



सत्यमेव जयते

Government of Gujarat

Pharmaceuticals and Medical Devices



Outline



GOVERNMENT OF GUJARAT

1 Overview - India

2 Gujarat Scenario

3 Government Initiatives

4 Investment Opportunities

5 Key Partners/Investors



Overview - India

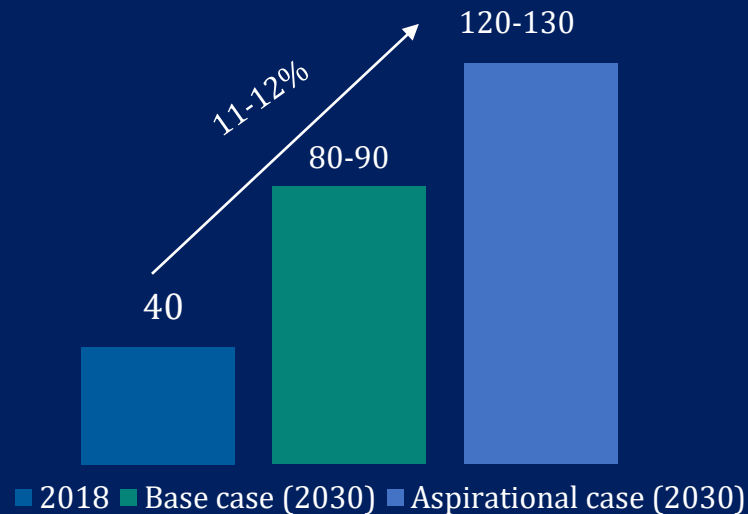
No. 1 global provider of generic medicines

2nd largest pharmaceutical and biotech workforce in the world

2nd largest number of US FDA approved facilities

3rd largest market in terms of volume

Projected size of Indian pharma industry, US\$ billion

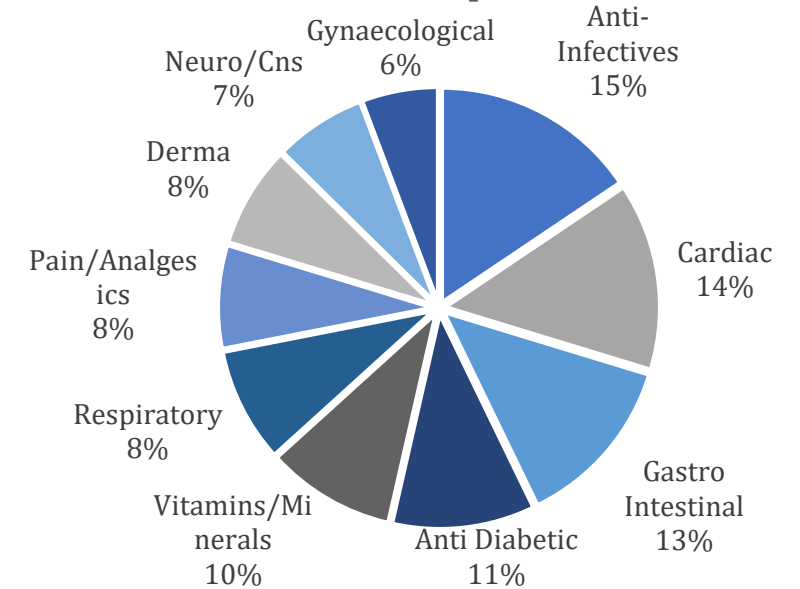


- Contributes 1.72% to the country's GDP
- 3rd largest market for APIs globally, and manufactures 500+ different APIs
- 3000 pharma companies with 10,500 manufacturing units
- Cost of manufacturing is 33% lower than in the western markets
- Accounts for 60% of the global vaccine production
- Contributes 40 to 70% of the WHO demand for DPT and BCG Vaccines and 90% demand for measles vaccines
- 100% FDI allowed under automatic route for greenfield projects



GOVERNMENT OF GUJARAT

Sector Composition



India exports vaccines to 200 countries

60,000 generic brands across 60 therapeutic areas; Generic drugs account for 70% of revenue

*QE – Quick Estimates

API – Active Pharmaceutical Ingredients
USFDA – US Foods and Drug Administration

Source: India Surging ahead report, Exports Data by Directorate General of Foreign Trade(Statistics division)
Annual report by Department of Pharmaceuticals 2019-20; ESI 2020-2021

