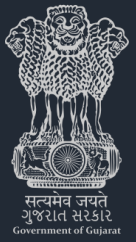


CELEBRATING
20 Years of
VIBRANT GUJARAT
(2003-2023)
AS THE SUMMIT OF SUCCESS



Development of Bulk Drug Park at Bharuch



Pharmaceuticals
Government of Gujarat

ibrant
GUJARAT 2024
10-12 Jan
Gateway to the Future | 10th Global Summit

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Project Concept

Background

- ▶ Bulk Drug Park was part of the Government of India's initiative to boost pharmaceuticals sector and reduce the dependence on import for Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs).
- ▶ The aim was to strengthen the domestic manufacturing of bulk drugs and reduce the country's vulnerability to disruptions in the global supply chain.
- ▶ It involves the creation of integrated manufacturing clusters that house multiple units engaged in the production of bulk drugs and APIs. These parks will provide conducive environment for pharmaceutical companies, including infrastructure support, common facilities and shared resources.

Promotion of Bulk Drug Park Scheme by GoI

One time grant-in-aid for development of CIF



₹ 1000 Cr

Or

70% of the project cost

**In case of Plain States*

One time grant-in-aid for development of CIF



₹ 1000 Cr

Or

90% of the project cost

**In case of North Eastern & Hilly States*

Objective of Bulk Drug Park



Facilitating convenient access to state-of-the-art infrastructure aims to substantially reduce the production costs of bulk drugs.



Elevate India's self-reliance in bulk drugs by enhancing the competitiveness of the domestic industry.



Facilitate industry compliance with environmental standards cost effectively via innovative waste management strategy



Harness advantages derived from resource optimization and economies of scale.



Project Concept

Target Segment for Bulk Drug Park

Production Linked Scheme (PLI), segments identified by DoP, Gol



Fermentation based
KSMs/Drug Intermediates



Fermentation based niche
KSMs/Drug
Intermediates/APIs

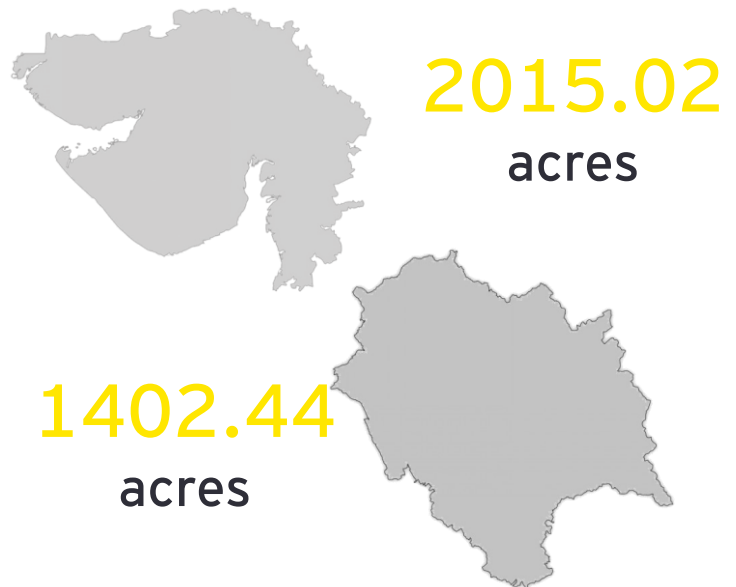
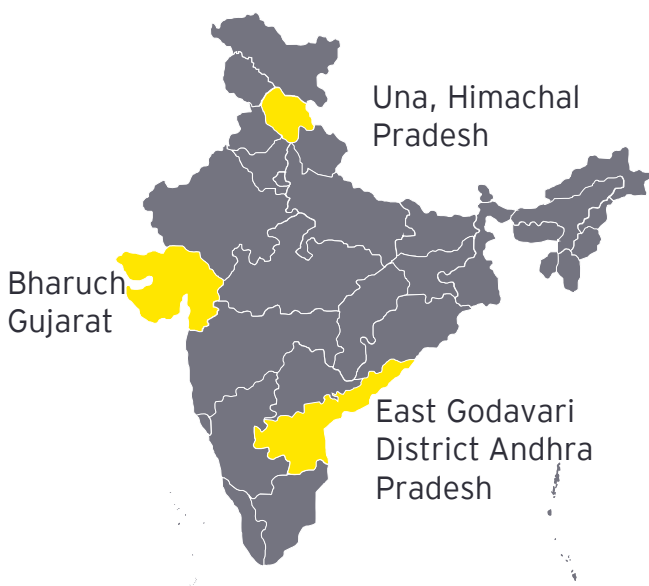


Key Chemical Synthesis
based KSMs/Drug
Intermediates



Other Chemical Synthesis
based KSMs/Drug
Intermediates/APIs

Development of Bulk Drug Park in India



1402.44
acres



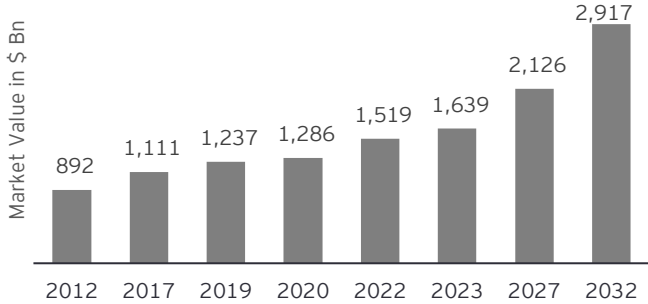
13
States

Proposal submitted to
Department of
Pharmaceuticals, Gol

Market Potential

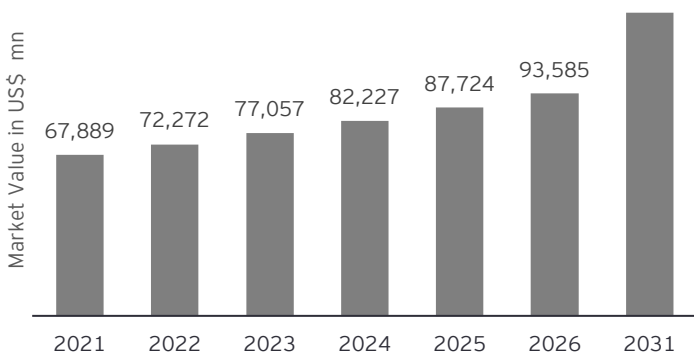
Global Pharmaceutical Sector

Global Pharmaceutical Market Size 2012-32



- ▶ In 2022, the other therapeutics market reached a value of US\$ 89.48 Bn, growing at a CAGR of 5.21% from US\$ 65.64 Bn in 2016
- ▶ In 2022, oncology market reached a value of US\$ 34.37 Bn, growing at a CAGR of 7.96% from US\$ 21.71 Bn in 2016

