

PHARMACY PROFESSION IN GUJARAT: AN OVERVIEW

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REVIEW ARTICLE

¹Kempaiah Suresh, ¹Balamuralidhara V*, ¹Pramod Kumar TM, ²Puranik SB

¹Regulatory Affairs Group, Dept. of Pharmaceutics, JSS College of Pharmacy, JSS University, Sri Shivarathreshwara Nagara, Mysore – 570 015, Karnataka, India.

²Head Regulatory Affairs, Anthem Biosciences, Bangalore - 560099

*Corresponding Author's E-mail: baligowda@gmail.com

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ABSTRACT

Pharmacy is the health profession that links the health science with chemical science and it is charged with ensuring the safe and effective use of pharmaceutical drugs. Gujarat has been one of the pioneer States in India with an exemplary track record. The State of Gujarat have country's most dynamic entrepreneurs who are original and fast-paced in their thinking and focused in their drive for growth and profitability. Accounting for 16 percent of the country's total industrial output and 18percent of the country's total investment, Gujarat is one of the most industrialised states in the country. It has a strong base of educational institutions imparting courses in Pharmacy and some of the institutions have international repute to its credit. Gujarat is one of the fastest growing states in the Country and nearly 3,200 Pharma and biotech companies are housed in the State. Gujarat is a vibrant pharmaceutical manufacturing hub for Medical Devices fortified with sound knowledge based institutions and skilled human resource available in the state, it provides innovative, quality and affordable health care solution to masses. In this short review author provides some of the glimpses of the pharmacy profession in Gujarat.

Keywords: Pharmacy profession, Gujarat, Education, Health, Drug.

INTRODUCTION

On May 1, 1960, Gujarat was created out of 17 northern districts of the former state of Bombay. Gandhinagar, the capital city of Gujarat is located close to Amdavad (Ahmedabad), the commercial capital. Located on the western coast, Gujarat is India's seventh largest state in terms of area and ninth largest in terms of population. The state's capital, Gandhinagar, is the second planned city in the country (after Chandigarh) and is located just 32 kilometres (km) from Ahmedabad, the commercial capital of Gujarat. The State of Gujarat as some of the country's most dynamic entrepreneurs who are original and fast-paced in their thinking and focused in their drive for growth and profitability. Accounting for 16 percent of the country's total industrial output and 18percent of the country's total investment, Gujarat is one of the most industrialised states in the country. (1)

Gujarat Food and Drugs Administration

Drugs Control Administration (DCA), Gujarat came into existence on 1st May 1960 after separation of Gujarat State from Greater Bombay State and Mr. B.V. Patel became the first director of DCA, Gujarat. DCA, Gujarat was entrusted implementation of Drugs and Cosmetics Act 1940 and Rules 1945 and Drugs Magic Remedies (Objectionable Advertisement) Act 1954. Mr. B.V. Patel played a vital role in establishing well defined administrative structure, policies and procedures of DCA, Gujarat. He seeded the present culture of this department industry friendly, prompt and strict action against law breakers. He also took initiative to establish state of art Drug Laboratory equipped with latest equipment's at Vadodara. (2)

Functions of FDCA

- To carry out inspection and grant license under FSSA act to food manufactures/Dealer/Wholesales/retailers/h

awker and to prosecute unlicensed manufacturer/sellers. To look after sanitation and hygiene of food units and people working in it. To draw as and when required food samples and to prosecute responsible persons selling/manufacturing/adulterated/misbranded foods in the respective courts. To educate people regarding the menace of food poisoning and enable them to take the precautions to prevent it. To provide information regarding FSSA act 2006 to the needed and to help people to understand the act better.

Decentralization of Powers

- Commissioner, FDCA is the Licensing Authority and Controlling Authority under Drugs and Cosmetic Act – 1940. Commissioner, FDCA has delegated powers of Licensing Authority for Cosmetics and Homeopathy manufacturing to Joint Commissioner (Drug). Joint Commissioner (Ayurved) has been notified as Licensing Authority for Ayurvedic Drug Manufacturing. Commissioner, FDCA has delegated powers of Licensing Authority for drug sales licenses to all Assistant Commissioners for the districts allocated to them. Thus, for smooth and efficient working, decentralization of powers has been worked out. However, Commissioner, FDCA monitors the entire activities as Controlling Authority

ORGANISATION (Food and Drugs Administration)

- The entire organisation is under the supervision of Health and Family Welfare Gujarat State the Administration is headed by Commissioner, it works as three tier system.