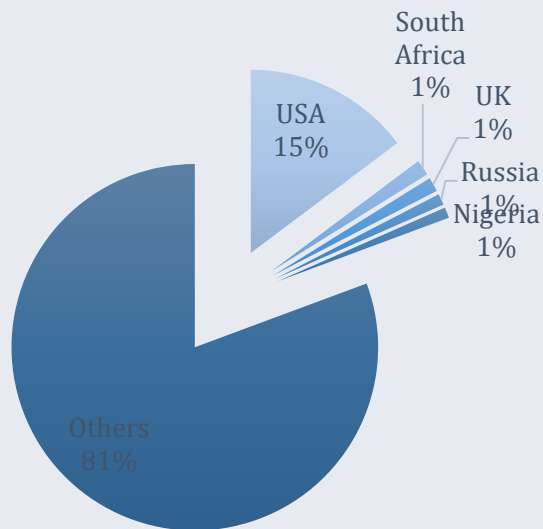
Exports in Pharmaceuticals



India exported pharmaceuticals at a recorded growth of 7.91% in FY 21*

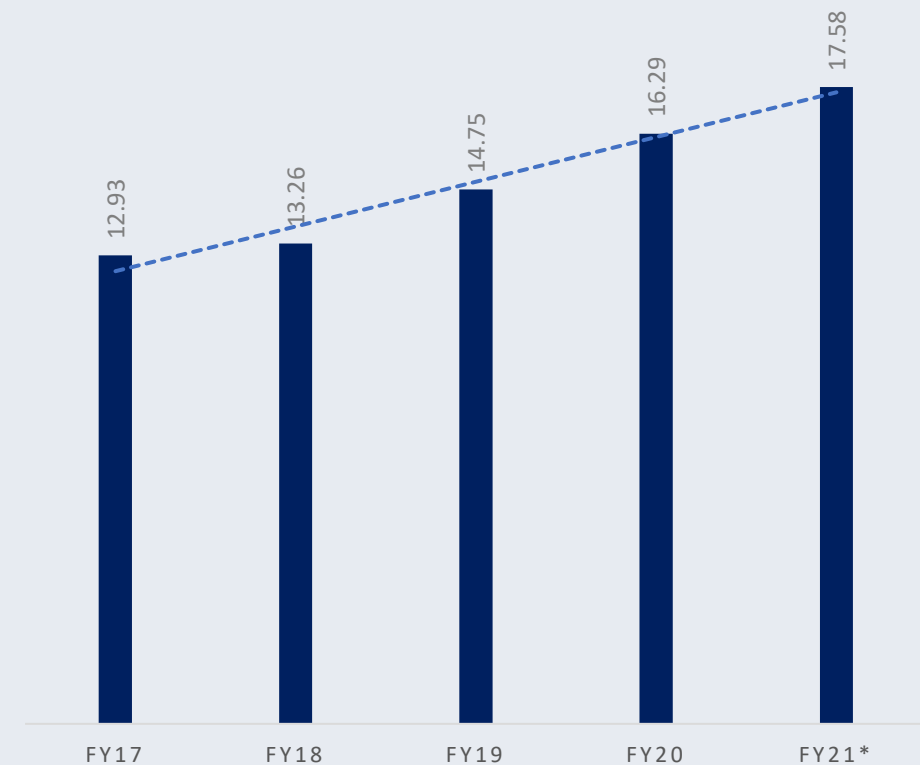
The total turnover of Indian Pharma industry reached US\$ 41.4 billion in FY20; Important segments of pharma industry are Generic Drugs, OTC Medicines, API/Bulk Drugs, Vaccines, Contract Research & Manufacturing, Biosimilars & Biologics

India's Pharma Exports during April-Feb 2021 (% share)



- Indian Pharma Exports stood at US\$17.58 billion in FY21*
- India exports pharmaceuticals to over 200 countries, where USA, South Africa, UK, Russia and Nigeria account for almost 20% of the total.
- USA was the biggest importer in the year with US\$ 2.5 billion worth of imports, primarily driven by exports of Covid-related drugs by India throughout the year

Pharma Exports in US\$ billion



Advantage India



GOVERNMENT OF GUJARAT

Favorable FDI Policies

100% FDI allowed in pharma sector through automated approval route for greenfield projects

Up to 74% FDI through automatic route in brownfield projects.

Department of Pharmaceutical approved 17 FDI proposals worth US\$ 216 million under brownfield pharmaceutical projects during April 2020 to December 2020.

Zero duty for technology upgrades through Exports Promotion Capital Goods (EPCG) Scheme

Skilled Workforce

India has sizeable number of skilled workforce as well as high managerial and technical expertise. The labour costs are 50-55% cheaper than in U.S.A

Lower Production Costs

The cost of production is nearly 33% lower than that of western countries



Progressive IP Rights

New and progressive patent laws incentivize investors to invest in R&D.



Strong public-private partnerships

The GoI encourages multi-billion dollar investment with 50% public funding through PPP model, to enhance innovation and capacity

Medical Device Industry

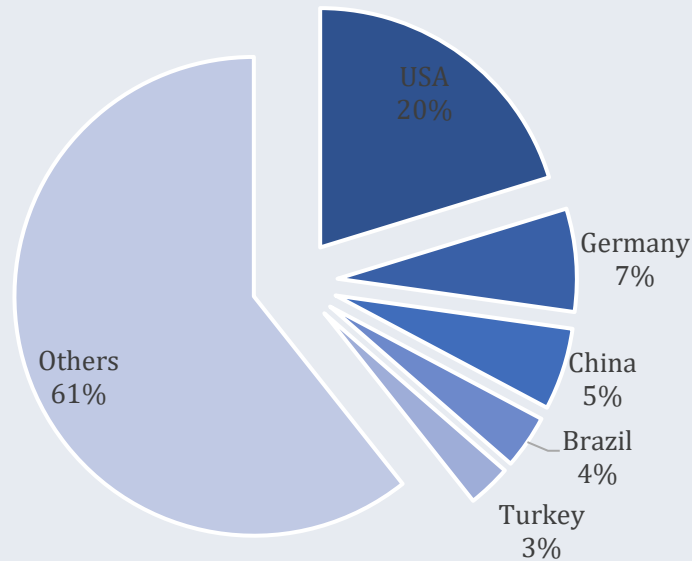


India is one of the top 20 global medical device markets and 4th largest market in Asia. The market size is expected to reach US\$ 50 billion by 2025.

2nd largest PPE Kits manufacturer with production capacity of 1 million kits per day.

India exported medical devices and related instruments worth US\$ 991.75 million from Apr 2020 to Feb 2021.

