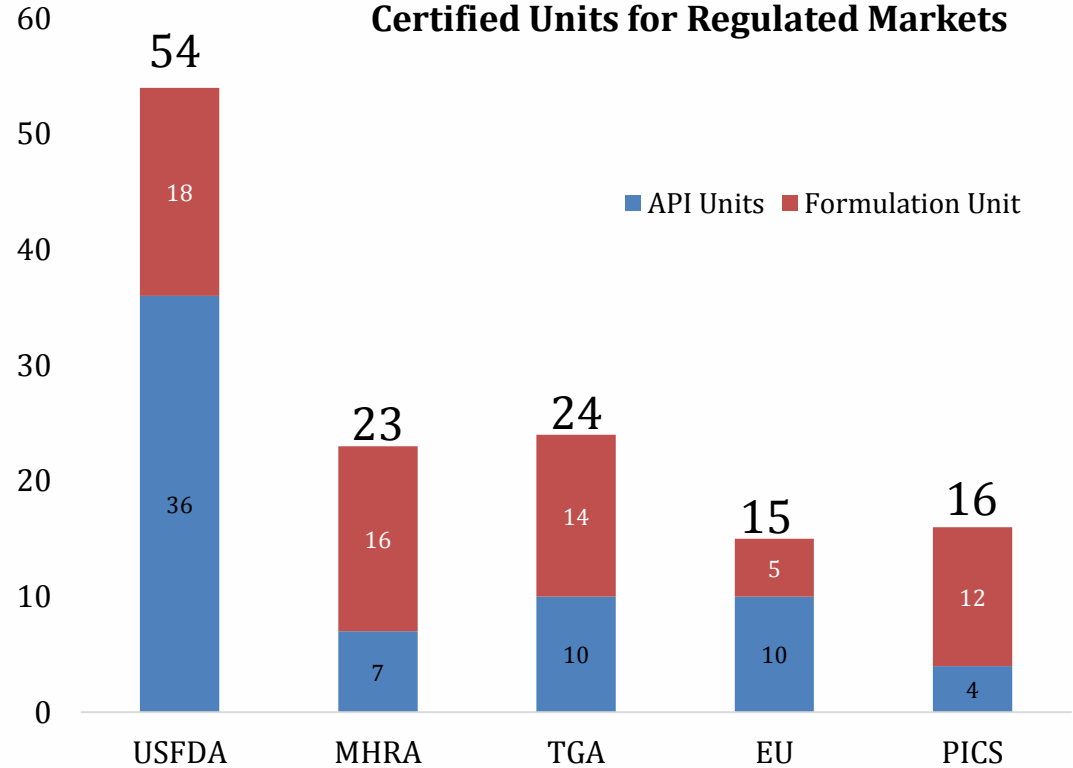
Key statistics

Pharma Exports from Gujarat (~USD Million*)