• Head Office

Head Office constantly monitors working of circle offices. Process applications for grant of manufacturing Licenses, product licenses, approvals of technical persons, grant of various certificates like WHO GMP, State GMP, COPP, FSC, Non conviction certificates etc., take actions for NSQ test reports and inspection reports of

manufacturing unit. Intelligence Branch (IB) headed by Deputy Commissioner (IB), keeps vigilant watch and in co-ordination with circle offices, takes prompt actions on any information related manufacturing / selling of spurious, misbranded or drug/cosmetics manufactured without licenses.

- FDCA, Gujarat has a complaint module on its web site to enable citizens to send online complaint regarding drug and food, FDCA, Gujarat also has 24X7 toll free services for citizens to register the complaint telephonically

- Technical
- Joint Commissioner
- Adjudating Officer
- Deputy Commissioner
- Assistant Commissioner
- Technical Officer
- Designated Officer
- Senior Drugs Inspector
- Senior Food Safety Officer
- Drugs Inspector
- Food Safety Officer
- Administration
- Public Relation Officer
- Administration Officer
- Legal Advisor
- Assistant Commissioner(CS)
- Statistics and Planning Officer
- Research Officer
- Establishment Officer
- Account Officer
- Legal Officer
- **Circle Offices**

- At present 25 Circle offices in various districts and they ensure implementation of above acts in the districts allocated to them. Drugs Inspectors of circle offices have been assigned duties to inspect pharma dealers and they submit their reports to concerned Assistant Commissioner of the circle.

- Drugs Inspectors and Senior Drugs Inspectors of circle offices regularly draw samples of allopathic drugs, ayurvedic drugs, homeopathic drugs, cosmetics and raw materials used to manufacture them

from dealers, manufacturing units, doctors, hospitals, CHC, PHC etc. and send them to Food and Drug Laboratory, Vadodara for testing and analysis of the samples. If the sample is declared of "Not of Standard Quality", they initiate actions as per the policy of the department and as per the provisions of Drugs and Cosmetics Act – 1940 and rules thereunder and report to head office.

- Circle Offices constantly keep vigilant watch to prevent and curb menace of habit forming drugs and carry out raids to take strict actions against law defaulter. Assistant Commissioners and Senior Drugs Inspectors inspect pharmaceutical and cosmetics manufacturing units and submit their reports to Commissioner, FDCA. Assistant Commissioners and Senior Drugs Inspectors also jointly inspect following categories of units with officers of CDSCO under CLAA scheme/WHO GMP.
- Blood Banks and Blood Components, Large Volume Parenterals Manufacturing Units, Sera and Vaccines Manufacturing Units, DNA / Biotech products Manufacturing Units, New Medical Devices Manufacturing Units, Inspection for grant of WHO GMP Certificates.
- Assistant Commissioner
- Designated Officers
- Senior Drugs Inspector
- Drugs Inspector
- Senior Food Safety Officer
- Food Safety Officer
- **Food and Drugs Laboratory**
- Joint Commissioner (Testing)
- FDL (Food and Drugs Testing)
- Senior Scientific Officer
- Junior Scientific Officer
- Senior Scientific Assistant
- Junior Scientific Assistant
- Regional Food Testing Lab Rajkot
- Junior Scientific Officer
- Senior Scientific Assistant
- Junior Scientific Assistant
- Regional Food Testing Lab Bhuj
- Senior Scientific Officer
- Junior Scientific Officer
- Senior Scientific Assistant

- Junior Scientific Assistant

Following Act are implemented in the state of Gujarat

- Drugs and Cosmetics Act 1940
- Drugs and Cosmetics Rules 1945.
- Drugs (Price Control) Order 2013.
- Drugs and Magic Remedies (Objectionable Advertisement) Act 1954.
- Drugs and Magic Remedies (Objectionable Advt.) Rules 1955.
- Food Safety and Standard Act 2006
- Food Safety and Standard Rules and Regulations 2011.
- Cigarettes and Other tobacco products (Prohibition of advertisement and regulation and trade and commerce production, supply and distribution) Act 2003.