Exports of Medical Devices from Apr 2020 to Feb 2021



Quick Facts

- Manufacturing clusters in Gujarat, Haryana, Maharashtra, Karnataka, Andhra Pradesh, Telangana, and Tamil Nadu are the manufacturing clusters of medical devices industry
- 100% FDI allowed under automatic route
- 4000 health-tech startups in India
- 800 private players in the sector in India

Growth Drivers

- Skilled manpower having capacity to make devices under Make in India initiative
- Growing R&D opportunities with presence of prominent contract research organizations
- Ageing population and increasing life expectancy rate can induce home based healthcare services

Government Initiatives (1/3)



GOVERNMENT OF GUJARAT

Pharma Vision 2020	Aims at making India a global leader in end-to-end drug manufacturing. Approval time for new facilities have been reduced
National Medical Device Policy 2017	Make in India drive in medical device sector
National Pharmaceutical Pricing Policy 2012	Regulating the prices of essential drugs
Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) 2008	Quality medicines at affordable prices - 6068 functional kendras till 2019-20
Cluster Development Programme for Pharma Sector(CDP-PS)	To enhance quality, productivity and innovative capabilities of SME pharma sector



Assistance to Bulk Drug Industry, Medical Device Industry, Pharmaceutical Industry (CDP-PS) to build common facilitation centres



Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)



Pharmaceuticals Promotion and Development Scheme (PPDS) – extending financial support to conduct promotional events for facilitating investments, growth and exports

Government Initiatives (2/3)



Schemes	Incentives
<p>Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs), Drug Intermediaries and Active Pharmaceutical Ingredients (APIs) in India</p>	<ul style="list-style-type: none"> • Identified list of 53 KSMs/APIs to be manufactured • Fermentation based products – 20% Incentive for first four years, 15% for fifth year & 5% for sixth year on incremental sales • Chemically synthesis products – 10% incentive for five years on incremental sales • Outlay of INR 6940 crore
<p>Scheme for Promotion of Bulk Drug Parks (2020-2025)</p>	<ul style="list-style-type: none"> • Grants-in-aid to 3 Bulk drug parks with maximum limit of INR 1000 crore per park or 70% of project cost, whichever is less • For North east & Hilly states – INR 1000 per Bulk Drug park or 90% of project cost, whichever is less • Assistance in common facilities include – Solvency Recovery & Distillation Plant, Central Effluent Treatment Plants, Captive Power Plants, Steam & Cooling Systems, Incubation Facilities, Common Logistic Facilities etc • Outlay of INR 1000 crore (maximum limit) per Bulk Drug park for common infrastructure facilities • Implemented through one time grant-in-aid to State Implementation Agency (SIA)

Government Initiatives (3/3)



GOVERNMENT OF GUJARAT

Schemes	Incentives
Production Linked Incentive Scheme for domestic manufacturing of Medical Devices (2020-2025)	<ul style="list-style-type: none">• Incentive of 5% on incremental sales• Expected Incentive of INR 3420 crore• Implemented through a Nodal agency called as Project Management Agency (PMA)• Target segments of medical devices eligible include – Cancer care/Radiotherapy, Radiology, Imaging & Nuclear Imaging medical devices etc
Scheme for Promotion of Medical Device Parks (2020-2025)	<ul style="list-style-type: none">• Grant-in-aid to 4 Medical Device parks with maximum limit of INR 100 crore per park or 70% of project cost for common infrastructure facilities, whichever is less• For North east & Hilly states – INR 100 crore per park or 90% of project cost of common infrastructure facilities• Common infrastructure facilities include – Component testing Centre, Electromagnetic Interference Laboratory, Biomaterial/Biocompatibility testing Centre, radiation testing centre etc• Outlay of INR 400 crore for 4 medical device parks• Implementation through State Implementation Agency

Transformation in Pharma Industry



GOVERNMENT OF GUJARAT

Key Areas

Value Chain

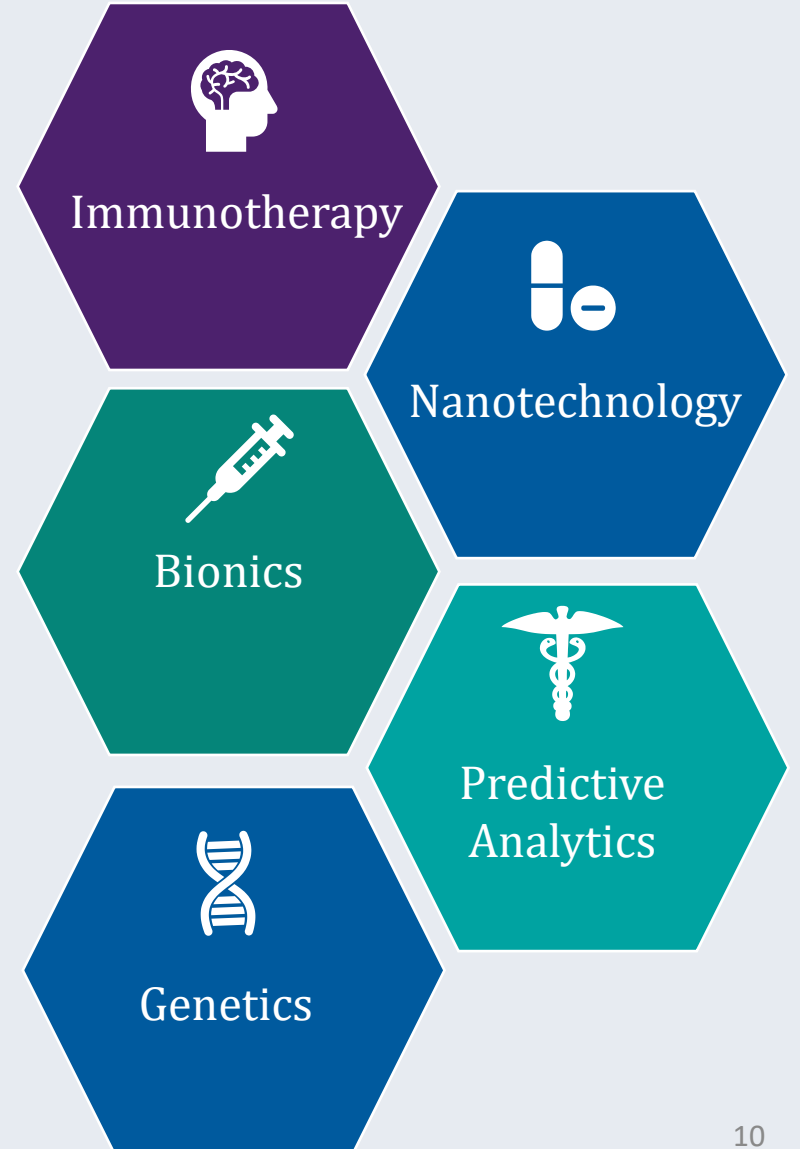
Government and Insurers - Taking the center stage, pressuring pharmaceutical companies to reduce prices and demonstrate greater value from their therapies