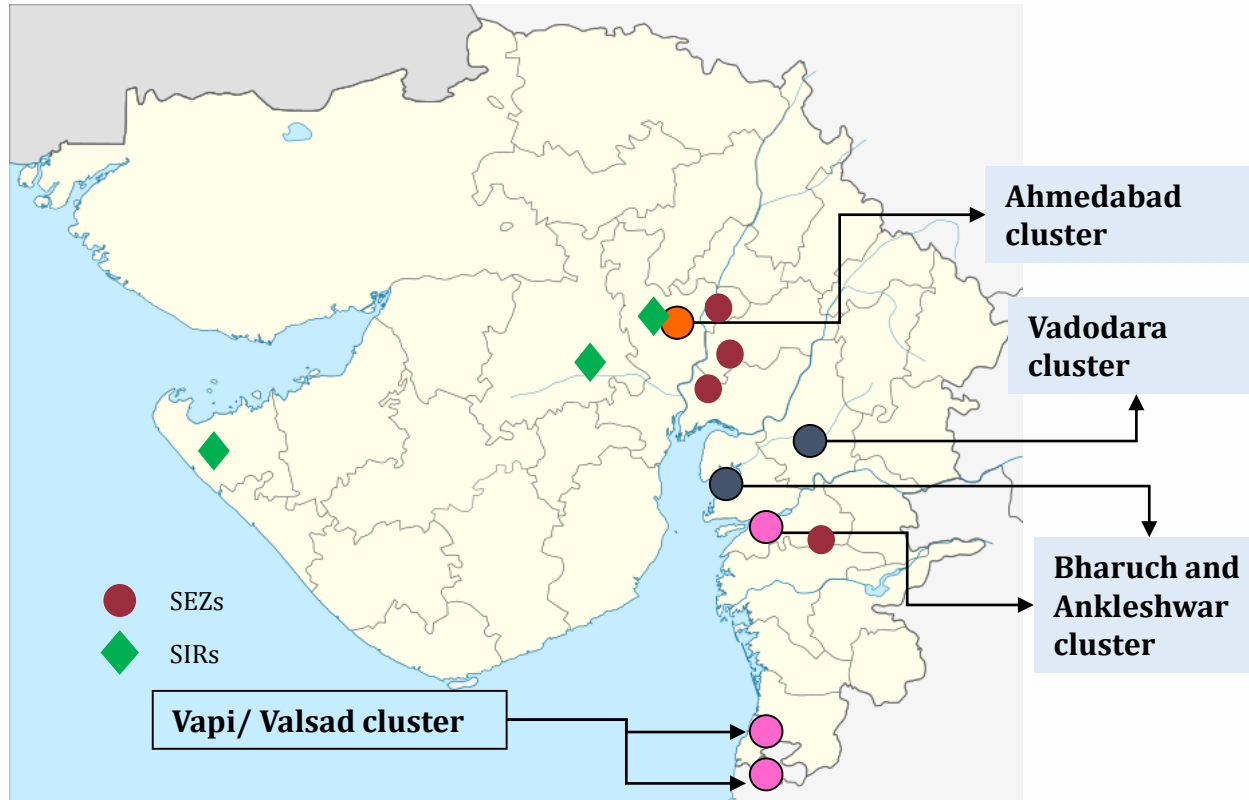
*1 USD = 65 INR

Certified Units for Regulated Markets



255 WHO Compliant Units in Gujarat

Pharma Clusters in Gujarat (1/2)



Zydus Infrastructure Pvt. Ltd.

Location: Ahmedabad

Area: 49 hectare

CPL Infrastructure Pvt. Ltd.

Location: Ahmedabad

Area: 122 hectare

HBS Pharmaceuticals SEZ

Location: Bharuch

Area: 125 hectare

Dishman Infrastructure Ltd.

Location: Ahmedabad

Area: 106 hectare

Pharma Clusters in Gujarat (2/2)



Characteristic of Pharma clusters in Gujarat

Location	Existing Products	Potential future products
Ahmedabad	<ul style="list-style-type: none"> • Formulations • API • Finished Dosages • Biological Products • Contract Manufacturing 	<ul style="list-style-type: none"> • Biological Manufacturing • Medical Devices • CRO • CRAMS
Vadodara	<ul style="list-style-type: none"> • Finished Dosages • Bio-generics 	<ul style="list-style-type: none"> • API • CRAMS • Biological Manufacturing
Bharuch & Ankleshwar	<ul style="list-style-type: none"> • APIs • Formulations • Vaccines 	<ul style="list-style-type: none"> • APIs for global companies
Vapi & Valsad	<ul style="list-style-type: none"> • Formulations • APIs • Device and Diagnostics 	<ul style="list-style-type: none"> • Intermediate & Finished Dosages

Educational Infrastructure



Provisional Intake Capacity
of Pharmacy Colleges in
Gujarat is approx. **4500**



Education / research institutes

- L M College of Pharmacy, Ahmedabad
- Institute of Pharmacy - Nirma University, Ahmedabad
- National Institute for Pharmaceutical Education and Research (NIPER) - Ahmedabad
- Faculty of Pharmacy, MS University, Vadodara
- B.V. Patel Perd Center