Functions undertaken by CDSCO-National Level Regulatory System Statutory Functions

- Laying down standards of drugs, cosmetics, diagnostics and medical devices.
- Laying down regulatory measures, amendments to Acts and Rules.
- To regulate market authorization of new drugs.
- To regulate clinical research in India.
- As Central Licencing Approving Authority (CLAA) for certain categories of drugs i.e. for Blood Banks, L.V.P., Vaccines, Sera and medical Devices.
- Import licensing for drugs and Cosmetics
- Testing of drugs by Central Drugs Labs
- Publication of India Pharmacopeia.

Functions Undertaken by CDSCO-National Level Regulatory System other Functions

- Co-ordinating the activities of the State Drugs Control Organizations to achieve uniform administration of the Act: and policy guidance.
- Guidance on technical matters.
- Participation in the WHO GMP certification scheme.
- Monitoring adverse drug reactions (ADR)
- Conducting training programmes for regulatory officials and Govt. Analysts.

- Work relating to Drugs Technical Advisory Board (DTA) and Drugs Consultative Committee(DCC).
- Screening of drug formulations available in Indian market.
- Evaluation/Screening of applications for granting No Objection Certificates for export of unapproved/banned drugs. (2)

Functions undertaken by State Level Regulatory System

- **Statutory Functions**
- Licensing of drug manufacturing and sales establishments
- Licensing of drug testing laboratories
- Approval of drug formulations for manufacture.
- Monitoring of quality of Drugs and Cosmetics manufactured and marketed in state.
- Investigation and prosecution in respect of contravention of legal provisions
- Administrative actions.
- Pre-and port-licensing inspection
- Recall of sub-standard drugs.

FDCA, Gujarat Team

- Training on priority to sharpen knowledge of officers not only to maintain performance of FDCA but also to achieve newer landmarks.

Induction training of newly appointed officers in service training includes: In House training by FDCA's Senior Officers. Training by experts from Industry in association with NGOs/Associations like DIA , IPA< IDMA etc. On line web based training by UL Eduneering, USA. Motivating officers for in service study-post graduation and Ph.D. s well.

Gujarat Food and Drugs Administration - regulate Cosmetics Public Testing Lab. Medical Devices, Disinfectants Ayurvedic Drugs Allopathic Drugs Homeopathic Drugs Diagnostic Reagents Blood Bank Blood Storage Centres Pharmacies Retail and Wholesale, Food.

Statistics as on 15th February, 2016-Gujarat State

Manufacturing Units

- Allopathic 2292 Ayurvedic 672
Cosmetics 392 Homeopathy 8 **WHO GMP compliance** Mfg. Units 172 Loan Licence firms 269 Total 441

Pharma Traders

- Pharmacies 15673 Wholesale 14378 Pharmacies and Wholesalers 3405
- Total 33546
- There are about 47 Blood Banks and 92 Blood storage Centres in Gujarat.(2-3)

Food and Drugs Laboratory

The objective of Food and Drugs Laboratory is to evolve and consistently maintain a Quality Management System across all departments so as to conform to National and International standards in all its testing aspects.

Implement and maintain a high standard of unbiased and impartial testing as per Good Laboratory Practices and ISO/IEC/17025: 2005(E) for Food and Drugs items. Continuous process of quality improvement in testing by imparting Training to food and drugs Analysts in highly sophisticated computerized instruments as well as by familiarizing all the staff with the content of quality documents in phased manner, so that they may comply with the policies and procedures laid down in the manual.

Participate in Inter-laboratory Proficiency testing for improving the calibration/testing status.

