



Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals



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#### 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) Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector.
- Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.
- 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.
- 5) Promotion of public private partnership in pharmaceutical related areas.
- 6) International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.

- 7) 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.
- 8) Technical support for dealing with national hazards in pharmaceutical sector.
- All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/ monitoring.
- 10) All matters relating to National Institutes for Pharmaceuticals Education and Research.
- 11) Planning, development and control of; and assistance to, all industries dealt with by the Department.
- 12) Bengal Chemicals and Pharmaceuticals Limited.
- 13) Hindustan Antibiotics Limited & its subsidiaries as & JVs.
- 14) Indian Drugs and Pharmaceuticals Limited & its subsidiaries
- 15) Karnataka Antibiotics and Pharmaceuticals Limited.
- 16) Rajasthan Drugs and Pharmaceuticals Limited.
- 17) Bengal Immunity Limited.
- 18) Smith Stainstreet Pharmaceuticals Limited.

The work of the Department has been divided into three Divisions viz. Pharmaceuticals 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 Secretary who holds charge of this Department w.e.f 01.10.2014.

Sanda III

Chapter

#### AN OVERVIEW OF PHARMACEUTICALS INDUSTRY

- 2.1 Financial Performance of the Drugs and Pharmaceuticals Industry
- 2.2 Imports
- 2.3 Exports
- 2.4 Pharma Export Promotion Council (Pharmexcil)
- 2.5 International Cooperation/Export Promotion of Pharmaceuticals
- 2.6 Proposed Major areas of International Cooperation
- 2.7 India Pharma Summit 2015
- 2.8 Pharmaceutical Promotion Development Scheme (PPDS)
- 2.9 Workshops for Capacity Building of Pharma Industry and Regulation



## CHAPTER - 2 AN OVERVIEW OF THE PHARMACEUTICALS INDUSTRY

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

The financial performance of the Drugs and Pharmaceuticals Industry for the years 2011-12 to 2013-14 and the quarterly performance during the year 2014-15 (up to September 2014) are given in the table 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. income. In the September 2014 quarter, operating expenses of the industry increased by 6.5 %. Among operating expenses, raw material expenses (major cost head of the industry) increased by 8.4% and wage bill by 13.9%. Even though the industry did not perform well at the operating level, its PAT increased by 17.8% in the September 2014 quarter. This was possible due to a sharp rise in other income and fall in interest expenses.

#### Drugs and Pharmaceuticals: Growth and Profitability in the Year 2014-15

(% change over year ago)

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No.	Particulars		Quarterly		Annual			
		March'14	June'14	Sept.'14	2011-12	2012-13	2013-14	
1	Net Sales	14.07	18.38	4.58	16.20	9.82	12.71	
2	Total expenses	13.34	11.11	8.07	16.70	5.38	15.62	
3	Raw Materials, Stores & spares	10.90	3.62	5.84	11.05	4.04	8.91	
4	Salaries & Wages/ Compensation	15.74	13.63	13.97	17.65	15.76	14.97	
5	Power & fuel	5.95	-2.03	7.93	19.96	20.35	4.62	
6	Depreciation	8.34	27.95	30.62	13.66	10.21	16.44	
7	Interest expenses	20.13	-9.31	-18.20	23.91	23.82	12.51	
8	Direct Tax provision	23.19	77.78	12.48	-52.14	36.61	40.31	
9	PBDIT net of P&E	29.04	93.14	-0.41	14.21	9.09	17.83	
10	PAT net of P&E	84.64	308.75	17.82	-2.31	25.93	45.39	
11	PBDIT net of P&E as % of Net Sales	17.81	23.21	16.98	18.19	18.12	19.30	
12	No. of Companies data -count	153	152	151	371	290	199	

Source: Centre for Monitoring Indian Economy (CMIE) Pvt Ltd data as on February 13,2015.

The net sales of the Drugs & Pharmaceuticals Industry registered a y-o-y growth of 16.20%, 9.82% and 12.71 % respectively during the years 2011-12 to 2013-14, for the selected sample of companies, as per CMIE data. Net sales of the industry grew by 14.07 % in the March 2014 quarter and 18.38 % in the June 2014 quarter. In the September 2014 quarter, sales growth witnessed a deceleration, when net sales grew by merely 4.6% y-o-y. The industry had clocked sales growth of 9-19 % during the preceding three quarters.