R&D, Manufacturing, Marketing and Exports

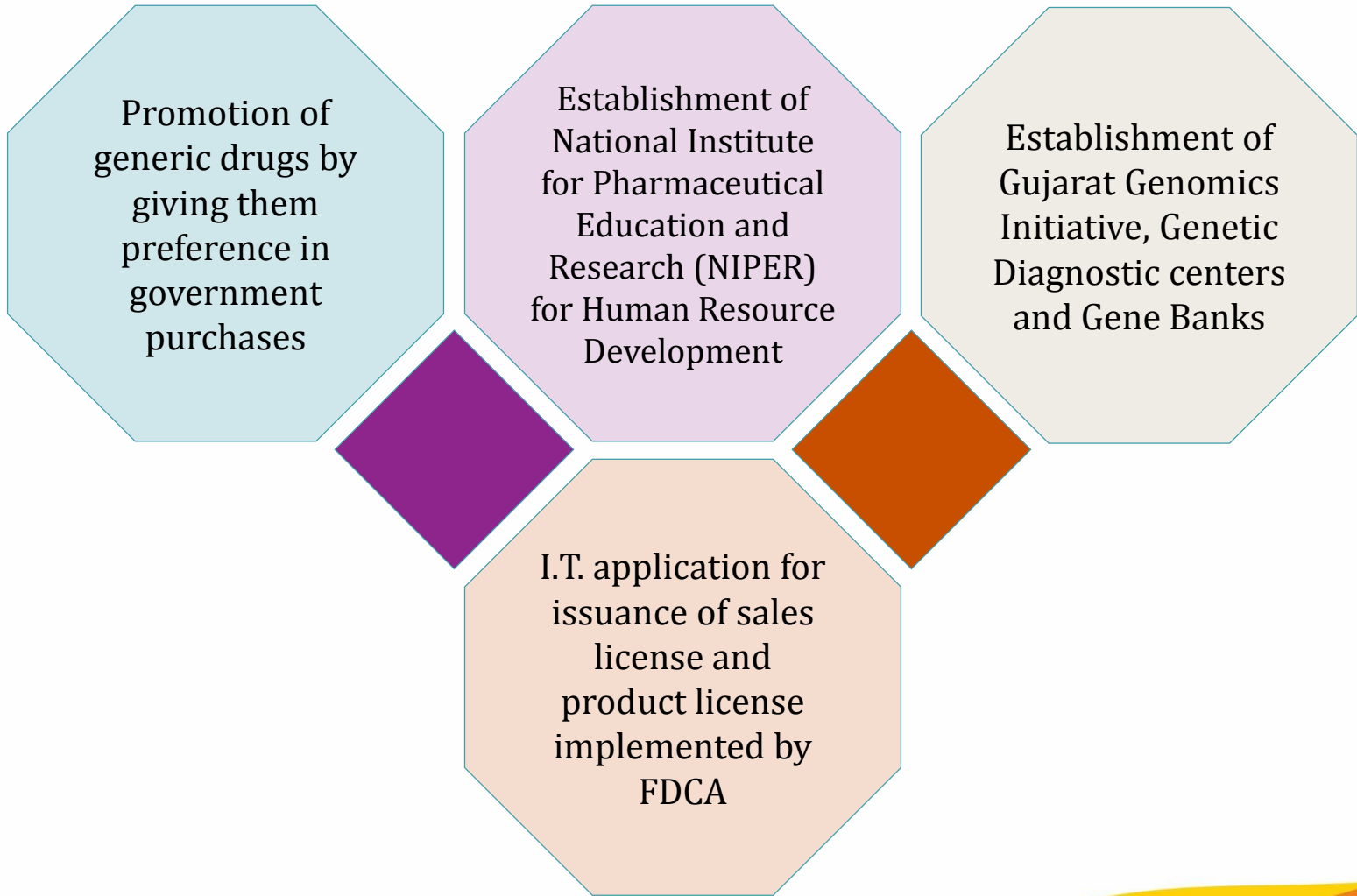
- Zydus Cadila Healthcare Ltd.
- Claris Life sciences Ltd.
- Cadila Pharmaceuticals Ltd.
- Intas Pharmaceutical Ltd.
- Sun Pharma
- Torrent Pharmaceuticals Ltd.
- Dishman Pharmaceuticals
- Abott Laboratories
- Wyeth
- Jubilant Organosys

Contract research organizations

- Lambda Therapeutics
- Quintiles Research (India) Private Limited
- Thermofisher Biopharma Services (i) Pvt. Ltd.
- Synchron Research Services Private Limited
- B A Research India Limited

L M College of Pharmacy, Ahmedabad, established in 1947, is the oldest Pharmacy institute in India

State Government Initiatives



Future plans for Gujarat's pharmaceuticals and medical devices industry



In October 2016, Government of India has announced **3** landmark parks in Gujarat

- API Park
- Formulations Park
- Medical Devices Park



India's **first National Government Medical Devices Laboratory** also to be established in Gujarat.

Growth Drivers for Gujarat's pharmaceutical industry



Accessibility

- Increasing accessibility due to growth in medical infrastructure, new business models
- Huge potential to tap rural markets

Affordability

- Leveraging global technologies to cut down costs
- Rising income and increase in insurance coverage

Rising Patient Pool

- Rising population and changing lifestyles

Generics Drugs Market

- Lowered production cost and skilled manpower & technical competency

Government Policy

- Conducive policies
- Ease of Doing Business

State Government Assistance for Micro, Small and Medium Enterprises (1/2)



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 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 Patent Registration

- 75% of expenditure incurred for obtaining patents

State Government Assistance for Micro, Small and Medium Enterprises (2/2)



Assistance for Technology Acquisition

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

Assistance for Saving in Consumption of Energy & Water

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

Assistance for Venture Capital

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

GST: Next step towards uniform national tax regime



- The Goods and Services Tax (GST) Bill passed in 2016
- Government of Gujarat has also ratified the GST Bill
- Coverage under GST:
 - ✓ Excise Duty, Service Tax, Countervailing Duty, Special Additional Duty
 - ✓ VAT, CST, Entry Tax, Octroi, Local Body Tax, Entertainment Tax, Luxury Tax, Goods under Medicinal and Toilet Preparations Act
- Concessional rates for select goods being considered – under discussion at Central Government level

FDCA: Food and Drugs Control Administration



XLN is a software for transparent and speedy disposal of various Licensing applications and reducing the time lag between the Collection of Samples to declaration of Results to dissemination of information to stake holders.