Use of Artificial Intelligence – To streamline value chain, improve drug approval rates and lower the associated costs in drug manufacturing

Diagnosis

From treatment-oriented procedures to preventive diagnostic and care. Consumers pushing towards self medication

Digital transformation technologies to help improve engagement with patients and customers



Gujarat – Pharmacy To Nation



GOVERNMENT OF GUJARAT

Quick Facts

Second highest no of export-oriented companies in India (649) until 2018-19

Over 4000 manufacturing licenses issued for allopathic, homeopathic, ayurvedic and cosmetic drugs

Gujarat FDCA issues 2000 product licenses every month

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

40% of India's machinery for pharma sector is based in Gujarat

53% of India's total registered medical device manufacturers have presence in Gujarat

Gujarat accounts to one third share in India's pharma market

130 USFDA approved units

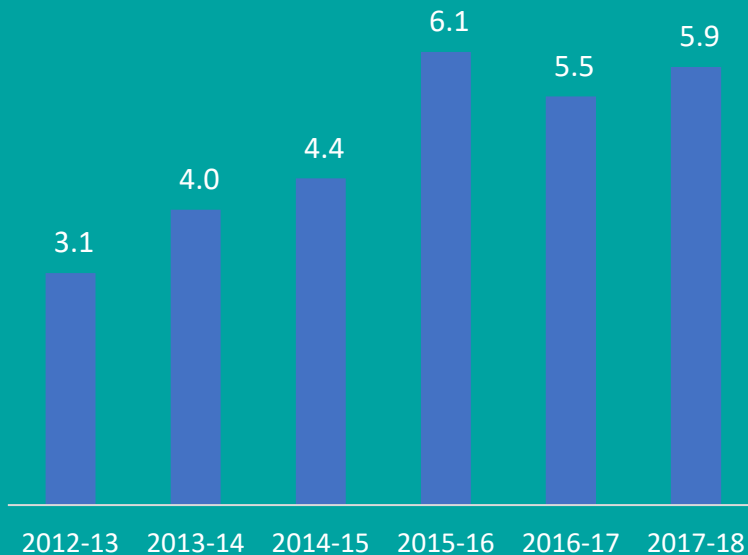
628 WHO GMP manufacturing units

Over 4.5 lakh product licenses issued

Pharma companies have applied for registration of 180 new units to be set up in Gujarat in 2018

US\$ 1.6 billion allocated to Health and Family Welfare department by government of Gujarat in Budget 2021-22