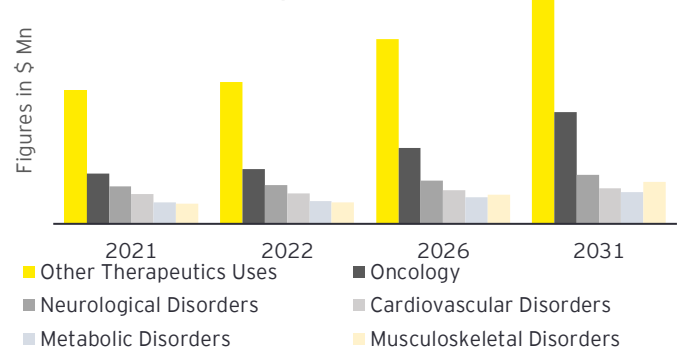
Asia-Pacific Pharmaceutical Market Size 2021-31



- ▶ In the Asia Pacific pharmaceutical API manufacturing market in 2021, the other therapeutics uses segment held a significant share at 46.22%, with oncology following closely at 15.98%.
- ▶ The other therapeutics segment is projected to grow at a CAGR of 7.05%, while oncology is expected to experience a higher growth rate at 8.78% in 2031.
- ▶ India has secured among the top 12 destination for biotechnology globally.
- ▶ The biosimilar market in India is poised for substantial growth, with an estimated CAGR of 22%, projecting it to reach US\$ 12 Bn by 2025.

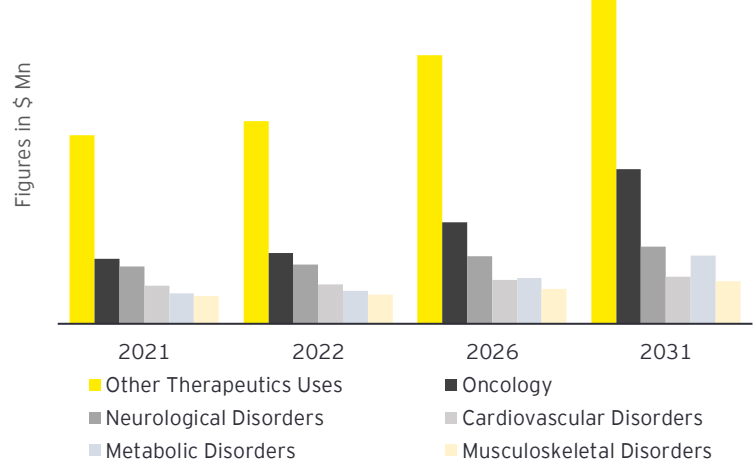
- ▶ In 2022, the global pharmaceuticals market reached a value of US\$ 1.59 Tn, growing at a CAGR of 6.43% from US\$ 892 Bn in 2016.
- ▶ Anti-infective drugs constitutes 15.5% followed by oncology drugs at 13.9% and central nervous system drugs at 11.2%.

Global Pharmaceutical API Manufacturing Market, Segmentation By Therapy Area 2021-31



- ▶ The Asia Pacific pharmaceutical API manufacturing market witnessed substantial growth, increasing from US\$ 53.27 Bn in 2016 to US\$ 67.88 Bn in 2021, reflecting a CAGR of 4.97%
- ▶ The API pharmaceutical market in the region is anticipated to experience continued growth, with a projected CAGR of 6.63% by 2031.

Asia-Pacific Pharmaceutical API Manufacturing Market, Segmentation By Therapy Area 2021-31