XLNINDIA.GOV.IN (ALL STATES- FDCA/DCD/FDA/DCA/DDC)
XLN - Xtended Licensing, Laboratory & Legal Node
 DeTY, A NIC Product, for Dept. of Health & Family Welfare **

Click STATE Buttons to LOGIN | MH | GU | KA | AP | WB | JH | BI | CH | DL | UP | CT | MP | RJ | TN | HR | GJ

All **Regulators & Stakeholders**, hereby instructed to ensure :-
 1. R.P. should login with Pharmacy Council REGS/30 as UserID & **REGS/30A** as the Password on this website.
 2. R.P. should then, update his/her Profile, Upload his PASSPORT size scanned Photo in jpg and REGS-CERTIFICATE in pdf format.
 3. UserID - GJREGS21897 where GJ is State Code, 82 for Regt.Pharmacist and 0221897 is Regs.No of R.P.

Name of Functionality	GJ	MH	KA	CO	HP	AP	KA	WB	Total
LOGINS - Staff (Today)	43	133	55	0	12	31	26	17	315
LOGINS - Pharm	84	499	4	0	0	0	0	0	607
Retailers/Wholesalers	2918	7259	1856	678	3081	4326	2910	22	21117
Total Licenses	4058	2491	1374	3768	7269	12216	4038	47	51925
Online Applications	5250	7919	1139	2919	197	8199	2474	0	17911
Total Inspections	24207	44193	4848	3458	254	4008	16963	0	74543
Grant / Reject	5131	7580	1027	263	146	805	2477	0	17157
Sample Returned	2408	2494	378	7	51	0	0	0	5370
NSQ Samples detd.	1414	1335	53	0	0	842	202	0	4848
Canceled/Expired/Expired	4093	3276	451	0	0	558	0	0	13118
Total NSQ send	4706	14420	1911	304	1473	0	0	0	42714

0 indicates, Data NOT available, ONLINE Applications ONLY in GJ, MH



- End-to-end online system. No physical file required.
- Auto reminder for renewal of licenses
- Centralized approval system for licenses
- One database accessed by states
- Single SignOn for multiple states

Gujarat model replicated in **13** states and declared as rapid roll out for all states by DeTY, GoI.

FDCA – Laboratory Capabilities

- Food and Drug Laboratory (FDL) – Vadodara and Patan; Regional Food Laboratory - Rajkot and Bhuj can carry out testing of **Allopathic Drugs, Ayurvedic Drugs, Homoeopathic Drugs, Cosmetics, Food Articles.**
- These laboratories are equipped with state of the art testing facilities **AAS, Spark emission, spectrophotometers, HPLC with Auto Sampler, Gas/Liquid chromatography, Spectrophotometers, FTIR**
- FDCA is equipped with **Mobile Drug Testing Lab** having key sophisticated instruments like **Raman Spectrophotometer, Near Infrared, XRS (X-Ray Spectrometer).** These Mobile Labs (India's first Mobile Drug Testing Lab) have facility of detecting any spurious drugs on spot.

Investment Opportunities



High End Drugs

Contract Research and Manufacturing Services industry (CRAMS)

Active Pharmaceutical Ingredients (API)

Biopharmaceuticals

Formulations

Medical Devices and Diagnostic Kits

Pharma Retail Chains

Pharma Machinery

Key Department / State Government Agencies



Health and Family Welfare Department

Health and Family Welfare Department

7th Floor, Block 7, Sardar Patel Bhavan, Sachivalaya, Gandhinagar, Gujarat, India - 382010

<http://www.gujhealth.gujarat.gov.in/>

Phone: 079-23251401

E-mail: sechfwd@gujarat.gov.in

Food and Drugs Control Administration

Food and Drugs Control Administration

Block No 8, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat, India - 382010

<https://gujhealth.gujarat.gov.in/food-and-drug-control-administration.htm>

Phone: 079-23253417

E-mail: comfdca@gujarat.gov.in

Industries and Mines Department

Industries and Mines Department

5th Floor, Block 3, New Sachivalaya, Gandhinagar, Gujarat, India - 382010

<http://www.imd-gujarat.gov.in/>

Phone: 079-23250703

E-mail: secimd@gujarat.gov.in

Industrial Extension Bureau

Industrial Extension Bureau (iNDEXTb)

2nd Floor, Block No 18, Udyog Bhavan, Gandhinagar, Gujarat, India - 382010

<http://www.indextb.com>

Phone: 079-23256009

E-mail: indextb@indextb.com



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