Total Output in US\$ Billion



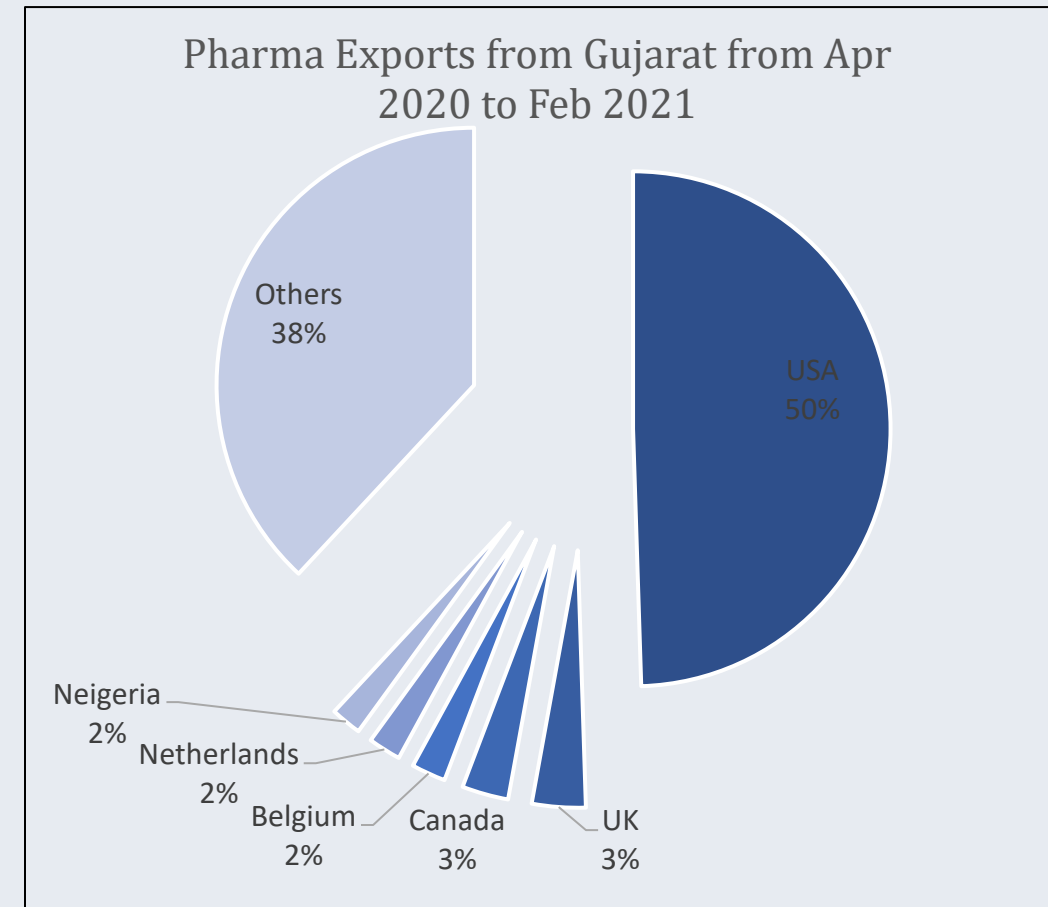
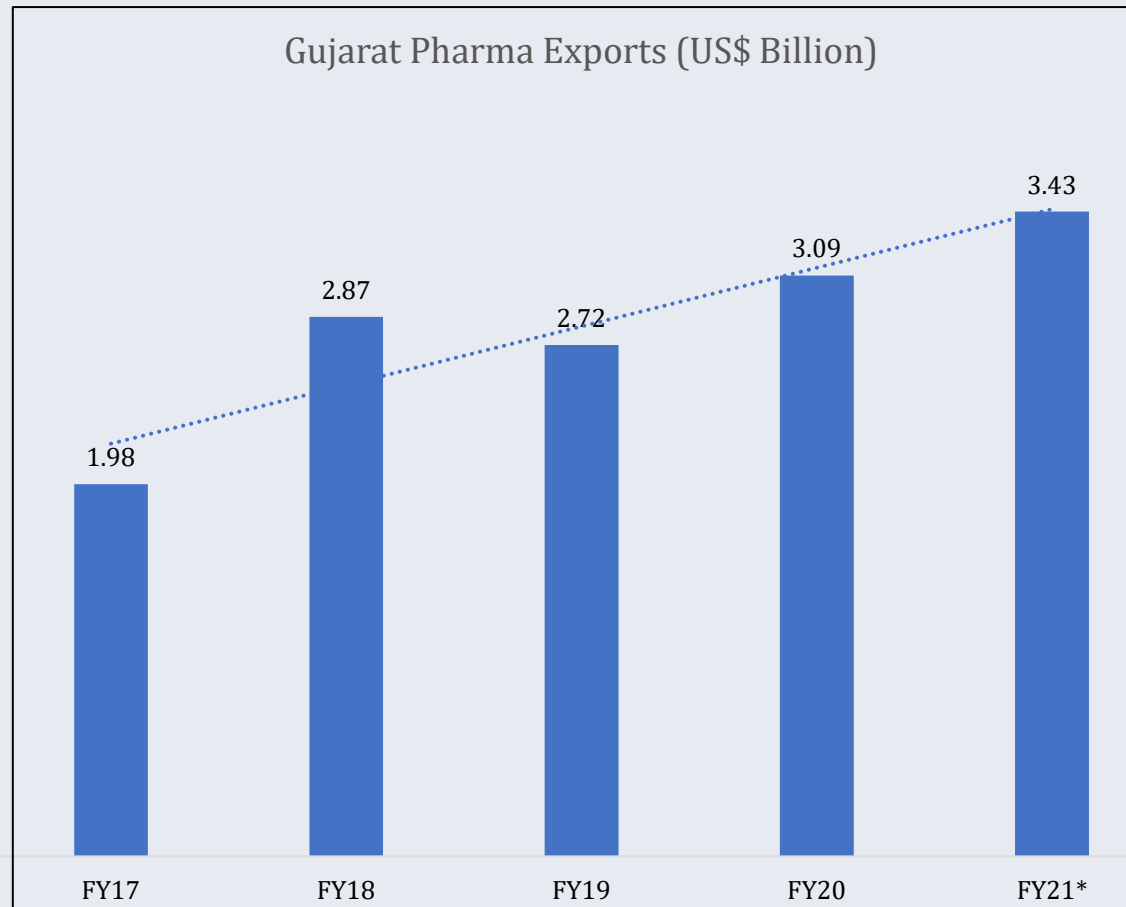
Exports of Pharmaceuticals in Gujarat



GOVERNMENT OF GUJARAT

Gujarat is biggest exporter of pharma products in India and accounts for 19.5% of India's pharma exports in FY21*

Gujarat witnessed Y-O-Y growth of 11% in drug exports in FY21*



Source: DGCIS; *figures till February 2021

Growth Drivers



GOVERNMENT OF GUJARAT



Ease of Doing Business

Introduced drug manufacturing license software, which enables the regulator to efficiently process the approval and renewal of applications received. Timelines for granting and renewal of manufacturing licenses to make the process quicker for drug manufacturers



Global Competitiveness

Vast talent pool with presence of strong academic institutions provides an edge to Gujarat at global level. Cluster driven approach facilitates clinical research trials



Strong R&D support

Key R&D segments include clinical research, genetic engineering, drug research and development