Source: OECD Library, National Statistics office, UN Comtrade

Market Potential

Indian Pharmaceutical Sector

3rd rank



Globally in pharmaceuticals production

14th rank



Pharmaceuticals in value

4%



Share in global pharmaceutical economy

8%



Global API Manufacturing Industry

20%



Share in Global supply of Generic Medicines

55%



Export to Highly Regulated Market

70%



WHO demand for DPT & BCG vaccines

90%



WHO demand for DPT & measles vaccines

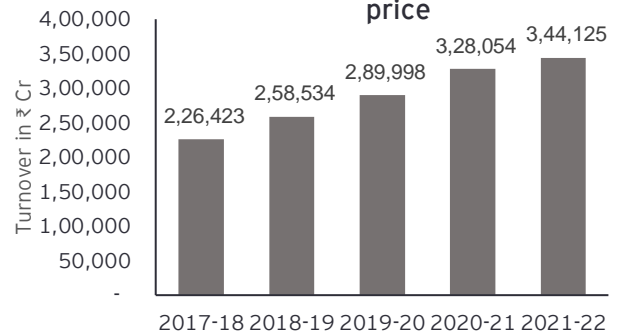
60%



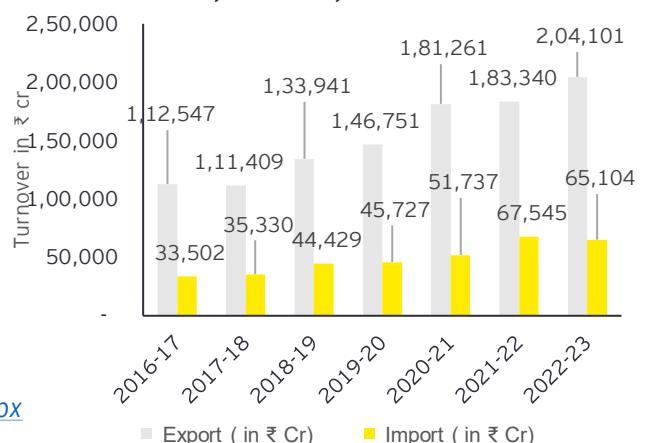
Global Vaccine Production

- ▶ Drug & Pharmaceutical sector attracted ₹ 1,27,000 Cr. in FDI from April 2000 to September 2023, constituting approximately 4.9% of total FDI.
- ▶ As on April 2023, India has 6,316 market authorization granted to Indian companies & 70 manufacturing sites registered with USFDA.
- ▶ The Indian Pharma Sector has been growing at a healthy rate over the last 5 years. The sector offers lower cost without compromising on quality
- ▶ Total export from Pharmaceutical sector stood at ₹ 2,04,101 Cr. during 2022-23 registering a CAGR of 15.05% between 2016-22.
- ▶ Total import amounted to ₹ 65,104 Cr., resulting in a trade surplus of ₹ 1,38,997 Cr.
- ▶ India is a major Pharmaceuticals exporter to over 200 countries.
- ▶ India fulfils more than half of Africa's need for generics medication, ~40% of generic demand in the US and about quarter of all medicine in the UK.

Pharma Sector's Growth at current price



Import & Export of Pharmaceuticals



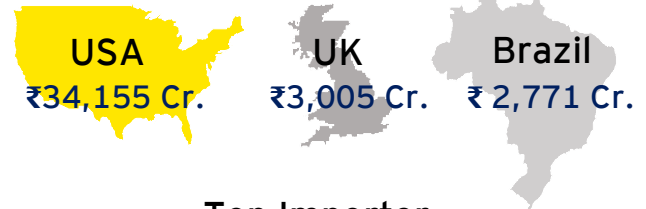
Source: Annual Report 2022-23, DoP, GoI, Pharmaceuticals Export Promotion Council of India 2023, <https://dashboard.commerce.gov.in/commercedashboard.aspx>

Market Potential

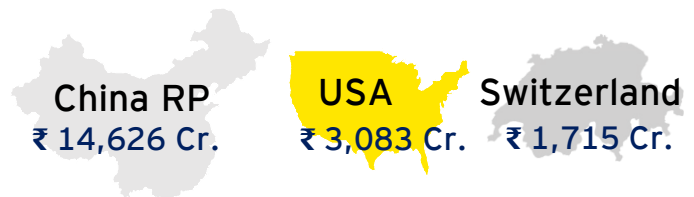
Indian Pharmaceutical Sector

- ▶ Average index of industrial production for the manufacturing of pharmaceuticals, medicinal chemicals and botanical products in FY 2022-23 stands at 217.
- ▶ USA holds as the key market for pharmaceutical products constituting ₹ 34,155 Cr. due to cost advantage that India has.
- ▶ Other top exporter countries are UK, Brazil, South Africa, Belgium etc.
- ▶ India's reliance on pharmaceutical imports persists, with the People's Republic of China maintaining its position as the primary importer of pharmaceutical products, accounting for ₹14,626 Cr.
- ▶ USA, Switzerland, Germany, Netherland, Singapore are the major importer of Pharmaceutical products.

Top Exporter

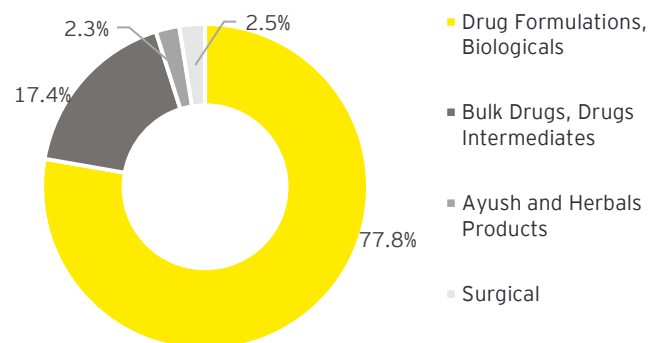


Top Importer

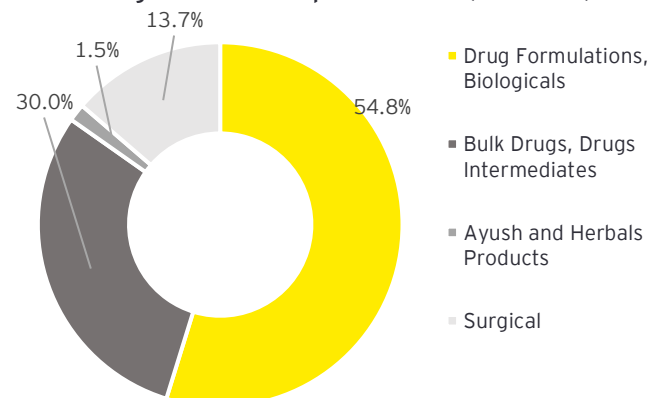


- ▶ Drug formulations account for 77.8% of pharmaceutical exports in 2022-23, followed by bulk drugs and drug intermediates at 17.4%
- ▶ Ayush and Herbals Products, as well as the Surgical segment, contribute 2.3% and 2.5%, respectively.
- ▶ In pharmaceutical imports for 2022-23, Bulk Drugs and Drugs Intermediates lead with a share of 54.8%, followed by Drug Formulations and Biologicals at 30.0%.
- ▶ Surgical imports constitute 13.7%, while Ayush and Herbal Products make up only 1.5%.
- ▶ The Indian API industry, valued at ₹ 798 Bn, is projected to grow to ₹ 1,307 Bn by 2026, with a compound annual growth rate (CAGR) of 8.57%.
- ▶ India is home to over 1500 API manufacturing units.

Segment-wise Export Details (2022-23)



Segment-wise Import Details (2022-23)



Source: Annual Report 2022-23, DoP, GoI, Pharmaceuticals Export Promotion Council of India 2023, <https://dashboard.commerce.gov.in/commercedashboard.aspx>

Growth Drivers

Demand for Pharmaceutical Products

- ▶ The increasing population and the aging demographic will contribute to a rising demand for healthcare services, consequently leading to an increased demand for pharmaceutical products.
- ▶ As per India Ageing Report 2023 by United Nations Population Fund (UNFPA) projected that India's elderly population will increase from 10.5% in 2020 to 20.8% by 2050.