Establishment

In 1960, the laboratory of Administration laboratory became testing Control the Gujarat State Drugs. In Sept 1979, Public Health Laboratory, Vadodara and Bhuj were merged with Drugs laboratory, Vadodara and it became Food and Drugs laboratory, Vadodara. In 1983-84, a separate Food Laboratory at Rajkot was established for testing of Food samples and Excise samples.

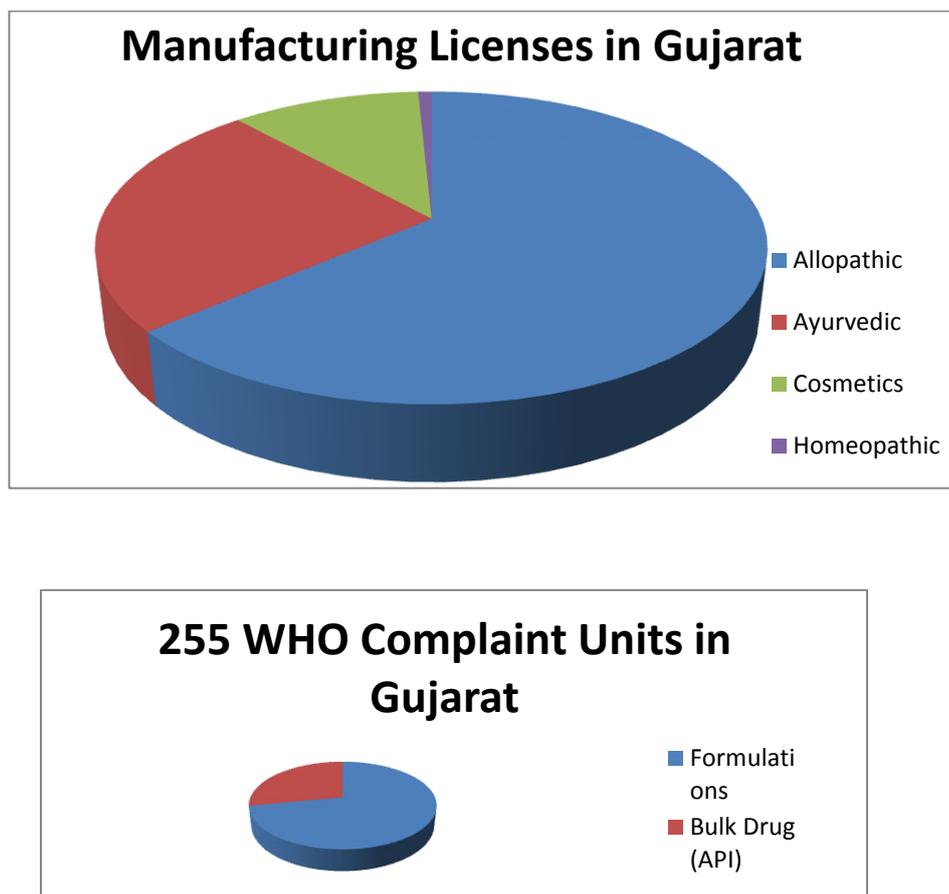


Figure 1: Status for manufacturing Licences and WHO Compliants in Gujarat

- There are 12 Government analyst 7 Food analyst and ancillary division like Animal House, Library, Work Shop, Stores, Administration, sample warden, Air Conditioning and Refrigeration. Labs are equipped with all types of instrumentation required for the analysis of Food and Drugs
- Samples are drawn from Sale and Manufacturing units, Central Medical Stores Organisation, ESI Hospitals Customs, Railway Authorities, other state Governments, Public and Private Bodies in Gujarat. Recent Progression includes automated sterility testing system, Solid phase Cytometric technique with epifluorescence microscopy, System detects bacteria, yeast molds and spores, Results within short time as compared to conventional method of 14 days. 1st Govt. Laboratory get accreditation in India. FICCI awarded FDL, Vadodara for the same.
- Some of the major achievements of Standard Laboratory which follow to maintain accreditation:
 - Standard Operating Procedure for working and Calibration.
 - Pursue reference standards.
 - Calibrations of equipment, validation of Instruments and certified reference materials.
 - Training of latest equipment, amendment in methods as well as technique.
 - Internal Quality checks by Repetition and Replicate testing.
 - Inter laboratory Participation as well as initiation.
 - Proficiency testing food
 - Internal audit
 - Check compliance of corrective actions
 - Desktop and On-site assessment by NABL as part of accreditation. (2, 3)