Policy Support

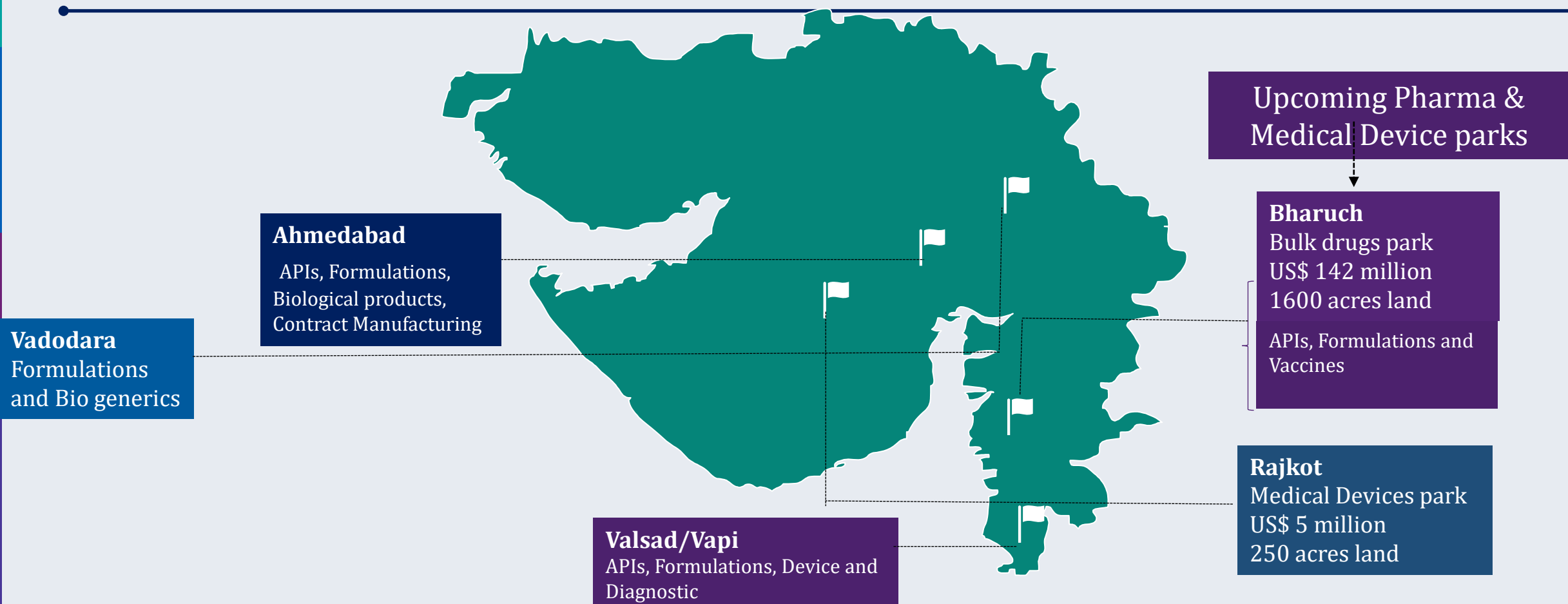
Giving impetus to SME's for installing ERP system, to obtain ISO and WHO GMP certification

Pharmaceuticals & Medical Devices identified as one of the thrust sectors in Gujarat Industrial Policy 2020

Pharma Clusters in Gujarat



GOVERNMENT OF GUJARAT



Advantages:

World class infrastructure for medical device & pharma manufacturing

Promote Exports

Accelerate commercialization of new technologies

Conducive business environment

Enable surgical start up to collaborate with industries

Medical Devices - Overview



GOVERNMENT OF GUJARAT

Medical Devices include: cardiac stents, drug eluting stents, catheters, intra ocular lenses, bone cements, heart valves, scalp vein set, orthopedic implants and internal prosthetic replacements



Prior to Medical Device Rules, Gujarat has registered 170 medical device units under the Central Licensing Approval Authority (CLAA) scheme



Around 80% of medical devices in India are imported



Upcoming medical devices park in Rajkot, Gujarat will encourage production and reduce import dependency on the global market



Central government is planning to streamline procedure for obtaining environment clearance by API units



The proposed medical device park would be a geographic cluster of surgical & medical device manufacturing, research and R&D testing laboratories



Up to 100% FDI allowed in manufacturing of medical devices/equipment's



The cost of production comes down due to usage of common facilities in a park and local players become price competitive globally



Present Institutional structure in Gujarat



B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre, Ahmedabad
બી.વી. પટેલ ઔષધીય શિક્ષણ અને સંશોધન વિકાસ (પર્ડ) કેન્દ્ર, અમદાવાદ
India's first multidisciplinary, postgraduate research institute

- Equipped with the latest and best R&D facilities, the institute runs a dedicated course with focus on medical device industry



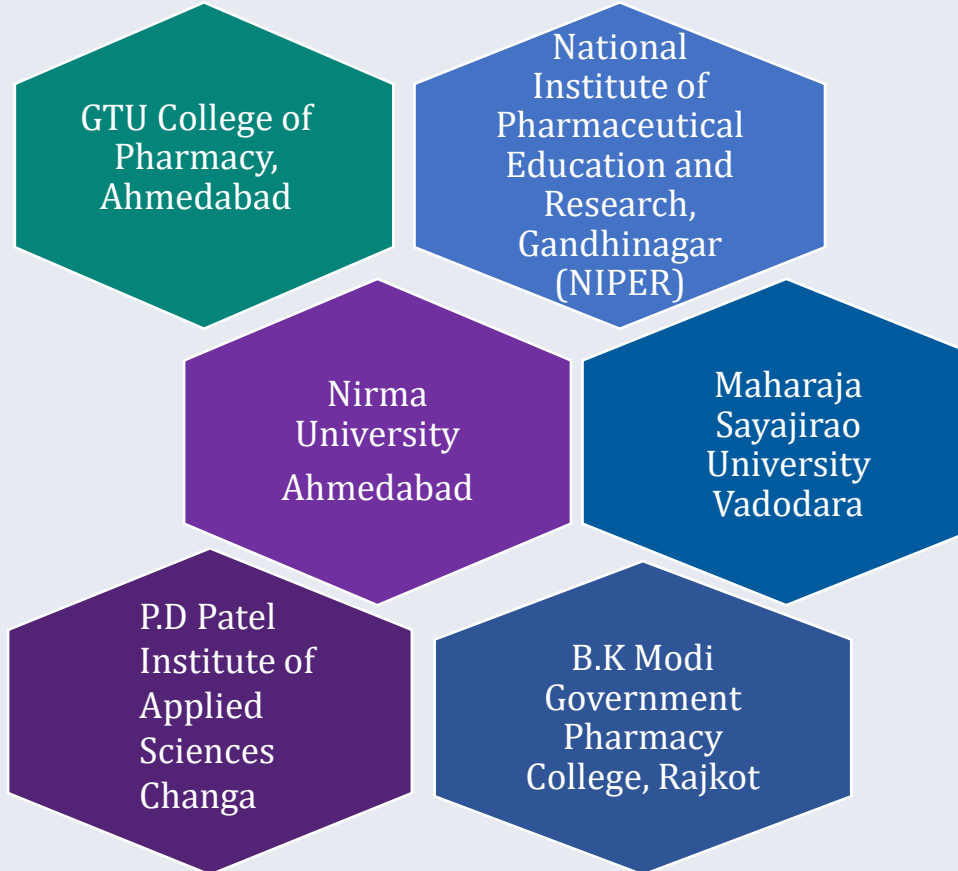
- Electronics and Quality Development Centre (EQDC), Gandhinagar is recognized by the Directorate of Standardization Testing and Quality Certification (STQC), Department of Information Technology, Ministry of Communication, GOI