The Profit after Tax (PAT) net of prior period and extraordinary items grew by 84.64 % in the March 2014 quarter, 308.75% in the June 2014 quarter and by 17.82 % in the September 2014 quarter as compared to the corresponding period last year. The increased growth in profits in June 2014 quarter was on account of strong sales growth, control over operating costs and rise in other

#### 2.2 IMPORTS

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

Year	Import of Medicines & Pharmaceuticals Products (Rupees in Crore)
2011-12	14287.66
2012-13	16965.09
2013-14	17944.05

Source: Industryoutlook.cmie.com

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. Manufacturers of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.



Imports of Drugs and Pharmaceuticals is done as per Foreign Trade Policy. However, import of some drugs and drug intermediates is still restricted under current Foreign Trade Policy. Imports which are restricted are basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS).

#### 2.3 EXPORTS

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

Year	Exports of Medicines & Pharmaceuticals Products (Rs. in Crore)
2011-12	544906.73
2012-13	602016.70
2013-14	690236.77

Source: Industryoutlook.cmie.com

## INTERNATIONAL COOPERATION/ EXPORT PROMOTION OF PHARMACEUTICALS

An important focus area for the Department of Pharmaceuticals is promotion of Indian Pharmaceutical Products in global market. The Department participated in the following International Cooperation events during 2014-2015:-

- (i) 11<sup>th</sup> India-Kazakhstan Inter-Governmental Commission (IGC) on Trade, Economic, Scientific, Technological, Industrial and Cultural Cooperation between India and Kazakhstan was held on 24-25 April, 2014 at Astana under the Chairmanship of Secretary (P&NG).
- (ii) 5<sup>th</sup> Joint Commission Meeting (JCM) between India and Surinam held on 13<sup>th</sup> January, 2015 at New Delhi.
- (iii) Second meeting of India-Vietnam Joint Sub-Commission on Trade and related issues held under the Co-chairmanship of Commerce Secretary on 19<sup>th</sup>-22<sup>nd</sup> January, 2015 at Hanoi, Vietnam.
- (iv) Meeting of India-US High Technology Cooperation Group (HTCG) and G2G Working Group on Biotechnology and Life Science under India-US High Technology Cooperation Group (HTCG) was held on 20<sup>th</sup> and 21<sup>st</sup> November, 2014 at New Delhi.

#### 2.4 PHARMA EXPORT PROMOTION COUNCIL (PHARMEXCIL)

The Department had played a pivotal role in the formation of Pharmexcil consequent to the recommendation from 9th Five Year Plan Working Group Report on Drugs and Pharmaceuticals. In the light of this, the Department constantly interacts with Pharmexcil in their work areas. The role of Pharmexcil is for facilitation of exports of Drugs, Pharmaceuticals, Biotechnology products, Herbal medicines and Diagnostics, to name a few. It is authorized to issue Registration-cum-Membership Certificate (RCMC) which is one of the requirements for the importers and exporters of commodities. In addition to this, Pharmexcil is concerned with giving export thrust to the various products through visits of delegations to various markets abroad, organizing of seminars, workshops and exhibitions. As a major area of work, Pharmexcil also holds Buyers/ Sellers meets and compiles detailed data base on pharma exports and problems in exporting pharma products.

#### 2.5 GRANT-IN-AID

The Department of Pharmaceuticals also provided financial assistance for the following activities/events for promotion and development of Pharma sector from Pharmaceuticals Promotion Development Scheme (PPDS) during Financial Year – 2014-15:-

