

# ANNUAL REPORT

## 2015-16



Government of India  
Ministry of Chemicals & Fertilizers  
**DEPARTMENT OF PHARMACEUTICALS**



# Annual Report 2015-16



Government of India  
Ministry of Chemicals & Fertilizers  
**Department of Pharmaceuticals**





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# Chapter 1

## INTRODUCTION

### 1.1 Mandate of Department of Pharmaceuticals









## CHAPTER – 1

### INTRODUCTION

#### 1.1 MANDATE OF DEPARTMENT OF PHARMACEUTICALS

The Cabinet Secretariat notified creation of a new Department, namely the Department of Pharmaceuticals, under the Ministry of Chemicals & Fertilizers which came into being w.e.f. 1<sup>st</sup> July 2008 with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other ministries.

Following works have been allocated to the Department of Pharmaceuticals:

- 1) Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
- 2) Medical Devices - Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
- 3) Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector.
- 4) Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.
- 5) Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- 6) Promotion of public – private – partnership in pharmaceutical related areas.
- 7) International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
- 8) Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
- 9) Technical support for dealing with national hazards in pharmaceutical sector.
- 10) All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/ monitoring.
- 11) All matters relating to National Institutes for Pharmaceuticals Education and Research.
- 12) Planning, development and control of; and assistance to, all industries dealt with by the Department.
- 13) Bengal Chemicals and Pharmaceuticals Limited.
- 14) Hindustan Antibiotics Limited & its subsidiaries as & JVs.
- 15) Indian Drugs and Pharmaceuticals Limited & its subsidiaries
- 16) Karnataka Antibiotics and Pharmaceuticals Limited.
- 17) Rajasthan Drugs and Pharmaceuticals Limited.
- 18) Bengal Immunity Limited.
- 19) Smith Stainstreet Pharmaceuticals Limited.

The work of the Department has been divided into three Divisions viz. Pharmaceuticals & Medical Device Industry Division, Public Sector Undertakings Division and R&D Division comprising of National Institute of Pharmaceutical Education & Research (NIPER) and Research & Development. The National Pharmaceuticals Pricing Authority an attached office of this Department, is entrusted with the work of fixation and revision of prices of pharmaceuticals products under Drug Price Control Order 2013.

Dr. V.K. Subburaj is the Secretary who holds charge of this Department w.e.f 01.10.2014.



# Chapter 2

## AN OVERVIEW OF PHARMACEUTICALS INDUSTRY

- 2.1 Financial Performance of the Drugs and Pharmaceuticals Industry
- 2.2 Imports
- 2.3 Exports
- 2.4 International Cooperation/Export Promotion of Pharmaceuticals
- 2.5 India Pharma 2016 and India Medical Expo 2016.
- 2.6 Pharmaceuticals Promotion Development Scheme (PPDS)







## CHAPTER - 2

### AN OVERVIEW OF THE PHARMACEUTICALS INDUSTRY

#### 2.1. FINANCIAL PERFORMANCE OF THE DRUGS AND PHARMACEUTICALS INDUSTRY

The financial quarterly performance of the Drugs and Pharmaceuticals Industry for quarter ended, March 2015 and the year 2015-16 (up to December 2015) is given below. The figures reported in the table show the percentage change in the respective items of income, expenditure, profitability etc as compared to the corresponding period the previous year.

impressive sales performance during the quarter.

The profit after Tax (PAT) net of prior period and extraordinary items, declined by (-) 27.35% (y-o-y) in the March 2015 quarter, by (-) 36.44% (y-o-y) in the June 2015 quarter but increased thereafter to 61.55% (y-o-y) in the quarter ended September 2015, as compared to the corresponding period last year. At the operating level, margins of the industry scaled up by 1698 basis points to 22.1% on account of a sharp drop in operating expenses, against a healthy growth in net sales. In the December

#### Drugs and Pharmaceuticals: Growth and Profitability in the Year 2015-16

(% change over year ago)

Sl. No	Particulars	Quarterly			
		March 2015	June 2015	Sept 2015	Dec 2015
1.	Total income	18.52	-0.25	13.44	15.28
2.	Net Sales	14.91	9.24	17.01	16.74
3.	Total expenses	22.57	12.56	7.10	-3.85
4.	Operating expenses	19.69	13.20	5.63	-3.44
5.	Raw Materials, Stores & spares	13.96	8.48	1.56	4.07
6.	Salaries & Wages	30.44	17.48	15.02	16.47
7.	Power & Fuel	-16.12	1.51	-51.6	-14.00
8.	Interest expenses	-5.35	6.89	28.56	20.85
9.	Depreciation	76.71	4.95	10.02	16.13
10.	PBT	-9.54	-29.07	50.61	395.38
11.	Total Tax provision	3.97	5.71	41.69	-30.80
12.	Net Profit (PAT)	-14.46	-36.42	53.98	-
13.	PAT net of P&E	-27.35	-36.44	61.55	-
14.	Total expenses net of P&E	20.12	12.14	8.06	-3.74
15.	PBDIT net of P&E	-2.50	-22.9	43.83	168.53
16.	PBDIT net of P&E&OI (Operating Profit)	-6.50	4.17	67.40	243.39
17.	Count	152	149	150	151

Source: Centre for Monitoring Indian Economy (CMIE) Pvt Ltd data as on 19.03.2016.

As per CMIE estimates, Sales of the Drugs and Pharmaceuticals Industry registered a (y-o-y) growth of 12-14%, 14-69% and 11.46% respectively, during the years 2012-13 to 2014-15. Net sales of the Drugs and Pharmaceuticals Industry grew by 14.91% (y-o-y) in the March 2015 quarter but declined to 9.24% (y-o-y) in the June 2015 quarter. In the September 2015 quarter, net sales witnessed an upturn, at 17.01% (y-o-y), and at 16.74% (y-o-y) for the December 2015 quarter. The profitability of the industry too improved during the said period. A healthy sales growth combined with an over three-fold rise in operating profits helped the industry to earn net profits equivalent to 13.1 % of income. In the December 2014 quarter, the industry had incurred a net loss equivalent to 8.4 % of income. Most of the leading drug manufacturers posted higher sales during the quarter under review as compared to the corresponding year-ago quarter. This was aided by a healthy growth in the companies' export revenues, especially from the US market. Lupin, Torrent Pharmaceuticals, Piramal Enterprises (PEL) and Glenmark Pharmaceuticals (GPL) led the pack by reporting

2014 quarter, Oxygen Bio Research, Piramal Pharmaceutical Development Services and PHL Capital got amalgamated into PEL. As a consequence of this, PEL had recognized a permanent diminution (of Rs. 24.2 billion) in the value of its investments in the intervening holding company of the companies that got amalgamated. This caused the industry's operating expenses to mount during the said quarter. Absence of such an expense in the December 2015 quarter, therefore, led the industry's operating expenses to fall by 3.7 per cent. Resultantly, the operating profits of the industry grew by a staggering 243.4 % and operating margins expanded during the quarter. Operating expenses, were at 19.69% (y-o-y) for the March 2015 quarter, at 13.2% in the June, 5.63% in the September and (-) 3.44% (y-o-y) in the December quarters respectively of the year 2015. PBDIT net of P&E&OI (Operating profit) registered a decline at (-) 6.5% (y-o-y) in the March 2015 quarter. It was 4.17% in June 2015 quarter, 67.4% in September and 243.39% (y-o-y) in the December 2015 quarters as compared to corresponding periods of the previous year.



As per CMIE estimates, investments in the drugs and pharmaceuticals industry is expected to remain buoyant during 2015-18 with companies in the industry altogether investing a little over Rs. 82 billion by March 2018.

## Investments

(Rs. million)

Year	Project completed
2011-12	65,448.90
2012-13	42,988.30
2013-14	19,205.90
2014-15	14,864.30
2015-16 (F)	27,099.60
2016-17 (F)	30,328.00
2017-18 (F)	24,600.00

Source:- CMIE

The demand for Indian generics is expected to remain healthy. The drug manufacturers are also likely to tap new markets to give a thrust to export revenues. Therefore, drugs companies are likely to step up capacity to meet the rise in demand. Warning letters and import alerts from US Food and Drugs Administration (FDA), the US drugs regulator, for India-based manufacturing units have escalated considerably over the last couple of years following the regulator's increasing focus on compliance. Nevertheless, Indian companies are expected to upgrade their facilities to match up to the required standards. Other than formulations and API, drug manufacturers are likely to make big investments in putting up facilities to manufacture vaccines and injections. Besides private players, State Government bodies eg. Kerala State Industrial Development Corporation (KSIDC) and Kerala Industrial Infrastructure Development Corporation (KIIDC) too are expected to invest in drugs & pharmaceuticals industry during the period under consideration.

## 2.2 IMPORTS

The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. Manufactures of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.

2) Imports of Drugs & Pharmaceuticals is done as per Foreign Trade Policy and the provisions of the Drugs & Cosmetics Act. There are certain incentives available to the exporters of Drugs & Pharmaceuticals which enables them Customs duty-free import of all inputs, required to manufacture the export products in line with Advance Authorizations granted by the DGFT. The quantities of inputs are as per published Standard Input-Output Norms (SIONs). In case of the export product do not have published SIONs or the inputs are different from the published SIONs, ad-hoc norms are considered. Being the Administrative Department, the Department of Pharmaceuticals is actively engaged in processing Pharma Industry's applications for fixation of ad-hoc norms. More than 650 such applications, both for Pharma formulations and Bulk drugs & drug intermediates, were processed in the Department during 2015.

3) In addition to conveying ad-hoc norms, the Department has also recommended publication of additional SIONs for a number of pharmaceuticals formulations and as many as 33 new SIONs are understood to have already been finalized for notification by the DGFT.

4) Import of some the drugs & drug intermediates is still restricted under current Foreign Trade Policy. Imports are restricted basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS). Applications received from the Pharma industry, through the DGFT, for import of either the Bulk Drugs or intermediates whose import is restricted, are processed in the Department and suitable inputs are provided based upon the Actual User Status and essentially of usage of the chemicals to be imported.

5) Quite a few applications from the Pharma industry for import of certain dual purpose chemicals, particularly Sodium cyanide-included in the Schedule to the Insecticides Act, are also processed and suitable recommendations are conveyed to the Central Insecticides Board under the Ministry of Agriculture, in the capacity of Administrative Department, for grant of import permits to the Actual Users in Pharma Industry.

## Import of medicinal and pharmaceuticals products for the last three years were as under:

Year	Import of Bulk Drugs & Drug Intermediates*		Import of Drug Formulations & Biologicals*	
	Quantity in (Thousand kgs)	(Value in US \$ Millions)	Quantity in (Thousand kgs)	(Value in US \$ Millions)
2012-13	222147.44	3189.1	1765.64	1690.3
2013-14	246466.56	3146.8	2226.93	1491.7
2014-15	249944.64	3245.6	2764.27	1562.5
<b>Total</b>	<b>718558.64</b>	<b>9582.1</b>	<b>6756.81</b>	<b>4744.5</b>

The Figures of import for first 9 months of 2015-16 are as follows:-

2015-2016 (April-Dec)	200134.83	2510.4	2307.20	1209.9
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\* Source: - Directorate General of Commercial Intelligence & Statistics, Kolkata.





## 2.3 EXPORTS

Exports of medicinal and pharmaceuticals products for the last three years were as under: -

Year	Exports of Medicines & Pharmaceuticals Products (Rupees in Crore)
2012-13	79840
2013-14	90341
2014-15	94275

## 2.4 INTERNATIONAL COOPERATION/EXPORT PROMOTION OF PHARMACEUTICALS

Department of Pharmaceuticals has the following MoUs with foreign governments:-

1. MoU between Department of Pharmaceuticals Government of India and Department of Pharmaceutical Industry, Ministry of Health of the Republic of Belarus to strengthen cooperation in the spheres of manufacturing and trade of pharmaceutical products between the two countries and desirous of simplifying the process of registration of pharmaceutical products
2. MoU between Department of Pharmaceuticals Government of India and The State Administration of Ukraine on Medicinal Products on Mutual cooperation in Trade, Industry, Joint Venture (JV), Research & Development (R&D) in Pharmaceuticals and Bio-pharmaceuticals sectors

### Joint working Groups (JWG)/High Technology Cooperation Group (HTCG)

Department of Pharmaceutical has the following Joint Working Groups/High Technology Cooperation Group:-

1. EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices - the last (6<sup>th</sup>) meeting of the JWG was held on 30<sup>th</sup> April, 2015 – 1<sup>st</sup> May, 2015 at New Delhi
2. India-Tunisia Joint Working Group on Drugs and Pharmaceuticals under the aegis of the Indo-Tunisian Joint Commission – the last (5<sup>th</sup>) meeting of the JWG was held on 5<sup>th</sup> November, 2013 at New Delhi
3. India-Ukraine Joint Working Group on Pharmaceuticals and Healthcare under the aegis of the Indo-Ukrainian Intergovernmental Commission on Trade, Economic, Scientific, Technical, Industrial and Cultural Cooperation – 1<sup>st</sup> meeting of the JWG was held on 15-16 April, 2013 at New Delhi. 2<sup>nd</sup> meeting was held in Kyiv (Ukraine) on 21-22 January, 2016
4. India-US High Technology Cooperation Group (HTCG) – the last meeting of G2G Working Group on Biotechnology and Life Sciences under HTCG was held on 21<sup>st</sup> November, 2014 at New Delhi

5. India-Belarus Joint Working Group on Pharmaceuticals has recently been constituted
6. India-Philippines Technical Working Group (TWG) for considering “Pharmazone” and “Registration and other Issues related to Pharmaceuticals” has also recently been constituted.

Department of Pharmaceuticals participated in the following International Cooperation events -

1. An Indian Pharma delegation, under the chairmanship of Shri Sudhansh Pant, Joint Secretary (Pharma) visited Suriname from 7-10 April, 2015 for assisting in upgrading the pharmaceuticals production facility and pharmaceuticals waste disposal facilities in Suriname.
2. First Joint Commission Meeting between India and CARICOM was held on 2<sup>nd</sup> June, 2015 in Georgetown, Guyana under the Co-Chairmanship of Shri R. Swaminathan, Special Secretary (AMS&CPV), MEA.
3. An Indian Pharma delegation, under the chairmanship of Dr. M. Ariz Ahammad, Joint Secretary, visited USA to participate in US-India BioPharma and Healthcare Summit at Boston (USA) on 11<sup>th</sup> June, 2015; Drugs Information Association (DIA) Annual Meeting at Washington DC (USA) on 14-15 & 17<sup>th</sup> June, 2015; and Bio 2015 Convention at Philadelphia (USA) on 16-17 June, 2015.
4. 2<sup>nd</sup> JWG Meeting between India and Fiji on Cooperation in the field of health and medicine in Suva, Fiji under the chairmanship of Joint Secretary, Ministry of Health & Family Welfare.
5. 12<sup>th</sup> India-Kazakhstan Inter-Governmental Commission Meeting held on 16-17 June, 2015 at New Delhi under the chairmanship of Secretary, Ministry of Petroleum & Natural Gas.
6. 3<sup>rd</sup> India-Philippines Joint Commission on Bilateral Cooperation (JCBC) held on 14<sup>th</sup> October, 2015 at New Delhi under the co-chairmanship of External Affairs Minister.
7. EU-India Sub Commission on Trade India-EU held on 15<sup>th</sup> October, 2015 at New Delhi.
8. As an outcome of the 6<sup>th</sup> meeting of the EU-India Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices held on 30<sup>th</sup> April, 2015 – 1<sup>st</sup> May, 2015, a Video Conference was held with European Union on 26<sup>th</sup> November, 2015.

The Department of Pharmaceuticals provided financial assistance for the following activities/events for promotion and development of Pharma sector from Pharmaceuticals Promotion Development Scheme (PPDS) during Financial Year – 2015-16:-

Sr. No.	Financial assistances
1.	Financial assistance to Green Chemistry to organize a Two day industrial awareness seminar on Green Chemistry at Hyderabad on 27-28 <sup>th</sup> April, 2015
2.	Financial assistance to SRM University for organizing Conference





Sr. No.	Financial assistances
3.	Financial assistance to Drugs Controller, Drug Control Department of Kerala for organizing a Workshop on "Accessibility, Availability and Affordability Medicines for All" on behalf of NPPA
4.	Financial assistances to Indian Drug Manufacturers' Association (IDMA) for conducting GMP Workshop for SMEs – Schedule M & Beyond at Chennai on 20 <sup>th</sup> June, 2015, Kolkata on 8 <sup>th</sup> August, 2015, Haridwar on 11 <sup>th</sup> September, 2015, Ahmedabad on 24 <sup>th</sup> October, 2015, Bengaluru on 28 <sup>th</sup> November, Mumbai on 12 <sup>th</sup> December, 2015, Nasik on 21 <sup>st</sup> December, 2015
5.	Financial assistance to PHD Chamber for conducting Seminar on Pharma Export on 24 <sup>th</sup> July, 2015 at New Delhi
6.	Financial assistance to Bulk Drug Manufacturer Association for conducting Technical Seminar to Celebrate "2015-Year of Active Pharmaceutical Ingredients" on 27 <sup>th</sup> July, 2015 at Hyderabad
7.	Financial assistance to Indian Drug Manufacturers' Association (IDMA) for organizing Seminar on Goods & Services Tax at Mumbai on 28 August, 2015, Chennai on 28 <sup>th</sup> September, 2015
8.	Financial assistance to ASSOCHAM for organizing Conference on Generic Medicines in India "Promulgating Growth & Access" on 3 <sup>rd</sup> September, 2015 at Chandigarh
9.	Financial assistance to PHD Chamber for organizing Conference on Pharmacology (in Pharmaceutical Sciences): R&D for Minimizing ADRs and Role of Pharmacists in New Delhi in 23 <sup>rd</sup> September, 2015
10.	Financial assistance to Durgapur Viswagandha Science Society for organizing a "Two-Day National Conference - Current Research in Pharmaceutical Sciences-Challenges and Opportunities in India" on 3-4 October, 2015 at Durgapur, West Bengal.
11.	Financial assistance to ASSOCHAM for organizing a Conference on "IPR in Pharmaceuticals: Balancing Innovation & Access" on 7 <sup>th</sup> October, 2015 at Ahmedabad (Gujarat)
12.	Financial assistance to NIPER, Hyderabad for conducting a National Conference on "Drug Discovery and Development: Global Scenario-Indian Perspective" 20-21 November 2015
13.	Financial assistance to PHD Chamber for organizing a Conference on Pharma Med 20154: 3As & Viability – A Global perspective in November, 2015
14.	Financial assistances to ASSOCHAM for organizing Conferences-cum-Awareness Programs on "Quality Management in Pharmaceutical Manufacturing" GMP to drive future growth on 3 <sup>rd</sup> December, 2015 at Dehradun, on 28 <sup>th</sup> January, 2016 at Gangtok and on 16 <sup>th</sup> March, 2016 at Goa
15.	Financial assistance to FABA in connection with BIOASIA 2016 from 8-10 February, 2016 at Hyderabad

## GRANT-IN-AID

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of Pharma sector from Pharmaceuticals Promotion Development Scheme (PPDS) during Financial Year – 2015-16:-

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14.	Financial assistances to ASSOCHAM for organizing Conferences-cum-Awareness Programs on “Quality Management in Pharmaceutical Manufacturing” GMP to drive future growth on 3 <sup>rd</sup> December, 2015 at Dehradun, on 28 <sup>th</sup> January, 2016 at Gangtok and on 16 <sup>th</sup> March, 2016 at Goa
15.	Financial assistance to FABA in connection with BIOASIA 2016 from 8-10 February, 2016 at Hyderabad

## 2.5 INDIA PHARMA 2016 AND INDIA MEDICAL EXPO-2016 AT BANGALORE FROM 7-9 JANUARY, 2016

Department of Pharmaceuticals in association with the Federation of Indian Chambers of Commerce & Industry (FICCI), has organized the INDIA PHARMA 2016, the major composite event in India for the Pharmaceutical industry and INDIA MEDICAL EXPO 2016, an International Exhibition & Conference on the Medical Devices sector at Bangalore International Exhibition Centre, Bengaluru, Karnataka from January 7-9, 2016. Both the events consisted of an International Exhibition & conference along with a series of concurrent events, such as CEOs' Forum, Buyer Seller Meet etc. The prime objective of organizing these co-located events is to project India as an attractive investment destination for Pharma and Medical Devices sectors and to bring Foreign Investment to new areas of these sectors such as Research & Developments, Clinical Trails by promoting Joint Ventures with the Indian Manufacturers and bringing in best practices in the sector from around the world. These events provided a platform to global investment community to connect with stakeholders in the Pharma & Medical Devices sectors in India, Central and State Governments, leading business leaders and top executives from the industry, academics and experts from the world. These events had participation from Pharma Formulation, Bulk Drugs, Machinery and Technology segment of the Pharmaceutical and Medical Electronics Industry and Medical Electronic & Devices and the Indian States who showcased the investment opportunities and policies during the 3 day exhibition and the State Investment Roundtable/Global Investment meet. The Global Investment Meet/State Roundtables provided ample opportunities to the Overseas Investors to get updated with the developments happening in the Indian Pharmaceutical & Medical



Hon'ble Union Minister (C&F) Shri Ananth Kumar at India Pharma 2016

Device Industry and provided a platform to the foreign companies to enter into Joint Venture with the Indian Companies. These events also helped in propelling the desired growth for this sector which is the need of this hour.

### India Pharma Awards

The 1st India Pharma Awards were conferred on 7th January, 2016 in Bengaluru by Shri Ananth Kumar Hon'ble Minister (Chemicals & Fertilizers) in 12 categories to different Pharma and Medical Devices companies.

## 2.6 PHARMACEUTICALS PROMOTION DEVELOPMENT SCHEME (PPDS)

The Objective of Pharmaceuticals Promotion Development Scheme (PPDS) is promotion, development and export promotion in Pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector. Under PPDS the Department of Pharmaceuticals on its own or through financial support by way of Grant-in aid to the Institutions, organizations, Voluntary organizations or Non-Government Organizations as mentioned in Rule 206 of GFR 2005.

- i) Conduct Training/knowledge improvement programs/ activities on issues/subjects relevant to growth of pharmaceutical industry. An indicative list of subject is as under:-
  - a) Quality Management System/Quality Improvement Program
  - b) How to handle USFDA notice?



Hon'ble Union Minister (C&F) the Shri Ananth Kumar and Hon'ble Minister of State (C&F) Shri Hansraj Gangaram Ahir, along with officials of department of Pharmaceuticals

- c) Success Story Presentation - Pharmaceutical Entrepreneur
  - d) Government regulations/guidelines for clinical trials in India versus USA, EU etc.
  - e) Waste Management
  - ii) Organize Summits, Convention, Exhibitions, Pharmacy week, meetings etc. in India and abroad and produce promotional materials like films, displays etc.
  - iii) Conduct research studies, sector reports etc.
  - iv) Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc.
  - v) Give awards to achievers in pharmaceutical industry.
  - vi) For any other activity not covered under above categories which may be decided by the Department of Pharmaceuticals from time to time.
- The Department of Pharmaceuticals provided financial assistance for the following activities/events for promotion and development of Pharma sector from Pharmaceuticals Promotion Development Scheme (PPDS) during Financial Year – 2015-16:-

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1.	Financial assistance to Green Chemistry to organize a Two day industrial awareness seminar on Green Chemistry at Hyderabad on 27-28 <sup>th</sup> April, 2015
2.	Financial assistance to SRM University for organizing Conference
3.	Financial assistance to Drugs Controller, Drug Control Department of Kerala for organizing a Workshop on “Accessibility, Availability and Affordability Medicines for All” on behalf of NPPA
4.	Financial assistances to Indian Drug Manufacturers’ Association (IDMA) for conducting GMP Workshop for SMEs – Schedule M & Beyond at Chennai on 20 <sup>th</sup> June, 2015, Kolkata on 8 <sup>th</sup> August, 2015, Haridwar on 11 <sup>th</sup> September, 2015, Ahmedabad on 24 <sup>th</sup> October, 2015, Bengaluru on 28 <sup>th</sup> November, Mumbai on 12 <sup>th</sup> December, 2015, Nasik on 21 <sup>st</sup> December, 2015
5.	Financial assistance to PHD Chamber for conducting Seminar on Pharma Export on 24 <sup>th</sup> July, 2015 at New Delhi
6.	Financial assistance to Bulk Drug Manufacturer Association for conducting Technical Seminar to Celebrate “2015-Year of Active Pharmaceutical Ingredients” on 27 <sup>th</sup> July, 2015 at Hyderabad
7.	Financial assistance to Indian Drug Manufacturers’ Association (IDMA) for organizing Seminar on Goods & Services Tax at Mumbai on 28 August, 2015, Chennai on 28 <sup>th</sup> September, 2015
8.	Financial assistance to ASSOCHAM for organizing Conference on Generic Medicines in India “Promulgating Growth & Access” on 3 <sup>rd</sup> September, 2015 at Chandigarh
9.	Financial assistance to PHD Chamber for organizing Conference on Pharmacology (in Pharmaceutical Sciences): R&D for Minimizing ADRs and Role of Pharmacists in New Delhi in 23 <sup>rd</sup> September, 2015
10.	Financial assistance to Durgapur Viswagandha Science Society for organizing a “Two-Day National Conference - Current Research in Pharmaceutical Sciences-Challenges and Opportunities in India” on 3-4 October, 2015 at Durgapur, West Bengal.
11.	Financial assistance to ASSOCHAM for organizing a Conference on “IPR in Pharmaceuticals: Balancing Innovation & Access” on 7 <sup>th</sup> October, 2015 at Ahmedabad (Gujarat)
12.	Financial assistance to NIPER, Hyderabad for conducting a National Conference on “Drug Discovery and Development: Global Scenario-Indian Perspective” 20-21 November 2015
13.	Financial assistance to PHD Chamber for organizing a Conference on Pharma Med 20154: 3As & Viability – A Global perspective in November, 2015
14.	Financial assistances to ASSOCHAM for organizing Conferences-cum-Awareness Programs on “Quality Management in Pharmaceutical Manufacturing” GMP to drive future growth on 3 <sup>rd</sup> December, 2015 at Dehradun, on 28 <sup>th</sup> January, 2016 at Gangtok and on 16 <sup>th</sup> March, 2016 at Goa
15.	Financial assistance to FABA in connection with BIOASIA 2016 from 8-10 February, 2016 at Hyderabad



# Chapter

# 3

## PHARMACEUTICAL INDUSTRY-OTHER ACTIVITIES

3.1 Pharmaceuticals Industry

3.2 Pharmaceuticals Policy

3.3 Medical Device Industry

3.4 Uniform Code For Pharmaceuticals Marketing Practices (UCPMP)

3.5 Foreign Direct Investment in Pharmaceuticals Sector







## CHAPTER – 3

# PHARMACEUTICAL INDUSTRY

### 3.1 PHARMACEUTICALS INDUSTRY – OTHER ACTIVITIES

The annual turnover of the Indian Pharmaceutical Industry is estimated to be about 165202.3<sup>1</sup> Crores during the year 2014-15. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs. 78792.3<sup>2</sup> Crores. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in Organic Chemical Synthesis and Process Engineering.