E-Governance

- FDCA, Gujarat makes optimum use of information technology for achieving

excellence in performance FDCA Gujarat is the first State to initiate online software for sales and manufacturing licenses. After successful implementation of Sales Licensing Software since 1st January 2007 and with proven sustainability of the software, Drugs Controller General India (DCGI), Government of India praised and recommended this software to all State Drugs Controllers at several occasions. In turn, Drugs Controllers of other states requested Government of Gujarat to provide Gujarat Model of the software. Till date four states namely, Maharashtra, Karnataka, Kerala and Andhra Pradesh have started implementation recently and other six states namely Madhya Pradesh, Goa, Himachal Pradesh, Chennai, West Bengal and Chhattisgarh are in the process of implementations. Bulk SMS alerts to all dealers, FDCA officers and state Drugs Controller regarding not of Standard Quality drug for prompt and effective recall. (2,3)

Gujarat Pharma Industry

- Brief over view of the evolution of Gujarat's Pharma Industry Alembic Chemical Works Co. Ltd., one of the oldest pharma companies in India, was set up in Vadodara in 1907, just six years after India's first domestic pharmaceutical unit-Bengal Chemical and Pharmaceutical Works was set up in Calcutta. Sarabhai Chemicals was started soon thereafter. The industry had received strong support from the academic field. In 1940; the Drugs Laboratory in Vadodara was established, followed by LM College of Pharmacy. Further in 1989, the B.V. Patel Education Trust, Ahmedabad and Gujarat Branch of Indian Pharmaceutical Association (IPA)-established the B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre in Ahmedabad. In the last few decades, the invested capital to labour ratio has risen significantly. The employment almost doubled between 1979-80 and 1997-98. Over the years, the industry has developed strong linkages with related sectors and industries such as chemicals, pharma machinery, information technology, etc. There are currently approximately 3,500 drug manufacturing units in Gujarat. State houses several established companies such as Torrent Pharma, Zydus Cadila, Alembic, Sun Pharma, Claris, Intas Pharmaceuticals and Dishman Pharmaceuticals, which have operations in the world's major pharma markets. Over the last few years, Gujarat's contribution in the growth of India's pharmaceutical industry has been significant. The state commands 42 percent share of India's pharmaceutical turnover and 22 percent share of exports. (4,5)
 - At the forefront of the growth in the pharmaceutical industry in India is Gujarat. Accounting for nearly 42 percent share of India's pharmaceutical turnover, 22 percent of its drug exports and 20 percent of its chemicals output, Gujarat's pharmaceutical industry has evolved into an innovation-driven, knowledge-focused industry. Going forward, to attain a leading position in the globe.
 - Key Features of Gujarat FDA
 - 109 years of excellence
 - Only manufacture of Doxorubicin HCL Liposome injection in the World at present
 - Only manufacturer of Vitamin C and Dapsone in India
 - 80% of World's Isoniazid (used for treatment of tuberculosis) is produced in Gujarat
 - 70% of India's cardiac stents manufactured from Gujarat
 - 58% India's orthopaedic implants manufactured is from Gujarat
 - 40% of CRAMS Companies
 - 3324 manufacturing licenses HOMETO-40% of CRO in the country
 - 33% of India's pharma sector turnover; 28% of India's Pharma export
 - Produces 35% of India's Diagnostic Reagent.
- Gujarat, an established manufacturing base for bulk drugs and formulations, is poised to capture global opportunities to become a Global Pharmaceuticals Hub. (5,6)