- Grant in aid to M/s MITCON Consultancy & Engineering Services Ltd, Pune for conducting 'Evaluation Study' on Working of 'Pharmaceutical Promotion and Development Scheme' during 11<sup>th</sup> Five Year Plan period
- 2. Grant in aid to Centre for Monitoring Indian Economy for subscribing CMIE products 2014-15
- 3. Grant in aid to IIDM for conducting Evaluation study of creation of IPR facilitation Centre
- Grant in aid to Biogenesis Health Cluster in connection with World Congress of Gerontology and Geriatrics 3<sup>rd</sup> International Conference on Healthy Ageing in the Changing World 2014 & Conference on Women and Girl Child for Social and Economic Equality 2014
- 5. Grant in aid to CII in connection with 12<sup>th</sup> National Pharmaceutical Conclave held on 12-13 December, 2014 at New Delhi
- 6. Grant in aid to NIPER, Guwahati in connection with Pharma Conference at Guwahati
- 7. Grant in aid to NIPER Mohali in connection with Academia Industry Business Meet
- Grant in aid to FICCI for conducting Workshop at Chennai, Mumbai, Bangalore, Indore and Gandhinagar/ Ernakulam on Capacity Building for Phama Industry
- Grant in aid to Pharmexcil for conducting Seminar on Export opportunities in Pharmaceutical in Uzbekistan and Peru at Mumbai
- 10. Grant in aid to PHD Chamber for 3<sup>rd</sup> Annual Conference on Pharma Med 2014
- 11. Grant in aid to FABA for organizing BioAsia 2015: New Era of Life Sciences Opportunities in Transition
- 12. Grant in aid to World Ayurveda for organizing Sixth world Ayurveda Conference at Arogya 2014
- 13. Grant in aid to ASSOCHAM for organizing 3<sup>rd</sup> National Conference on 'Waste to Wealth: The action Agenda'
- 14. Grant in aid to NIPER Hyderabad for organizing National Conference/Workshop at Nipper Hyderabad

#### 2.6 PROPOSED MAJOR AREA OF INTERNATIONAL COOPERATION

 Pharmexcil has organized the Seminar on Export Opportunities of Pharmaceuticals products in Latin American Countries (LAC) on 10<sup>th</sup> February 2015 in Mumbai and another seminar on Export opportunities in Pharmaceuticals in Uzbekistan is also proposed to be organized by Pharmexcil in March, 2015.

- India-EU Joint Working Group (JWG) on Pharmaceuticals was constituted under the aegis of the India-EU Sub-commission on Economic Cooperation for which Department of Commerce is the nodal Department. This JWG is co-chaired by the Joint Secretary, Department of Pharmaceuticals from the Indian side and there are representatives from other concerned Departments. 6<sup>th</sup> Meeting of India-EU Joint Working Group on Pharmaceuticals, Biotechnology and Medical Devices is proposed at New Delhi on 30<sup>th</sup> April and 1<sup>st</sup> May, 2015.
- 6<sup>th</sup> meeting of the India-Tunisia Joint Working Group on Drugs and Pharmaceuticals under the aegis of the Indo-Tunisian Joint Commission is proposed to be held in February-March, 2015 at Tunis, Tunisia.

#### 2.7 INDIA PHARMA SUMMIT 2015

Department of Pharmaceuticals is going to organize 6<sup>th</sup> India Pharma Summit 2014-2015 on 23<sup>rd</sup> March, 2015at Mumbai in association with Federation of Indian Chamber of Commerce and Industry (FICCI) and WHO India. The theme for this year's deliberations is – "Policy Landscape Reforms for Strengthening Indian Pharmaceuticals Industry".

#### 2.8 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,



- 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?
  - c) Success Story Presentation-Pharmaceutical Entrepreneur
  - d) Government regulations/guidelines for clinical trials in India versus USA, EU etc.
  - e) Waste Management
- 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 ets.
- 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.

#### 2.9 WORKSHOPS FOR CAPACITY BUILDING OF PHARMA INDUSTRY FOR COMPLIANCE TO WHO GMP STANDARD

Department of Pharmaceuticals in association with Federation of Indian Chamber of Commerce and Industry (FICCI) and WHO is organizing the workshops on Capacity Building of SME's in strengthening quality management systems and best practices for the process improvements, global regulatory requirements and compliance, including WHO GMP requirements of Pharma Industry and Regulation at Bengaluru, Chennai, Gandhinagar, Indore and Mumbai.