The domestic Pharma Industry has recently achieved some historic milestones through a leadership position and global presence as a world class cost effective generic drugs manufacturer of AIDS medicines. Many Indian companies are part of an agreement where major AIDS drugs based on Lamivudine, Stavudine, Zidovudine, Nevirapine are supplied to Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa. Many US Schemes are sourcing Anti Retrovirals from Indian companies whose products are already US FDA approved.

The Indian Pharmaceutical companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental Protection in production and supply of bulk drugs. This speaks of the high quality standards maintained by a large number of Indian Pharma companies as these bulk active ingredients are used by the buyer companies in manufacture of dosage forms which are again subjected to stringent assessment by various regulatory authorities in the importing countries. More of the Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovascular and CNS group. Along with Brazil & China, India has carved a niche for itself by being a top generic Pharma player.

Many Indian companies have got various international regulatory approvals for their plants, from agencies like USFDA, MHRA-UK, TGA-Australia, MCC-South Africa etc. Outside USA, India has the highest number of USFDA approved plants for generic drugs manufacture. Major share of Indian Pharma exports is going to developed western countries and it speaks not only about excellent quality of Indian pharmaceuticals but also about the reasonableness of the prices. Some of the leading Indian Pharma companies derive 50% of their turnover from International business.

### 3.2 PHARMACEUTICAL POLICY

The Department of Pharmaceuticals notified the National Pharmaceutical Pricing Policy-2012(NPPP-2012) on 07.12.2012 with the objective to put in place a regulatory framework for pricing of drugs to ensure availability of required medicines – “essential medicines” – at reasonable prices, even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The salient features of this policy are as under:-

- All the medicines, as under National List of Essential Medicines (NLEM) -2011, that takes care of the healthcare needs of the majority of the population of the country, will come under Price Control.
- Nearly 680 formulations, spread over 27 therapeutic categories including HIV, diabetes, heart diseases, cancer etc have come under price control.

Subsequently, to implement the NPPP-2012, the new Drugs (Prices Control) Order, 2013 was notified on 15.05.2013 to control the prices of specified dosages and strengths as under National List of Essential Medicines-2011(NLEM-2011). The medicines of dosages and strengths as specified under the National List of Essential Medicines (NLEM)-2011 have been brought under price control based on a concept of Ceiling Price by having the Simple Average Price of all the branded and/or generic versions of such medicine having market share more than and equal to 1% of the total domestic market turnover of that medicine. The medicines not listed under NLEM-2011 are under monitoring and no manufacturer can increase the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months. As per the provisions of Drugs (Prices Control) Order, 2013, all the existing manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, are required to revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable).

Ministry of Health & Family Welfare has constituted an expert core committee to review and recommend the revision of National List of Essential Medicines (NLEM-2011) in the context of contemporary knowledge of use of therapeutic products. Once the revised NLEM-2011 is announced by the Ministry of Health and Family Welfare, NPPA would fix the prices of those strength, dosage forms of medicines appearing in revised NLEM-2011.

### 3.3 MEDICAL DEVICES INDUSTRY

Medical devices industry is a multi-product industry, producing wide range of products. Manufacturing and trade in medical

<sup>1</sup> Source (pharmatrac/nppa/dgcis)

<sup>2</sup> Source (dgcis)



devices is also growing quite steadily. Double digit growth rates indicate its importance in health care. Medical devices industry mostly depends on imports. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovative cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

It is estimated that the global market for medical devices is over US\$ 220 billion. United States of America, with about 45% market share is the dominant market for medical devices in the world followed by European market with a share of 30% and Japan with a share of 10%. Medical devices sector in India is relatively small as compared to the rest of the manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the 4th largest market in Asia after Japan, China and South Korea. Although accurate data is not available, an educated guess would place the sector at about Rs. 30,900 Crores in production terms. The medical devices industry can be broadly classified as consisting of (a) medical disposables and consumables (31.3%); (b) medical electronics, hospital equipments, surgical instruments (53.7%); (c) Implants (7.1%); and (d) Diagnostic Reagents (7.9%). Medical devices Industry in India is predominantly import driven accounting for over 65% of the total market and approximately 80% of import in categories (b), (c) and (d).

Table given below indicated the disposable and consumable items imported and exported in the year 2014-2015:-

INDUSTRY PROFILE	
Turnover	% Distribution
0-10 Cr	65
10-50 Cr	25
50-100 Cr	5
100-500 Cr	3
500+ Cr	2

SOURCE : AIMED

Various sources expect the Medical Electronics industry to reach around USD 2+ Billion in 2015 growing at a CAGR of 17% for the last five years from a size of USD 850+ Million in 2009. It is believed that the growth will not only sustain but may increase beyond 17%.

Large multinational corporations (MNC) controlling the global industry backed by multiple approvals, certification of accredited organizations and capacity to produce verified clinical trial record are able to control the major share compared to the home grown devices which lacked standardization, certification or seal of quality approval even from local authority. Lack of national regulation helped the foreign multinational corporations in doing business in this sector. The Drugs and Cosmetics (Amendment) Bill, 2015 for providing a separate chapter for regulation of the complete range of medical devices is now under legislative process.

Commodity	Import value (INR in lakhs)	Country of maximum Import	Export value (INR in lakhs)
Syringes with needles	24328.14	USA, Singapore, Spain	21470.29
Suture needles	7749.28	USA, Singapore	11883.75
Tubular metal needles	9183.18	USA, Singapore	300.14
Hollow needles	255.04	USA	23.18
Other Tubular needles	9484.11	Singapore, Japan, Australia	6052.83
Urine catheters	1926.39	Switzerland, Malaysia, Germany	15422.80
Cardiac catheters	23025.43	USA, Ireland, Germany	3017.25
IV Cannulae	15992.23	Singapore, USA, Spain	46994.62
Other cannulae	85231.96	Ireland, USA, China	67367.27
Oxygen/gas mask	5439.51	USA, UK, Germany	1221.67
Wound dressing	3089.82	Brazil, USA, Germany	13115.02
Absorbable dressing	3059.28	USA, Denmark, Israel	439.32

SOURCE: NATIONAL HEALTH SYSTEMS RESOURCE CENTRE (NHSRC), M/o HEALTH & FAMILY WELFARE

At present, the Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Requirement for high end medical equipments are met by multinational companies. It is estimated that there are about 800 manufacturers in the country and based on their turnover, the industry profile of these manufacturers is as given in table below.

Besides, the others issues facing the Indian medical device industry include training and capacity building programme, interaction with medical device regulators, policy to promote local manufacture of medical devices, granting subsidies and incentives and promoting higher education relevant to medical devices industry to bring fresh talent and techniques into research and development. There does not exist a single nodal authority for medical device industry.



The Medical Device Industry in the country which is in a very nascent stage in the country because of which the government had constituted a Task Force to identify issues relating to the promotion of domestic production of high end Medical Devices and Pharmaceutical Manufacturing Equipment in the Country. The Task Force since has submitted its recommendations to the Government which is being examined. There was no nodal department to overlook the problems faced by this sector. As such, the government has amended the business allocation in respect of Department of Pharmaceuticals by mentioning industry related work against D/o Pharmaceuticals while the regulatory work remains with Ministry of Health & Family Welfare. FDI upto 100% through automatic route for manufacturing of medical devices has been allowed.

### **3.4 UNIFORM CODE FOR PHARMACEUTICALS MARKETING PRACTICES (UCPMP)**

UNIFORM CODE FOR PHARMACEUTICALS MARKETING PRACTICES (UCPMP) for pharmaceutical as well as Medical Device Industry was announced to be implemented voluntarily for a period of six months w.e.f. 1.1.2015. This has further been extended upto 31.12.2015. In the meantime, 29/7/2015, the implementation of the UCPMP was reviewed by Hon'ble Minister (C&F) with the stakeholders and it was decided to consult Ministry of Health &

Family Welfare and Medical Council of India (MCI) and to obtain their views for making it statutory by implanting it through essential commodity act and by amending Drugs and cosmetics act, 1940. A meeting this regard was held on 18/11/2015 with the M/o H & FW, MCI and stakeholder and as to how to go further in this matter.

### **3.5 FOREIGN DIRECT INVESTMENT IN PHARMACEUTICALS**

Foreign Direct Investment (FDI) up to 100% has been in operation in Pharmaceutical Sector since 2001. However, during the period of August 2006 to December 2010, acquisitions of some of the major Indian Pharma Companies like Ranbaxy and Piramal, led to a strong apprehension that these takeovers could affect the domestic Pharma Industry especially the Generic Medicines. Department of Industrial Policy & Promotion in November, 2011 revised the FDI Policy which now provides that 100% FDI in pharmaceutical sector is permissible through automatic route for greenfield investment and through Government approval route for brownfield investment. Further in brownfield investment 'non-compete' clause is not allowed except in special circumstances with the approval of the Foreign Investment Promotion Board (FIPB).





# Chapter

# 4

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

4.1 NPPA

4.2 Drug Price Equalization Account (DPEA)







## CHAPTER 4

# NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

**4.1** The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers was formed by the Govt. of India vide Resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995.

Salient features of DPCO, 2013.

- The National List of Essential Medicines (NLEM), 2011 is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of DPCO, 2013 which constitutes the list of scheduled medicines for the purpose of price control.
- Ceiling prices of scheduled formulations are based on "market based data" unlike cost based calculations under DPCO, 1995.
- The price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule.

The functions of the National Pharmaceutical Pricing Authority (NPPA) are:

- To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), in accordance with powers delegated to it.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- To deal with all legal matters arising out on the decisions of the Authority.
- To render advice to the Central Government on changes/revisions in the drug policy.
- To render assistance to the Central Government in parliamentary matters relating to drug pricing.

### Price Fixation:

Under the market-based approach adopted in DPCO, 2013, the ceiling price of a scheduled drug is determined by first working

out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular drug formulation having a market share of one percent and above, and then adding a notional retailer margin of 16 percent to it. The maximum retail price (MRP) for that particular drug formulation must not exceed the notified ceiling price plus applicable local taxes.

The DPCO 2013 contains 680 scheduled drug formulations spread across 27 therapeutic groups, which effectively comes to 628 scheduled drug formulations if we net those appearing in more than one therapeutic group. NPPA has fixed the ceiling prices of 530 formulations under DPCO, 2013 as on 31<sup>st</sup> October 2015. For remaining 98 formulations, NPPA has not been able to fix the ceiling prices due to non-availability of market based data.

The status of fixation of ceiling prices under DPCO, 2013 is given as under:

### Pricing Status of scheduled formulations as on 31.10.2015

Sl. No.	Particulars		
1.	Total number of NLEM medicines		680
2.	Medicines appearing in more than one therapeutic group of DPCO, 2013		52
3.	Net medicines for which prices are to be fixed		628
	Break up of number of items dealt under different category		
4.	Ceiling prices fixed upto 25th Authority Meeting (held on 29.10.2015)	530	
5.	Ceiling price fixation pending due to non-availability of Market based price data	98	
	<b>Total =(4)+(5)</b>		<b>628</b>

Statement showing range of reduction in price with respect to the highest price on the basis of data furnished by IMS-Health/Pharmatrac/pharmaceutical companies.

S. No.	% reduction with respect to Maximum PTR	No. of drugs
1.	0<= 5%	80
2.	5<=10%	50
3.	10<=15%	57
4.	15<=20%	43
5.	20<=25%	65
6.	25<=30%	49
7.	30<=35%	26
8.	35<=40%	34
9.	Above 40%	126
	<b>TOTAL</b>	<b>530</b>



The prices are notified through Gazette Notifications which are also uploaded on NPPA's website at [www.nppaindia.nic.in](http://www.nppaindia.nic.in). The ceiling prices become operative and legally enforceable from the date on which the price is notified in the Gazette.

NPPA has also notified 247 retail prices of new drugs on request of the manufacturers till 31st October, 2015.

NPPA is also empowered, in extra-ordinary circumstances, if it considers necessary to do so in public interest, to fix the ceiling price or retail price of any drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified. NPPA may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year. Accordingly, NPPA has fixed prices of 106 non-scheduled anti-diabetic and cardio vascular medicines under paragraph 19 of DPCO, 2013 on 10.7.2014.

## Monitoring and Enforcement:

Non-compliance with the notified ceiling price in case of scheduled drug formulations or, in other words, the MRP breaching ceiling price plus applicable local taxes would be tantamount to overcharging the consumer, which is liable to be recovered from the pharmaceutical company along with interest thereon from the date of overcharging. The excess collection on account of overcharging along with interest is recoverable as arrears to land revenue under the Public Demand Recovery Act. Further, non-compliance of price notification issued by NPPA, depending upon the gravity of the offence, could also attract prosecution under the Essential Commodities Act (ECA), 1955.

No manufacturer shall increase the maximum retail price of a non-scheduled drug formulation more than ten percent of maximum retail price during preceding twelve months.

The notified ceiling price with respect to scheduled formulations is valid for a period of five years from the date of original price notification, but subject to annual revision to be notified by NPPA which would be effective from the first day of April every year as per the annual wholesale price index (WPI) notified by the Department of Industrial Policy and Promotion with respect to the previous calendar year. The revision may mean increase or decrease in ceiling price depending upon whether the WPI is positive or negative.

Monitoring and enforcement under the provisions of DPCO, 2013 is the joint responsibility of NPPA and the State Drug Controllers. NPPA, along with State Drugs Controllers also undertakes market surveillance of prices of scheduled drugs under which following activities are done:

- Purchase of samples by NPPA officers from across the country,
- Examination of test samples received from State Drug Controllers,
- Examination of complaints received from individuals / NGOs/ VIP references, etc.

Based on analysis, specific cases are identified for recovery of overcharged amounts; and fixation of prices, wherever required.

NPPA also monitors the availability of essential formulations and identifies shortages, if any, and takes remedial steps.

Monitoring and Enforcement activities from 2007-08 to 2015-16 (upto October, 2015) are given as under:

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging
2007-2008	1450	840	456
2008-2009	520	284	172
2009-2010	464	246	208
2010-2011	553	225	216
2011-2012	559	156	152
2012-2013	626	165	163
2013-2014	993	389	389
2014-2015	3898 #	924	924
2015-2016*	2104 #	382	382

\*387 cases under process on 31.10.2015

#Cases of Overcharging referred from State Drug Controllers are included under the column 'Samples Collected'.

## New Initiatives:

(a) Pharma Jan Samadhan (PJS), a web enabled system was developed by the NPPA with the assistance of National Informatics Centre (NIC). It was launched on 12<sup>th</sup> March 2015. It serves as a robust e-governance tool for protection of consumer interest through effective implementation of the DPCO, 2013. The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval and refusal of supply or sale of medicines without good and sufficient reasons.

Any individual or consumer organization or stockiest / distributor / dealer / retailer or State Drugs Controller can lodge a complaint online through the PJS portal. Action on the complaint received through PJS with complete information is initiated within 48 hours by the NPPA.

(b) Pharma Data Bank (PDB) - Integrated Pharmaceutical Database Management System (IPDMS): This was launched by the Hon'ble Minister for Chemicals and Fertilizers on 25<sup>th</sup> June, 2015. IPDMS has been developed by the NPPA in collaboration with the National Informatics Centre (NIC). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed in Form II, Form III and Form V of DPCO, 2013. Application for price approval of 'new drug' in Form-I can also be filed through this portal. Online submission of application under Form IV will be made available shortly. 508 pharma companies have registered under IPDMS till 30<sup>th</sup> October, 2015 while 455 companies are in the process of registration. Information regarding 37053 products has been registered by pharma companies whereas submission of information on 3,450 products is in process as on 30<sup>th</sup> October, 2015. PDB is expected to benefit industry, consumer and the regulator. It provides industry with a user friendly mechanism to comply with the mandatory requirement of





filing returns; NPPA would be able to fix prices on the basis of price disclosure by companies and remove its dependency on private databases; and the consumer will be able to access price data with respect to each scheduled / non-scheduled formulation and take informed decision on cost-effective treatment. Retailers will also have access to real time price data. It will also help NPPA to easily monitor price compliance.

(c) Price Monitoring and Resource units (PMRUs) – NPPA has initiated setting up of Price Monitoring and Resource Units (PMRUs) in States/Union Territories under the Central Sector Scheme of 'Consumer Awareness, Publicity and Price Monitoring' that would provide all necessary support to the State Drugs Controllers to discharge the monitoring and enforcement activities mandated under the DPCO, 2013. Each unit will function under direct supervision of the concerned State Drugs Controller. PMRUs will be the key collaborating partners of NPPA for information gathering; and to ensure that the benefits of DPCO, 2013 trickle down to the grassroots level. The scheme would be implemented initially for two years in seven states on pilot basis with central funding.



Hon'ble Union Minister (C&F) Shri Ananth Kumar, Hon'ble Minister of State (C&F) Shri Hansraj Gangaram Ahir, along with senior officers of department of Pharmaceuticals and NPPA

### Studies on cardiac stents and orthopaedic implants

NPPA submitted a report to the Department of Pharmaceuticals on pricing of cardiac stents based on information collected and analyzed from Form V details submitted by companies and the study conducted by National Health System Resource Centre (NHSRC). As advised by the Department of Pharmaceuticals, NPPA

recently got a study conducted on pricing of orthopaedic implants, through NHSRC, New Delhi.

NPPA in discharge of its advisory responsibilities made recommendations to the government for inclusion of additional drug formulations to the National List of Essential medicines based on considerations of mass consumption, rationality and essentiality.

### Outreach activities:

NPPA organized a series of workshops / seminars at various places in 2014-15; and at Trivandrum, Raipur and Mumbai in 2015-16 (upto 31<sup>st</sup> October 2015) as part of its outreach activities. These workshops organized in collaboration with the State Drugs Controllers helped in dissemination of information about DPCO, 2013 and NPPP, 2012. The workshops also brought many experts from the pharmaceutical sector, academicians, health experts, civil rights activists and government officers who gave their perspectives on pharmaceutical pricing, patenting of medicines, innovations in the pharmaceutical sector and national and international best practices on the subject.

### Recovery of overcharged amount:

NPPA has initiated about 1350 cases of overcharging as on 31<sup>st</sup> October, 2015 (1220 cases under DPCO 1995 & 130 cases under DPCO 2013) where demand notices have been issued to pharmaceutical companies. The demanded amount works out to Rs.5015.37 crore (Rs.4804.42 crore under DPCO 1995 and Rs.210.95 crore under DPCO 2013) for sale of medicines at prices higher than that fixed by NPPA /Government. However, only an amount of Rs.379.04 crore (Rs.312.62 crore under DPCO 1995 and Rs.66.42 crore under DPCO 2013) has been recovered as on 31<sup>st</sup> October, 2015, from pharmaceutical companies. Out of the balance outstanding amount, Rs.3726.88 crore is locked up in litigation.

Action for recovery of the overcharged amount along with interest thereon is a continuous process. NPPA takes action as per the provisions of DPCO, 1995/ DPCO, 2013 read with Essential Commodities Act, 1955. The ongoing litigation procedures in the various High Courts and the Supreme Court hamper the recovery of overcharged amount from the pharmaceutical companies.

### 4.2 DRUG PRICE EQUALIZATION ACCOUNT (DPEA)

Drug Prices Equalisation Account (DPEA) has been maintained by Government under the provisions of Drugs (prices Control) Order, 1979. Under the Drugs (Prices Control) order, 1979 (DPCO, 1979), there were 345 bulk drugs under price control. The Department computed tentative liabilities in respect of 47 bulk drugs only on suo-moto basis covering 172 cases till the Interim stay dated 30.6.1997 was granted by the Hon'ble Bombay High court in the Writ petition No. 2368/1996 filed by the Indian Drugs Manufacturer's Association (IDMA) and Organisation of pharmaceutical producers of India (OPPI) restraining the Department and its committees etc., from issuing fresh notices to the drug companies calling for information required for determining liabilities. Out of these 172 cases where the liabilities have already been determined



tentatively and communicated to the companies, only 72 such cases during the period 1994-97 could be referred to the Drugs Prices Liabilities Review Committee (DPLRC) constituted on 21.3.1994 under the Chairmanship of a judge of Hon'ble Delhi High Court retired in October, 1994) alongwith two Members to review/ determine the liability in such cases. Out of these 72 cases, the Committee after deliberation in each case and giving adequate opportunity of Hearing to the drug companies to present their point of view gave reports in 47 cases. In view of the stay granted by the Hon'ble Bombay High Court the Committee had not taken up the other 25 cases and also any fresh case. On the basis of the recommendations of the DPLRC, Department issued demand notices in 45 cases. Most of these companies filed Writ petition in the different High Courts against the demand notices. The total amount of liability on the basis of the recommendations of the

DPLRC is to the tune of Rs. 228.47 crore (appx). Total amount in DPEA as on 31.03.2015 is Rs. 299.45 crores (Approximately).

Since, no new cases could be taken up by DPLRC for determination of the DPEA liability because of the stay granted by the Hon'ble Bombay High Court, there was no work with the DPLRC. Hence a conscious decision was taken by the Government to keep the DPLRC under suspended animation w.e.f. 31 December, 2005 vide Resolution dated 16<sup>th</sup> December, 2005. At that time 25 cases were pending with the DPLRC because of stay, where no quantification could be done. In addition to these 25 cases, there may be a large number of DPEA liability cases in respect of 298 bulk drugs where information from the companies concerned is to be gathered for determination of the DPEA liability. The aforesaid W. P. No. 2368/1996 has been dismissed by Hon'ble High Court vide its judgement dated 22.12.2011

# Chapter 5

## PUBLIC SECTOR UNDERTAKINGS

- 5.1 Central Public Sector Undertakings
- 5.2 Status of Annual Accounts
- 5.3 The Jan Aushadhi Scheme









## CHAPTER - 5

### PUBLIC SECTOR UNDERTAKINGS

#### 5.1 CENTRAL PUBLIC SECTOR UNDERTAKINGS

There are five Central Public Sector Enterprises (CPSEs) under the administrative control of this Department of Pharmaceuticals. Of the five, three viz. Indian Drug & Pharmaceuticals Limited (IDPL), Hindustan Antibiotic Limited (HAL) & Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and are referred to Board for Industrial & Financial Reconstruction (BIFR) while the Rajasthan Drugs & Pharmaceuticals Limited (RDPL) reported losses for the first time during the year 2013-14. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

Production & Sales of 5 CPSEs during the last 3 years is as under:

(Rs. In Crore)

CPSEs	2012-13		2013-14		2014-15		2015-16 (Upto December, 2015)	
	Prod.	Sale	Prod.	Sale	Prod.	Sale	Prod.	Sale
KAPL	247.39	214.21	275.73	241.59	281.81	247.24	247.40	228.05
RDPL	86.22	85.67	54.93	43.50	25.04	24.90	21.03	22.88
HAL	48.73	52.09	27.37	30.11	17.28	18.54	8.38	7.87
BCPL	36.32	27.37	1.97	16.87	64.10	45.84	68.32	65.36
IDPL	58.71	59.47	62.87	60.18	71.50	61.56	58.41	57.27

Initiatives taken to improve the performance of CPSEs during 2015-16 are as follows:

1. Performance Management – Regular review of performance of CPSEs – Performance review meetings of all CPSEs was held on 29.07.2015.
2. Revival of IDPL and HAL – The revival package of IDPL and HAL is under active consideration of Government of India.
3. Pharma Park Development – The matter of Pharma Park in IDPL, Hyderabad/IDPL, Rishikesh/IDPL, Chennai is under consideration of Government of India.
4. Status of WHO-GMP in RDPL – The Company has embarked upon expansion, modernization and upgradation programme (Phase II) to qualify for WHO-GMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of Government of India and other Government.
5. BCPL – Ointment & Betalactam Block and Panihati Project have been completed while Cephalosporin Block is under commissioning. Besides this, OSD Project & ASVS Project are being commissioned.

#### I) KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (KAPL)

##### BACKGROUND:

KAPL is a Profit making Joint Sector Company incorporated in the year 1981 (with 59% share by Government of India and 41% share by Government of Karnataka through KSIIDC). The basic objective of the Company is to make available life saving drugs of good quality to Government Hospitals and other Institutions along with Private Medical Practitioners. The Company has WHO-GMP Certified manufacturing facilities for Dry Powder Injectables, Liquid Injectables, Tablets, Capsules, Dry Syrups and Suspensions.

The paid-up share capital of the Company as on date is Rs. 13.49 crores.