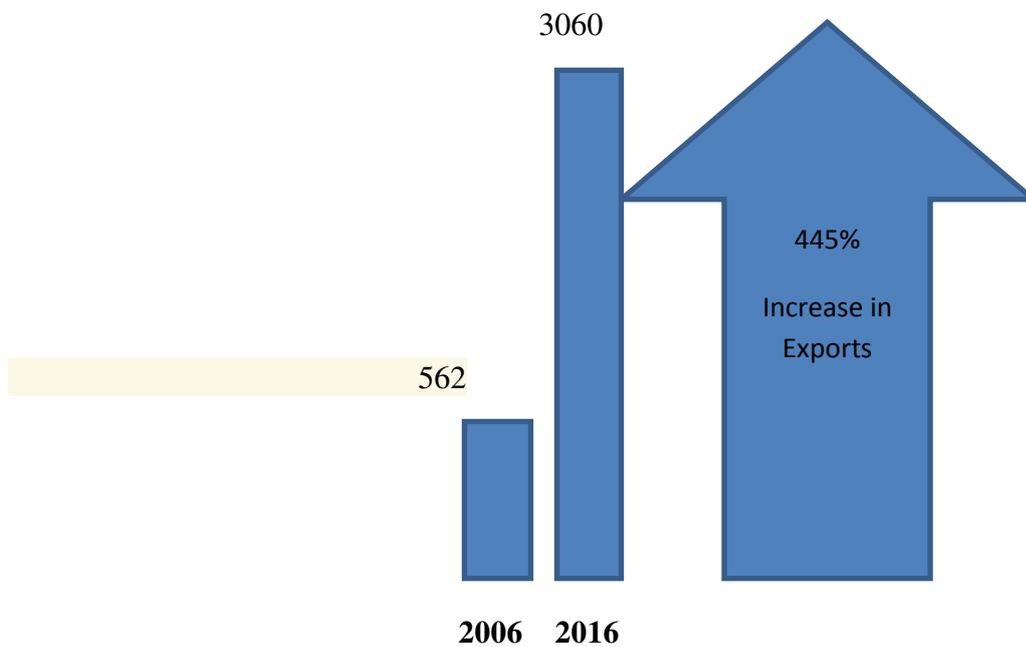
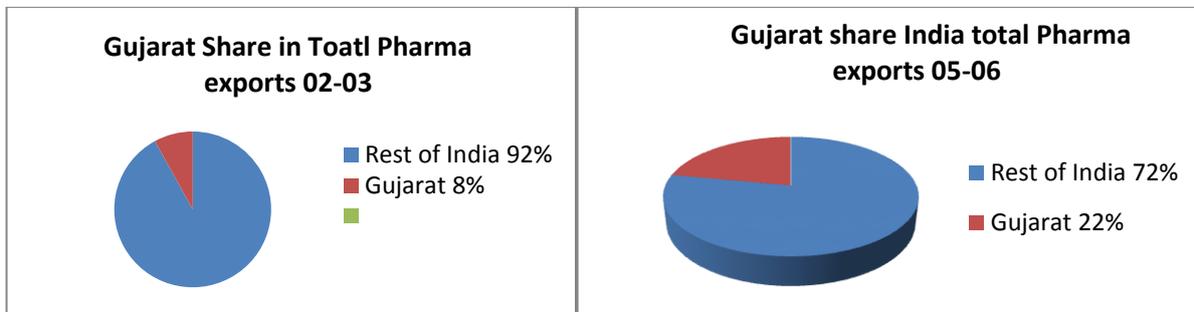
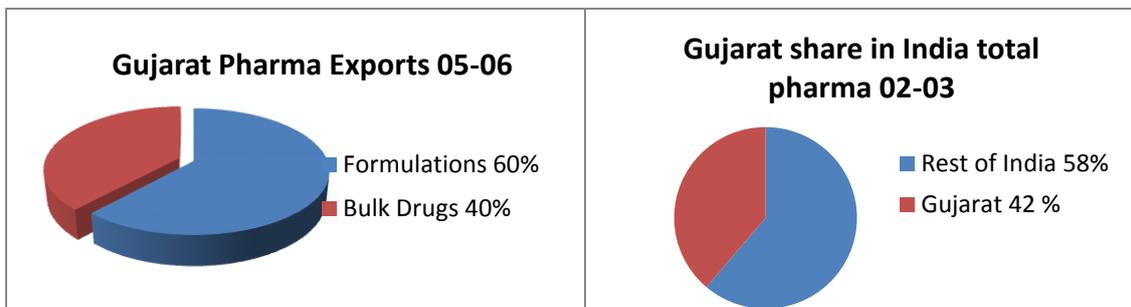