Sanda III



# Chapter

PHARMACEUTICAL INDUSTRY-OTHER ACTIVITIES

- 3.1 Pharmaceuticals Industry
- 3.2 Creation of IPR Facilitation Centers in Pharmexcil
- 3.3 Pharmaceuticals Policy
- 3.4 Foreign Direct Investment in PharmaceuticalsSector





## CHAPTER – 3 PHARMACEUTICAL INDUSTRY

#### 3.1 PHARMACEUTICALS INDUSTRY-OTHER ACTIVITIES

The annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 128044.29<sup>1</sup>Crores during the year 2013-14. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is Rs. 63293.91<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 chemicals' 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(SHE) 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 Indian companies are now seeking regulatory approvals in USA in specialized segments like Anti-infectives, Cardiovasculars, CNS group. Along with Brazil & PR 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.

#### <sup>1</sup> Source CMIE (Industry Outlook)

#### 3.2 CREATION OF IPR FACILITATION CENTRES IN PHARMEXIL

After appraising the working of IPR Facilitation Centre Scheme during 11<sup>th</sup> Five Year Plan (2007-2012), the Scheme has been revised with following three components with a total plan outlay of Rs. 5 Crore during 12<sup>th</sup> Five Year Plan:

(A) AWARENESS/SENSITIZATION PROGRAMME ON IPR

This programme is for granting financial assistance of upto Rs. 1 lakh for organizing sensitization programmes to equip the Pharma Industries to effectively use IP as part of their business strategy. It will result in increasing awareness and understanding of IP issues within the Pharma business community, particularly through awareness raising campaigns and targeted training programs. Optimal use of modern information and communication technologies, will help so as to enhance the capacity of Pharma Industry to maximize their benefits form the use of the IP systems.

(B) INTERACTIVE SEMINARS/WORKSHOPS

This programme/scheme is for granting financial assistance of upto Rs. 2 lakhs to organize seminars/workshops which will provide a forum to pharma Industry Associations and other stakeholders, including professionals having working experience of the sector to share knowledge, experience and create mass awareness on various aspects of IPR.

(C) ASSISTANCE FOR SETTING UP OF IPR FACILITATION CENTRE FOR PHARMACEUTICALS

The primary objective is setting up of IP Facilitation Centres near the Pharma Clusters to provide the IPR related services primarily to Medium and Small Pharmaceutical manufacturers. In the remaining period of the 12<sup>th</sup> Five Year Plan, the scheme will focus on creating additional IPR Facilitation Centres at Ahmedabad and Chandigarh (Mohali) and the existing IPR Facilitation Centres at Hyderabad managed by Pharmexcil will be supported. The scheme provides for Rs. 75 lakh as one time grant and Rs. 23 lakh as recurring expenses for three years for a single IPR facilitation centre and a provision of Rs. 2.00 lakh towards contingencies and other miscellaneous charges.

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#### 3.3 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:

<sup>&</sup>lt;sup>2</sup> Source CMIE (Industry Outlook)



- 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, have 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).

#### 3.4 FOREIGN DIRECT INVESTMENT IN PHARMACEUTICAL SECTOR

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 at present 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 'noncompete' clause is not allowed except in special circumstances with the approval of the Foreign Investment Promotion Board (FIPB). Also, FDI upto 100% through automatic route for manufacturing of medical devices has been allowed.



## Chapter

NATIONAL PHARMACEUTICAL PRICING AUTHORITY 4.1 NPPA 4.2 Drug Price Equalization Account (DPEA)





## CHAPTER 4 NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

**4.1** NPPA The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizer 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 drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers.

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

Salient features of DPCO, 2013.

- Drug formulations listed under the National List of Essential Medicines under price control.
- Ceiling price calculations are based on "market based data" as opposed to cost based under DPCO, 1995.
- Controls only drug formulation price as opposed to both bulk drugs and their formulations under DPCO, 1995.

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

- To implement and enforce the provisions of the Drugs (Prices Control) Order (DPCO), 1995 / 2013 in accordance with powers delegated to it.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- (iii) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- (iv) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- (v) To deal with all legal matters arising out of the decisions of the Authority.
- (vi) To render advice to the Central Government of changes/ revisions in the drug policy.
- (vii) To render assistance to the Central Government in parliamentary matters relating to drug pricing.