##### PRODUCTION AND SALES:

(Rs. in crore)

Particulars	2012-13	2013-14	2014-15	Upto 30.09.2015
Production	247.39	275.13	281.81	163.36
Sales	223.58	241.59	247.24	152.22

##### PAST ACHIEVEMENTS:

- Mini Ratna CPSE
- ISO 9001 (QMS) AND ISO 14001 (EMS)
- PIC/S Certification

##### PLANT MACHINERY AND CAPACITY

CAPACITY UTILISATION		(in %)		
Sl. No.	Particulars	2012-13	2013-14	2014-15
1	Liquid Parenterals	172	140	127
2	Vials (Dry Powder)	81	82	93
3	Tablets	212	127	120
4	Capsules	150	148	143



## PRODUCT PROFILE AND RANGE:

### PHARMA – TRADE

VOLUME BRANDS(HIGH)	REGULAR BRANDS(LOW)	CARDIO-DIABETIC BRANDS
GRENIL (ANTIMIGRAINE)	KAMADOL-P / INJ (ANALGESIC)	KAPRIL (CARDIAC)
GRENIL-F (ANTIMIGRAINE)	VERIXIME (ANTIBIOTIC)	KAPRIL – H (CARDIAC)
CYFOLAC FORTE (SYMBIOTIC)	VITATROL PLUS (ANTIARTHRITIC)	LOTACE (CARDIAC)
CYFOLAC (PROBIOTIC)	VITALPHA-C (ANTIARTHRITIC)	LOTACE – 50H (CARDIAC)
REMCC (COUGH & COLD)	NUMOL-A (ANALGESIC)	CIDOGREL (CARDIAC)
REMCC XP (EXPECTORANT)	MAXIFLAM-SP (ANALGESIC)	CIDOGREL-A (CARDIAC)
REMCCLM (ANTIALLERGIC)	HUSKY (BOWEL REGULATOR)	GLIMKAP (ANTI-DIABETIC)
ZINFE XT / SYP (HAEMATINIC)	FUBAC (SKIN ANTIFUNGAL)	GLIMKAP-M (ANTI-DIABETIC)
ZINFE SR (HAEMATINIC)	OLIGEL (TOPICAL ANALGESIC)	PIOKAP (ANTIDIABETIC)
VERCLAV (ANTIBIOTIC)	CETRIAX (ANTIBIOTIC)	PIOKAP-MF (ANTIDIABETIC)
TOPRAZOLE (ANTIULCER)	CETRIAX-S (ANTIBIOTIC)	PERTENOL (CARDIAC)
NUMOL MR (MUSCLE RELAXANT)	PIPMAX (ANTIBIOTIC)	-
-	APIFEAST (HERBAL APPETISER)	-

## POPULAR BRANDS:

### PHARMA – TRADE

No	Products	Therapy Segments	NLEM	Monopoly	Market Value
1.	Grenil Group	Anti-Migraine	NO	NO	Rs. 12.00 Crs
2.	Cyfolac Forte Group	Pre & Probiotics	NO	NO	Rs. 4.00 Crs
3.	Remcc Group	Cough & Cold	NO	NO	Rs. 3.00 Crs
4.	Zinfe Group	Haematinic	NO	NO	Rs. 2.00 Crs
5.	Verclav Group	Antibiotc	YES	NO	Rs. 4.00 Crs

## AGROVET:

No	Products	Therapy Segments	Monopoly	Market Value
1.	K-Cycline	Insecticides	NO	Rs. 3.00 Crs
2.	Kalvimine Group	Feed Supplement	NO	Rs. 2.00 Crs
3.	K-Live	Hepato - Protective	NO	Rs. 2.00 Crs

## MANPOWER AS ON 31.03.2015

EXECUTIVES	NON-EXECUTIVES	TOTAL
244	484	728

## DISTRIBUTION NETWORK:

### PHARMA

The Company has been expanding its operations in Retail Trade Sector with a planned effort so as to cater to the needs of the Private Medical Practitioners. In this direction the Company has been periodically launching New Products in the various Therapeutic Segments. The Domestic operations spans through the country manned by a highly dedicated Professional Field Force and backed by a well knit Channel of Distribution ensuring KAPL's presence at the Metro as well as Micro Markets.

KAPL has its Branches located in almost all the State Head Quarters. The Company also has an excellent Distribution Network at almost 20 branches at Major Cities catering to the respective State area through Channel Marketing. The supplies are made effective through approved Stockists to Retailers, Nursing Homes and Dispensing doctors in the Trade Segment and directly to Institutions in Rate Contract (RC) & Non-Rate Contract (NRC) Sectors.



## MARKETING: Share of Institutions and retail:

### PHARMA:

The Company has been mainly focusing on Prescription Market as Medical Professional as our Customers, where many of the MNCs and Private Pharma Players have a major share. The Company is also dependant on PPP Policy for Institutional Business, where our concentration is on Govt. Hospitals, State Government Hospitals, Corporates, PSU Hospitals, Defence and Insurance. Has potential to expand in Trade Segment and also to increase volumes by focusing on CPSE Hospitals and large Corporate Hospitals. Also need to look at increase in Product Mix and Injectable Range. Another opportunity for expansion is in ayurvedic Range, where Ayurveda, a holistic and complete treatment was invented by India.

### AGROVET:

The Company is focusing on Agro Dealers, Department of Agriculture / Horticulture for Agro Products.

Products are being focused on Veterinary Practitioners, Farmers, Animal Husbandary Department of all States and Milk Unions for Veterinary Products and Feed Supplements.

### NEW PRODUCTS(PHARMA & AGROVET)

- a) Apifeast Syrup
- b) Numol SP Tablet
- c) Taspin MP Inj.
- d) Kapcure Plus Spray

### FUTURE PLANS:

The Cephalosporin Project is scheduled to start from January 2016.

### TARGETS FOR 2016-17:

Rs. 270 crores net of Excise is proposed under MoU.



Hon'ble Union Minister for Chemicals & Fertilizers Shri Ananth Kumar alongwith senior officials of department of Pharmaceuticals and others

## II RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED (RDPL)

Rajasthan Drugs & Pharmaceuticals Limited (RDPL) is a Central Public Sector Unit in Joint Sector with a total paid-up equity capital of Rs. 4.98 crores where Government of India (GoI) and Rajasthan State Industrial Development & Investment Corporation Limited (RIICO, Govt. of Rajasthan) hold 51% and 49% respectively. It was

incorporated in 1978 and commercial production started in 1981. The Company has its manufacturing facilities & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan).

This is a formulation unit engaged in production of Tablets, Capsules, Liquid Orals, ORS Powder & Ophthalmic medicines in a Schedule 'M' compliant facility.

The company, under the quality management, has a well-equipped laboratory with modern equipments like HPLC, FTIR, etc., for ensuring high quality parameters. The company is also working towards obtaining ISO 9001:2008 & WHO-GMP certifications.

The Company has enhanced its manufacturing capacities by installing new machines and at the same time the workers have also acquired skills and expertise for attaining high productivity.

The company is also engaged in expansion, modernization and upgradation of its manufacturing facilities to WHO-GMP Standards.

The company has carved for itself a name in the institutional market in India as a reputed manufacturer of high quality lifesaving drugs and other specialized medicines, with its marketing activities spread throughout the country.

The company is engaged in manufacture and selling of medicines of high quality at reasonable rates to the Govt. of Rajasthan, Central Government Institutions, viz ESIC, Defence, Railways, other PSUs and also to other State Govt. Institutions.

RDPL is proud to be a prime partner in the novel and noble endeavor of Govt. of India in the implementation of 'JANAUSHADHI' programme where quality generic medicines (unbranded) are made available to the public at large in the country at affordable prices.

The company is further diversifying its activities into Pharma Prescription Markets (Open Trade Sales), Veterinary Markets, Marketing of Ayurvedic and other Indian system of medicines in order to enhance its market share and also in its endeavour to achieve profitability for the organization.

### FINANCIAL PERFORMANCE OF THE COMPANY

(All figures in Rs crores)

Years	Production	Sales
2012-2013	83.24	85.67
2013-2014	54.93	43.51
2014-2015	25.04	24.90
2015-2016 (Upto Oct 2015)	14.31	13.46

### Product Profile of the Company

The Company has been dealing in following products:

- Anti-Infectives
- Anti-Malarial
- NSAIDS
- Antacids
- Analgesic, Anti-Pyretics & Anti-Inflammatory
- Anti-Emetics





- Anti-Spasmotics
- Anti-Diarrhoeal / Anti-Amoebic

### Cough Expectorants

#### Project undertaken and Future projects:

The Company has embarked upon expansion, modernization & upgradation programme (Phase II) to qualify for WHO-cGMP certification to become eligible for exploring International Markets as well as for participating in the Internationally Funded Projects of GOI and other Governments.

The Company has submitted a Detailed Project report (DPR) to Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India for sanction of Grant-in-aid to the tune of Rs. 13.01 crores for financing the Phase-II plan so as to complete the project for becoming eligible for making application for WHO-cGMP. Rs. 11.39 crores were sanctioned by Govt. of India as Grant-in-Aid. Out of total amount sanctioned, company has received Rs. 4.55 Crore in October 2012 and rest of the amount i.e., Rs. 6.84 crore was received in month of March 2015. It is envisaged to complete the project by March 2016.



### BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED (BCPL)

#### Background

Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) were constituted in 1901 by Acharya Prafulla Chandra Roy, a renowned scientist and academician. Government of India nationalised BCPW in 1980 under the name Bengal Chemicals & Pharmaceuticals Limited (BCPL) in 1981. BCPL was declared sick in 1993 and was sanctioned scheme for revival in 1995 by Board for Industrial & Financial Reconstruction (BIFR). In 2004, the scheme of revival was modified and the plan was sanctioned by BIFR.

#### Business Operations

Headquartered in Kolkata, BCPL is engaged in the business of industrial chemicals (Alum), branded and unbranded generic pharmaceuticals, hair oil and disinfectants such as phenol, naphthalene balls, bleaching powder, toilet cleaners and floor cleaners.

**Manufacturing Locations:** At present BCPL has four factories; at Maniktala and Panihati in West Bengal, Mumbai and Kanpur.

**Maniktala Unit:** This unit primarily produces Division II products which include branded as well as unbranded generic pharmaceuticals. Under the BRPSE scheme several projects such as capacity expansion of tablets, capsules and ointment blocks, complete overhaul of ASVS and Liquid blocks and implementation of Greenfield projects were envisaged for the Maniktala unit. The ASVS project is planned to be taken up during 2015-16. The Greenfield Projects (Betalactum & Cephalosporin Blocks) and modernisation of Ointment block that were initiated as envisaged in the plan. These projects are planned to be commissioned by April 2015.

**Panihati Unit:** Panihati unit, located near Kolkata, primarily produces Division I (Alum) and Division III products which include Phenol, Naphthalene Balls, and other disinfectants. Commercial production in most of the renovated production-blocks such as Alum, Phenol, Naphthalene and White Tiger have commenced

**Mumbai Unit:** Mumbai unit, produces Hair Oil under the brand name 'Cantharidine'. The commercial space developed has been leased out to third parties for generation of additional sources



of income. Commercial space of the order of 43,206 sq. ft. has presently been leased out by the company

**Kanpur Unit:** Kanpur Unit, set up in 1949, primarily produces Division II products which includes tablets and capsules and small quantity of Hair Oil.

**Past Achievements:** The company has retained its brand position in home products even during the crisis period and well set to capitalise on tense brands now.

**Sickness and Revival:** The Company was referred to BIFR in 1992. The revival package for BCPL was approved by the Government on 21<sup>st</sup> December 2006. The package of Rs 490.60 Cr was approved which comprised of restructuring of exiting debts on the books of BCPL, capital investments, support for development of marketing infrastructure and promotional measures, grant for wage revision and implementation of VRS and funds for payment of non-Government dues.

## Plant Machinery and capacity & recognition as on 30.09.2015:

SL No	PRODUCTS	UNIT	INSTALLED CAPACITY Per Annum	PRODUCTION For (2014-15)	PRODUCTION For 1st Half (2015-16)
1.	ALUM	MT	8000.00	5733.09	2400.90
3.	TABLETS	CR	15.00	3.62	7.84
4.	CAPSULES	CR	5.00	2.00	3.71
5.	OINTMENTS	MT	60.00	59.38	8.57
6.	HAIR OIL	KL	800.00	239.80	54.94
7.	PHENEOL	KL	3000.00	1691.97	805.43
8.	NAPHTHALENE	MT	450.00	152.47	49.16
9.	DISINFECTANTS	KL	1200.00	282.83	170.95

## Modernisation of plants (Government assistance projects and status)

(Rs. in Cr.)

Projects	Investments	Status
Ointment & Common items –Maniktala	29.57	Completed
Betalactam Block-Maniktala	30.39	Completed
Cephalosporin Block- Maniktala	29.75	Under Commissioning
Panihati Project	27.95	Completed
OSD project at Kanpur	34.44	To be completed
ASVS - Maniktala	29.64	To be completed
Pre-operative expenses	17.07	
Total	198.81	

## STATUS OF IMPLEMENTATION OF PROJECTS:

Particulars	Status
ASVS Section	To be taken up during 2016-17
<b>Kanpur:-</b> Tablet, ORS, renovation /up gradation of existing blocks, QA, Utilities, amenity, Sterile Block etc.	

## Product profile and range:

The products manufactured under each of these business segments are mentioned below:

### Division wise Product Segmentation

Division	Description
Division I	<ul style="list-style-type: none"> <li>Ferric Aluminium Sulphate (Alum)</li> </ul>
Division II	<ul style="list-style-type: none"> <li>Tablets</li> <li>Capsules</li> <li>Liquid Preparation</li> <li>Ointment</li> <li>Antiseptic Liquid</li> <li>Injectables</li> <li>Aqua Ptychotis</li> <li>Eutheria</li> <li>Kalmegh</li> </ul>

Division	Description
Division III	<ul style="list-style-type: none"> <li>Pheneol</li> <li>Bleaching Powder</li> <li>Klin Toilet</li> <li>Lysol</li> <li>Cantharidine Hair Oil</li> <li>Naphthalene Balls</li> <li>Liquid Soap (For Industrial Use)</li> <li>White Tiger (Floor Cleaner)</li> <li>Aguru (Essence)</li> </ul>



**Popular brands:** Pheneol – Lamp brand, White Tiger, Naphthalene. Cantharidine Hair Oil.

## Manpower as on 01.11.2015:

Particulars	01.11.2015 Nos.
EXECUTIVES	74
SUPERVISORS	116
Workers	190
<b>Grand Total</b>	<b>380</b>

## Distribution network if any:

The company has a strong distribution network pan India with 11 Depots and 10 C&F Agencies.

## Performance:

Details of Production & Sales of BCPL from 2011-12 onwards are as under:

(Rs. in Crore)

Particulars	2011-12	2012-13	2013-14	2014-15	2015-16 Upto Oct'15 (Provisional)	2015-16 Nov'15- Mar'16 (Projection)
Production	59.22	36.33	19.71	64.10	53.84	52.00
Sales	45.71	25.45	15.83	45.84	49.24	52.00
EBITDA	(2.92)	(22.90)	(20.36)	1.65	1.35	5.00
Profit/ Loss	(10.70)	(40.69)	(36.55)	(17.32)	-	-

## DPE rating:

Year	MOU Assessment
2009-2010	"Poor" as the audited Balance Sheet could not be submitted on time
2010-2011	
2011-2012	
2012-2013	
2013-2014	
2014-15	"Good"

## Marketing: Share of Institutions and retail

SR. No.	DIV & PRODUCTS	MARKET PROFILE/Major clients
1.	DIV I – FERRIC ALUM	NTPC (KAHELGAON & BARH) SAIL (DURGAPUR, IISCO, BOKARO, REFRACTORY UNIT, IISCO CHASNALA) BCCL (BOWRA & BLOCK II) IPCL (FARAKKA, SAGARDIGHI, DISERGARH) PHE (MALDA, SILIGURI) OTHER PRIVATE PARTY
2.	DIV II – GENERIC TABLET, CAPSULE, OINTMENT, INJECTION, LIQUID	AFMSD, ESIC, RAILWAY, SAIL, DHS, APMSIDC, OTHER STATE GOVT, SECL, AND OTHER PSU

SR. No.	DIV & PRODUCTS	MARKET PROFILE/Major clients
	DIV II – BRAND AQUAPTYCHOTIS, EUTHERIA, KALMEGH	MAINLY OTC PRODUCT. TRADE BUSINESS
3.	DIV III – COSMETIC & HOME PRODUCTS	MAINLY TRADE BUSINESS (70-75%) AND (25 TO 30 %) INSTITUTION BUSINESS LIKE CSD, PHE, METRO RAILWAY, NMDC, JADAVPUR UNIVERSITY ETC.

## Future projects:

**ASVS Project:** It is planned to start ASVS Project as the product is not available in the country at the moment in required quantity as both the Government sector units namely BCPL and Central Research Institute (CRI), Kasuali, have stopped production of ASVS for the last 6 years. Construction will be resumed in the next financial year i.e., 2016-17.

## Targets for 2016-17

Rs. in Cr.

Production	80.00
Turnover	70.00



Shri Hansraj Gangaram Ahir, Minister of State (Chemical & Fertilizer) visiting Maniktala Factory



Dr. V. K. Subburaj (Secretary, Department of Pharmaceuticals) paying homage to Acharya P. C. Ray at Maniktala Factory





Ointment Manufacturing- Validation completed,  
Commercial Production taken



External Solution Filling Line



Betalactum Block at Maniktala Factory:



Cephalosporin Block at Maniktala Factory (Non Betalactum Tablets):

### HINDUSTAN ANTIBIOTICS LTD. (HAL)

The details of production, sales and net profit / loss for the year 2014-15 (upto 31st March, 2015)

(Rs. in Crores)

	2012-13	2013-14	2014-15 (Prov.)*
Production	48.73	27.66	17.28
Sales Turnover	52.09	30.11	18.54
Net Profit (Loss)	(69.37)	( 84.23)	(70.55)

\*Provisional

HAL is passing through critical financial crisis due to shortage of working capital required for running its operations. Due to this financial crisis its operations are running at very low level. Many of the statutory payments like Provident Fund, Gratuity, Income tax, Sales Tax etc. are also outstanding. The working capital facilities are also not forthcoming from the Banks as the Company's account has become NPA.

The Deptt. of Pharmaceuticals considering the financial crisis being faced by HAL directed the Company to make the 2<sup>nd</sup> Rehabilitation Package which should include modernization of plant & machinery, requirement of working capital, VRS cost, new Utility-Set-up for Formulation business, waiver of government loans and interest etc.

IFCI Ltd. a Consultant appointed by Govt. of India prepared Techno-economic Viability (TEV) Report and submitted to the Govt. of India. On the basis of the TEV Report submitted by IFCI and the direction given by GOI the detailed proposal was prepared by the Company and submitted to IDBI. On the basis of the proposal of the Company the MDRS is finalized by IDBI. On the basis of the proposal of the Company the MDRS is finalized by IDBI. The said





MDRS of the Company is under active consideration of the Govt. of India.

### NEW PROJECTS :

The following new projects are taken up for capacity expansion and productivity improvement in 2015-16.

1. Expansion of Steptocycline Plant costing Rs. 1.71 crores (Being Commissioned)
2. New Cooling Tower costing Rs. 0.95 crores (Commissioned)
3. Briquette Based Boiler and Rationalisation of Steam header costing Rs.1.30 crores (Being Commissioned)
4. Upgradation of IV Fluid Plant costing Rs.6.28 crores (Being executed)

### NEW PRODUCTS :

New speciality products are being introduced for specific requirement of the Defence Forces, Narcotic Control Bureau etc.

### STATUS OF HAL AFTER IMPLEMENTATION OF MDRS.

1. All liabilities including statutory authorities, bank loans, manpower related (Gratuity, PF, other dues) will be fully cleared.
2. Salary / wage bill will be reduced by around Rs. 18-20 Crores due to VRS.
3. Formulation Plants will be upgraded to GMP standards and Streptocycline (Agro products) production capacity will be enhanced.
4. Utility cost will be reduced due to installation of Briquette based boiler, Efficient chiller and cooling tower.
5. Production will boost up to the levels of Rs. 130-450 Crores turnover over the period of time due to availability of working capital.

## INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

### Background:

Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated as a public limited company on 5<sup>th</sup> April, 1961 under the Companies Act, 1956. The Registered Office of the Company is located at IDPL Complex, Dundahera, Gurgaon and its Head Office at SCOPE Complex, Lodhi Road, New Delhi. The main objectives of the company were creating self-sufficiency in respect of essential life saving medicines, to free the country from dependence on imports and to provide medicines to the millions at affordable prices. IDPL was basically conceived and established as a part of Healthcare Infrastructure and has played a pioneering infrastructural role in the growth of Indian Drugs Industry base.

IDPL has three main Plants at Rishikesh (Uttarakhand), Gurgaon (Haryana), Hyderabad (Telangana) and two 100% wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Ltd. Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Ltd. (BDOCL) at Muzaffarpur (Bihar). In addition, IDPL has one Joint Venture Undertaking,

promoted in collaboration with the Odisha State Government, namely, Orrisa Drugs & Chemicals Ltd. (ODCL) Bhubaneswar. IDPL is a sick company in Public Sector within the meaning of Sick Industrial Companies (Special Provisions) act, 1985 (SICA).

### Past Achievements:

The main objective of setting-up IDPL was not to earn profits but to encourage indigenous production of pharmaceuticals and to support various health programmes of the Central Government. IDPL did reasonably well on this account despite the fact that it was the first integrated and monolithic venture in the Public Sector engaged in production of low margin products. IDPL earned Profit before Depreciation, Interest & Tax (PBDIT) from 1965 to 1968 and again from 1971 to 1974. It earned net profit from five years continuously from 1974 to 1979; the Company lost its profitability primarily due to change in Government policy about import of bulk drugs from supply to pharma Industry. The Imports which were canalized through IDPL till 1979 were entrusted to State Trading Corporation (STC). This was the task assigned to IDPL as per needs of the time. IDPL was thus divested of a profit making segment. Today, it can fulfil other needs to meet gaps in public health by supplying essential drugs.

### Sickness and Revival if any

The role of IDPL was, however, not redefined even in the eighties. It continued to function on the basis of its old model of sixties which lost its relevance to a great extent by eighties. In the circumstances, the net worth of the IDPL became negative in 1982-83. The causes were (i) large monolith-type integrated production facilities (typical model followed in 1950s-1960s) producing chemicals, bulk drugs & formulations (ii) outdated plant & machinery and obsolete technology for bulk drugs (but for formulations not outdated) (iii) excess manpower (13283 in 1983-84) and high wage bill and maintenance of huge township, schools and hospitals. (iv) frequent changes at top management (average tenure of Chairman & Managing Director was 18 months) (v) medicines produced by IDPL were under price control by the Government prior to liberalization in 1991 (vi) shift in Government policy resulting in shifting of the canalization agency from IDPL to STC (vii) intense competition from private pharma sector companies which did not have to bear burden of social infrastructure of setting up and maintaining townships, schools, hospitals etc. and had learner production facilities. Production has been stopped in October 1996 at Rishikesh & Hyderabad & Muzaffarpur Plant due to shortage of working capital.

### Revival status since 1.4.1994

The Board for Industrial & Financial Reconstruction (BIFR) declared IDPL as a sick industrial Company on 12<sup>th</sup> August. 1992. On 10.2.1994 BIFR approved the Rehabilitation Scheme under Section 17(2) of SICA for its implementation w.e.f. 1.4.1994. The package sanctioned by BIFR in 1994 failed primarily because (i) full funds were not released to the Company as envisaged (ii) capital restructuring was not done (iii) banks did not provide adequate working capital requirements (iv) working capital funds were diverted to meet fixed expenses of subsidiary units. (v) Land could not be sold (vi) sales targets were fixed at very ambitious levels. On



23.1.1996, BIFR appointed Industrial Development Bank of India (IDBI) as Operating Agency (OA) for Techno-Economic Analysis and preparation of Revival Package. The issue of revival of the company remained pending in BIFR as well as with the Govt. Attempts were made in 2001-02 to privatize the Company. OA, however, did not find any proposal worthy of recommendations to BIFR.

After failure to privatize IDPL, BIFR ordered its winding –up on 4.12.2003. Govt. filed an appeal before Appellate Authority for Industrial Financial Reconstruction (AAIFR) on 10.2.2004 against BIFR order. AAIFR admitted the appeal filed by the Government on 2.8.2005 and directed that a Road Map for revival of IDPL be submitted. Ministry/ Department constituted an Expert Committee under the Chairmanship of Director NIPER and Technical Audit of the Plants & Machineries carried out by the Committee, it would be feasible to revive IDPL. Committee found the plant & machineries for production of formulations in a reasonably good shape which can be optimally utilized with minimal investment for compliance of Scheme-M requirements. It was also opined that the emerging position of IDPL in the present market scenario is to be conceptualized. IDBI supported the recommendations of the Expert Committee. Having regard to these developments, AAIFR in its hearing held on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL and to pass further orders in accordance with law.

Keeping in view of the above a DRS was prepared by IDPL in consultation with ICRA Management and submitted to the BRPSE for consideration and recommendation. After approval of the BRPSE and A Note for Cabinet Committee on Economic Affairs is prepared and submitted for approval on 11.5.2007. The Note was considered by CCEA in its meeting held on 17.5.2007 and referred the matter to Group of Minister (GoM). GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensuring the viability of the Company. The observations made by GoM, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y report submitted to the Ministry/DoP.

A revised DRS again prepared by IDPL in consultation with IDBI (OA) taking cut off date as 31<sup>st</sup> March, 2011. BIFR observation that cut off date needed the approval of BIFR bench. Thereafter in the BIFR meeting held on 20.8.2014 cut off date was approved as 31.3.2014. Accordingly, the revised updated DRS has been prepared taking cut off date 31.3.2014 and submitted to the DoP/ Ministry in January 2015 for consideration and approval. The said rehabilitation plan of the company is under consideration of the Government of India.

### IDPL WHOLLY OWNED SUBSIDIARIES

#### IDPL (Tamil Nadu), Chennai.

IDPL (Tamilnadu) Chennai was incorporated in September, 1965, initially it was a Surgical Instruments Plant and later diverted for formulations. In terms of revival package approved by BIFR in 1994 this Plant was converted into a wholly owned subsidiary in the name and style of IDPL (Tamilnadu) Limited, Chennai with

effect from 1.4.1994. IDPL (Tamilnadu) is a Schedule-M compliant plant and engaged in manufacture about 20-25 pharmaceuticals formulations. The production achieved for the F.Y. 2014-15 was Rs. 10.50 crores.

#### Bihar Drugs & Organic Chemicals Ltd. (BDOCL, Muzaffarpur

Bihar Drugs & Organic Chemicals Ltd., Muzaffarpur was incorporated in 1979, converted into a wholly owned subsidiary with effect from 1.4.1994. IDPL holds the entire equity capital of this Unit. At present there is no production activity in this Plant since November, 1996.

#### Orissa Drugs and Chemicals Ltd (ODCL) (Joint Undertaking of IDPL and Orissa Govt)

Orissa Drugs & Chemicals Limited (ODCL) was incorporated in 1979 and commissioned fully for production from September, 1983. ODCL is a Joint Sector Undertaking promoted by Indian Drugs & Pharmaceuticals Ltd. (IDPL) and Industrial Promotion & Investment Corporation of Orissa (IPICOL). IDPL holds 51% of the equity shares and 49% is with IPICOL. BIFR passed orders for winding up in April, 2003 under the provisions of SICA Act, 1985. High Court of Orissa had appointed a provisional Liquidator. This has since been stayed by a larger Bench of the Odisha High Court.

Presently Company is engaged in manufacture of pharmaceuticals formulations in the form of Tablets, Capsules, Powder, ORS and Injectables etc. ODCL Plant is Schedule-M compliant and production for the F.Y. 2014-15 was Rs. 18.70 crores which was the highest ever achieved by ODCL.

**IDPL TODAY** - Presently IDPL is engaged in manufacturing about 110 formulations. In-house production of formulation during the year 2014-15 was **Rs.71.50** crores, Items-wise details are as under:

S. No	Item	Unit	Annual Installed Capacity	Qty. Produced	Value (Rs.in lakhs)
1	Tablets	Million Nos.	1623	527.81	3025.31
2	OCP	Million Nos.	1638	208.52	286.70
3	Capsules	Million Nos.	740	153.48	1985.74
4	Liquid Oral 110 ml.	Kilo Litres	696	308.44	325.72
5	Dry Syrup 60 ml	Lac Bottle	36	23.04	300.75
6	Injectables (Amp)	Million Nos.	24	1.99	67.11
7	ORS	Million Nos.	15	4.80	168.89

#### Modernization of Plants (Government assistance projects and status):

The Up-gradation & Modernization of IDPL Plants are in progress. It is expected to complete the modernization work soon. Rishikesh Plant is Schedule 'M' compliant and is WHO-GMP compliant and



received COPP for 4 products. Whereas Gurgaon Plant is also schedule-M for Tablet section. IDPL will restart its Hyderabad Formulation Unit during the year 2015-16 and project work has been started.