Growing market for Generic Drugs

- ▶ India holds the position of being the largest supplier of generic medicines, contributing to a 20% share in the global supply. This is accomplished through the manufacturing of 60,000 different generic brands spanning across 60 therapeutic categories.
- ▶ India caters to about 60% of the global vaccine demand.

Govt. of India Initiatives

- ▶ In 2020, Union Cabinet approved the production linked incentives (PLI) scheme, focusing on stimulating domestic manufacturing of KSMs, Drug Intermediates and APIs. The scheme entails providing fiscal incentives to qualifying manufacturers engaged in the production of 41 identified eligible products encompassing 53 APIs for a duration of six years.
- ▶ Government has granted permission for upto 100% FDI through automatic route for greenfield projects and upto 74% in case of brownfield projects.

Growth Drivers

Large pool of qualified personnel

- ▶ India has a large, growing, trained and skilled workforce providing robust support for the establishment of large-scale pharmaceutical manufacturing projects.
- ▶ According to the India Skill Report 2022, there has been a slight improvement in employment and job readiness levels in the pharmaceutical sector, reaching 44.62%.
- ▶ 7 National Institutes of Pharmaceuticals Education & Research (NIPERS)-hubs of innovation & advanced research
- ▶ As per All India Survey on Higher Education 2019-20, India has nearly 9.46 Mn students in STEM

Purchasing capacity and its affordability

- ▶ One of the largest healthcare insurance -Pradhan Mantri Jan Arogya Yojana (PMJAY) (Ayushman Bharat) programme for secondary and tertiary care.
- ▶ Approx. 500 Bn beneficiaries covered up to US\$ 6,800 per annum with 24,000+ empanelled hospitals.
- ▶ Under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) a Govt of India scheme to provide medicine at affordable price across the country. As on March 23, number of pharmacy stores are 9,303 across the country.
- ▶ 1800 drugs & 285 surgical items are covered under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) scheme

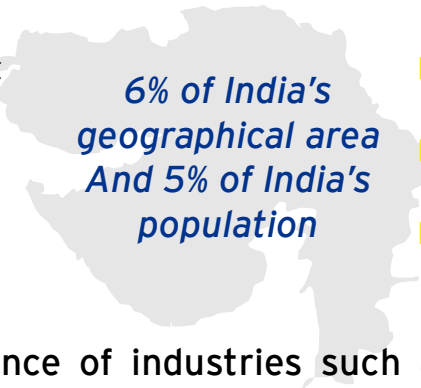
Digitization

- ▶ In recent times, digitization has emerged as a pivotal driver for the pharmaceutical industry, facilitating the delivery of high-quality and hyper-personalized customer experiences. Additionally, it plays a crucial role in enhancing business resilience and overall performance.
- ▶ With the launch of Centre of Excellence, artificial intelligence is emerging as the focal point of India's primary vision of "Make AI in India" and "Make AI work for India."

Gujarat - Competitive Advantage

Gujarat overview

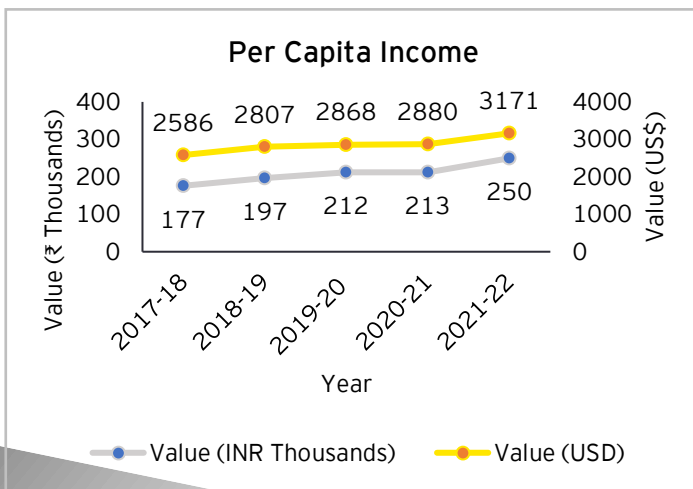
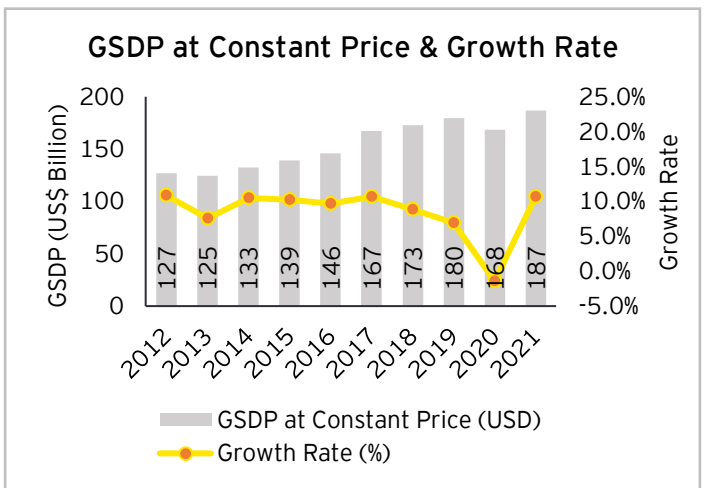
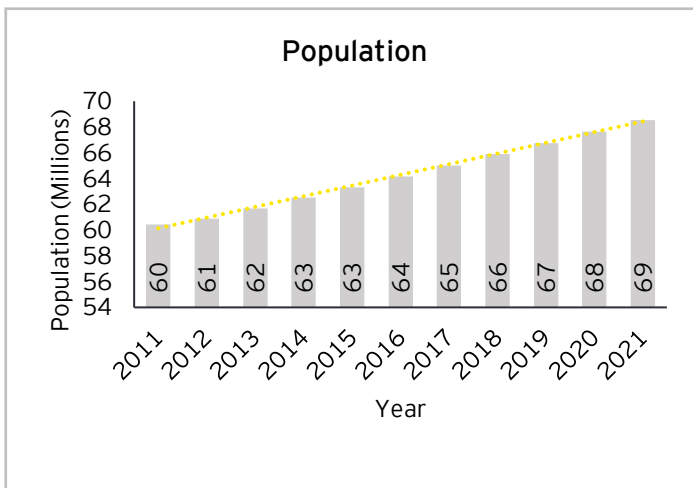
- ▶ 8.3% of India's GDP: GSDP at current price ~US\$ 269 Bn
- ▶ 37% share of manufacturing sector in State's GDP
- ▶ 18% of India's industrial output