The organizational structure of NPPA is given as per Annexure II :

#### **Price Fixation :**

Under the provisions of the Drugs (Price Control) Order, 2013, the prices of scheduled formulations which are based on National List of Essential Medicines (NLEM)-2011 issued by the Ministry of Health and Family Welfare are to be fixed based on market based data. No one is permitted to sell any scheduled drug / formulation at a price higher than the ceiling price fixed by NPPA/Government.

NPPA has fixed the ceiling prices of 509 formulation packs under DPCO, 2013. NPPA is in the process of collecting market based information for fixing the prices of remaining formulations.

Out of NLEM-2011, NPPA has fixed the ceiling prices of 509 formulations packs under DPCO, 2013. Status on the progress on pricing under DPCO, 2013 is given as under :

#### Pricing Status as on 31.12.2014

SI. 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 upto19th Authority Meeting (held on 10.12.2014)	509	
5.	Ceiling price fixation pending due to non- availability of Market based price data	102	
6.	Common items under DPCO, 1995 and DPCO, 2013 for which price notification is due in April, 2015.	17	
	Total = (4)+(5)+(6)		628

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

S. No.	% reduction with respect to Maximum PTR	No. of drugs
1.	0<= 5%	52
2.	5<=10%	45
3.	10<=15%	56
4.	15<=20%	44
5.	20<=25%	66
6.	25<=30%	55
7.	30<=35%	30
8.	35<=40%	34
9.	Above 40%	127
	TOTAL	509

The prices are notified through Gazette Notifications which are also uploaded on NPPA's website at www.nppaindia.nic.in.

NPPA has also notified 139 retail price of new drugs on request of the manufacturers till 31st December, 2014.

As per the provisions of DPCO, 2013, no person shall sell the scheduled formulations at prices higher than the ceiling price (plus



local taxes as and wherever applicable) so fixed and notified by the Government.

#### **Monitoring and Enforcement :**

The prices of medicines which are not covered in the Schedule - I of DPCO, 2013 are also monitored by NPPA. As provided in the DPCO, 2013, no manufacturer shall increase the maximum retail price of a non-scheduled drug more than ten percent of maximum retail price during preceding twelve months. Wherever the increase is beyond ten percent of maximum retail price, NPPA is empowered to reduce price to the level of ten percent of maximum retail price for next twelve months. The manufacturer shall be liable to deposit the Overcharged amount, if any, along with interest thereon from the date of increase in price in addition to the penalty. However, there is no control on the launch price of non-scheduled medicines. Concerned manufacturer of such medicines fix the launch price themselves.

NPPA is also empowered, in case of extra-ordinary circumstances, if it considers necessary so to do 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, the 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 108 non-scheduled anti-diabetic and cardio vascular medicines under paragraph 19 of Drug Price Control Order, 2013 on 10.7.2014 based on the internal guideline issued by the NPPA on 29.05.2014. Although the said internal guideline of the NPPA has been withdrawn with effect from 22.09.2014 but the concerned notification for price fixation of the said non-scheduled medicines continue to be in force.

A separate Enforcement Division was created during the year 2007-08 to facilitate suo-moto detection of violations of DPCO, 1995 with the following objectives:

- (i) Market Surveillance of prices of scheduled drugs;
  - m Purchase of samples by NPPA officers all over India to ensure compliance; and
  - m Examine complaints by individuals / NGOs/VIP references.
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- (ii) Based on the analysis, specific cases are identified for
  - m Recovery of overcharged amounts; and
  - m Fixation of prices, wherever required.

NPPA is also entrusted with the job of monitoring the availability of drugs and to identity shortages, if any, and to take remedial steps to make the drugs available. NPPA is carrying out this responsibility mainly through the State Drugs Controllers and other available information. As and when the reports for shortages of particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock and to make the drugs available.