## Product profile and Range:

Presently, IDPL is manufacturing nearly 86 products (PPP) & 25 products (Non-PPP) in the form of Capsules, Tablets, Dry Syrup, Liquid Oral and Injection, based on mainly following therapeutic groups:

- Antibacterial /Anti-infective, Analgesic /Anti-inflammatory, Gastrointestinal, Respiratory Tract, Contraceptive, Vitamins/ Mineral, Anti allergic, Anti fungal Antimalarial Anti diabetic Cardiovascular.

**Popular Brands:** Deacos, 110 ml, Sukcee Tab, Cebxin-Z are popular brands

## Manpower

Presently IDPL has 70 regular employees and 110 on contract in different location of the Company including 100% wholly owned Subsidiaries Company. The company has not been permitted to go for regular appointment being BIFR Company. Only contractual employees are hired by the company on yearly basis extendable subject to performance.

**Distribution network if any;** Company is selling its products to institutions through distribution networks of 19 Depots (C&F) located all over the country.

## Performance

### IDPL Key Financial Indicators (Production, and Sales, Profit/ loss) Figure from the year 2011 to 2014

Subject	2011-12	2012-13	2013-14	(Rs in Crore)
				2014-15 *Under Audit
Production	50.78	58.71	62.83	71.50
Sales	50.69	59.47	60.18	63.50
Profit/ loss(EBIDTA)	-7.91	-3.95	-2.25	3.80
Net Profit/loss	-251.32	-173.21	-171.56	-168
DPE Rating	Good	Very Good	Good	Good

**Marketing: Share of Institutions and retail:** The Company is only supplying to institutional clients and Govt departments who place orders on PPP. This policy was revised in February 2014. As per this policy Govt institutions can buy 103 medicines from 5 CPSU at NPPA certified prices.

Major Institutional clients of IDPL are ESI Corporation, Ministry of Health, Defence, Railways, State Governments/Corporations and Public Sector Enterprises Hospitals who place orders under different categories of Therapeutic Medicines.

Apart from above the company is fully supporting Jan Aushadhi Programme of Govt of India and is regularly supplying large numbers of medicines.

**New Products launched** – Cefexime 100 mg, & 200 mg., Cefuroxime Axetil 250mg & 500mg., Aceclofenac 100mg, Aceclofenac 100mg. + Paracetamol 500mg, Glimpride 1mg & 2mg, Atorvastatin 10mg, & 20mg., Ciporal 250mg & 500mg, Metformin 500mg, Pentoprazole 40mg.

## Future Projects:-

To make all IDPL Plants WHO-GMP compliant fund of Rs 7.40 Cr has been released by the Govt.

## Targets for 2016-17:

Production : Rs 77 Crore  
Sale : Rs 77 Crore

**Conclusion:** IDPL has also played a major role in the strategic National Health Programmes like Family Welfare Programme & Population Control (Mala-D & Mala-N) anti-malarials (Chloroquine) and prevention of dehydration (ORS) by providing quality medicines. IDPL has encouraged indigenous production and intervention for price control in market by manufacturing generic drugs.

IDPL has been supporting Government in meeting emergent situations arising due to National calamities like Cyclone, Flood, and Earthquake etc. Recently in Odisha, Uttarakhand and J&K floods. IDPL contributed significantly by providing life saving medicines on time.

## BLISTER PACKING MACHINE(GURGAON PLANT)



TABLET COMPRESSION MACHINE(GURGAON PLANT)







PLANETARY MIXER (GURGAON PLANT)



COMPRESSION MACHINE-RISHIKESH



MICROBIOLOGY LAB- RISHIKESH



ARCHIVE ROOM-RISHIKESH



WORK IN PROGRESS AT IDPL HYDERABAD



AHU'S WITH DUCTING INSTALLED IN MEZANINE.



COOLING TOWER READY FOR COMMISSIONING.



REFRIGERATION PLANT READY FOR COMMISSIONING.



ODCL BHUBANESWAR, A JOINT VENTURE OF IDPL





TABLET SECTION- ODCL



INJECTIBLE SECTION-ODCL

## 5.2 STATUS OF ANNUAL ACCOUNTS

Details of Annual Accounts finalized and laid on the table of Parliament till date are as under:-

Karnataka Antibiotics & Pharmaceuticals Limited	2013-14
Rajasthan Drugs & Pharmaceuticals Limited	2013-14
Hindustan Antibiotics Limited	2013-14
Indian Drugs & Pharmaceuticals Limited	2011-12
Bengal Chemicals & Pharmaceuticals Limited	2013-14

## 5.3 JAN AUSHADHI SCHEME

### Introduction:

Availability of quality medicines at affordable prices for all, especially the poor and the disadvantaged, was always a major concern for the Government of India. Department of Pharmaceuticals under Ministry of Chemicals & Fertilizers has been taking several regulatory and fiscal measures from time to time towards this objective. A countrywide campaign for ensuring availability of generic medicines at affordable prices to all, a project in the name "Jan Aushadhi", was initiated by the Department of Pharmaceuticals way back in 2008 as a direct market intervention strategy by opening Jan Aushadhi Stores (JAS) in the country.

The first one of this kind was opened in Nov 2008 at Amritsar in Punjab.

The original target of the campaign was to establish Jan Aushadhi Stores in every district of our country.

### Progress during 12<sup>th</sup> Five-year Plan period:

As on end March 2012, only 112 stores could be opened. To have an accelerated growth of the campaign, a New Business Plan was released during Aug 2013 with an ambitious target of opening 3000 Jan Aushadhi Stores by the end of 2016-17. The plan also contained certain changes in the scheme. Still by the end of previous financial year, 2014-15, the number of Jan Aushadhi Stores could reach a level of 99 functional Stores only.

### Revamped Jan Aushadhi Scheme 2015:

Effective implementation of JAS has been analyzed through organizing brain storming sessions and discussions with various stake holders and BPPI submitted their Strategic Action Plan (SAP 2015) to achieve the objectives set by the Government. Key areas of significance identified are Availability, Acceptability, Accessibility, Affordability, Awareness and Effective Implementation of the Scheme. Accordingly, a new Strategic Action Plan was prepared and the same was approved during September, 2015.

### Major changes in Jan Aushadhi Scheme Action Plan:

Financial support to JAS: An amount of Rs.2.5 lakhs shall be extended to NGOs/agencies/individuals establishing JAS in government hospital premises where space is provided free of cost by Govt. to operating agency:

Rs. 1 lakh reimbursement of furniture and fixtures

Rs. 1 lakh by way of free medicines in the beginning

Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner, etc

JAS run by private entrepreneurs / pharmacists / NGOs / Charitable organizations that are linked with BPPI headquarters through internet shall be extended an incentive up to Rs. 1.5 lakhs. This will be given @ 10% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 1.5 lakhs. In NE states, i.e. naxal affected areas and tribal areas, the rate of incentive will be 15% and subject to monthly ceiling of Rs. 15,000 and total limit of Rs. 1.5 lakhs.

Trade margin to retailers and distributors: Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

### Progress achieved during 2015-16 as on 31<sup>st</sup> Jan 2016:

Availability: Our basket of products and services is now augmented by adding more medicines reaching a level of 500+ medicines and 150+ surgical and consumables. Apart from procurement of medicines from CPSUs, BPPI is supplementing supply by direct purchase of medicines from private sector companies through



open tendering process so as ensure availability of adequate medicines and to avoid any stock-out situation. BPPI has initiated the required action to take this figure to 3000 by the end of March 2017.

### Supply Chain:

#### From Suppliers CWH C&F Agents Distributors JAS

BPPI has established a central warehouse at IDPL Complex, Gurgaon to store adequate stock of medicines. Also appointed C&F agents in 4 states and 30 Distributors spread over different states through an open tendering process.

**Acceptability:** To ensure the quality of medicines procured from the CPSUs and private manufacturers for supplying to Jan Aushadhi Stores, each batch of drugs is tested at BPPI's empaneled NABL accredited laboratories thereby ensuring quality, safety and efficacy of medicines and conformance with required standards. Only after being certified by these laboratories, medicines are despatched to C&F agents, Distributors and JASs.

**Accessibility:** Number of Jan Aushadhi Stores functioning as on date has reached 133 (spread over 20 States/UTs), out of which 34 stores have been opened during the current financial year, 2015-16.

By the end of this financial year, BPPI is putting all out efforts to have its presence in all the States in our country. BPPI is trying to achieve a figure of 300 Jan Aushadhi Stores by the end of the current financial year. Thereafter, attempt shall be made to open at least one JAS in all the 543 Parliamentary constituencies in India. The target remains same, to open 3000 JAS by the end of the 12<sup>th</sup> Five Year plan period.

**Awareness:** The awareness among common people regarding the JAS is very poor. Media campaigns would play an important role in educating people about use of generic medicines. In this context, BPPI has initiated various steps, especially in those States where the Jan Aushadhi Stores are now functioning so that people take full advantage of the availability of generic medicines at affordable prices at the Jan Aushadhi stores. There are 133 Jan Aushadhi Stores functional at present (as on 5.2.16), few of which were established earlier. These stores need to be promoted in an organized way as the awareness is very less. Limited and non-availability of the medicines was another challenge. It is most important to create awareness among all stakeholders about the scheme, the business opportunity, the store locations and the medicines available with Jan Aushadhi

BPPI intends to create awareness about Jan Aushadhi and its stores in the towns where Jan Aushadhi Stores are already established using integrated media platform. Facelift of the Jan Aushadhi stores is required with standardized branding across all old stores as well as in the new stores.

Various publicity channels like print media, visual media, SMS and

other direct communication methods will be taken up. BPPI has already taken part in 4 exhibitions / workshops, Dhan Foundation at Indian Habitat Centre, Perfect Health Mela 2015, IITF 2015, and India Pharma Expo 2016.

### IITF (Delhi) participation:



*Hon'ble Minister of state for Chemicals & Fertilizers, Shri Hansraj Gangaram Ahir*



Displayed a 28sq.ft. stall at IITF and got very good response. Almost 250 enquiries for New JAS and 150 diabetic patients were registered. Jan Aushadhi participated for the first time at IITF. The stall showcased the features of Jan Aushadhi Scheme, spread awareness about the generic medicines through distribution of disease specific pamphlets, its availability at affordable prices for all, highlighting the difference of prices of Jan Aushadhi medicine vis-à-vis their branded equivalent. Any individuals, NGO's, Hospitals who wished to join hands in this noble cause were provided with the guidelines with regard to opening Jan Aushadhi Stores.

IPE 2016: Space was booked for 80 sq.mt. Numerous queries for opening new JAS, were received by BPPI and many consumers got in touch with them, and they were able to contact many large scale manufacturers under one roof.





Hon'ble Minister of Chemicals & Fertilizers, Shri Ananth Kumar with Hon'ble Minister of State for Chemicals & Fertilizers Shri Hansraj Gangaram Ahir inaugurating Jan Aushadhi stall at Bengaluru.



#### Other factors in ensuring success of the scheme:

The success of this initiative is dependent on other agencies too, such as Ministry of Health & Family Welfare, different State Governments, active co-operation of Hon. Members of Parliament, Hon. Members of different Legislative Assemblies, IMA, Hospitals run by Private groups and Charitable institutions, NGOs, Practicing Doctors etc. State Governments are having their own schemes like free distribution of medicines. Non-prescription of Generic Medicines by the doctors is another factor. BPPI is continuing its efforts to persuade Doctors to prescribe only generic medicines. For this BPPI is working in close association with other organizations and Govt. departments. Seminars / Workshops inviting Doctors, Scientists, Government officials and other stakeholders will be also organized.

#### Budgeted Sales:

The sales projection for 2015-16 and 2016-17 are Rs. 10 Cr and Rs. 100 Cr respectively.

#### Jan Aushadhi scheme ahead:

The endeavor of BPPI is to make available at Jan Aushadhi Stores all the commonly used generic drugs covering all the therapeutic groups. In the coming years, Jan Aushadhi scheme shall provide the complete spectrum of Health care products and services, starting from making available all the generic drugs covering all the therapeutic groups.



# Chapter

# 6

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH  
(NIPERs)







## CHAPTER-6

# NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPER), S.A.S NAGAR, MOHALI

### BACKGROUND

Indian Pharma Industry has been a global leader in Generic drugs. In order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources/talent pool is very critical. Thus Government of India has set up National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar Mohali as a registered society under society registered ACT 1860, subsequently the institute was given statutory recognition by an act of Parliament NIPER Act, 1998 and NIPER has been declared as an Institute of National Importance.

During 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institute. Subsequently a NIPER at Madurai was approved in 2012. During 2015-16 Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan.

NIPER	Mentor Institute	Academic Session Started
NIPER, Mohali	-	1992
NIPER, Ahmedabad	B.V. Patel PERD Centre, Ahmedabad	2007
NIPER, Guwahati	Guwahati Medical College, Guwahati	2007
NIPER, Hajipur	Rajendra Memorial Research Institute of Medical Science (RMRIMS-Patna) under ICMR	2007
NIPER, Hyderabad	CSIR-Indian Institute of Chemical Technology, Tarnaka, Hyderabad	2007
NIPER, Kolkata	CSIR-Indian Institute of Chemical Biology, Kolkata	2007
NIPER, Raebareli	CSIR-Central Drug Research Institute, Lukhnow	2007
NIPER, Madurai	Under Process	-
NIPER, Chhattisgarh	Under Process	-
NIPER, Maharashtra	Under Process	-
NIPER, Rajasthan	Under Process	-

The Students at all NIPERs are admitted through Common Admission Test conducted by NIPER SAS Nagar, Mohali in

association with other NIPERs. All the new NIPERs except NIPER Mohali are presently governed by a Steering Committee under the chairmanship of Secretary, Department of Pharmaceuticals.

Various initiatives taken to consolidate NIPERs is as follows:-

#### Measures to improve NIPERs performance.

1. Performance management: Regular Steering Committee meetings
2. A Search cum selection committee has been constituted under the chairmanship of Prof. Dr. V. Nagarajan, Professor Emeritus in Neurosciences, Dr. MGR Medical University, Tamil Nadu to select and recommend names for the posts of Directors of NIPERs - Guwahati, Hajipur, Hyderabad and Raebareli.
3. Constituted Academic Standard Committee under the chairmanship of Prof. Syed E. Hasnain, Professor of Biological Sciences, IIT, Delhi and Former Vice-Chancellor, Hyderabad University to improve Governance, academics & student welfare of NIPERs. The committee submitted its report and is under examination.
4. Build Academic- Industry linkages with NIPERs: MOU
  - In NIPER Statute, Industry leaders are in their Board of Governors.
  - Department has identified that Academia-Industry linkage is a basic requirement for translating research into development (commercialization) and Innovation; and also to fix accountability among Educational Institutions. Accordingly the issue has been pursued with NIPERs and Public and Private Pharma Industry with regular reviews and visits.

#### With Private Pharma Industry:

NIPER	Private Pharma Industry
Hyderabad	1. Dr. Reddy Labs
	2. Bharat Biotech
	3. NATCO
Ahmedabad	4. Cadila Pharmaceuticals
	5. Cadila Healthcare (Zydus)
	6. Sahjanand Technologies
	7. Johnson & Johnson
Mohali	8. Sun Pharma
	9. Wockahardt
	10. Panacea Biotech
	11. Medley Pharmaceuticals Ltd.



### With Central Public Sector Enterprises :

NIPER	CPSE
Mohali	1. Rajasthan Drugs and Pharmaceuticals Ltd., Jaipur.
Ahmedabad	2. Hindustan Anti-biotics Limited, Pune.
Guwahati	3. Karnataka Anti-biotics & Pharmaceuticals Limited, Bengaluru.
Hajipur	4. Bengal Chemicals and Pharmaceuticals Limited, Kolkata
Kolkata	5. Bengal Chemicals and Pharmaceuticals Limited, Kolkata
Rae Bareli	6. Indian Drugs & Pharmaceuticals Limited Rishikesh/Gurgaon/ Hyderabad.

### NIPER-WISE-DEPARTMENTS-

S. No.	Department	NIPER, Mohali	NIPER, Ahmedabad	NIPER, Hyderabad	NIPER, Guwahati	NIPER, Hajipur	NIPER, Kolkata	NIPER, Rae Bareli
1.	Medicinal Chemistry	✓	✓	✓			✓	✓
2.	Natural Products	✓	✓				✓	✓
3.	Traditional Medicine	✓						
4.	Pharmaceutical Analysis	✓	✓	✓				
5.	Pharmacology and Toxicology	✓	✓	✓	✓			
6.	Regulatory Toxicology	✓		✓				
7.	Pharmaceutical Technology (Biotechnology)	✓						
8.	Pharmaceutical Technology (Formulations)	✓						
9.	Pharmaceutical Technology (Process Chemistry)	✓		✓				
10.	Pharmaceutics	✓	✓	✓				✓
11.	Biotechnology	✓	✓		✓	✓		
12.	Pharmacy Practice	✓			✓	✓		
13.	Clinical Research	✓						
14.	Pharmacoinformatics	✓				✓	✓	
15.	Pharmaceutical Management	✓		✓				
16.	Medical Devices	✓	✓					
	<b>TOTAL</b>	<b>15</b>	<b>7</b>	<b>7</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>

### ADMISSION SESSION

42

### NUMBER OF STUDENTS, NIPER-WISE

### DEGREE-WISE

S. No.	Name of NIPER	M.S. (Pharma)	M. PHARMA	M. TECH	MBA	PHD	TOTAL
1.	NIPER, Mohali	170	22	24	45	25	286
2.	NIPER, Ahmedabad	54				9	63
3.	NIPER, Hyderabad	83	-	8	18	16	125
4.	NIPER, Guwahati	26	3	NA	NA	4	33
5.	NIPER, Hajipur	25	13	-	-	6	44
6.	NIPER, Kolkata	39	-	-	-	-	39
7.	NIPER, Rae Bareli	36	NA	NA	NA	NA	36
	<b>TOTAL</b>	<b>433</b>	<b>38</b>	<b>32</b>	<b>63</b>	<b>60</b>	<b>626</b>



## NUMBER OF STUDENTS ADMITTED IN M.S. (Pharma)

Sl. No.	Department wise admission	NIPER, Mohali	NIPER, Ahmedabad	NIPER, Hyderabad	NIPER, Guwahati	NIPER, Hajipur	NIPER, Kolkata	NIPER, Rae Bareli	TOTAL
1.	Medicinal Chemistry	<u>43</u>	<u>8</u>	<u>30</u>			<u>17</u>	<u>17</u>	<u>115</u>
2.	Natural Products	<u>16</u>	<u>6</u>				13		35
3.	Traditional Medicine	<u>5</u>							5
4.	Pharmaceutical Analysis	<u>9</u>	<u>9</u>	<u>15</u>					33
5.	Pharmacology and Toxicology	<u>23</u>	<u>7</u>	<u>15</u>	<u>18</u>			<u>6</u>	<u>69</u>
6.	Regulatory Toxicology	<u>9</u>		8					17
7.	Pharmaceutical Technology (Biotechnology)								
8.	Pharmaceutical Technology (Formulations)								
9.	Pharmaceutical Technology (Process Chemistry)								
10.	Pharmaceutics	<u>17</u>	<u>11</u>	<u>15</u>				<u>13</u>	<u>56</u>
11.	Biotechnology	<u>29</u>	<u>6</u>		5	4			44
12.	Pharmacy Practice				<u>3</u>	<u>13</u>			16
13.	Clinical Research								
14.	Pharmacoinformatics	<u>19</u>				<u>8</u>	<u>9</u>		36
15.	Pharmaceutical Management								
16.	Medical Devices		7						7
	<b>TOTAL</b>	<u>170</u>	<u>54</u>	<u>83</u>	<u>26</u>	<u>25</u>	<u>39</u>	<u>36</u>	<u>433</u>

## Total numbers of students in all NIPERs (2015-16)

NIPER	Masters			PH.D					Total	Grand Total (Master + Ph.D)
	I	II	Total	I	II	III	IV	V		
NIPER, Mohali	261	196	457	25	27	22	27	13+1	115	
NIPER, Ahmedabad	54	32	<b>86</b>	9	-	-	4	2	15	
NIPER, Hyderabad	109	107	216	16	13	11	12	9*	61	
NIPER, Guwahati	29	32	61	4	3	2	4	-	13	
NIPER, Hajipur	38	22	60	5	4	4	3	5	21	
NIPER, Kolkata	39	42	81	-	-	-	-	-	-	
NIPER, Rae Bareli	36	38	74	-	-	-	-	-	-	
<b>TOTAL</b>	<b>566</b>	<b>469</b>	<b>1035</b>	<b>50</b>	<b>47</b>	<b>39</b>	<b>50</b>	<b>30</b>	<b>225</b>	<b>1260</b>

\* One student got Ph.D (Including)

## Total Passout/ Graduation from NIPERs (2015-16)

NIPER	Masters					PH.D	TOTAL
	MS (Pharma)	M. Pharma	M. Tech	MBA	Total		
NIPER, Mohali	131	16	21	28	196	26	26
NIPER, Ahmedabad	31	-	-	-	31	-	-
NIPER, Hyderabad	81	-	07	20	108	1	1
NIPER, Guwahati	27	5	-	-	32	4	4
NIPER, Hajipur	148	80			228	Nil	Nil
NIPER, Kolkata	49	-	-	-	49	-	-
NIPER, Rae Bareli	38	-	-	-	38	-	-
<b>TOTAL</b>	<b>505</b>	<b>101</b>	<b>28</b>	<b>48</b>	<b>682</b>	<b>31</b>	<b>31</b>



## NATIONAL INSTITUTE OF PHARMACEUTICALS EDUCATION AND RESEARCH (NIPER), S.A.S. NAGAR, MOHALI.

Chairman of Board of Governors/ Steering Committee (with period) – to be designated

Director (Officiating): Prof. K. K. Bhutani (01.01.2010-04<sup>th</sup> March, 2016)

Prof. Saranjit Singh (04.03.2016- till date)

### Historical Milestones (incl. Inauguration date):

1992	Registered as a Society
1994	First Director and Core Faculty joined
1998	Institute of National Importance: NIPER Act
1998	Admission of first Batch of Masters' and Ph.D. students
2001	First Convocation held
2004	Establishment of National Bioavailability Centre
2005	Third Convocation held
2006	Visit of Prince Charles
2009	Establishment of SMPIC

### Mentor Institute if any: Not applicable

### Achievements till date

**Academic excellence:** In 2015, the Institute has published 65 articles in journals of repute till date. NIPER has filed 7 patents in 2014. Since the inception of academic programme (till Sept. 2015), 2434 students have passed out (Masters 1783, MBA 450 & Ph.D. 201).

### Research activities (Recent)

**Neglected diseases** - Research is carried out in the areas of tuberculosis, leishmaniasis and malaria. New molecules are being synthesized and their mechanisms of action are being worked out.

### Other diseases

Metabolic pathways in diseases like inflammation, infection, cancer, diabetes, neurodegeneration are being worked out.

### Drug development and formulation

- Improvement of oral bioavailability, synergistic anticancer efficacy and reduced toxicity of drugs has been attempted.
- New formulations are being developed.

### Other areas

- Chemo-enzymatic synthesis of drugs
- Monograph on herbals is being developed.
- Study of the effect of RNA aptamers on stabilization of misfolded proteins

- Mass production of recombinant human PON1 enzyme with enhanced activity towards desirable substrate(s) and its long-term stability
- Assessment of an appropriate and reliable method to diagnose neuropathic pain

### Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy

Man-Power	Sanctioned	In-Position	Vacancy
Academic	61+1* = 62	31	30+1* = 31
Non-Academic	217+6** = 223	130	87+6** = 88

\*indicates post of Director

\*\*indicates posts created by BoG

### Finances: Government-Allocations, releases, utilization, balance during the last 4 years.

(Rs in crores)

YEAR	Allocation BE	Allocation RE	Total Release	Expenditure
2011-12	24.23	24.77	24.77	28.83
2012-13	27.55	22.82	22.82	30.10
2013-14	23.57	19.20	19.20	33.53
2014-15	17.03	20.87	20.87	31.14

### Learning Environment/ Academics

#### A. Number and Names Departments/ Disciplines (with opening year): Ten/Fifteen

- Medicinal Chemistry (1998)
- Pharmaceutics (1998)
- Natural Products (1998)
- Natural Products: Traditional Medicine (2008)
- Pharmacology & Toxicology (1998)
- Pharmacology & Toxicology: Regulatory Toxicology (2007)
- Pharmaceutical Analysis (1999)
- Biotechnology (1998)
- Pharmaceutical Technology (Formulations) (1998)
- Pharmaceutical Technology (Process Chemistry/Bulk Drugs) (1998)
- Pharmaceutical Technology (Biotechnology) (2004)
- Pharmacy Practice (2002)
- Clinical Research (2011)
- Pharmaceutical Management (2002)
- Pharmacoinformatics (2003)

#### B. Students

- Degrees/programmes offered and Subjects offered (with year) with admission status

Level Masters/ Doctoral	Degree MS/MBA/M.Tech/Ph.D	Discipline	No. of students admitted	
			2014-15	2015-16
Masters'	M.S. (Pharm.)	Medicinal Chemistry	37	43
Doctoral	PhD		07	02
Masters'	M.S. (Pharm.)	Pharmacoinformatics	17	19
Doctoral	PhD		04	01





Level Masters/ Doctoral	Degree MS/MBA/M.Tech/Ph.D	Discipline	No. of students admitted	
			2014-15	2015-16
Masters'	M.S.(Pharm.)	Natural Products	16	16
Doctoral	PhD		03	03
Masters'	M.S.(Pharm.)	Traditional Medicine	04	05
Masters'	M.S.(Pharm.)	Pharmaceutical Analysis	08	09
Doctoral	PhD		00	02
Masters'	M.S.(Pharm.)	Pharmacology & Toxicology	21	23
Doctoral	PhD		04	04
Masters'	M.S.(Pharm.)	Regulatory Toxicology	08	09
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology	07	07
Doctoral	PhD	(Formulations)	00	00
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Process Chemistry)	13	14
Doctoral	PhD		04	00
Masters'	M.Tech.(Pharm.)	Pharmaceutical Technology (Biotechnology)	09	10
Doctoral	PhD		00	00
Masters'	M.S.(Pharm.)	Pharmaceutics	14	17
Doctoral	PhD		02	06
Masters'	M.S.(Pharm.)	Biotechnology	28	29
Doctoral	PhD		03	05
Masters'	M.Pharm.	Pharmacy Practice	07	08
Doctoral	PhD		00	02
Masters'	M.Pharm.	Clinical Research	07	07
Masters'	MBA (Pharm.)	Pharmaceutical Management	39	45

## 2. Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning

Year	MS (admitted)	Completion rate	MBA (admitted)	Completion rate	Ph.D. (admitted)	Ph.D. (graduated)
1998-99	27	100%	-	-	24*	-
1999-00	35	100%	-	-	1	-
2000-01	37	100%	-	-	9	-
2001-02	43	100%	-	-	10*	-
2002-03	55	100%	28	100%	17	10
2003-04	69	97%	29	100%	21	14
2004-05	86	98.8%	29	96.5%	14	9
2005-06	87	100%	20	95%	14	15
2006-07	91	97.8%	30	100%	27	4
2007-08	100	99%	35	97%	35	10
2008-09	128	98.4%	40	92.5%	22	12
2009-2010	150	98%	44	97.7%	20	11
2010-2011	251	91.6%	61	95%	46	9
2011-12	244	95%	58	100%	34	25
2012-13	271	94.46%	65	98.46%	40	25
2013-14	174	95.97%	28	100%	23	20
2014-15	196	Continuing	39	Continuing	27	27
2015-16	216	Continuing	45	Continuing	25	18

\* Includes admissions in all semesters of the calendar year



## 3. Teacher-Student ratio

Course	Ratio
Ph.D.	4.5
Masters' (Science)	7.71
MBA (Pharm.)	15.0

5. Student Satisfaction surveys and Employers perceptions: Assessment of faculty performance by students is conducted each semester and the feedback received is provided to the faculty for correction, if any.