- ▶ 33% share in India's total exports
- ▶ 40% cargo of the entire country is handled by Gujarat Ports
- ▶ Huge base of MSMEs (~1.3million)

Gujarat has strong presence of industries such as Chemicals & Petrochem, Textiles, Pharmaceuticals, Automobiles, Gems & Jewellery, Ceramics, etc.

Macroeconomic trend



Industrial Production Data

Gujarat enjoys the status of industrially developed state of India with its 18.14% share to Country's industrial output, the largest among the states of India in the year 2019-20. The Net Value Added (NVA) has increased from ₹8,944.8 billion in 2010-11 to ₹1,902.57 billion in 2019-20. As per Annual Survey of Industries, the number of factories has increased from 26,842 in the year 2018-19 to 28,479 in the year 2019-20, showing a growth of 6.10% over the previous year.

Source: CEIC; <https://gujecostat.gujarat.gov.in/>

Gujarat - Competitive Advantage

Key advantages

Ease of doing business



Ranked among the top achievers in 'Ease of Doing Business' ranking 2020



1st Rank in Logistics Performance Index (LEADS Index) in 2018, 2019, 2021 & 2022



1st Rank in NITI Aayog's Export Preparedness Index of states - 2020 & 2021



1st Rank in Good Governance Index (GGI) in 2021



Ranked among the top achiever state in 'LEADS' ranking 2022



National Start-Up Rankings in 2021 (Start-Up Megastars), 2019 and 2018



Top performer by labour force participation rate and minimum man-days lost due to labour unrest

Talent pool

Gujarat has emerged as one of the top states in India with excellent infrastructure for technical education. The state currently has 350+ engineering colleges, 41 polytechnics and 770+ Industrial Training Institutes (ITI) inculcating quality education. The government through its Gujarat Skill Development Mission is also providing training courses to the youth and making them industry ready.

11

Institutes of National Importance

116

Graduate & **60** Post Graduate Colleges

33,000+

Trained technical professionals annually

113

diploma courses

41,000+

Trained Diploma professionals annually

Gujarat - Competitive Advantage

Infrastructure & connectivity



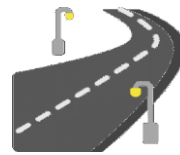
Longest coastline
1,600 km
48 seaports



5,300 km
Railway
network



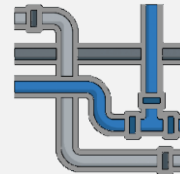
19 Airports
(including
4 intl. airports)
*Upcoming airport at
Dholera SIR*



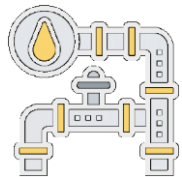
75,000+ km of road
network
7,873 km of national
highways



Power surplus State
48 GW total capacity
44% from renewables



Statewide water
network
62,778 km Narmada
Canal
120,000 km
distribution



1st statewide
extensive
piped natural gas
grid - 3,370 km
network



Ahmedabad-Mumbai
semi-highspeed rail
Bullet train
(*upcoming*)



Delhi-Mumbai
Industrial corridor -
DMIC covering 23/33
districts



239 GIDC
Industrial estates
with
Plug & play facility



1st Global
Business District
- GIFT City



1st Platinum rated
Green industrial city
- Dholera Semicon
City

Pharma Ecosystem in Gujarat

Key Differentiators

30%



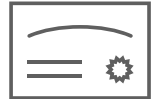
Pharmaceutical Industries contributes to India's total turnover

25%



Total Pharmaceutical export of India

1327



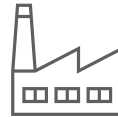
WHO GMP manufacturing units

37



Pharmaceutical Cluster in the State

1,567



Bulk Drug Manufacturing units

150



USFDA approved units

40%



India's pharma machinery manufacturing

40%



India's Contract Research Organizations

6000+



Allopathic drugs manufacturing unit

2.64 Cr



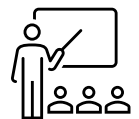
MT/annum
Current production capacity in bulk drug sector