The achievements from 2007-08 to 2014-15 (upto Dec., 2014) are given as under:

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging	Identified for Price fixation Para 8(6) violation
2007-2008	1450	840	456	384
2008-2009	520	284	172	112
2009-2010	464	246	208	38
2010-2011	553	225	216	9
2011-2012	559	156	152	4
2012-2013	626	165	163	2
2013-2014	993	389	389	0
2014-2015 *	993	290	290	0

\*125 cases under process on 05.01.2015



#### **Recovery of Overcharged amount:**

Since inception of NPPA, there are 1108 cases as on 31.12.2014 (1079 cases under DPCO 1995 & 29 cases under DPCO 2013) where demand notices have been issued by NPPA to Pharmaceutical companies amounting to Rs.4030.22 crore (Rs.3897.77 crore under DPCO 1995 & Rs.132.45 crore under DPCO 2013) for selling their medicines at prices higher than the price fixed by NPPA / Govt. of which Rs.344.75 crore (Rs.290.17 crore under DPCO 1995 & Rs.54.58 crore under DPCO 2013) has been recovered till 31.12.2014 leaving a balance of Rs.3685.47 crore (Rs.3607.60 crore under DPCO 1995 & Rs.77.87 crore under DPCO 2013). Out of the balance amount of Rs.3685.47 crore, Rs.3469.20 crore (Rs.3467.01 crore including cases in r/o M/s Cipla Ltd. & its associate companies wherein no coercive action can be taken in pursuance of the order of Supreme Court of India under DPCO 1995 & Rs.2.20 crore under DPCO 2013) is pending in various High Courts & Supreme Court, Rs.50.59 crore is pending for recovery with Collectors of various States under DPCO 1995, Rs.5.05 crore is pending with BIFR / Official liquidators under DPCO 1995 & Rs.160.63 crore (Rs.84.95 crore under DPCO 1995 & Rs.75.68 crore under DPCO 2013) is under process.

Action for recovery of the overcharged amount alongwith interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO'1995/ DPCO'2013 read with EC Act 1955. The recovery of the overcharged amount is affected due to Court orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order / notification issued by NPPA / Government under DPCO 1995. Inclusion of some Bulk Drugs under Price Control (schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different courts of India. NPPA / Government is defending such cases through SG, ASG's and Senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early Hearing / disposal of the case.

The Status of cases of overcharging under DPCO 1995/DPCO, 2013 since inception of NPPA till December 2014.

(Amount in Rs. crore)

SI. No.	Particulars	Aug 1997 to March 2006	2006-2007	2007- 2008	2008- 2009	2009- 2010	2010- 2011	2011- 2012	2012- 2013	2013-2	014	2014-2	015	Cumulative (Aug, 97 to
		2006								DPCO, 1995	DPCO, 2013	DPCO, 1995	DPCO, 2013	December, 2014)
1.	No. of cases	334	67	116	134	88	42	40	103	88	2	67	27	1108
2.	Overcharged amount demanded including interest whenever updated	1883.38	48.4	366.57	337.71	69.99	106.84	58.57	128.76	383.22	0.00	514.33	132.45	4030.22
3.	Total amount realised till date against the demand raised during the year	141	0.8	17.76	31.74	23.24	20.27	8.82	9.46	34.69	0.02	2.39	54.56	344.75
4.	Amount outstanding	1742.38	47.60	348.81	305.97	46.75	86.57	49.75	119.30	348.53	-0.02	511.94	77.89	3685.47
5.	Amount still under litigation including cases referred to collector and contested by the companies in the court of law	-			-		-		-	-		3467.01	2.19	3469.2
6.	Cases referred to collector & amount still to be recovered											50.69	0.00	50.59
7.	Pending with BIFR/ Official Liquidator											5.05	0.00	5.05
8.	Amount pending relating to the overcharging cases under process											84.95	75.68	160.63



## ACHIEVEMENTS FOR THE PERIOD JUNE, 2014 TO DECEMBER, 2014 IN RESPECT OF NPPA

#### Pricing

Since May, 2014, prices of 69 more scheduled drugs have been notified bringing the total number of scheduled drugs where prices have been notified to 509. A statement showing reduction in price of formulations with respect to Highest PTR of NLEM formulations (From May to December, 2014) as a result of pricing exercise of NPPA for these 69 scheduled drugs is given below:

S. No.	% reduction with respect to Maximum PTR	Formulations
1.	0<= 5%	14
2.	5<=10%	4
3.	10<=15%	9
4.	15<=20%	4
5.	20<=25%	5
6.	25<=30%	11
7.	30<=35%	5
8.	35<=40%	0
9.	Above 40%	17
	Total	69

In addition to above, NPPA has fixed the prices of 106 nonscheduled formulations on 10.9.2014 under Para 19 of DPCO, 2013. Out of 106 non-scheduled formulations, 22 are of diabetic formulations and remaining 84 are cardio-vascular formulations. The price benefit likely to accrue to the common man is estimated to be close to Rs. 350 crores per annum.