## 6. Employability/ Placements Status

### Year wise Companies participated in campus selection/placements

Year	Total	Joined in Industry	Higher studies in India	Higher studies in Abroad	Joined in Academics	Not Interested	Sponsored Fellowship Non-PhD
1999	27	9	13	2	3	0	0
2000	35	10	15	5	5	0	0
2001	37	19	11	4	3	0	0
2002	43	21	6	2	6	0	0
2003	55	43	7	2	3	0	0
2004*	28	25	0	0	3	0	0
2005	96	55	13	0	18	0	0
2006	113	78	0	0	0	23	0
2007	104	52	31	5	0	0	0
2008	119	70	12	0	0	0	0
2009	133	72	12	3	7	0	0
2010	164	103	19	0	0	6	3
2011	190	90	21	1	0	4	1
2012	288	98	16	3	0	6	2
2013	284	156	11	4	0	0	8
2014	336	161	19	1	N.A.	N.A.	N.A.
2015	202	132	11	N.A.	N.A.	N.A.	N.A.

\* Includes Only MBA Students and onwards carry both M.S. Pharm & MBA because from year 2004 – 3 semester program was changed to 4 semester program and rest of the students passed out earlier by December itself.

N.A. Information not available

## Companies visited for 2015 batch

Abbott, Lupin, Pune, Evalueserve, Mankind, BMS, Fresenius Kabi, Biocon, Nitin Pharmaceuticals, GSK, Novartis, BSN Medical, Hospira, IMS Health, Curadev, Indegene, Ranbaxy Labs, Gurgaon, DMV, Intas Biopharma, Dr. Reddy's, Integral Bioscience, Sun Pharma, Smart Analyst, Z S Associate, Syngene, Kimia Bio Science, Grail Research, PharamACE, Blue Ocean, Sentiss Pharma, Borienger Illeium, Macleods, Roche, Rescon Patners, Bres Med Healthcare, Yes Regulatory, Delvinsight Business Research, Biological E, Natural Remedies, Bioxcel.

## Last 2 years placements status: in campus/off campus

Batch	Total Number of Students Placed	Campus Placement	Higher Studies	Off Campus Placement
2012-14	181	115	20	46
2013-15	143	92	11	40

The total number of Off Campus Placement & number of students going for Higher Studies is collected by the departmental placement representatives. Placement Cell does not maintain data of these categories as students frequently change the companies. This data is collected till October of the passing batch year.

**Ranking by Subject if any. Not available****C. Teachers**

## 1. Recognition to Faculty

Shanti Swaroop Bhatnagar Award, Ranbaxy Research Award, National Bioscience Award, National Bioscience Women Award (Young), JC Bose Fellowship, INSA Young Scientist Award, IBM Faculty Award, Distinguished Educator and Researcher Award (AAiPS), Chemical Research Society of India medal, OPPI Award, Punjab Ratan Award, Shakuntala Amir Chand Prize (ICMR), Professor D. Nasipuri, Memorial Award, Member, WHO Expert advisory panel on the International Pharmacopoeia and Pharmaceutical Preparations, Advisor, WHO expert committee on specifications for pharmaceutical preparations, Innocentive Award and others Members, Fellows, National Academies

## 2. Peer review system

Member, Editorial Boards of internal, peer-reviewed journals

**Research**

## 1. Active Research Areas

Thrust areas: Leishmaniasis, Tuberculosis, Malaria, Diabetes  
Drug discovery: Chemical tools, Phyto-chemical tools, Informatics tools, Proteomics, Functional Genomics  
Drug development: Formulation Development, Impurity Profiling, Pharmaceutical Nanotechnology, Herbals  
Hospital and community pharmacy

## 2. Research Publications/ Institution and per Faculty and High Impact factor: 188 (in 2014). Average impact factor: 3.49. Two publications have been published in journals with impact factors &gt; 10.

## 3. Awards: Please see above

## 4. Competitive Research Grants:

## 5. Research Student Completions: Please see above

**Land and Civil Works if any: Not applicable**

## 1. Land availability issues/challenges and alternatives

## 2. Campus development / Civil Work progress if any

a) PMC name:

b) Date of approval of Designs & Drawings:

c) Date of approval of Bill of Quantities

d) Phase of construction:

**Infrastructure: Central facilities/ Centres etc.**

Computer center

Library and information center

Central animal facility

Technology development center

Central Instrumentation laboratory

National bioavailability center

Center for pharmaceutical nanotechnology

National toxicology center

Impurity profiling and stability testing laboratory

National center for safety pharmacology

**National Centres if any**

National bioavailability center

Center for pharmaceutical nanotechnology

National toxicology center

**Academia-Industry partnership**

1. Capacity utilization of Common facilities viz., Technology Development Centre/ SMPIC/National Bio-availability Centre etc.

Center	Number of Samples Analyzed (2014-15)
NTC (TEM)	290
SMPIC	300
CIL	33609 (1395 External + 32214 In-House)

2. Consultancy projects/Knowledge Process Outsourcing (KPO)/ Contract Research Organisation (CRO)/ Contract Research & Manufacturing Services(CRAM)/ IPRs, etc. : Total receipts for consultancy projects during 2015-16 till date is Rs. 50.33 lacs. Industry had also contributed to the cost of PCT filing of a patent whose technology was licensed out.
3. Entrepreneurship / Incubators: A proposal for setting up of incubators on the campus has been submitted for approval as a part of XII five year plan.

**Innovation / knowledge transfer**

1. Patents and Commercialisation: 170 (filed)/37 (granted)/07 (licensed)
2. Research income earned from industry: Rs. 50.33 lacs (receipts in 2015-16 till date)
3. Citation per faculty: 797 (2015 till date)

NIPER, S.A.S. Nagar has recently signed MoUs with the following industries. The MoUs were exchanged with leaders of pharmaceutical industry in the august presence of the President of India Shri Pranab Mukherjee on 4<sup>th</sup> Nov., 2015 as a part of Visitors conference held from Nov. 4-6, 2015.

- a. Rajasthan Drugs and Pharmaceuticals Limited – CPSE
- b. Sun Pharma
- c. Wockhardt Ltd.
- d. Panacea Biotec
- e. Medley Pharmaceuticals Ltd.

**Institution leadership**

1. Institutional Recognition
  - Recognized as among the top 100 Indian Innovator companies and research organizations (2014) (Thompson Reuters)
  - Recognized as one of the four institutes in the country with AAAA+ ranking by Career360 magazine (Outlook group) (March 2014)
  - Awarded Thomson Reuters Innovation Award 2011
  - Astra Zeneca endowment fund set up (Rs. 60 lakh)
  - Bristol-Myer-Squibbs has funded one student each for PhD and Masters' programme since 2008



- Eli Lilly and Merck have granted funds for carrying out research work
  - Chosen as one of the destinations (apart from USA and UK) by Government of Kazakhstan for award of *Bolashak* scholarship to its nationals to pursue research programme in pharmaceutical sciences
  - Received state and national awards for efforts to promote Rajbhasha
2. Collaboration/partnership with International Institutions: Please see above

## Impact of NIPER

Please see Sl. No. 16 above. The success of NIPER, S.A.S. Nagar has encouraged the GoI to set up more NIPERs across the country to meet the growing demands of the pharmaceutical sector. In addition, NIPER has carried out training programmes for personnel from India and abroad under ITEC-SCAAP, capacity building programmes (World Bank-sponsored) and SMPIC. Participation in rebuilding of public sector enterprises like IDPL, BCPL, HAL, etc.

Training and analytical services provided to small and medium-scale enterprises (SMEs): Setting up of a centre for SMEs

Member of committee evaluating 'Investigational New Drugs' (IND) applications

Member of committee revising Indian pharmacopeia

Contribution of monographs to Ayurvedic pharmacopeia of India

Carried out study on "Impact of TRIPS on pharmaceutical prices with special focus on generics in India", under the workplan of WHO biennium and MHFW (GOI)

Third party Evaluation if any: The most recent third party of evaluation of NIPER's activities was carried out by a committee of experts from PGIMER, Chandigarh, constituted by Department of Pharmaceuticals, to evaluate the progress of the Institute's XI five year plan activities.

Events/ Workshops/ Conferences organised during the year

June 12, 2015	HVAC and Infrastructure Designing in Pharmaceutical Industry
Sept. 5, 2015	Documentation and SOPs (SMPIC)
Oct. 26-Nov. 5, 2015	Pharmaceutical Quality by Design: A Risk-Based Approach (ITEC-SCAAP)

## Photographs:

1. Institute / Infrastructure
2. Faculty and Students
3. Convocation if any/ Student activity if any
4. Visit of VIP/Sr. Official
5. Hindi Pakhwada/Swath Bharat/ National Integration Day

## Highlights of visit of the Hon'ble Minister of State, Ministry of Chemicals and Fertilizers, Shri Hansraj Gangaram Ahir, to NIPER, S.A.S. Nagar, on Oct. 01, 2015



Inauguration of Pharmaceutical Heritage Centre by Hon'ble Minister of State for Chemicals & Fertilizers Shri Hansraj Gangaram Ahir



Release of Annual Report by Hon'ble Minister of State for Chemicals & Fertilizers Shri Hansraj Gangaram Ahir





## Academic-Industry Linkages of Niper Mohali with Rajasthan Drugs and Pharmaceuticals Ltd, Panacea Biotech, Wockahardt, Medley Pharmaceuticals Ltd. and Sun Pharma



### NIPER AHMEDABAD

Chairman of Board of Governor/ Steering Committee (with period): **Dr V.K. Subburaj IAS**

Director/ Project Director (with period);

#### Director

**Dr KiranKalia** : 16 Nov 2014 till date

Historical Milestones (incl.Inauguration date)

- (i) Inaugration / Arrival of 1<sup>st</sup> Batch to NIPER Ahmedabad: 01 Oct 2007
- (ii) 1<sup>st</sup> Convocation: 25 Jun 2010
- (iii) 2<sup>nd</sup> Convocation: 03 March 2013
- (iv) 3<sup>rd</sup> Convocation : 19 Oct 2015

Mentor Institute if any: **B.V.Patel PERD Centre**

Achievements till date: Department of Pharmaceutical has recognized NIPER –Gn as

#### National Centre for Medical Devices

Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy

Till date posts are not sanctioned for NIPER Ahmedabad. All faculty and staff are on contract basis.

Details of faculty & staff is appended below:

1. Regular Faculty: 01, Director
2. Contractual Faculty: 11
3. Contractual Admin staff: 06

Finances: Government- Allocations, releases, utilization, balance during the last 4 years.

In crores

Year	Allocation BE in INR	Allocation RE in INR	Total Release	Expenditure in INR
2011-12	24.5	4.5	3.37	3.24
2012-13**	16.5	16.5	6.71	4.34
2013-14	20	6.94	6.79	4.92
2014-15	20	4.5	4.5	5.2
2015-16	21.96	19.76	19.76	NA

\* 2009-10 Core construction Rs. 130,00,000/- & incubator Grant Rs. 100,00,000/- is not included

\*\* 2012-13 Construction Grant Rs. 157,00,000/- is not included



## Learning Environment/ Academics

### A. Number and Names Departments/ Disciplines (with opening year)

Sr No	Department	Year of opening
01	Biotechnology	2007
02	Natural Products	
03	Pharmaceutics	
04	Medicinal Chemistry	2010
05	Pharmaceutical analysis	
06	Pharmacology& Toxicology	
07	Medical Devices	2012

### B. Students

Degrees/programmes offered and Subjects offered (with year) with admission status

Level Masters/ Doctoral	Degree/MS/ MBA/M.Tech/ Ph.D	Discipline	No. of students admitted	
			2013-14	2014-15
Masters	MS	7 Disciplines	38	36
Doctral	Ph.D	NIL	NIL	NIL

Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning

Year Batch wise	Masters level		Doctoral level	
	Admission	Completion with Year	Admission	Completion
2007-09	31	31 (2009)	NIL	NIL
2008-10	36	33 (2010)	NIL	NIL
2009-11	42	35 (2011)	NIL	NIL
2010-12	63	58 (2012)	NIL	NIL
2011-13	46	44 (2013)	07 (2011)	Nil completed 02 Continues 05 drop out
2012-14	53	52 (2014)	09 (2012)	Nil Completed 04 Continues 05 drop out
2013-15	38	31	NIL	NIL
2014-16	36	continued	NIL	NIL
2015-17	56	Continued	09	Continued

Note: The institute has 100% pass result for all the batches.

The difference of admission and completion is due to drop out of students for personal reasons or not reporting at all after taking admission in the counselling.

Teacher-Student ratio : Presently 1: 8.4 (12 Faculty : 101 students)

Student Satisfaction surveys and Employers perceptions:

student's satisfaction: Good,

Employers Perception: Training imparted is of reasonably good standard

Employability/ Placements Status

Year	List of companies participated	Placement
2015	Torrent pharmaceuticals, Zydus Healthcare, INTAS Pharma, Oxygen Healthcare, Relisysy, Envision Pvt Ltd.	25

\* All figures indicate students placed in campus

Last 2 years placements status: in campus/off campus

2014 batch					
Stream	Total No of student	Opted for placement	IN campus	Off campus	Total placement
PE	12	11	6	0	6
MCD	5	5	2	1	3
NP	9	9	0	4	4
MD	5	4	1	0	1
BT	10	8	3	3	6
PC	6	5	0	0	0
PA	5	4	2	2	4
<b>Total</b>	<b>52</b>	<b>46</b>	<b>14</b>	<b>10</b>	<b>24</b>

2015 batch					
Stream	Total No of student	Opted for placement	IN campus	Off campus	Total placement
PE	6	6	6	0	6
PA	5	3	3	0	3
BT	5	5	3	0	3
MC	3	2	2	0	2
MD	5	5	5	0	5
PC	3	3	2	0	2
NP	4	3	3	0	3
<b>Total</b>	<b>31</b>	<b>28</b>	<b>25</b>	<b>0</b>	<b>25</b>

Ranking by Subject if any. **First preference of students is Pharmaceutics**

### C. Teachers

- Recognition to Faculty: Sardar Patel University has recognised two faculty as Ph.D. guides
- Peer review system: Not in force, To be implemented in near future





## Research

### 1. Active Research Areas

#### Pharmaceutical Analysis:

- Analytical and bioanalytical method development and validation using traditional and Quality by Design (QbD) approaches
- Use of micro-extraction techniques in simultaneous determination of drugs
- Pharmacokinetic studies of drugs and metabolites
- Impurity profiling of drug substances
- Forced degradation studies and characterization of degradation products
- Pre-formulation (physicochemical parameters & excipient compatibility) studies
- Secondary metabolite profiling of herbal products

#### Medicinal Chemistry:

- Design and synthesis of target compounds: thiazoles, thiophenes, benzimidazoles as anti-inflammatory, anticancer and anti-diabetic agents
- Synthesis of neuroprotective molecules and their PK & PD studies
- Computer aided drug designing and study of Structure activity relationship
- Design and synthesis of target compounds as anticancer and DPP-IV inhibitor
- Ionic liquid mediated C-C and C=C bond forming reactions
- Synthesis of Bax activating molecules to drag cancerous cells towards apoptosis

#### Pharmacology and Toxicology:

- Control diabetes mellitus and its complications especially nephropathy
- Development of immunosuppressive human xenograft mice model
- Neuroprotection against cerebral ischemia, traumatic brain injury, alzheimer's, etc.
- Pharmacological screening of synthetic and herbal products
- Behavioural studies on learning & memory, depression and anxiety
- PK&PD and bioavailability studies of herbal drugs
- Absorption Digestion Metabolism Excretion (ADME) and toxicological studies
- *In-vitro* and *in-vivo* correlation

#### Medical Devices:

- Research on osteoconductive coating materials for bone tissue engineering
- Studies on anti-proliferative and antithrombotic coatings for polymer.

- Development of polymer based implants for peripheral nerve regeneration
- Synthesis of nanofibres of biomaterials for various application like bone regeneration, nano coating and support for skin regeneration .
- Surface modification of nanomaterials for biomedical applications
- Fabrication of artificial cornea and contact lens with newer approach
- Synthesis of magnetic nanoparticles for diagnostics and therapeutic applications
- Chemical modification of polymers for thrombo-resistive blood bags and catheters
- Development of microbe resistant polymer for hospital beds

#### Awards

- Best Poster Award:
- Awarded Gufic prize:  
Competitive Research Grants-DBT  
Research Student Completions: None  
Eminent Alumni: None

Land and Civil Works if any

Land availability issues/challenges and alternatives : **Lease agreement of 60 acres of land was signed on 08 Dec 2008 and Possession of the land was given on 06 Apr 2009**

Campus development / Civil Work progress if any

PMC name: **HSCL**

Date of approval of Designs & Drawings: **30 Dec 2014 by Steering Committee**

Date of approval of Bill of Quantities: **17 Sep 2015 steering committee approved the BOQ for phase-I**

Phase of construction: **Steering Committee approved the BOQ of phase-I and estimated cost for construction of for phase-I & II. (Phase-II and III have been merged and made Phase-II)**

Infrastructure: Central facilities/ Centres etc.

National Centres if any : **National Centre for Medical Devices**

Academia-Industry partnership

1. Cadila Pharmaceuticals
2. Cadila Healthcare Limited:
3. Sahjanad Laser Technologies
4. Johnson & Johnson
5. Hindustan Antibiotics Limited

Innovation / knowledge transfer

- 1 Patents and Commercialisation : **07 Patents have been filed where faculty or student of NIPER Ahmedabad is involved.**
- 2 Research income earned from industry : **NIL**

Institution leadership

- 1 Institutional Recognition



## 2 Collaboration/partnership with International Institutions : NIL

Impact of NIPER Total: 218.245

Third party Evaluation if any : NIL

Events/ Workshops/ Conferences organised during the year- 7 events are organised.

Date	Activity name	Target group	Sponsored by	Remarks
04 July 2015	One day seminar on Academia Industry Linkage	Faculty & Students	Institute	Secretary, DOP was the Chief Guest
15 Aug 2015	Independence Day	Faculty & Students	Institute	
24 Aug 2015	One Day Seminar on Flow Cytometry	Faculty & Students	In Collaboration with B D Bioscience	
01 Sep-15 Sep 15	Hindi Pakhwada	Faculty & Students	Institute	
02 Oct 2015	SwachataAbhiyan	Faculty & Students	Institute	
18 Oct 2015	2 <sup>nd</sup> Alumni meet	Students, Alumni and Faculty	Institute	
26 Oct-31 Oct 2015	Vigilance Awareness week	Faculty & Students	Institute	Address by Chief Manager SBI , Drive in Road branch

## Institute / Infrastructure Third Convocation (19 Nov 2015)



## MOUs during visitor's conference : 4<sup>th</sup> NOV 2015



## Institute / Infrastructure



Convocation if any/ Student activity if any



## NIPER GUWAHATI

**Chairman of Board of Governor/ Steering Committee (with period):** Dr. V.K. Subburaj

**Director/ Project Director (with period):**

Director In Charge: Prof. Kabul C. Saikia,

Period: w.e.f 01/11/11 till February 2016

Dr. A.K. Adhikari Feb 2016 till date

Project Director: Prof. Babul Bezbaruah

Period: 01-01-2012 till date

### Historical Milestones (incl. Inauguration date):

NIPER, Guwahati was inaugurated on 16<sup>th</sup> September 2008 by the then Hon'ble Union Minister for Chemicals and Fertilizers and Steel, Shri Ram Vilas Paswan. Foundation Stone of NIPER-Guwahati campus was laid by Shri Ananth Kumar, Hon'ble Union Minister of Chemicals and Fertilizers, in the presence of Shri Tarun Gogoi, Hon'ble Chief Minister of Assam, Shri Sarbananda Sonowal, Hon'ble Minister of State (i/c) for Youth Affairs and Sports, Smt. Bijoya Chakrabarty, Hon'ble M.P., Guwahati and several distinguished personnel from Govt. of India and Govt. of Assam on 30th May 2015.

**Mentor Institute if any:** Gauhati Medical College, Guwahati, Assam-781032

### Achievements till date:

- Ph.D – 17 (enrolled), Degree awarded – 4
- Total M.S. (Pharm.) (since inception), Students enrolled – 250  
Passed out - 191 (58 students are currently pursuing their P.G. course)
- Among the passed out students, many students got admission in Ph.D. programs in various National & International Universities/Institutes. Most of the other students got placed in various Pharmaceutical Industries and Consultancies.
- Publications: In total, 50 research papers have been published in various National and International Journals.
- Awards: Several awards at different seminars & conferences have been conferred to NIPER-Guwahati students.

### Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy:

All Academic and Non-academic staff posts are on Yearly Contract basis.

Academic Staff: Assistant Professors 02 and Programme Officer 01

Guest Faculties: 15

Non-Academic Staff: 14

### Finances: Government- Allocations, releases, utilization, balance during the last 5 years.

(Fig in Crores)

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2011-12	17.5	7.78	0.00	2.77
2012-13	18.8	13	5.22	10.61

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2013-14	18.8	3	2.88	3.73
2014-15	21	4	3.91	4.18
2015-16	21	21	21	9.19 (upto 30.09.15)

Note:

- Since there has been no revision of Budget Estimate (BE), the original Budget Estimate (BE) may be considered as Revised Estimate (RE)
- During F/Y. 2012-13 the actual expenditure has been more than Budget Estimate(BE) / Total Release on account of expenditure on NIPER Campus Construction out of grants received in previous years
- During F/Y. 2013-14 the actual expenditure has been more than Total Release amount. The excess amount has been spent out of accumulated unspent funds of previous years

### Learning Environment/ Academics

#### Number and Names Departments/ Disciplines (with opening year)

The first batch of students was admitted in 2008. NIPER Guwahati offers Masters' and Ph.D. degrees in 3 streams and caters to the various needs of pharmaceutical industry. Namely

- Pharmacology & Toxicology  
Masters: started in 2008  
Doctoral: started in 2011
- Biotechnology  
Masters: started in 2010  
Doctoral: started in 2014
- Pharmacy Practice  
Masters: started in 2008  
Doctoral: started in 2016

#### Students

#### i) Degrees/programmes offered and Subjects offered (with year) with admission status

Level Masters/ Doctoral	Degree MS/MBA/M. Tech/Ph.D	Discipline	No. of students admitted	
			2014-15	2015-16
Masters	MS	Pharmacology and Toxicology	19	18
Masters	MS	Biotechnology	8	5
Masters	M. Pharm	Pharmacy Practice	5	3
Doctoral	Ph.D	Pharmacology and Toxicology	2	2
Doctoral	Ph.D	Biotechnology	1	1
Doctoral	Ph.D	Pharmacy Practice	-	1

#### ii) Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning

Year	Masters level		Doctoral level	
	Admission	Completion	Admission	Completion
2008-10	19	19	-	-
2009-11	27	27	-	-





Year	Masters level		Doctoral level	
	Admission	Completion	Admission	Completion
2010-12	36	36	-	-
2011-13	38	38	4	-
2012-14	37	36	4	-
2013-15	35	35	2	-
2014-16	32	-	3	4
2015-17	26	-	4	-

**iii) Teacher-Student ratio:**

Biotechnology: 1:5  
Pharmacology and Toxicology: 1:10  
Pharmacy Practice: 1:10

**iv) Student Satisfaction surveys and Employers perceptions :**  
Not yet started

**v) Employability/ Placements Status**

- Year wise Companies participated in campus selection/ placements In the year 2010, 03 students were placed through campus placements. From the year 2011-15 there were no campus placements
  - Last 2 years placements status: in campus/off campus Although, there were no campus placements in last two years; most of the students got placed in reputed companies/ institutions through off campus. Some of the students were also enrolled in Ph.D programme in various national and international universities/research institutes.
- vi) Ranking by Subject , if any.** Not evaluated as the institute is still under Mentor Institute.

• **Teachers -**

- Recognition to Faculty - Nil
- Peer review system – None

**Research**

**Active Research Areas**

**BIOTECHNOLOGY :**

Development of Biopharmaceuticals using Synthetic Biology approaches

**Genomics and Proteomics to study various diseases** like Multiple Myeloma, Acute Myeloid leukemia, Chronic Myeloid leukemia, Myodisplastic syndrome, Ischemia-Stroke disorder, Diabetes, Neuropathic Pain, etc.

**PHARMACOLOGY AND TOXICOLOGY :**

Cancer, CNS disorders (Depression, anxiety Parkinson's), Diabetes, Drug induced toxicities and Investigation of activity of plants from north east India for their pharmacological activity.