1.26



Lakh
Employed in Pharmaceutical sector

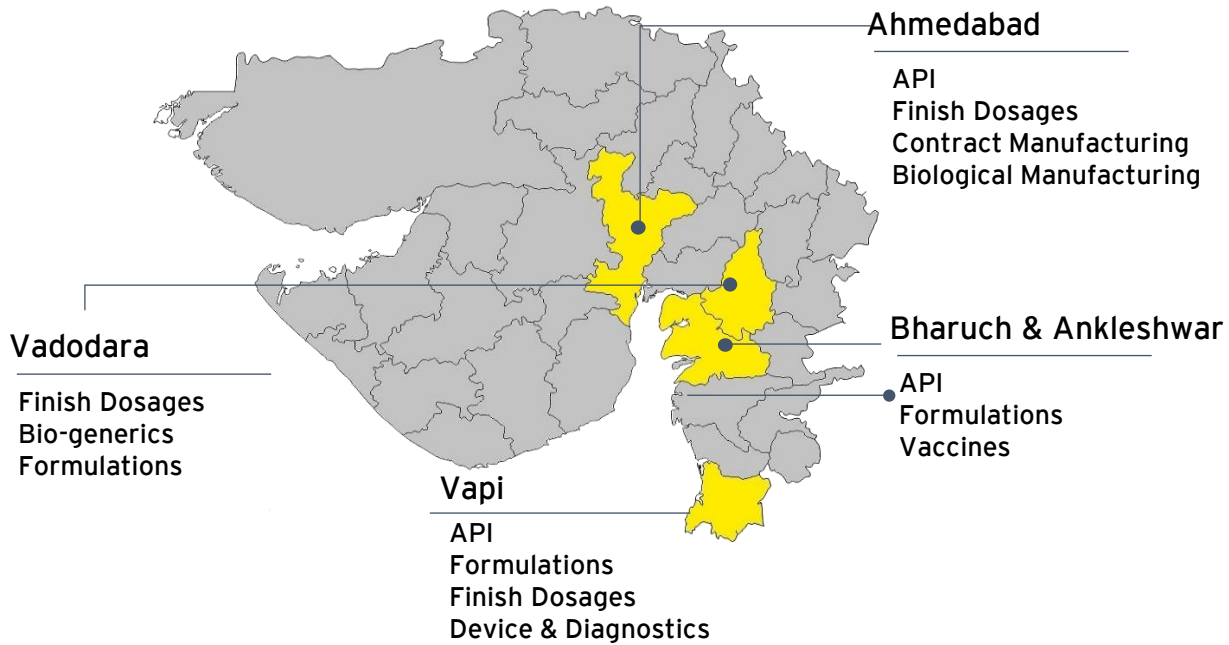
9.46



Mn
Student in STEM
(Science, Technology, Engineering & Maths)

Pharma Ecosystem in Gujarat

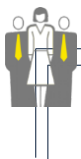
Pharmaceutical Clusters in Gujarat



Ahmedabad, Ankleshwar, Bharuch, Vapi & Valsad clusters are into manufacturing of APIs.



Major Export Destinations of Gujarat Pharma products are US, the European Union, UK, Russia, Australia, African countries etc.



Skilled workforce with high managerial and technical competence is readily available in with over 5,900 B. Pharma & 12,945 MBA seats in Gujarat.



With increasing investments in R&D sector, introduction of new products and medicines development, has boosted research-based growth.



Home to 48 medical 83 pharmaceutical and 37 bio-tech colleges and universities



Major R&D Centers in Gujarat : Torrent Research Center, Zydus Research Center and Sun Pharma Advance Research Company Ltd.

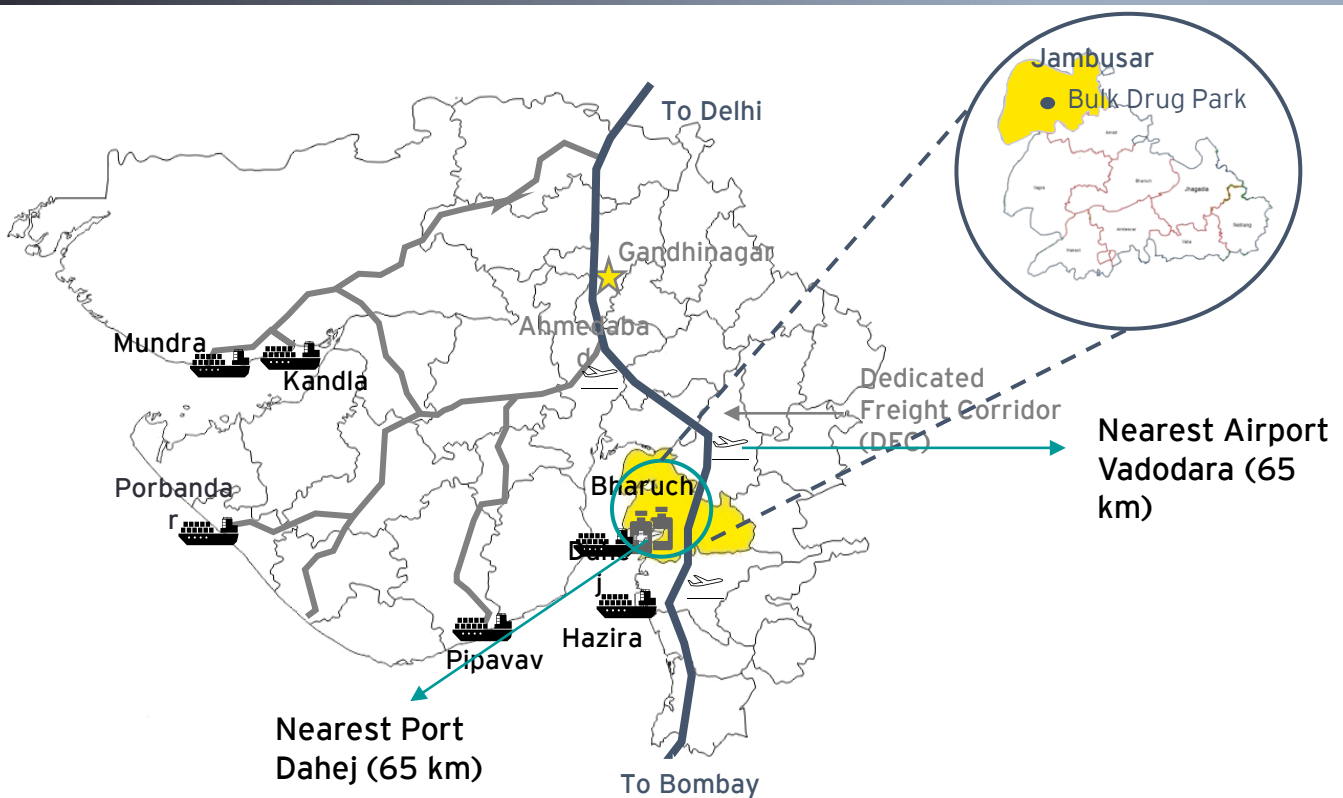
Project Information


GIDC Overview

Gujarat Industrial Development Corporation (GIDC), was established in 1962 by Government of Gujarat, as the nodal agency to oversee industrial development in the state by setting up industrial estates and promoting industrial growth. GIDC has established total 239 estates till date. The primary functions of the corporation are to