Since May 2014, NPPA has notified prices of 251 formulations (i.e., 69 Ceiling Prices, 76 Retail Prices and 106 prices of Non-Scheduled formulations) under DPCO 2013 which has resulted into an estimated benefit of Rs. 558 crore to the end consumers. These formulations/drugs are used in cancer, diabetes, HIV, AIDS, heart diseases, etc.

#### **New Drugs**

Since May 2014 NPPA has also notified retail price of 76 new drug formulations on request of the manufacturers/marketing companies as per DPCO 2013.

#### Monitoring

From June, 2014 to December, 2014, 592 cases of overcharging were identified. They are being processed further for recovering the overcharged amount from the pharma companies.

#### Overcharging

NPPA has issued 76 demand notices for Rs.431.90 crore (Rs.352.99 crore under DPCO 1995 & Rs.78.91 crore under DPCO 2013) consisting of overcharged amount alongwith interest thereon from 01.06.2014 to 31.12.2014. During the said period, NPPA has received 78 demand drafts for an amount of Rs.12.38 crore (Rs.5.68 crore under DPCO 1995 & Rs.6.70 crore under DPCO 2013) from the Pharmaceuticals companies against the demand raised in the past and the aforesaid period.

#### **Consultation with Stakeholders**

NPPA conducted detailed consultations with stakeholders including civil society organizations, public health experts, State Drug Controllers and representatives of Pharma industry & trade.

## 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-motu 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 (no liability in one cases and one case linked with another case). 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 31.12.2014 is Rs. 299.50 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 wastaken 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 since been dismissed by Hon'ble High Court vide its judgement dated 22.12.2011



## Chapter

#### 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 last year 2013-14. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE.

of the company was to make available life saving drugs of good quality to Karnataka Government hospitals and other institutions. The Company has been manufacturing facilities for Dry Powder Injectables, Tablets, Capsules, Dry Syrups and Suspensions. The paid – up share capital of the company as on date is Rs. 13.49 crores.

by Government of Karnataka through KSIIDC]. The basic objective

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

Rs. in lakhs

CPSEs	2011-	2011-12		2012-13		13-14	2014-15 upto Dec.14	
	Production	Sale	Production	Sale	Production	Sale	Production	Sale
KAPL	25100.00	22310.00	24739.00	21421.00	27573.00	24159.00	20549.00	18390.00
RDPL	8225.85	8271.89	8622.03	8567.27	5493.36	4350.55	1218.00	1251.00
HAL			4873.00	5209.00	2766.00	3011.00	793.00	805.00
BCPL	517.00	4825.00	3632.00	2737.00	197.00	1687.00	4679.00	3190.00
IDPL	5078.00	5069.00	5871.00	5947.00	6283.00	6018.00	5299.00	4600.00

Initiatives taken to improve the performance of CPSEs during 2014-15 are as follows:

- 1. Performance Management Regular review of performance of CPSEs 2 meetings held on 26.11.2014 and 12.1.2015.
- 2. IDBI Operating Agency submitted Modified Draft Rehabilitation Scheme (MDRS) for HAL and IDPL
- 3. Exploring Pharma Park Development at
  - a. IDPL Hyderabad.
  - b. IDPL Rishikesh
  - c. IDPL Chennai
- 4. Revival of RDPL
  - a. Raw material arrangement in collaboration with KAPL
  - b. WHO-GMP
  - c. Pursuing with Government of Rajasthan for preferential policy towards RDPL in drugs procurement.
- 5. BCPL Completion of Betalactam& Cephalosporin Blocks.