**PHARMACY PRACTICE:**

Adverse Drug Reaction (ADR) monitoring, Drug Drug Interaction (DDI) studies, Drug utilization, Pharmacovigilance studies, ADR monitoring of Anti-TB therapy

**Research Publications/ Institution and per Faculty and High Impact factor**

Institutional publications:

Total: 50

Highest Impact factor: 5.6

Dr. Utpal Mohan, Asst. Prof., Dept. of Biotechnology, NIPER Guwahati

International Publications: 09

National Publications: 01

Highest Impact Factor: 6.5

No. of Patents (Applied): 01

Dr. Ranadeep Gogoi, Asst. Prof., Dept. of Biotechnology, NIPER Guwahati

International Publications: 04

National Publications: 03

Highest Impact Factor: 2.94

**Awards:** Several awards at different seminars and conferences have been conferred to NIPER, Guwahati students.

**Competitive Research Grants:** 03 sponsored research projects running 01 DBT-Twinning Project , 01 DST-WOS-A Project, 01 DBT-Institutional Hub

**Research Student Completions:**

Ph.D Thesis Submitted: 04

**Eminent Alumni:** Students are still pursuing their careers at different centres of higher education.

**Land and Civil Works if any:**

Land availability issues/challenges and alternatives:

Govt. of Assam handed over 89 acres of land for new NIPER Campus at Changsari.

**Campus development / Civil Work progress if any:**

Foundation Stone of NIPER-Guwahati campus at Changsari, Guwahati was laid by Shri Ananth Kumar, Hon'ble Union Minister of Chemicals and Fertilizers, in the presence of Shri Tarun Gogoi, Hon'ble Chief Minister of Assam, Shri Sarbananda Sonowal, Hon'ble minister of State (i/c) for Youth Affairs and Sports, Smt. Bijoya Chakrabarty, Hon'ble M.P., Guwahati and several distinguished personnel from Govt. of India and Govt. of Assam on 30th May 2015. The Construction work of administrative block and girl's hostel has been initiated.

- PMC name: **EPIL**
- Date of approval of Designs & Drawings: 11-09-2013
- Date of approval of Bill of Quantities: 30-12-2014
- Phase of construction: Phase-1 construction has started from the month of June 2015.

**Infrastructure: Central facilities/ Centres etc.**

The Animal House, Biotechnology Lab, Ph.D. Lab and Computer laboratory at NIPER-Guwahati has been developed with NIPER fund. The students of NIPER-Guwahati use library and other



infrastructural facility of the Mentor Institute. Facilities of DBT sponsored IBT-hub is actively used by the students of NIPER-Guwahati.

**National Centres if any:** DBT-Institutional Biotech Hub

**Academia-Industry partnership:** NIPER-Guwahati has signed MoU with Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), a PSE, to initiate Academia-Industry collaboration at the Visitor's conference New Delhi on 4<sup>th</sup> November 2015.

1. Capacity utilization of Common facilities viz., Technology Development Centre/ SMPIC/National Bio-availability Centre etc. – In process
2. Consultancy projects/Knowledge Process Outsourcing (KPO)/ Contract Research Organisation (CRO)/ Contract Research & Manufacturing Services (CRAM)/ IPRs etc. – This will be initiated in due time.
3. Entrepreneurship / Incubators: - In process

## Innovation / Knowledge transfer

1. Patents and Commercialisation: We are currently in the process of submitting one patent application in the area of Biopharmaceuticals. In due course of time, efforts would be directed for commercialization of the Patent.
2. Research income earned from industry: **NIL**
3. Citation per faculty –

Dr. Utpal Mohan, Assistant Professor, Dept. of Biotechnology - 50

Dr. Ranadeep Gogoi, Assistant Professor, Dept. of Biotechnology – 1

## Collaboration: With National and International Institutions

Research Collaboration with NIPER Hyderabad & NIPER Mohali is going on. Apart from that NIPER Guwahati has collaboration with Gauhati University, IIT Guwahati and College of Veterinary Science, Guwahati, to promote Drug research and development.

## Institution leadership: NIL

### Impact of NIPER:

The establishment of NIPER-Guwahati has given a strong boost to the promotion of Pharmaceutical Education & Research in the North East region of India for the first time. The students of NIPER-Guwahati, are getting educated and trained in the field of Pharmaceutical Science and hence increasing the percentage of educated manpower of the country. Research efforts of NIPER Guwahati have revived the studies on medicinal value of local herbs of North East Region. NIPER-Guwahati is also moving ahead in the field of Biopharmaceuticals.

**Third party Evaluation if any:** System not yet in place.

### Events/ Workshops/ Conferences organised during the year

- Scientific talk (Speaker – Dr. Probodh Borah, Professor, Dept. of Microbiology, College of Veterinary Science, Assam Agricultural University, Guwahati) Topic : Bioinformatics in Pharmacological Research & Drug Designing Date : 16<sup>th</sup> September 2015

- Scientific talk (Speaker – Mr. Sreenath R. N., Deputy General Manager-Technical, Karnataka Antibiotics and Pharmaceuticals Limited) Topic: Industry Academia Relationship. Date : 16<sup>th</sup> September 2015.

## Institute/Infrastructure







ACADEMIC-INDUSTRY LINKAGES OF NIPER GUWAHATI WITH KARNATAKA ANTI-BIOTICS LTD.

### NIPER HAJIPUR

Chairman of Board of Governor/Steering Committee (with period):  
**Dr. V. K. Subburaj**

Director/ Project Director (with period): **Dr. Pradeep Das**, since inception of NIPER Hajipur (Sep. 2007) till date

Historical Milestones (incl. Inauguration date):

Foundation: 26<sup>th</sup> November 2007

Start of first Session November 2007 offering Masters Degree in three disciplines

Inauguration: 5<sup>th</sup> February 2008

1<sup>st</sup> Convocation 7<sup>th</sup> August 2010

Start of PhD programmes 2011 in Biotechnology and Pharmacoinformatics

Start of PhD programme in Pharmacy Practice 2014

2<sup>nd</sup> Convocation 20<sup>th</sup> February 2015

Mentor Institute if any : Rajendra Memorial Research Institute of Medical Sciences (RMRIMS-Patna) under ICMR

Achievements till date: NIPER Hajipur has awarded

Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy

Academic 10 on contract

Non-Academic 10 on contract

Finances: Government- Allocations, releases, utilization, balance during the last 5 years.

In crores

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2011 – 12	22.75	00.01	0.00	00.00
2012 -13	3.70	1.70	0.45	00.45
2013 – 14	3.70	3.50	3.50	3.50
2014 - 15	4.00	4.00	4.00	4.00
2015-16	6.00	6.00	6.00	NA

Learning Environment/ Academics

Number and Names Departments/ Disciplines (with opening year)

THREE Departments

Biotechnology	2007
Pharmacoinformatics	2007
Pharmacy Practice	2007

#### Students

Degrees/programmes offered and Subjects offered (with year) with admission status.

Level	Degree	Discipline	No. of students admitted	
			2014-15	2015-16
Masters/ Doctoral	MS/MBA/M. Tech/Ph.D			
Masters	M S Pharm	Biotechnology	12	04
Masters	M S Pharm	Pharmacoinformatics	12	08
Masters	M Pharm	Pharmacy Practice	15	13
Doctoral	PhD	Biotechnology	3	3
Doctoral	PhD	Pharmacoinformatics	0	1
Doctoral	PhD	Pharmacy Practice	1	2

Completion rates: Students pass out year wise against capacity and admission at PG, PhD, PDF since the beginning

Year	Masters level		Doctoral level	
	Admission	Completion	Admission	Completion
2007-09	29	29		
2008-10	30	27		
2009-11	34	32		-
2010-12	42	40		-
2011-13	43	42	5	Nil
2012-14	21	19	5	Nil
2013-15	39	39	5	Nil
2014-16	39	Continuing	4	Nil
2015-17	25	Continuing	6	Nil

Teacher-Student ratio 1:10

Student Satisfaction surveys and Employers perceptions

We obtain evaluation of teaching faculty every year from all the students. Performance of the faculty is being evaluated by renowned scientists of the country on annual basis.

Employability/ Placements Status:

- Year wise Companies participated in campus selection/ placements:
- Last 2 years placements status: in campus/off campus: Most of the students passing out of NIPER Hajipur are getting jobs.

Ranking by Subject if any. Not available.

#### Teachers

Recognition to Faculty: Faculty of NIPER Hajipur has been invited for delivering lectures at different National level conferences. They have been invited as examiners in examinations and viva at Universities/Institutes like Jawaharlal Nehru University, Institute of Microbial Technology, Central University of Bihar, Vanasthali University, NIPER-Mohali, BITS Pilani, at Masters and PhD levels.



Peer review system: Performance of the faculty is being evaluated by renowned scientists of the country on annual basis. The annual contract of employment of the faculty is renewed on that basis.

## Research:

1. Active Research Areas
  - Biotechnology
  - Cancer
  - HIV
  - Leishmaniasis
  - tRNA modification and their role in protein synthesis
  - Pharmacoinformatics
  - Computer Aided Drug Design
  - Development of Chemical database
  - Pharmacophore modelling and QSAR model development
  - In silico Drug development against cancer using
  - Biostatistics
  - Survival Analysis and Reliability
  - Pharmacy Practice
  - Drug utilization research
  - Pharmacovigilance
  - Comparative effectiveness research
  - Diabetes
  - Safety efficacy and prescription pattern
2. Research Publications/ Institution and per Faculty and High Impact factor
 

Thirteen publications (1 publication per faculty), average impact factor 2.9 per paper.
3. Awards
4. Competitive Research Grants:
5. Research Student Completions: The students (189) at Masters level take up research projects for their MS Thesis. We have not produced any PhD thesis as the first batch of PhD students are still continuing their research work.

Eminent Alumni: Several students are pursuing PhD from foreign universities.

Land and Civil Works if any:

1. Land availability issues/challenges and alternatives: Land could not be provided by the state government so far. Civil work could not be started in the present (transient) campus as the lease deed has not been.
2. Campus development / Civil Work progress if any
  - c) PMC name: Not applicable, the reason is stated above.
  - d) Date of approval of Designs & Drawings: Not applicable, the reason is stated above.
  - e) Date of approval of Bill of Quantities: Not applicable, the reason is stated above.

- f) Phase of construction: Not applicable, the reason is stated above.

Infrastructure: Central facilities/ Centres etc.

NIPER Hajipur has established a Biotechnology laboratory at NIPER campus. Also various facilities at mentor institute are shared with NIPER. It includes PCR and RT-PCR, DNA sequencer, FACS Calibur, Automatic Cell Counter, Fully Automatic Auto-Analyzer, Automatic Tissue Processor, Florescent microscope, HPLC, X-ray Diffraction (machine), Ultrasonography machine, Cold Room, Liquid Nitrogen System, etc.

National Centres if any nil

Academia-Industry partnership MoU signed with Bengal Chemical and Pharmaceuticals Ltd.

Innovation / knowledge transfer

1. Patents and Commercialisation nil
2. Research income earned from industry nil
3. Citation per faculty

Collaboration: With National and International Institutions

Rajendra Memorial Research Institute of Medical Sciences, Patna  
Mahavir Cancer Center Patna

Indian Institute of Technology Delhi

Indian Institute of Technology Patna

Institute of Microbial Technology, Chandigarh

Indira Gandhi Institute of Medical Sciences Patna

S S Hospital and Research Center Patna

Institution leadership

1. Institutional Recognition

NIPER Hajipur has been recognised as a leading institute of pharmaceutical education and research in this part of country. Several students of our institute have been making impact in pharmaceutical industries and research institutes of national and international levels.

2. Collaboration/partnership with International Institutions

We are planning to start international collaboration in near future.

Impact of NIPER: NIPER Hajipur has successfully produced 171 students in three disciplines namely, Biotechnology, Pharmacoinformatics and Pharmacy Practice who are either employed in different pharmaceutical industries or pursuing their higher education in different institutes or universities across the globe. Many of our ex-students are engaged as teaching faculty at different institutions.

Third party Evaluation if any: For assessment of faculty panel of experts meet on annual basis for evaluation of their performance and renewal of annual contract.



Events/ Workshops/ Conferences organised during the year:

Date	Activity name	Target group	Sponsored by	Remarks
20 <sup>th</sup> February 2015	Second Convocation	Students	NIPER	Degrees were awarded to 133 students were awarded
16 <sup>th</sup> Sep. to 29 <sup>th</sup> Sep. 2015	Hindi Pakhwara	All staff and students	NIPER	Several competitions like Vaad-vivaad pratiyogita, Nibandh lekhan etc were organized and prizes were distributed among the winners.
2 <sup>nd</sup> Oct. 2015	Swachh Bharat Abhiyan	All staff and students	NIPER	All the members actively participated in the event. Essay competition among students and staff was conducted.
29 <sup>th</sup> October to 3 <sup>rd</sup> Nov. 2015	Vigilance awareness week	Staff and students	NIPER	Pledge and awareness programmes.
26 <sup>th</sup> Nov. 2015	Foundation Day	Students and staff	NIPER	Oration by Dr. G P S Raghava Chief Scientist, IMTECH Chandigarh followed by cultural programmes.



**ACADEMIC-INDUSTRY LINKAGES OF NIPER HAJIPUR WITH BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED, KOLKATA.**



## NIPER HYDERABAD

Chairman of Board of Governor/ Steering Committee (with period)

Steering Committee Chairman: Dr V.K.Subburaj, Secretary, DoP, Gol (October 2014- till date)

Director/ Project Director (with period)

Project Director: Dr Ahmed Kamal, Outstanding Scientist, CSIR-IICT (March 2009- till date)

Historical Milestones (incl. Inauguration date)

2007	<b>Inaugurated</b> on 19 <sup>th</sup> October, 2007 Started M.S. (Pharm.) courses
2010	<b>First convocation:</b> Dr Seyed E. Hasnain, Vice Chancellor, University of Hyderabad was the Chief Guest, degrees were awarded to 85 students
2011	Ph.D Programmes started



2012	<b>Second convocation:</b> Dr Viswa Mohan Katogh, Secretary & DG, ICMR was the Chief Guest, degrees were awarded to 131 students ( Two batches) Started MBA (Pharm.) in Pharmaceutical Management
2013	<b>Third convocation:</b> Dr T. Ramasami, Secretary DST was the Chief Guest, degrees were awarded to 73 students In-house Journal "Current Trends in Pharmaceutical Sciences" was started
2015	<b>Fourth convocation:</b> Dr APJ Abdul Kalam, Former President of India was the Chief Guest, degrees were awarded to 97 students

Mentor Institute if any

CSIR-Indian Institute of Chemical Technology, Tarnaka, Hyderabad-500007

Achievements till date

Master Students Passed Out	:	494
Students pursuing PhD course	:	61
Research Publications	:	>300
Sanctioned extramural research projects	:	11

Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy

Sanctioned: Nil

In-position: Academic: 22 (contractual); Non-Academic staff: 52 (contractual)

Finances: Government- Allocations, releases, utilization, balance during the last 5 years.

Amount Rs. in Crores

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2015-16	35	35	35	15.2 <sup>#</sup>
2014-15	22	14.17	14.17	15.39
2013-14	25	23	23	22.45
2012-13	22	22	20.3	20.82
2011-12	7.0	6	6	7.35

<sup>#</sup> Figures are upto 20<sup>th</sup> Nov, 2015

### Learning Environment/ Academics

#### A. Number and Names Departments / Disciplines (with opening year)

Program	Discipline	Opening year
M.S. (Pharm)	Medicinal Chemistry, Pharmaceutical Analysis, Pharmacology & Toxicology	2007
	Pharmaceutics	2010
	Regulatory Toxicology & Process Chemistry	2013
MBA (Pharm)	Pharmaceutical Management	2012
Ph.D	Medicinal Chemistry, Pharmacology & Toxicology and Pharmaceutics	2011
	Pharmaceutical Analysis	2012

#### B. Students

(i) Degrees/programmes offered and Subjects offered (with year) with admission status

Level Masters/ Doctoral	Degree MS/MBA/M. Tech/Ph.D	Discipline	No. of students admitted	
			2014-15	2015-16
Masters	M.S.(Pharm)	Medicinal Chemistry	30	30
		Pharmaceutical Analysis	15	15
		Pharmacology & Toxicology	15	15
		Pharmaceutics	15	15
		Regulatory Toxicology	07	08
	MBA (Pharm)	Pharmaceutical Management	18	18
		M. Tech (Pharm)	Pharmaceutical Technology (Process Chemistry)	07
Doctoral	Ph.D	Medicinal Chemistry	5	7
		Pharmaceutical Analysis	3	3
		Pharmacology & Toxicology	3	3
		Pharmaceutics	2	3
Total			120	125

(ii) Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning

Year	Masters level		Doctoral levels	
	Admission	Completion	Admission	Completion
2007	41	-	-	-
2008	47	-	-	-
2009	57	41	-	-
2010	75	44	-	-
2011	75	56	9	-
2012	98	75	12	-
2013	112	73	11	-
2014	107	97	13	-
2015	109	108	16	1

(iii) Teacher-Student ratio

Faculty: Student ratio of ~1:10

(iv) Student Satisfaction surveys and Employees perceptions

- Periodical surveys are conducted to solicit the feedback from the students with regard to various aspects of academics, infrastructure and other matters
- Researchers / Scientists from various organizations have expressed their satisfaction about the quality, commitment of NIPER-H students during their project work





- The prominent invited speakers/recruiters from various leading organizations have been giving a positive opinion about the quality of NIPER-H students and also their performance after their employment with them

## (v) Employability/ Placements Status

- Year wise Companies participated in campus selection/ placement  
Every year students were placed in reputed companies' like- Novartis, Biocon, Dr Reddy's, GVK, Mylan, AstraZeneca, Shasun, Lupin, Aurobindo Biological E etc.
- Last 2 years placements status: in campus/off campus

Year	2011	2012	2013	2014	2015
In campus	91	88	85	82	82
Placements (%)					

## (vi) Ranking by Subject if any. - To be formulated

### C. Teachers

Brightest Minds to Mentor the Best Brains – NIPER has some of the talented and dedicated faculty who come from the best institutions around the world.

#### (i) Recognition to Faculty

- Associate fellow of AP academy of Sciences were conferred to four faculty of Institute for their outstanding contributions in scientific research
- Indus Foundation best teacher award for institute faculty

- Prof Manjeet Singh Prize for Best Molecular Pharmacology manuscript for institute faculty

#### (ii) Peer review system

The performance of the faculty is assessed periodically. The assessment is based on the student feedback, output from the research activities and contributions to institutional growth.

### Research

#### (i) Active research areas: Focus areas: cancer, diabetes, anti-infective

- ✓ Design and synthesis of new chemical entities
- ✓ Development of screening assays
- ✓ Development of process & scale up technologies
- ✓ Novel drug delivery systems viz., nano-technology in drug delivery
- ✓ Development of new bio-analytical methods
- ✓ Drug metabolism and pharmacokinetic studies

#### (ii) Research Publications/ Institution and per Faculty and High Impact factor

More than 300 research publications during the last five years

#### (iii) Awards Received by Faculty: OPPI Young Scientist Award, IDMA Young Pharmaceutical Analyst Award

#### (iv) Competitive Research Grants-

Sl. No.	Principal Investigator	Amount of fund	Project Mode	Agency
1	N. Satheesh Kumar	Rs. 12.5 lakhs	Grant-in-Aid	ICMR, India
2	N. Satheesh Kumar	Rs 17 Lakhs	Grant-in-Aid	DST, India
3	Dr Ashutosh Kumar	Rs 23.59 lakhs	Grant-in-Aid, collaborative with NIPER-Guwahati	DBT, India
4	Dr Ashutosh Kumar	Rs 20.56	Grant-in-Aid, collaborative with University of Manchester	DST, India and UKIERI, UK
5	Dr V.G.M. Naidu	Rs 30 Lakhs	Grant-in-Aid, collaborative with Chemveda India Pvt Ltd,	DBT-SBIRI, India
6	Dr. S. Sunitha	Rs 10.8 Lakhs	Grant-in-Aid	SERB, India
7	Dr Wahid Khan	USD 10,000	Sponsored	YRDC, Israel
8	Dr Wahid Khan	Rs 24.97 Lakhs	Grant-in-Aid	DBT, India
9	Dr M. Mallika	Rs 25 lakhs	Grant-in-Aid	DBT, India
10	Dr Wahid Khan	USD 10,000	Sponsored	YRDC, Israel
11	Dr Wahid Khan	Rs 28.7 Lakhs	Grant-in-Aid, collaborative with CRIUM Hyderabad	AYUSH, India





## (v) Research Student Completions

- ✓ The research programme started in 2011 with 9 students
- ✓ Currently 61 PhD students are pursuing their research work
- ✓ One student was awarded the PhD degree this year (2015)

(vi) Eminent Alumni: Many of NIPER-Hyderabad Alumni are placed in responsible positions in leading pharmaceutical companies and in some Govt. organizations. The institute is constantly receiving good feedback about their performance.

## Land and Civil Works if any

- (i) Land availability issues/challenges and alternatives  
NIPER-H has been allocated 50 acres of land from the State Govt. Registration formalities completed in January, 2014. The PMC has been identified to carry out the development.
- (ii) Campus development / Civil Work progress if any
  1. PMC name: National Project Construction Corporation Limited
  2. Date of approval of Designs & Drawings: In process
  3. Date of approval of Bill of Quantities: -
  4. Phase of construction: -

## Infrastructure: Central facilities/ Centres etc.

- Classrooms, Information & Knowledge Centre, Wi-Fi Campus, Laboratories, Central Instrumentation Facility, Animal house, Centre for molecular modeling, Residential Accommodation etc.
- Some major facilities includes:-
  - Central Instrumentation Laboratory- With NMR, LCMS, Flow cytometer facility
  - Central animal house facility

## National Centres if any

National Centre for Research & Development in Bulk Drugs (NCRDBD, Hyderabad): A dedicated facility with kilo lab/pilot plant is in the process of establishment.

## Academia-Industry partnership

- ✓ Students are regularly carrying out their research project with various pharma industries
- ✓ A number of seminars/workshops are being organized in association with industry
- ✓ Some of the faculty are collaborating with pharma industry to address their problems
- ✓ Training programmes for outside students have been conducted in association with Indian Institute of Biotechnology (IIBT), Hyderabad

## Innovation / knowledge transfer

- (i) Patents and commercialization- Some of the inventions are in the process of being filed as patents
- (ii) Research income earned from Industry- 30 Lakhs
- (iii) Citation per faculty- Average 338 citations per faculty

## Collaboration:

Collaborated with several National and International Institutions

## Institution leadership

- (i) Institutional Recognition: NIPER-H has been well recognized by various bodies viz OPPI, FICCI, Pharmexcil, IDMA, BDMA and British Council.
- (ii) Collaboration/partnership with International Institutions : University of Minnesota, USA, University of Manchester, UK, University of Lausanne, Switzerland, Hebrew University of Jerusalem, Israel.

Impact of NIPER: Creating excellent human resource by imparting high quality education and training in pharmaceutical sciences which would help the pharmaceutical industry. Serving as an excellent research institute by focusing on thrust areas of national and international relevance. Fostering academic and industrial collaborations to address some of the key issues in the pharma sector.

Third party Evaluation if any : Yet to be carried out

Events/ Workshops/ Conferences organised during the year

Date	Activity name	Target group	Sponsored by
26-27 <sup>th</sup> March 2015	National Conference on Innovative Processes for Bulk Drugs (IPBD)	Academia & Industry	Dept. of Pharmaceuticals
10 <sup>th</sup> April 2015	Hands-On Workshop on Pk/Pd Software and Molecular modelling	Academia & Industry	NIPER-Hyderabad
20-21 <sup>st</sup> November 2015	Conference on Drug Discovery & Development	Academia & Industry	Dept. of Pharmaceuticals



Dr. APJ Abdul Kalam as Chief Guest at the 4th convocation



Dr. Kalam awarding a gold medal (Mar, 2015)



Inauguration of NMR facility by Shri Hansraj Gangaram Ahir, Hon'ble Minister of State, Ministry of Chemicals & Fertilizers (Mar, 2015)



Dr. V. K. Subburaj, Secretary DoP, visiting the research labs of the institute (Jan, 2015)



Mr Sudhansh Pant, Joint Secretary, DoP at NIPER Pavilion in BioAsia 2015 (Feb, 2015)



Inauguration of Conference on "Drug Discovery & Development" by Dr.V. K. Subburaj, Secretary DoP (Nov, 2015)



Exchange of MoU's in Visitor's Conference-2015 at Rashtrapati Bhavan (Nov, 2015)







## NIPER, KOLKATA

**Chairman of Board of Governor/ Steering Committee (with period):** Dr. V.K.Subburaj Secretary, DoP, Govt. of India.

**Director/ Project Director (with period):**

- i) Director in charge, since October, 2014 and Project Director, since December, 2014 to 5<sup>th</sup> July, 2015: Prof. Chitra Mandal, Acting Director, CSIR-IICB

- ii) **Regular Director, from 6<sup>th</sup> July, 2015: Dr. Ravichandiran V.**

**NIPER-Kolkata was inaugurated on November 05, 2007**

Convocation was conducted on Aug 21/2015. Dr. V. K. Subburaj, IAS, Chairman Steering Committee of NIPERs and Secretary to the Govt. of India, presides over the Convocation and Dr. Ashok Rakhit from St. John's University, Queens, New York, USA was the Chief Guest

**Mentor Institute if any:** CSIR-Indian Institute of Chemical Biology, Kolkata

**Achievements till date:** As per information available, a total of 283 students have graduated. Among them, 190 are engaged in companies and academic institutions. Out of the seven batches, 66 students are carrying out PhD in institutes including 12 in abroad and out of them 12 have been awarded the degrees.

**Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy:** No permanent sanctioned posts till date. All the administrative works are managed by the retired Govt. Employee and outsourcing with the help of the Mentor Institute.

**Regular Director of NIPER-Kolkata joined on 6<sup>th</sup> July, 2015.**

**Finances:** Government- Allocations, releases, utilization, balance during the last 5 years.

Rupees in Crores

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2011-12	21.75	3.50	3.09	Total: 2.46
2012-13	4.50	1.75	1.75	Total: 2.78
2013-14	4.50	4.50	4.40	Total: 3.23
2014-15	5.00	4.38	4.38	Total: 3.81
2015-16	8.00	8.00	6.30 (upto 30.11.15)	Total: 1.67 <b>Up to 31.10.2015</b>

### Learning Environment/ Academics

Number and Names Departments/ Disciplines (with opening year)

No.	Names Departments/Disciplines	Opening Year
1	Medicinal Chemistry	2007
2	Natural Products	-DO-
3	Pharmacoinformatics	-DO-

### Students

1. **Degrees/programmes offered and Subjects offered (with year) with admission status:**

Level	Degree	Discipline	No. of students admitted	
			2014-15	2015-16
Masters/ Doctoral	MS/MBA/M. Tech/Ph.D			
Masters	M.S. (Pharm.)	Medicinal Chemistry	16	17
		Natural Products	12	13
		Pharma co informatics	14	09

2. **Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning**

Year	Masters level		Doctoral level	
	Admission	Completion	Admission	Completion
2007-2009	29	29	NIL	NIL
2008-2010	32	32	NIL	NIL
2009-2011	40	40	NIL	NIL
2010-2012	49	49	NIL	NIL
2011-2013	47	47	NIL	NIL
2012-2014	37	37	NIL	NIL
2013-2015	49	49	NIL	
2014-2016	42	Pursuing 3 <sup>rd</sup> & 4 <sup>th</sup> Semester		
2015-2017	39	Pursuing 1 <sup>st</sup> Semester	NIL	

3. **Teacher-Student ratio**

Academic year	Faculty* student ratio
2007-2009	1.96:1
2008-2010	1.75:1
2009-2011	1.42:1
2010-2012	1.16:1
2011-2013	1.21:1
2012-2014	1.54:1
2013-2015	1.16:1
2014-2016	1.36:1
2015-2016	0.90:1

\*All Guest Faculties

4. **Student Satisfaction surveys and Employers perceptions:** Students are highly satisfied with the mode of teaching and project work carried out by them.
5. **Employability/ Placements Status:**
1. **Year wise Companies participated in campus selection/ placements:** Since inception, fourteen Pharma Companies came to NIPER-Kolkata to recruit students.
2. **Last 2 years placements status: in campus/off campus:** Most of the students have been absorbed in the Industries, Colleges and Research institutes. A number of students are pursuing higher studies within the country as well as abroad. Placement was achieved for these students according to their options for employment in companies as well as in centres for teaching and higher studies.
6. **Ranking by Subject if any:** Yet to be received.