- ▶ Identify, acquire and aggregate land in the state suitable for industrial development
- ▶ Plan and develop aggregated land into industrial areas
- ▶ Plotting and allotment of land
- ▶ Providing basic infrastructure in industrial areas

Project Location- Jambusar Bharuch

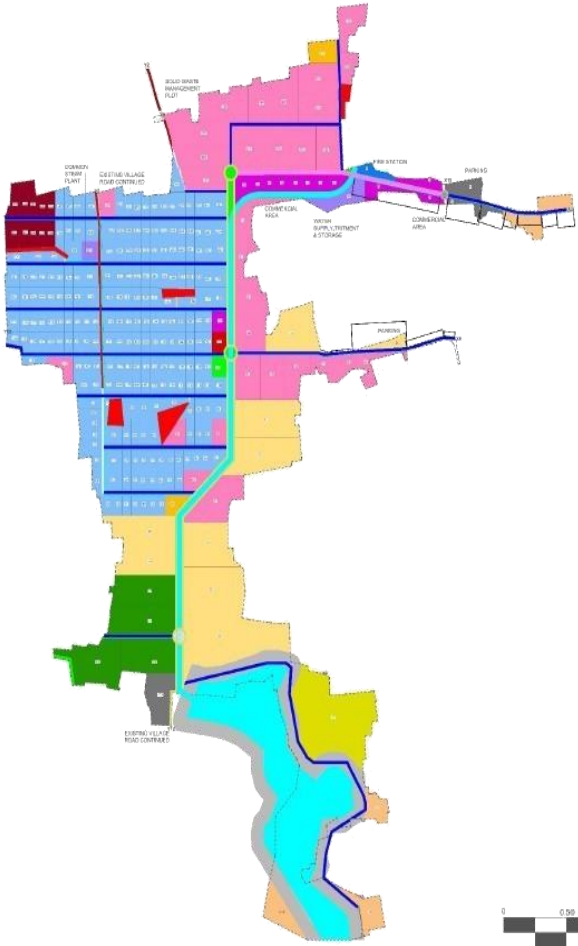


	Nearest Railway Station: Bharuch (48) km		Nearest NH: NH-228 (24) km
	Deep Sea Discharge (Marine Discharge) (11) km		Nearest Industrial Cluster: Gujarat PCPIR (25) km

	Investment Potential (Approximate)	₹16,000 Cr.		Generate Employment ~ 68,000 Opportunity
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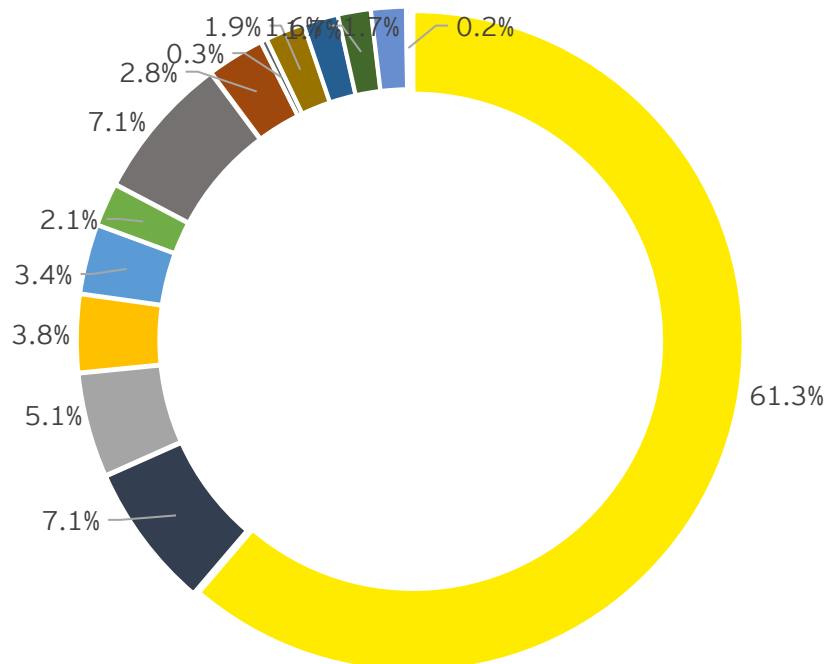
Project Information

Master Plan of Bulk Drug Park



499.8 ha	Industrial Plot Area
57.7 ha	Road Area
41.8 ha	CETP Complex
30.9 ha	Central Rainwater Nala
27.8 ha	Warehouse Zone
16.9 ha	Commercial Area
58.1 ha	Area under CRZ
22.6 ha	Green Belt Area
2.6 ha	Village Buffer & Common Green
15.1 ha	TSDF Complex
13.6 ha	Housing Area
13.4 ha	Parking Area
13.6 ha	Utility Area
1.5 ha	Common Facility Center

- Industrial Plot Area
- Road Area
- CETP Complex
- Central Rainwater Nala
- Warehousing Zone
- Commercial Area
- Area under CRZ
- Greenbelt Area
- Village Buffer and Common Green
- TSDF Complex
- Housing Area
- Parking Area
- Utility Area
- Common Facility Center