Education Infrastructure and allied organizations



Major R&D centres in Gujarat

Torrent Research Centre	Zydus Research Centre	Sun Pharma Advanced Research Company Ltd (SPARC)
--------------------------------	------------------------------	---



40% of India's Contract Research Organizations are based in Gujarat

Piramal Pharma Solutions

- Early stage drug discovery services, In Vitro screening, ADME services etc

Synchron Research Services

- Bioavailability, Pharmacokinetic, Pharmacovigilance

Cliantha Research Ltd.

- Bioequivalence, Biosimilars, Biometrics and Personal health care

Lambda Therapeutic Research Ltd.

- Medical Imaging, Scientific writing, Quality assurance

FTF Pharma

- Identification of new products, Non infringing and IP strategy, Clinical trials

Accutest Research Labs

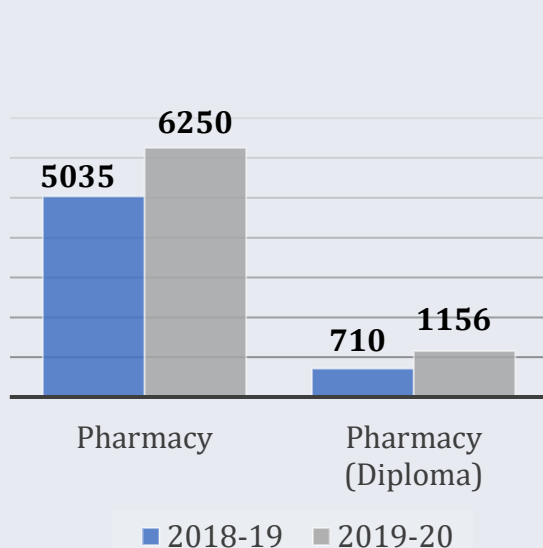
- Microbiological, Study of medical device, Pre clinical testing, Herbal formulation

Veeda CR

- Patient trials for generics, NCE & Biopharmaceutics

India's first pharmacy college, L. M. Pharmacy College (1947) in Gujarat, offers diploma, degree and master's programmes