## Teachers

**Recognition to Faculty:** All the guest faculties invited from the Mentor Institute and other Institutes of Kolkata, such as Calcutta University, Jadavpur University, Indian Association for the Cultivation of Science, Bose Institute, Saha Institute of Nuclear Science and SSKM Hospital, TCG Life Sciences and they are well recognized in their own areas.

**Peer review system:** Yet to be introduced

## Research

- Active Research Areas:** Synthetic and plant based drug discovery, immunology and immune diagnostics, cellular and molecular biology, recombinant DNA technology and monoclonal antibody technology, novel drug delivery systems, chemical and biochemical process technology, etc.
- Research Publications/ Institution and per Faculty and High Impact factor:** 15 research papers have been published in renowned international journals from the project work of the MS (Pharm.) students.
- Awards:** Not recorded
- Competitive Research Grants:** NIL
- Research Student Completions:** NIL
- Eminent Alumni:** None

**Land and Civil Works if any:**

**No land has been received and possession taken over from the State Government till date.**

**outstanding issues still remain:**

- Land availability issues/challenges and alternatives
- Campus development / Civil Work progress, if any
  - PMC name:
  - Date of approval of Designs & Drawings
  - Date of approval of Bill of Quantities
  - Phase of construction

**Infrastructure: Central facilities/Centres etc.:** Provided by the Mentor Institute (CSIR-IICB)

**National Centres if any:** NIL

**Academia-Industry partnership:**

- Capacity utilization of Common facilities viz., Technology Development Centre/ SMPIC/National Bio-availability Centre etc.: NIL
- Consultancy projects/Knowledge Process Outsourcing (KPO)/ Contract Research Organisation (CRO)/ Contract Research & Manufacturing Services(CRAM)/ IPRs etc.: NIL
- Entrepreneurship / Incubators: NIL
- During the year under report the following initiative have been taken:
  - Director, NIPER-Kolkata visited BCPL Corporate Office facility at Maniktala, 6, Ganesh Chunder Avenue and

Panihati Factory also visited Bengal Immunity Centre on 04/09/2015. On 09/10/2015 a combine team consisting of Dr. Ravichandiran V., Director, NIPER-Kolkata; Dr. Samit Chattopadhyay, Director, CSIR-IICB; Dr. Arun Bandopadhyay; Dr. Rupak Bhadra and Dr. P. Jaisankar; Dr. Asish Kumar Banerjee and Dr. K. K. Datta visited BCPL for collaborative partnership with NIPER.

- NIPER-Kolkata has signed a MoU with Bengal Chemical and Pharmaceuticals Ltd. (BCPL), Kolkata to develop a new product related to identifying and detoxifying agent, a newer adjuvant which is least toxic to the animal and best immunogenic with regard to Anti-snake Venom serum production.

**Innovation/knowledge transfer:**

- Patents and Commercialisation: NIL
- Research income earned from industry: NIL
- Citation per faculty: NIL

**Collaboration: With National and International Institutions:**

Rare Diseases Initiative: NIPER, Kolkata took up a novel programme of establishing a rare disease initiative at NIPER, Kolkata.

Strengthening Academia and academia relationship:

Undertaken MoU with BCPL

**Institution leadership**

- Institutional Recognition: Yet to be received
- Collaboration/partnership with International Institutions: NIL

**Impact of NIPER:**

- A total of 283 students have graduated.
- 190 students are engaged to work in companies/ institutions.
- 66 students are carrying out Ph. D. in institutes including 12 in abroad. About 12 students have already been awarded.

**Third party Evaluation if any:** NIL

**Events/Workshops/Conferences organised during the year:**

Date	Activity name	Target group	Sponsored by	Remarks
21 <sup>st</sup> August 2015	4 <sup>th</sup> Convocation of NIPER Kolkata	2012-14 & 2013-15 Students	NA	Total 86 students were awarded their degree certificates
2 <sup>nd</sup> October, 2015	Swachh Bharat Abhiyan	For all	CSIR-IICB jointly with NIPER-Kolkata	Clean India Mission
31 <sup>st</sup> October, 2015.	Rashtriya Ekta Diwas	For all students & staff	NIPER-Kolkata	National Unity.



4th Convocation of NIPER-Kolkata



Address by Dr. V. K. Subburaj, IAS, Secretary, Department of Pharmaceuticals and Fertilizers, Govt. of India, and the Chairman of the Steering Committee of NIPERs on the occasion of 4th Convocation of NIPER-Kolkata



ACADEMIC-INDUSTRY LINKAGE OF NIPER KOLKATA WITH BENGAL CHEMICALS AND PHARMACEUTICALS LIMITED

## NIPER, RAEBARELI

**Chairman of Steering Committee (with period):** Dr V.K. Subburaj

Secretary

Department of Pharmaceuticals

Ministry of Chemicals & Fertilizers, Govt. of India

**Period:** Since Oct, 2014

**Project Director (with period)**

Dr. P.K. Shukla, Project Director, NIPER, Raebareli and Head & Senior Principal Scientist

Division of Microbiology, CSIR-Central Drug Research Institute, Lucknow-226021 (India)

**Period:** From 1st September, 2012

**Historical Milestones (incl. Inauguration date)**

The National Institute of Pharmaceutical Education and Research (NIPER), Raebareli started functioning from 14th November, 2008 Research

Institute, Lucknow. To begin with, 20 students were admitted through a joint entrance examination conducted by NIPER, Mohali. The Institute expanded its activities from here on and offered M.S. (Pharm.) courses in Medicinal Chemistry and Pharmaceutics from the academic year 2008-2009. During the academic year 2012-2013 a new stream of M.S. (Pharm.) Pharmacology and Toxicology has been started. Before starting the new course a new laboratory was created. The first convocation of the Institute was held on 15th December, 2010 at CSIR-CDRI Lucknow. Professor Lalji Singh, Bhatnagar Fellow & the former Director, Centre for Cellular and Molecular Biology, Hyderabad, addressed the convocation as Chief Guest.

**Mentor Institute if any**

CSIR-Central Drug Research Institute, Sector 10, Jankipuram Extension, Sitapur Road, Lucknow 226031, Uttar Pradesh, INDIA





## Achievements till date

### Year Achievements

2008 The National Institute of Pharmaceutical Education and Research (NIPER), Raebareli started functioning from 14th November 2008 under the mentorship of the Central Drug Research Institute, Lucknow.

2010 1st Batch (2008-10) of 20 Students passed out successfully.  
2010 The first convocation of the Institute was held on 15th December 2010 at CSIR-CDRI Lucknow and a total of 20 students of batch 2008-10 received their degrees.

2011 2nd Batch (2009-11) of 28 Students passed out successfully.

2012 3rd Batch (2010-12) of 30 Students passed out successfully.

2013 4th Batch (2011-13) of 31 Students passed out successfully.

2014 The second convocation of NIPER, Raebareli was held on 7th April, 2014 in CSIR-CDRI, Lucknow and a total of 89 students from three batches (2009-11, 2010-12 and 2011-13), received their degrees.

2014 5th Batch (2012-14) of 37 Students passed out successfully.

2015 6th Batch (2013-15) 38 Students passed out successfully (out of 39 Students)

### Manpower-Academic and Non-Academic staff-Sanction/In-position/Vacancy

\*The Institute recruits teachers/staff on yearly contractual basis:

**Manpower – Academic:** 8 faculty members

**Manpower – Non- Academic:** 19 persons

**Finances: Government- Allocations, releases, utilization, balance during the last 5 years.**

(Amount in Rs. Crore)

Year	Allocation BE	Allocation RE	Total Release	Expenditure
2011-12	6.50	4.00	3.50	3.60
2012-13	4.50	3.00	3.00	3.75
2013-14	4.50	4.70	4.50	3.20
2014-15	15.00	4.45	4.45	3.95
2015-16	7.00	5.51	5.50	NA

### Learning Environment/ Academics

#### A. Number and Names Departments/ Disciplines (with opening year)

- M.S. (Pharm.) Medicinal Chemistry (2008)
- M.S. (Pharm.) Pharmaceuticals (2008)
- M.S. (Pharm.) Pharmacology & Toxicology (2012)

#### B. Students

Degrees/programmes offered and Subjects offered (with year) with admission status

#### Level Masters/ Doctoral Degree

**MS/MBA/M.Tech/Ph.D Discipline No.of students admitted 2014-15 2015-16**

Masters M.S. (Pharm.) Medicinal Chemistry 19 17

Pharmaceutics 13 13

Pharmacology 06 06

Completion rates: Students pass out year wise against capacity and admission at PG, Ph.D, PDF since the beginning

### Year Masters level Doctoral level

#### Admission Completion Admission Completion

Years	Masters level	Doctoral level
2008-09	20	20
2009-10	28	28
2010-11	30	30
2011-12	31	31
2012-13	37	37
2013-14	39	38
2014-15	38	Perusing
2015-16	36	perusing

Teacher-Student ratio

11 : 1

Student Satisfaction surveys and Employers perceptions = NA

### Employability/ Placements Status

- Year wise Companies participated in campus selection/ placements

### Placement Status till 2015

Batch. No.	Year	Total of Students	No. of Students Placed
1	2008-10	20	17
2	2009-11	28	10
3	2010-12	30	16
4	2011-13	31	13
5	2012-14	37	16
6	2013-15	39	10
7	2014-16	38	Pursuing (III Sem)
8	2015-17	36	Pursuing (I Sem)

**Total 259**

- Last 2 years placements status: in campus/off campus

#### Batch. No. Year Total of Students No. of Students Placed

2013-15 39 10

2014-16 38 Pursuing (III Sem)

Ranking by Subject if any.

#### C. Teachers

- Recognition to Faculty = NA
- Peer review system – Performance of teachers is being evaluated by taking feedback from the

students.

**Research = NA**

### Land and Civil Works if any

- Land availability issues/challenges and alternatives



## Land Allotment:

The Govt. of Uttar Pradesh has issued order for making available approx. 50 Acres land free of cost to NIPER, Raebareli.

ii. Campus development / Civil Work progress if any = NIL

- PMC name:
- Date of approval of Designs & Drawings:
- Date of approval of Bill of Quantities
- Phase of construction:

Infrastructure: Central facilities/ Centres etc.- CDRI facilities are being utilized.

National Centres if any = NA

Academia-Industry partnership = NA

Innovation / knowledge transfer = NA

Collaboration: With National and International Institutions = NA

Institution leadership = NA

Impact of NIPER

Third party Evaluation if any = NA

19. Events/ Workshops/ Conferences organised during the year

Date	Activity name	Target group	Sponsored by	Remarks
20th – 21st				
February, 2015				
7th NIPER (RBL) – CSIRCDRI				
Symposium				
- ICMR & DRDO -				



ACADEMIC INDUSTRY LINKAGE OF NIPER RAE-BARELI WITH INDIAN DRUGS AND PHARMACEUTICALS LTD. RISHIKESH.





# Chapter

## NEW INITIATIVES

- 7.1 Constitution of Task Forces to promote the development of the drugs and Pharmaceuticals sector
- 7.2 Cluster Development Programme for Pharma Sector (CDP-PS)
- 7.3 New Initiatives Taken by National Pharmaceutical Pricing Authority (NPPA)
- 7.4 National Centre for Research and Development in Bulk Drug (NCRDBD) at NIPER
- 7.5 Collaborative TB and Kala Azar Research Project of NIPER, Mohali









## CHAPTER – 7

### NEW INITIATIVES

#### 7.1 CONSTITUTION OF TASK FORCES TO PROMOTE THE DEVELOPMENT OF THE DRUGS AND PHARMACEUTICALS SECTOR.

[I] The Government acknowledging the need for addressing the constraints in the growth of Pharmaceutical Sector had constituted a Task Force on enabling private sector to lead the growth of pharmaceutical industry under the Chairmanship of Secretary, D/o Pharmaceuticals on 31/10/2014. After several round of stakeholder consultation, the Task Force submitted its recommendations to the Government (report available at [pharmaceuticals.gov.in/documents-reports/recommendation-of-task-force-on-enabling-private-sector-to-lead-the-growth-of-pharmaceutical-industry](http://pharmaceuticals.gov.in/documents-reports/recommendation-of-task-force-on-enabling-private-sector-to-lead-the-growth-of-pharmaceutical-industry)). The report of the Task Force was released by Honourable Minister of Chemicals and Fertilizers on 22.06.2015.

- Financial Assistance in form of soft loan/interest subsidy
- Increase funding support to early stage entrepreneurs in Pharmaceutical Sector
- Financial and technical assistance to improve financial sustainability of SMEs
- Pharmaceutical Venture Capital Fund

#### 3. INFRASTRUCTURE SUPPORT

- Establish required cold chain facilities
- Provide common infrastructure for biosimilars
- Establish formulation development centers
- Setup a mega complex for production of identified drug intermediates and raw materials



*Hon'ble Union Minister for Chemicals & Fertilizers, Shri Ananth Kumar, Hon'ble Minister of State for Chemicals & Fertilizers, Shri Hansraj Gangaram Ahir, Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals and other officials of the department*

The key recommendations are as under:-

#### 1. REGULATORY SUPPORT

- Setting up a High Level Coordination Committee
- Constitution of a promotional corporate body/registered society
- Create a Regulatory Cell in NIPERs and other Institutes
- Strengthening of CDSCO

#### 2. FUNDING SUPPORT

- Joint funding of schemes for collaboration in pharmaceutical sector

#### 4. R&D SUPPORT

- Formulate the national innovation strategy
- Create and fund an organization to support and promote biopharmaceutical innovation, R&D and national and international academia-industry partnership
- Create multiple Centers of Excellence (CoE)
- Academic institutes to undertake research related to technology transfer
- Promote interactions of experts between academia and industry



- DoP may coordinate with all government schemes supporting R&D in Pharma
- MoH&FW may institute an appellate mechanism for domestic as well as global clinical trials at one level above the delegated authority

## 5. PROCESS SUPPORT

- Support for dossier preparation for SMEs in registration of their products in targeted countries
- Make necessary changes in the documentation process (es)
- Support for studies and reports of Pharmerging Countries on their Pharmaceutical Industry development and opportunities
- Create special cells within the facilitating body for generic segment
- Promote mutually beneficial capital investment projects with the importing country(ies)
- Simplification of the approval process for clinical trials
- Rationalization of environmental clearances
- Provide flexibility to the pharmaceutical companies to file for test licensing

## 7. CAPACITY BUILDING

- Capacity building of regulations of the importing country (ies)
- Skill development of personnel required for upgradation to WHO-GMP and higher International standards
- Start scholarship programs for getting “industry-ready” skilled manpower
- Promote Continuous Medical Education (CME) programs in Pharma Sector

The above recommendation once implemented to provide a road map for the growth of pharmaceutical sector in the country.

**[II] The Task Force to identify issues relating to the promotion of domestic production of high end Medical Devices and Pharmaceutical Manufacturing Equipment in the Country was constituted under the Chairmanship of Secretary, D/o Pharmaceuticals on 31/10/2014.** After several rounds of stakeholder consultations, the Task Force has submitted its recommendation to the Government (report available at [pharmaceuticals.gov.in/documents-reports/recommendations-of-task-force-on-the-Medical-Devices-Sector-in-India-2015](http://pharmaceuticals.gov.in/documents-reports/recommendations-of-task-force-on-the-Medical-Devices-Sector-in-India-2015)). The report of the Task Force was released by Honourable Minister of Chemicals and Fertilizers on 08.04.2015.



*Hon'ble Union Minister for Chemicals & Fertilizers, Shri Ananth Kumar, Hon'ble Minister of State for Chemicals & Fertilizers, Shri Hansraj Gangaram Ahir, Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals and other officials of the department*

- Digitalization of clinical trial, licensing and quality control processes
- Parallel processing of regulatory clearances for imported drugs

## 6. PRICE CONTROL

- Review the implementation of DPCO, 2013
- Renationalization of Inverted duty structure on APIs and exemption from excise duty for production of APIs
- Revise the list of R&D equipment exempted from customs duty in consultation with NIPER

The key recommendations are as under:-

### 1. POLICY SUPPORT

- Create necessary bodies to drive the policies
- Preferential treatment in government procurement

### 2. INFRASTRUCTURE

- Set up manufacturing hubs/ clusters in PPP mode
- Set up Medical device parks
- Financing support



## 3. FACILITIES FOR EFFICACY AND SAFETY TESTING

- Medical device testing centers should be set up preferably in the PPP mode
- Designate "Centers of Excellence" (CoE) for supporting product development and validation
- Strengthen a made in India marking (BIS) specific to Medical devices in line with international standards like CE and FDA

## 4. SKILL DEVELOPMENT

Set up a Skill development committee with representative from Medical Device Industry, NIPERs and Healthcare Sector Skill Council (HSSC) under National Skill Development Council (NSDC)

## 5. R&D CAPABILITY

- Set up a system for IP exchange
- Set up/ promote Incubation centers
- Provide requisite financing support
- Promote industry specific "independent software vendor" by extending similar benefits

Devices and Pharmaceutical Manufacturing Equipment in the Country.

**[III] The Task Force for development of manufacturing capabilities in each medical vertical in Pharmaceutical production had been constituted under the Chairmanship of Secretary, D/o Pharmaceuticals on 31/10/2014.** After several round of consultations, the Task Force has finalised its recommendations and is shortly expected to submit the same to the Government.

## 7.2 CLUSTER DEVELOPMENT PROGRAMME FOR PHARMA SECTOR (CDP-PS)

With a vision to catalyze and encourage quality, productivity and innovation in pharmaceutical sector and to enable the Indian Pharmaceutical Industry especially SMEs to play a leading role in a competitive global market, Hon'ble Minister of Chemicals and Fertilizers approved the introduction of **Cluster Development Programme for Pharma Sector (CDP-PS)** on 27.10.2014. The said report was released by Hon'ble Minister of Chemicals and Fertilizers on 17.06.2015.



*Hon'ble Union Minister for Chemicals & Fertilizers, Shri Ananth Kumar, Hon'ble Minister of State for Chemicals & Fertilizers, Shri Hansraj Gangaram Ahir, Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals and other officials of the department*

## 6. POLICY FOR PRICING

- Separate price control order for medical devices
- Price control body
- Pricing & reimbursement policy

## 7. DUTY STRUCTURE

- Discounts on import duties
- Restrictions on import of second hand diagnostic equipment/ tools
- Incentivize and promote exports in the medical devices sector
- Taxes should be levied with references to MRP

## 8. REGULATORY

- Formulate "Medical Device Regulatory Act"
- Designate regulatory bodies for Medical Devices

The above recommendation once implemented to provide a road map for promotion of domestic production of high end Medical

The CDP-PS is a Central Sector Scheme. The total size of the scheme is proposed as Rs.125 Crores for CDP-PS for 12th Five Year Plan.

2. The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant –in – aid to be released in various phases for creation of identified infrastructure and common facilities in the form of Common Facility Centers(CFC) to Special Purpose Vehicles (SPVs) set up for the purpose.
3. Assistance under the Scheme will be Rs. 20.00 Crore per cluster or 70% of the cost of the project, whichever is less for creation of common facilities. Some of the indicative activities under the Common facilities are:
  - Common Testing Facilities
  - Training Centre
  - Effluent Treatment Plant
  - R&D Centres
  - Common Logistics Centre





4. Projects and Development India Limited (PDIL) has been chosen as the Project Management Consulting (PMC) for implementing the scheme. They have called for EOI/SPV and in the first lot, out of the six EOIs, one was found suitable by the Scheme Selection Committee (SSC) to be located in Tamilnadu. SSC has requested PDIL to call fresh EOI which they have done and the last date of receipt of the EOIs is 31/12/2015.

### 7.3 NEW INITIATIVES TAKEN BY NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

1) Pharma Jan Samadhan (PJS), a web enabled system was developed by the NPPA with the assistance of National Informatics Centre (NIC). It was launched on 12<sup>th</sup> March 2015. It serves as a robust e-governance tool for protection of consumer interest through effective implementation of the DPCO, 2013. The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to availability of medicines, overpricing of medicines, sale of 'new drugs' without prior price approval and refusal of supply or sale of medicines without good and sufficient reasons.

Any individual or consumer organization or stockiest / distributor / dealer / retailer or State Drugs Controller can lodge a complaint online through the PJS portal. Action on the complaint received through PJS with complete information is initiated within 48 hours by the NPPA.

(b) Pharma Data Bank (PDB) - Integrated Pharmaceutical Database Management System (IPDMS): This was launched by the Hon'ble Minister for Chemicals and Fertilizers on 25<sup>th</sup> June, 2015. IPDMS has been developed by the NPPA in collaboration with the National Informatics Centre (NIC). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed in Form II, Form III and Form V of DPCO, 2013. Application for price approval of 'new drug' in Form-I can also be filed through this portal. Online submission of application under Form IV will be made available shortly. 508 pharma companies have registered under IPDMS till 30<sup>th</sup> October, 2015 while 455 companies are in the process of registration. Information regarding 37053 products has been registered by pharma companies whereas submission of information on 3,450 products is in process as on 30<sup>th</sup> October, 2015. PDB is expected to benefit industry, consumer and the regulator. It provides industry with a user friendly mechanism to comply with the mandatory requirement of filing returns; NPPA would be able to fix prices on the basis of price disclosure by companies and remove its dependency on private databases; and the consumer will be able to access price data with respect to each scheduled / non-scheduled formulation and take informed decision on cost-effective treatment. Retailers will also

have access to real time price data. It will also help NPPA to easily monitor price compliance.

(c) Price Monitoring and Resource units (PMRUs) – NPPA has initiated setting up of Price Monitoring and Resource Units (PMRUs) in States/Union Territories under the Central Sector Scheme of 'Consumer Awareness, Publicity and Price Monitoring' that would provide all necessary support to the State Drugs Controllers to discharge the monitoring and enforcement activities mandated under the DPCO, 2013. Each unit will function under direct supervision of the concerned State Drugs Controller. PMRUs will be the key collaborating partners of NPPA for information gathering; and to ensure that the benefits of DPCO, 2013 trickle down to the grassroots level. The scheme would be implemented initially for two years in seven states on pilot basis with central funding.

### 7.4 NATIONAL CENTRE FOR RESEARCH AND DEVELOPMENT IN BULK DRUG (NCRDBD) AT NIPER

A scheme on National Centre for Research and Development in Bulk Drug (NCRDBD) at NIPER, Hyderabad has been approved by the SFC. The NCRDBD is proposed to become an innovation R&D provider in the field of bulk drugs in offering competitive and eco-friendly technologies in specified areas of products and processes. This centre will also provide centralized research facilities and technologies, analytical facilities and consulting services for process improvement and optimization. Special emphasis is given to empowerment of Micro Small & Medium Enterprises (MSME) sector.

### 7.5 COLLABORATIVE TB AND KALA AZAR RESEARCH PROJECT OF NIPER, MOHALI

Target specific New Drug Discovery for Anti Tubercular Agents is an interdepartmental collaborative project which aims at discovering high affinity ligands that can be developed into efficacious and less toxic drugs against TB. Among other things, this proposal would use technique of post genomic era in identifying the role of specific gene in causing and counteracting diseases. Phase I of the project has duration of 3 years and Phase II of 2 years. The total cost of the project is Rs. 4,88,00,000/-.

The Kala Azar Project aims at discovering new drugs to fight against Kala-Azar. The focus of the Project is to putting together a concerted effort to discover high affinity ligands that can be developed into efficacious and less toxic drugs against Kala Azar. It also consists of two phases. Phase I of the project has duration of 3 years and phase II of 2 years. The cost of project is Rs. 4,88,00,000/-. The fund is to be released in four equal instalments of Rs.1.22 crore for each of these projects. The release of first and second instalment of Rs. 1.22 crore each for both the projects were made in 2014 and 2015 respectively.

# Chapter

# 8

IMPLEMENTATION OF RAJBHASHA







## CHAPTER 8

### IMPLEMENTATION OF RAJBHASHA

#### Use of Hindi in official work

Every possible effort was made for implementation of the various provisions of the Official Language Policy of the Union of India including those of Official Languages Act, 1963 as well as Official Languages (Use for Official Purposes of the Union) Rules, 1976 and orders issued thereunder. All the documents mentioned in Sub Section (3) of Section 3 of the Official Languages Act, 1963 were issued bilingually i.e. in Hindi as well as in English. Letters received in Hindi and representations etc. signed in Hindi were replied to in Hindi as per provisions of the Rule 5 and Rule 7(2) of the Official Languages (Use for Official Purposes of the Union) Rules, 1976 (as amended in 1987).

#### Hindi Prayog Protsahan Pakhwara, 2015

Hindi Prayog Protsahan Pakhwara was observed in the Department from 14<sup>th</sup> to 28<sup>th</sup> September, 2015 with the objective to encourage the officers and employees of the Department to progressively increase the use of Hindi in their official work and also to help the Department to create an atmosphere conducive to use of Hindi.

In addition to the message issued by the Secretary (Pharma) requesting, inter-alia, all the officers/employees to make a commitment to use of Hindi, various Hindi competitions were held during the Pakhwara in which officers/officials participated

in unprecedented numbers and made this programme successful. Winners were awarded with cash prizes and Commendation Certificates.