Project Information

Proposed Infrastructure facilities

Core Infrastructure

 **29.4 Km**

Well Developed Road network

 **13.2 Km**

Developed Storm Water Drains

 **Gas Supply**

Uninterrupted gas at the doorstep

 **40 MLD**

Consistent supply of water

 **66 (2) & 220 (2)KV**

Uninterrupted 24X7 power supply

 **Telecom**

Telecom service by both Public & Private entity

Specialised Infrastructure



Central Effluent Treatment Plant



Sewerage Treatment



Common Steam Supply



Integrated TSDf



Common Solvent Recovery System



Research & Development



Lab Testing Facility



Common facility Centre



Admin Complex



Marine Discharge

Ecosystem Players

Prominent Players in Pharmaceutical Sector in Gujarat

SN.	Company Name	Product
1	Sun Pharmaceuticals	API & Pharmaceutical Formulation
2	Zydus Life sciences Limited	Pharmaceutical Formulation
3	Torrent Pharmaceuticals	API & Pharmaceutical Formulation
4	Intas Pharmaceuticals Ltd.	Pharmaceutical Formulation
5	Abott Heath Care Pvt Ltd	Nutrition Products
6	Baxter Pharmaceutical India P Ltd.	LVP
7	Otsuka Pharmaceuticals India P. Lts.	LVP
8	Glenmark Lifesciences Limited	Bulk Drug (API)
9	Ajanta Pharma Limited	Pharmaceutical Formulation
10	Emcure Pharmaceuticals	Pharmaceutical Formulation
11	IPCA Laboratories	API & Pharmaceutical Formulation
12	Alembic Pharmaceuticals Ltd	Pharmaceutical Formulation
13	Amneal Pharmaceuticals Pvt. Ltd.	Pharmaceutical Formulation
14	Mylan	Pharmaceutical Formulation
15	Dishman Carbogen Amics	Bulk Drug (API)
16	Lupin Limited	API & Pharmaceutical Formulation
17	Corona Remedies P. Ltd.	Pharmaceutical Formulation
18	Sanofi India Limited	Pharmaceutical Formulation
19	Macleods Pharmaceuticals Ltd	Bulk Drug (API)
20	Aarti Drugs	Bulk Drug (API)
21	Accent Microcell Industries	Bulk Drug (API)
22	ACME Pharmaceuticals Pvt Ltd	Pharmaceutical Formulation
23	Alkem Laboratories Ltd	Bulk Drug (API)
24	Troikaa Pharmaceuticals Ltd	Pharmaceutical Formulation
25	Abaris Healthcare Pvt Ltd	LVP/SVP

Approvals & Incentives

Production Linked Incentives (PLIs) for Promoting Manufacturing of Bulk Drugs in India

- ▶ **Objective :** The objective of the Scheme is to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs. Under the Scheme, financial incentives shall be given based on threshold investment and domestic sales made by selected applicant for the eligible products.

- ▶ **Target Segments :**
 - Key Fermentation based KSMs / Drug Intermediates
 - Niche Fermentation based KSMs / Drug Intermediates / APIs
 - Key Chemical Synthesis based KSMs / Drug Intermediates
 - Other Chemical Synthesis based KSMs / Drug Intermediates / APIs

- ▶ **Tenure of the Scheme :** Financial Year 2020-21 to Financial Year 2029-30

- ▶ **Rate of Incentive :**
 - Fermentation based products :
 - i. FY 2023-24 to FY 2026-27 : 20%
 - ii. FY 2027-28 : 15% and
 - iii. FY 2028-29 : 5%

 - Chemically Synthesized Products :
 - i. FY 2022-23 to 2027-28 : 10%

Please visit <https://plibulkdrugs.ifcilttd.com/docs/BD%20Guidelines.pdf> for more information regarding other approvals required.

Approvals & Incentives

Approvals

Pre Requisite

- ▶ GIDC Land Application

Pre Establishment

- ▶ Approval for Electrical Installation
- ▶ Building Plan Approval - GIDC
- ▶ Fresh Drug Manufacturing License
- ▶ Consent to Establish-GPCB
- ▶ New HT/LT Connection approval from DISCOM
- ▶ Tree Transit Permission -GIDC
- ▶ Water application-GIDC
- ▶ Building Permission-GIDC
- ▶ Fire NoC-Urban Development Department
- ▶

Pre Operation

- ▶ Factory licenses Application
- ▶ Factory Plan Application
- ▶ Consolidated Consent and Authorisation-GPCB
- ▶ License application under the contract labour act
- ▶ Registration application under the contract labour act
- ▶ Registration of Boiler/Economizer
- ▶ Retail Drug License-Pharmacy/Whole Sale License
- ▶ Shop & Establishment-UDD

Others

- ▶ Employers Registration Form for Professional Tax
- ▶ New Property Registration - Panchayat and Rural Housing Department
- ▶ Professionals Registration Form for Professional Tax
- ▶ Registration Application under the Interstate Migrant Workers Act
- ▶ Road Cutting Application - Roads and Building Department
- ▶ Stamping Of Weight and Measures
- ▶ Renewal of Consolidated Consent and Authorisation- GPCB
- ▶ License Renewal Application under the Contact Labour Act
- ▶ Renewal of Boiler Manufacturer/Erector/Fabricator/Repairer/Material Testing Lab
- ▶ Repairer Renewal Licence

Please visit **Investor Facilitation Portal** (<https://ifp.gujarat.gov.in/>) for more information regarding other approvals required.

Key Department Contacts

Relevant departments and useful links



रसायन एवं
उर्वरक मंत्रालय
MINISTRY OF
**CHEMICALS
AND FERTILIZERS**

सत्यमेव जयते



औषध विभाग
Department of
Pharmaceuticals

सत्यमेव जयते

Ministry of Chemicals & Fertilisers
<https://chemicals.gov.in/>

Department of Pharmaceuticals
<https://pharmaceuticals.gov.in/>



Food & Drugs Control Administration
<https://gujhealth.gujarat.gov.in//food-and-drug-control-administration.htm>



Gujarat Control Pollution Board
<https://gpcb.gujarat.gov.in/>



GIDC
<https://gidc.gujarat.gov.in/>



Industries Commissionerate
Government of Gujarat

Office of Industries Commissioner
<https://ic.gujarat.gov.in/>



Investor Facilitation Portal
<https://ifp.gujarat.gov.in/DIGIGOV/>

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.



Food & Drug Control Administration

Food & Drug Control Administration

Old Sachivalya, Block No.8, 1st Floor, Dr.
Jivraj Mehta Bhavan, Gandhi Nagar-
382010

Website:

[https://gujhealth.gujarat.gov.in//
food-and-drug-control-
administration.htm](https://gujhealth.gujarat.gov.in//food-and-drug-control-administration.htm)



Gujarat Industrial
Development Corporation



Gujarat Industrial Development Corporation

Block No. 3,4,5, Udyog Bhavan, Sector-
11, Gandhinagar-382011

Website:

<https://gidc.gujarat.gov.in/>

iNDEXTb
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ISO 9001 : 2015 Certified

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