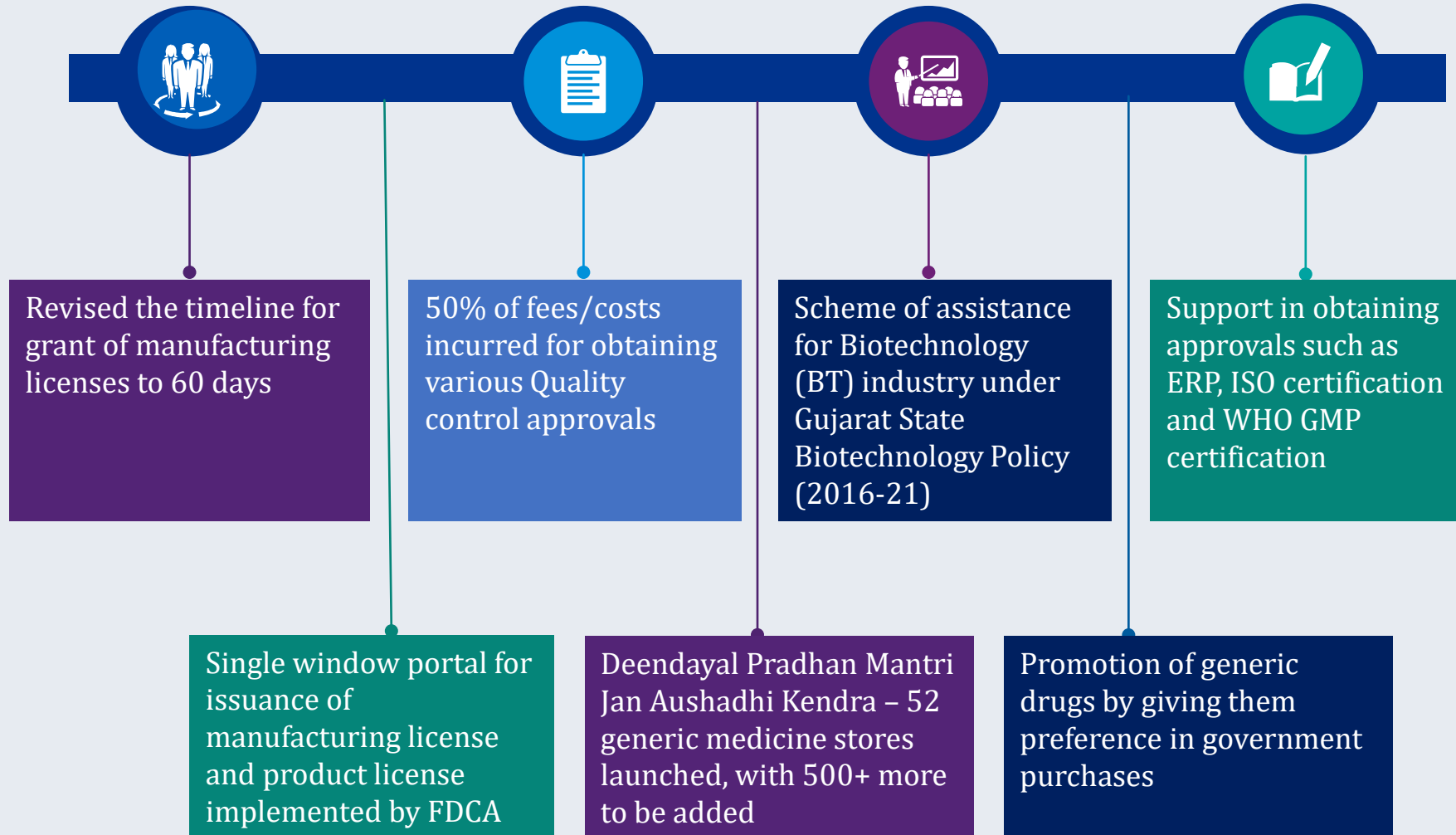
Pharmacy seats



State Government Initiatives



GOVERNMENT OF GUJARAT



*ERP – Enterprise Resource Planning

*ISO – International Standard Organization

*GMP – Good Manufacturing Processes

Industrial Policy 2020 – Incentives to Industries



GOVERNMENT OF GUJARAT

Pharmaceuticals and Medical Devices have been identified as Thrust Sector



Capital Subsidy for Large Industries

- Up to **12% of FCI for large units**
- Exemption of electricity duty for 5 years



Incentives to MSMEs

- **Capital Subsidy** for manufacturing sector – Assistance up to 25% of eligible loan amount up to INR 35 Lakhs
- **Interest Subsidy** for manufacturing & service sector – Assistance up to 7% of interest levied on term loan up to INR 35 lakhs per annum
- **Acquiring Foreign Patented Technologies** – Assistance up to 65% of the cost of acquiring foreign patented technologies with a ceiling of INR 50 Lakhs. Processed patents will also be included.



Research & Innovation

- Financial Assistance up to INR 5 crore for setting up R&D & product development centers by private companies



Relocation Incentives

- Provision of **Re-location subsidy** on case to case basis e.g. units willing to relocate from other countries and / or diversifying their supply chain through investment in Gujarat



Government Land for Long Term Lease

- Facilitation to industries in getting “Government Land” on long term lease up to 50 years to industrial enterprises @6% of the market rate

Industrial Policy 2020 – Key Incentives for Industrial Infrastructure



GOVERNMENT OF GUJARAT



Development of Industrial Parks

- **Industrial Parks** - Assistance upto 25% of eligible fixed capital investment (50% in case of Vanbandhu Talukas) in building and infrastructure upto INR 30 Crore. Stamp Duty reimbursements will be given to developers (100% of Stamp Duty) and individual units (50% of stamp duty)
- **Common Hostels / Dormitories** – Assistance of 50% upto INR 20 Crore.



Development of Common Industrial Infrastructure

- Assistance upto 80% of project cost for set up of Industrial Infrastructure such as construction and up gradation of roads, warehousing facilities, fire stations, underground utilities , etc. upto INR 25 crore



Common Environment Infrastructure

- Assistance upto 40% of eligible fixed capital investment in the project for **Common Effluent Treatment Plant, Waste Management System, upgradation of existing CETPs, common spray dryer, common multiple effect evaporator** etc. upto INR 50 Crore
- Assistance upto 25% of project cost for set up/ relocation / retrofitting of existing polluting industrial units into **Green Industrial Estates** upto INR 25 crore
- Assistance upto 50% of fixed installation cost to **Common Boiler Project by SPV** constituted by minimum 10 MSME upto INR 2 crore



Assistance for Sustainable Manufacturing

- 50% of capital subsidy up to INR 75 Lakhs to industries practicing at least 50% waste recovery through **Zero Liquid Discharge** as certified by GPCB
- Incentive to MSMEs @ 35% of cost of P&M and to large industries @ 10% of cost of P&M maximum up to INR 35 lakhs for **implementing cleaner production measures**



Skill and Training Support

- Fiscal incentive for skill enhancement up to INR 15,000/- per person per training to institutes

Growth Drivers for Investment Opportunities



GOVERNMENT OF GUJARAT

Medical Tourism

World class treatment at affordable price

Pharmaceutical machinery

Strong engineering sector to produce pharma machinery

Contract Research and manufacturing services

Highest CRAMS in India

OTC Drug market

Shift in consumers towards self medication

E Pharma

Digital India initiative leading to market penetration in rural areas

Pharma Ingredients

More than 1,000 medicinal plants grown to make APIs

Artificial Intelligence

Drug discovery, drug dosage & safety, manufacturing & supply chain, market access & commercialization



State of art academic institutions

Upskilling of manpower



*OTC – Over the counter

*CRAMS – Contract research and Manufacturing Services

Key Partners/Investors



GOVERNMENT OF GUJARAT



Connect for more Information

Health and Family Welfare Department Government of Gujarat, INDIA

7th Floor, Block 7,
Sardar Patel Bhavan, Sachivalaya,
Gandhinagar, Gujarat, India - 382010
<http://www.gujhealth.gov.in/>
Phone: 079-23251401
E-mail: sechfwd@gujarat.gov.in

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

Industrial Extension Bureau (iNDEXTb)

Block No. 18, 2nd floor, Udyog Bhavan,
Gandhinagar, Gujarat, India – 382 010
www.indextb.com
Phone: 079-2325 6009
E-mail: md.indextb@gmail.com