Figure 2: Pharma Exports from Gujarat (USD Million*) 1* = 65 INR

Gujarat State Pharmacy Council (GSPC)

Gujarat State Pharmacy Council (GSPC) is a statutory body constituted by the Government of Gujarat under the Pharmacy Act of 1948, consisting of six members elected by registered pharmacists amongst themselves, five members nominated by The Government of Gujarat, three Ex-Officio members and one member elected by Gujarat Medical Council.

- In 1949- Formation of Registration Tribunal of Bombay State.
- In 1954 Formation of Bombay State Pharmacy Council.
- 1964 Reorganization of Bombay State Pharmacy Council.
- In 1965 Formation of Gujarat State Pharmacy Council.
- Total number of Registered Pharmacist Registered in Gujarat is 62000.

There are about 32 Pharmacy Colleges in Gujarat. (7)

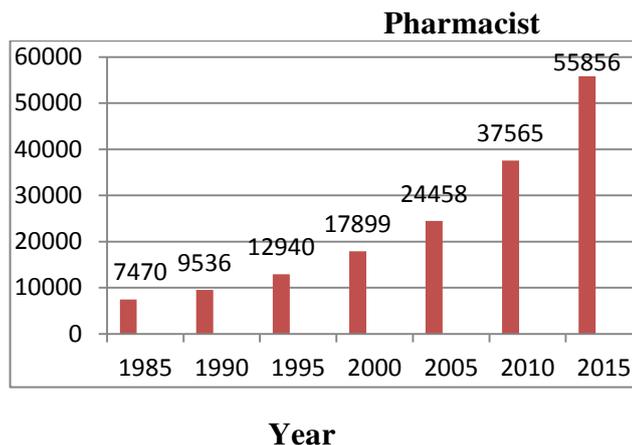


Figure 3: Registered Pharmacist Registered in Gujarat

CONCLUSION

The pharmacy education in Gujarat has witnessed tremendous expansion in last one decade. We have sixty Two thousands of pharmacists in the state. The entire details of the pharmacy related activities in Gujarat are brought under one roof. From the origin of pharmacy education, drugs control administration, pharmaceutical Industry and trade business establishment to all around development of pharmacy in Gujarat from the inception of it.

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

REFERENCES

1. Profile of Gujarat [Internet] Official Gujarat state portal, Gujarat; 2016 [cited 2016 Aug 02]. Available from: <http://www.gujaratindia.com/...profile/state-p>
2. Food and Drugs Administration, Gujarat [Internet]. Gujarat: FDA; 2016 [cited 2016 Aug 06]. Available from : <https://gujhealth.gujarat.gov.in/fdca-overview.htm>
3. Food and Drugs Administration, Gujarat [Internet]. Gujarat: FDA; 2016 [cited 2016 Aug 08]. Available from: <http://FDCA / FDA / DCD - XLNxlndia.gov.in/login.aspx>
4. Gujarat pharmaceutical Industry [Internet]. Gujarat; 2016 [cited 2016 Aug 16]. Available from: <http://www.in.kpmg.com/.../gujarat-pharma>
5. Gujarat pharma Industry [Internet]. Gujarat: kpmg; 2016 [cited 2016 Oct 07]. Available from: <http://www.in.kpmg.com/pdf/gujarat-pharma08.pdf>
6. Pharmaceutical- Vibrant Gujarat [Internet]. Gujarat; 2016 [cited 2016 Oct 08]. Available from: <http://vibrantgujarat.com/.../pdf/pharmaceutical-sector.pdf>
7. Gujarat pharmacy Council [Internet]. Gujarat;2016 [cited 2016 Oct 18] Available from: <http://www.gujaratstatepharmacycouncil.org/collegesInGujrat.htm>.