#### Review of the status of use of Hindi in the offices under the Department

Periodical review of the use of Hindi in the offices under the Department was made through the quarterly reports on progressive use of Hindi received from them in compliance with the targets set in the Annual Programme for use of Hindi for the year 2015-16,





# Chapter 9

GENERAL ADMINISTRATION  
9.1 Organisational Set Up







## CHAPTER – 9

### GENERAL ADMINISTRATION

#### 9.1 ORGANISATIONAL SET UP OF THE DEPARTMENT

The main activities of the Department are policy making, sectoral planning promotion and Development of Pharmaceutical industries. The administrative and managerial control of the public sector undertakings engaged in the manufacture of various, pharmaceutical items and some other organization is a major function of the Department.

2. The Department is headed by Secretary to the Government of India who is assisted by two Joint Secretaries one Economic Adviser.
3. There is an attached office namely “National Pharmaceutical Pricing Authority” which looks after Price fixation/revision of pharmaceuticals and other related matters. It also monitors the prices of decontrolled drugs and formulation and oversees the implementation of the provisions of the Drug (Price Control) Order.

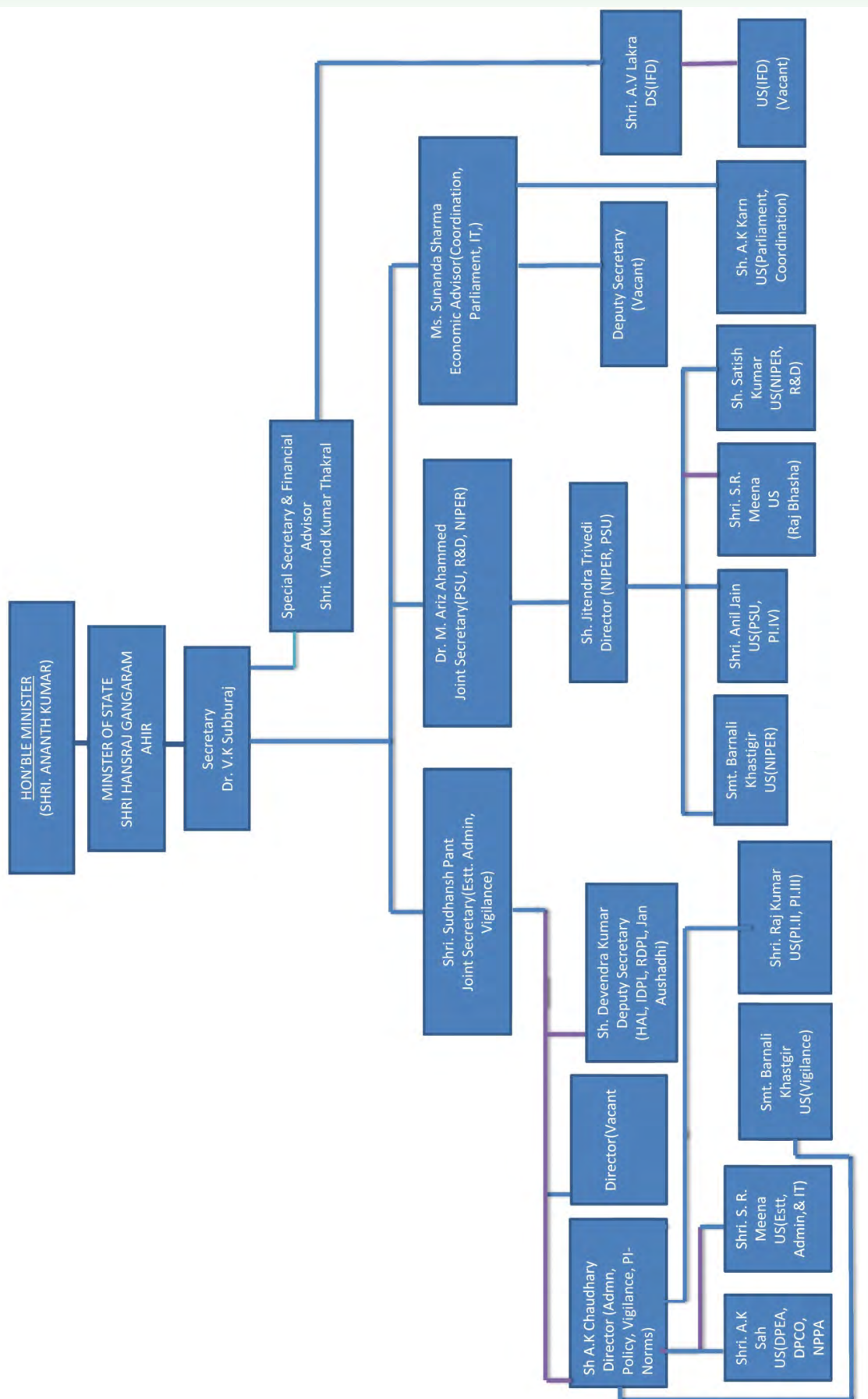
#### EMPLOYMENT OF SCHEDULED CASTES / SCHEDULED TRIBES / PHYSICALLY HANDICAPPED IN THE MAIN SECRETARIAT OF THE DEPARTMENT OF PHARMACEUTICALS

The status of employment of Scheduled Castes / Scheduled Tribes / Other Backward Classes / Physically handicapped in the main Secretariat of the Department of Pharmaceuticals, as on 31.12.2015 is as under:-

4. Officers in Group A include officers belonging to Central Secretariat Service besides officers on deputation from All India Services, Central Services and other Departments/ Undertakings. Appointment to posts in Group B and C is mostly done on the basis of nominations made by the Department of Personnel & Training.
5. The Department also monitors the progress of filling up of the posts reserved for the members of Scheduled Castes, Scheduled Tribes and other Backward Classes in the Public Sector Undertaking under the administration control of the Department.

Group	Total No. Of Posts	In position	Scheduled Castes	Scheduled Tribes	Other Backward Classes	Physically Handicapped
A	30	19	2	4	-	1
B	48	30	5	3	3	-
C	33	25	9	-	6	-
<b>Total</b>	<b>111</b>	<b>74</b>	<b>16</b>	<b>7</b>	<b>9</b>	<b>1</b>





# Chapter 10

## CITIZEN CENTRIC GOVERNANCE

- 10.1 Our Vision
- 10.2 Our Mission
- 10.3 Our Clients
- 10.4 Our Commitment
- 10.5 Our Services
- 10.6 Our Activities
- 10.7 RTI-2005
- 10.8 CPGRAMS







## CHAPTER – 10

### CITIZEN CENTRIC GOVERNANCE

#### 10.1 OUR VISION

Based on the mandate given to the Department of Pharmaceuticals through the allocated functions a vision has been fixed in concurrence with the Cabinet Secretariat, which is as follows:

“India: The largest global provider of quality medicines at reasonable prices.”

#### 10.2 OUR MISSION:

1. Ensure availability of quality drugs at reasonable prices as per the Pharma Policy.
2. Development of Pharma Infrastructure and Innovative Development in Pharma Sector including through PPP.
3. Promote Pharma Brand India.
4. Encourage environmentally sustainable development of Pharmaceutical Industry.
5. To establish NIPERs as nationally and internationally recognized brand in the field of education and research of pharmaceutical sciences for the benefit of human kind.

#### 10.3 OUR CLIENTS

- Citizens of India
- Pharmaceuticals Industry including Small and Medium Enterprises
- Pharmaceuticals companies seeking relief under DPCOs
- NPPA/ CPSUs/NIPERs

#### 10.4 OUR COMMITMENT

We are committed to provide impartial, sympathetic and prompt services to the public in matters relating to the pharmaceutical industries.

Our commitment is to take prompt steps to provide quick redressal of the grievances of our personnel and public at large.

Our commitment is to formulate policies and initiate consultations with all Industry Associations/stakeholders and to amend them whenever so required.

#### 10.5 OUR SERVICES

We formulate and implement policies relating to drugs and pharmaceuticals, dyestuff and dye intermediates.

#### 10.6 OUR ACTIVITIES

The key activities of the Department focus on:

1. Ensure availability of drugs at reasonable prices as per provisions of the Drug Prices Control Order 2013
2. Ensure proper functioning of the Central Pharma Undertakings in control of the Department.
3. Project Based Support and Revival Schemes for CPSUs
4. Ensure proper management of M Pharma and Ph.D. programs in NIPERs
5. Develop Human Resources, Infrastructure for Pharma R&D and Industry including Public-Private-Partnerships (PPP)
6. Formulate Scheme/ Project for promoting Pharma Brand India
7. Formulate Scheme/ Project for promoting environmentally sustainable development of Pharmaceutical Industry
8. Formulation of Annual Plan, Budget and Monitoring of Budget Expenditure

The Citizen Charter of the Department has been placed on the website of the Department.

#### 10.7 RIGHT TO INFORMATION ACT 2005

As per the provisions of the RTI Act 2005, all the relevant information relating to Department of Pharmaceuticals has been available on the web site in a manner, which is easily accessible and comprehensible to the public.

Central Public Information Officers and Appellate Authorities have been nominated in the department to provide information to the public.

#### 10.8 CPGRAMS (CENTRALIZED PUBLIC GRIEVANCES REDRESS AND MONITORING SYSTEM)

Public Grievances received offline and through CPGRAMS are monitored and disposed off regularly.





# Chapter 11

## INFORMATION AND COMMUNICATION TECHNOLOGY

- 11.1 Local Area Network (LAN)
- 11.2 Website and Social Media
- 11.3 Video Conferencing
- 11.4 Work Flow Automation
- 11.5 E-Governance
- 11.6 Training







## CHAPTER – 11

# INFORMATION AND COMMUNICATION TECHNOLOGY

Under Digital India program, Department of Pharmaceuticals has taken sincere initiatives towards adoption of E-Governance to deliver information and services online. This had led to benefits in terms of transparency, easy accessibility of services, improvement of internal processes and decision support system.

An IT based Computer Centre, set up by National Informatics Centre (NIC) is operational in the Department and is equipped with latest Servers and Client machines for providing various IT related services to the Department. NIC is delivering valuable key services like Technical consultancy, Networking, application development and implementation, Internet & E-Mail, database management and Training. With NIC's presence and expertise, Department had been instrumental in steering following IT/E-governance initiatives.

### 11.1 LOCAL AREA NETWORK (LAN)

All work places in the department are connected on Local Area Network (LAN) which is upgraded to make it IPv6 compliant is managed by the National Informatics Centre (NIC) to provide round the clock facilities for E-mail, intranet / internet and database access operations. The IPv6 compliant ICT hardware is available to all officers/ divisions/ sections for the use at their desktop.

### 11.2 WEBSITE AND SOCIAL MEDIA

A vibrant revamped Bilingual Web Site of department ie <http://pharmaceuticals.gov.in> was launched by the **Hon'ble Minister of State Shri Hansraj Gangaram Ahir** in September' 2015 and is hosted at NIC cloud to ensure security and maximum reach of information to the citizens. The website is developed by NIC using content management framework and is GIGW compliant. It provides details of organizational set up of the department, its functions, subordinate offices, policies, publications, statistical data/information on functional parameters.

Website for Jan Aushadhi Scheme of the Department <http://janaushadhi.gov.in> provides details of the scheme, list of generic medicines (unbranded) which are being dispensed through the Jan Aushadhi Stores (JAS) being setup in various districts of India. Website is revamped to facilitate the visitors to know the locations of the JAS already opened. It also provides comparative prices of Generic Medicines sold at Jan Aushadhi Stores and Branded Products.

Social media had enormous potential to reach people. To improve the quality of Government decision, policy making and create awareness, Dept. has created Facebook and Twitter accounts. Information regarding the conferences, Seminars, launches by Minister, MOS, Secretary and other officers of Dept. is posted on it promptly. Various posts to create awareness regarding generic medicines, Educational and Research institutes NIPERs, etc. also is posted on Facebook and twitter pages of Department.

### 11.3 VIDEO CONFERENCING

Video Conferencing facility is operational for Secretary. PSUs and Educational Institutes (NIPERs) have also installed the Video Conferencing facility. VC facility enables Department to interact with PSUs and NIPER frequently to monitor their performance and communicate the decisions. Pragati, Monitoring tool of PM office is conducted every month and Hon'ble PM interacts with all Secretaries and State CS to address issues which are long pending through Video Conferencing. Video Conferencing facility is also utilized for interacting with foreign delegates.

### 11.4 WORK FLOW AUTOMATION

Another initiative taken by Department towards Digital India is to implement automation of work flow inside the Department. eOffice is a standard product presently consists of e-File, e-Leave, e-Tour, Knowledge Management System (KMS), Personnel Information Management System (PIMS), Collaboration & Messaging Service (CAMS) and is aimed at increasing the usage of work flow and rule based file routing, quick search and retrieval of files and office orders, digital signatures for authentication, forms and reporting components. eOffice is being implemented to reduce duplicity of work, increases transparency and efficiency.

### 11.5 E-GOVERNANCE

Taking advantage of latest ICT enabled tools, Department of Pharmaceuticals with the support of NIC has taken sincere initiatives towards adoption of best practices. Various applications have been developed and implemented by NIC to strengthen, monitor and decision making and high availability of right information at right time.

- Aadhaar enabled Biometrics Attendance System (AEBAS) - Biometrics Attendance System records attendance of all employees (Permanent and Casual) of Department. Dept. of Pharmaceuticals has implemented AEBAS in the first phase and 17 finger reader devices are installed at offices of JS & above level officers and at all sections. Tablet devices are also installed at all gates of Bhawans to facilitate officials/staff to mark the attendance. 119 employees are registered and are marking the attendance regularly. Monthly register is generated for monitoring of attendance.
- SPARROW- Smart Performance Appraisal Report Recording online Window (SPARROW) application which allows Online submission of APAR and processing of IAS officers is implemented successfully.
- Parliament Questions and Assurances System – Repository of Parliament Questions and reminder system of Assurances is developed to facilitate Officials to keep record of all answered question and pending assurances.





- Visitor Management System - eVisitor System is a web based solution for Visitor Management. This facilitates citizens for online registration of requests for their visit and approval is given to authenticated visitors and gate pass is issued.
- Court Cases Monitoring System – This system is repository of all court cases of Department. It also keeps the track of forthcoming hearing dates of Cases and basic details of the case. It facilitates officials to generate useful reports.
- Online RTI-MIS – To dispose of and monitor RTI applications efficiently, Dept. has taken initiative to use Online RTI-MIS. Necessary training was imparted to concerned officials/staff to implement RTI-MIS successfully.
- CompDDO- CompDDO package implemented for processing salary of officials was upgraded to version 4.0 with additional features. This enables salary distribution through E-payment.
- Centralized Public Grievance Redress Monitoring System (CPGRAMS): CPGRAMS is implemented in the Department and all the attached office to address Public grievances received online with minimum delay.
- E-publishing of Tenders – E-publishing of tenders is implemented by uploading tenders on Central Public Procurement Portal. It has improved the accessibility of tenders.
- Other e-Governance applications like RTI Request & Appeal Management Information System, e-Samiksha, Pragati and

Foreign Visit Management System are functional in the Department to facilitate various sections.

To enhance e-Governance further following initiatives has been taken up.

- PSEs Performance Monitoring System- Performance of Public Sector Enterprises is to be monitored by Department and for the purpose; a web based application is under development to ensure monitoring and facilitate the top level officers in decisions making.
- Store Inventory System – Store Inventory System is being customised for implementation in the department. It will facilitate online issuance of items to employees and keep records of store and inventory.

### 11.6 TRAINING

NIC Computer Cell organises User Training for operational know how and awareness program to keep user well aware of use of latest IT technologies. Under Digital India Program, above said applications were implemented and training was imparted as when required. Training on e-Office is being imparted to all officers/staff (including JS level officials) of the department. All employees (including outsourced) were sensitized about operations of Aadhaar enabled Biometrics Attendance System (AEBAS). Concerned sections were trained on e-Samiksha, CPGRAMs, CompDDO, E-publishing, Court Cases Monitoring System. Training on Sparrow S/w is imparted to all IAS officials.

# Chapter 12

## ANNEXURE

Annexure – I [A] List of PSUs and Other Organizations

Annexure – I [B] Address and Name of various Organizations & PSUs

Annexure – I [C] List of Responsibility Centers and Subordinate Organizations

Annexure – II Organizational Chart of NPPA

Annexure – III Citizen's Charter for Deptt. of Pharmaceuticals- 2015-16







## CHAPTER –12

### ANNEXURE 1 [A]

#### List of Public Sector Undertakings

1. Indian Drugs & Pharmaceuticals Ltd, Dundahera Industrial Complex, Dundahera, Gurgaon, Haryana.
2. Hindustan Antibiotics Ltd, Pimpri, Pune, Maharashtra-411010
3. Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore-700013.
4. Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal-700013
5. Rajasthan Drugs and Pharmaceuticals Limited. Road NO.12, V.K.I. Area, Jaipur-302013.

#### OTHER ORGANISATIONS

1. Bengal Immunity Limited, Kolkata, West Bengal.
2. Smith Stanistreet Pharmaceuticals Ltd. Kolkata, West Bengal.





## ANNEXURE 1 [B]

### Address and Names of Head of various Organization & PSUs under the Department of Pharmaceuticals

Sl. No.	Address and Organization	Name	Designation
1.	Indian Drugs & Pharmaceuticals Limited (IDPL), Gurgaon	Shri Praveen Kumar	Chairperson & Managing Director
2.	Hindustan Antibiotics Limited (HAL), Pune-411010	Shri K.V. Varkey	Managing Director
3.	Karnataka Antibiotics & Pharmaceuticals Limited (KALP), Bangalore-700013	Shri K.M. Prasad	Managing Director
4.	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata-700013	Shri E.A. Subramanian	Managing Director
5.	Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Road No. 12 V.K.I Area Jaipur-302013	Shri S.B.Bhadrannavar	Managing Director



## ANNEXURE 1 [C]

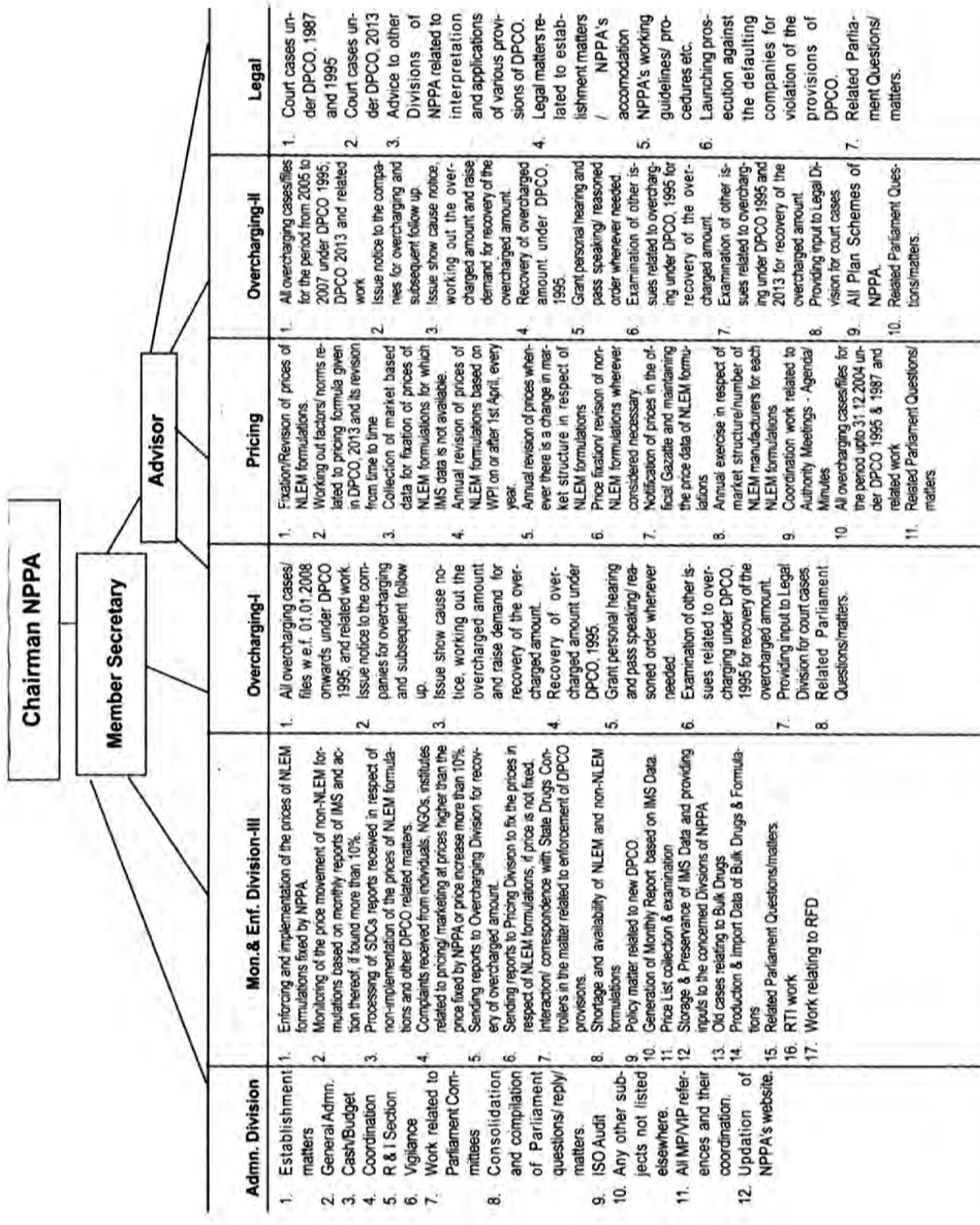
### List of Responsibility Centers and Subordinate Organizations

S. no.	Responsibility Centers and Subordinate	Landline Number	Email	Mobile Number	Address
1	Dr. K. K. Bhutani, (Officiating Director)	0172-2214690	director@niper.ac.in	09417203802	SAS Nagar, NIPER Mohali, Punjab - 160062
2	Dr. Kiran Kalia, (Director)	079-27439375	kirankalia@gmail.com	09824335881	B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre, Sarkhej Gandhinagar Highway, Thaltej, Ahmedabad-380054
3	Dr. Ahmed Kamal, (Project Director)	04057193157	projectdirector@niperhyd. ac.in	09440802784	NIPER, Hyderabad IDPL Township, Balangar, Hyderabad-500007
4	Dr. Pradeep Das, (Project Director)	0612-2636651	drpradeep.das@gmail. com	09431012380	Rajendra Memorial Research Institute of Medical Science (RMRIMS), Agam Kuan Patna-800 007 (BIHAR)
5	Dr. Chitra Mandal, (Project Director)	03324735368	Chitra_mandal@yahoo.com	09831036984	Indian Institute of Chemical Biology (IICB, under CSIR), Mentor Institute for NIPER, Kolkata 4, Raja S.C. Mullick Road, Jadavpur, KOLKATA- 700 032 (W.B.)
6	Prof (Dr) B.K. Bezbaruah (Project Director)	03612132751	niperghy@gmail.com	09864066772	NIPER Guwahati, Guwahati Medical College & Hospital Guwahati-781032
7	Dr. P Shukla	05223290093	pk_shukla@cdri.res.in	09335866066	NIPER Raebareli, Central Drug Research Institute Chatter Manzil P.O. Box 173, Lucknow-226001



# ANNEXURE – II

## Organisational Chart of NPPA





## ANNEXURE – III

### CITIZEN'S CHARTER FOR DEPTT. OF PHARMACEUTICALS- 2015-16

#### MANDATE

Give greater focus and thrust on the development of pharmaceuticals sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceuticals sector.

#### VISION AND MISSION

##### VISION

India: The Largest Global Provider of Quality Medicines at Reasonable Prices.

##### MISSION

1. Ensure availability of quality drugs at reasonable prices as per the Pharma Policy.
2. Development of Pharma Infrastructure and Innovative Development in Pharma Sector including through PPP.
3. Promote Pharma Brand India
4. Encourage environmentally sustainable development of Pharmaceutical Industry
5. To establish NIPERs as nationally and internationally recognized brand in the field of education and research of pharmaceutical sciences for the benefit of human kind.

#### SERVICES

Sl. No.	Services	Service Standard
1.	Adjudicating Review cases under DPCOs	Disposal within 90 days of the personal hearing of the review application
2.	Release of financial assistance to NPPA	Within 60 days of the receipt of the complete proposal from NPPA.
3.	Timely response to Grievances received on CPGRAMS	Initial Scrutiny and forwarding the application to the concerned officer/division in 5 days and final disposal in 60 days.

#### Grievance Redress Mechanism

Website url to Lodge Grievance <http://pgportal.gov.in>

Sl. No.	Name of the Public Grievance Officer	Helpline Number	Email	Phone Number
1.	Shri Devendra Kumar (Deputy Secretary), Nodal Officer	23389840	devendra[dot]kumar08[at]nic[dot]in	011-23389840

#### CONTACTS

Sl.No	Name	Designation	Phone	E-mail
1.	Dr. V.K. Subburaj	Secretary	011-23381573	subburaj[at]iasnic[dot]in
2.	Shri Sudhansh Pant	Joint Secretary	011-23385131	js[dot]pharma[at]nic[dot]in
3.	Dr. M. Ariz Ahammed	Joint Secretary	011-23074010	ariz[at]gov[dot]in
4.	Ms. Sunanda Sharma	Economic Advisor	011-23063341	sunanda[dot]sharma[at]nic[dot]in
5.	Shri R.K. Maggo	Director (Estt. & PSU)	011-23752664	rk[dot]maggo[at]nic[dot]in
6.	Shri Devendra Kumar	Dy. Secretary (Parl., Coord. etc. )	011-23389840	devendra[dot]kumar08[at]nic[dot]in





Sl.No	Name	Designation	Phone	E-mail
7.	Shri A.V. Lakra	Dy. Secretary (IFD)	011-23313431	ashim[dot]lakra64[at]nic[dot]in
9.	Shri A.K. Karn	US ( Parl., Coord. etc)	011-23782861	ak[dot]karan[at]nic[dot]in
10.	Shri S.R. Meena	US (Estt. & Admn)	011-23382096	sr[dot]meena65[at]nic[dot]in
11.	Shri Anil Jain	US (PSU)	011-23073048	anil[dot]j[at]nic[dot]in
12.	Shri Raj Kumar	US (PI-I and PI-II)	011-23071162	uspi3-pharma[at]nic[dot]in
13.	Ms. Barnali Khastigir	US (Vig., Niper)	011-23071162	barn[dot]khast[at]nic[dot]in
14.	Shri Ajit Kumar Sah	US (PI-I)	011-23323292	ak[dot]sah71[at]nic[dot]in

## INDICATIVE EXPECTATION FROM SERVICE RECIPIENTS

S.No.	Indicative Expectation from Service Recipients
1.	Please show courtesy to the Ministry Officers.
2.	State the requests/grievances clearly.
3.	Enclose documents required for review under DPCOs.
4.	Submission of proposals for release of funds enclosing relevant documents.



Government of India  
Ministry of Chemicals & Fertilizers  
**DEPARTMENT OF PHARMACEUTICALS**