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

#### BACKGROUND

KAPL is a profit making joint sector Company incorporated in the year 1981 [with 59% shares by Government of India and 41% shares

#### PAST ACHIEVEMENTS:

- Mini Ratna CPSE
- ISO 9001 (qms) AND iso 14001 (EMS)

#### PLANT MACHINERY AND CAPACITY

				(1170)
SI. No.	Particulars	2011-12	2012-13	2013-14
1.	Liquid Parenterals	146	172	140
2.	Vials	95	81	82
3.	Tablets	203	212	127
4.	Capsules	182	150	148

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(in %)



#### 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 [ANITMIGRAINE]	VERIXIME [ANTIBIOTIC]	KAPRIL – H [CARDIAC]
CYFOLAC FORTE (SYMBIOTIC)	VITATROL PLUS (ANTIARTHRITIC	LOTACE [CARDIAC]
CYFOLAC [PROBIOTIC]	VITALPHA – C [ANTIARTHIRITIC]	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 CREAM]	GLIMKAP – M [ANTI-DIABETIC]
ZINFE SR [HAEMATINIC]	OLIGEL [TOPICAL ANALGESIC]	GLIMKAP – PM [ANTI-DIABETIC]
VERCLAV [ANTIBIOTIC]	CETRIAX [ANTIBIOTIC]	PIOKAP [ANTIDIABETIC]
TOPRAZOL [ANTIULCER]	CETRIAX – S [ANTIBIOTIC]	PIOKAP – MF [ANTIDIABETIC]
TOPRAZOL D [ANTIULCER]	CEFPAR – SB [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 Crores
2.	Cyfolac Forte Group	Pre & Probiotics	NO	NO	Rs. 4.00 Crores
3.	Remcc Group	Cough & Cold	NO	NO	Rs. 3.00 Crores
4.	Zinfe Group	Haematinic	NO	NO	Rs. 2.00 Crores
5.	Verclav Group	Antibiotic	YES	NO	Rs. 4.00 Crores

MANPOWER AS ON 31.03.2014

(Nos.)

EXECUTIVES	NON-EXECUTIVES	TOTAL
240	498	738

#### **DISTRIBUTION NET WORK:**

#### 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 throughout 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 all the State Head Quarters. The Company also has an excellent Distribution Network at almost 19 Branches at Major Cities catering to the respective State areas through Channel Marketing. The supplies are made effective through approved Stockists to Retailers, Nursing Homes & 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 Govt. Hospitals, Corporates, PSU Hospitals, Defence& Insurance. Has potential to expand in Trade Segment & 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 & complete treatment was invented by India.

#### AGROVET:

Agro dealers and Department of Agriculture / Horticulture for Agro products.

Veterinary Practitioners, Farmers.

#### **NEW PRODUCTS:**

#### PHARMA

No	Products

- 1. Numol MR Tablets
- 2. Remcc LM Tablets
- 3. Toprazol D Capsules
- 4. Zinfe Syrup
- 5. Apifeast Syrup

#### FUTURE PLANS:

Presently Cephalosporin Project is under progress. Likely to be completed by end of Financial year.

#### Targets for 2015-16.

Rs. 265 crores net of Excise is proposed under MOU.



Pharma Block for KAPL



AWACS TROPHY





## II RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED (RDPL)

#### **Background:**

- a. Joint Venture of: Govt. of India (51 %) & RIICO Ltd. (Govt. of Raj. Entps.) (49 %)
- b. Authorised Capital: Rs.1000 Lacs (With paid up capital: Rs. 498.61 Lacs)
- c. Manufacturing facilities & registered office at Road no. 12, VKI Industrial Area, Jaipur (Rajasthan).
- d. Incorporated on 2<sup>nd</sup> November , 1978
- e. Commencement of Business on 05th July, 1979
- f. Production Started in Year March, 1981.
- g. Share Transfer from IDPL to President of India : 17<sup>th</sup> August, 2010
- h. 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 with its marketing activities spread throughout the country..

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- i. 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.
- j. 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.



#### **Past Achievements:**

RDPL is serving the nation from last 36 years (approximate) in the field of providing quality medicines at affordable price with the motto "**Health for All**". RDPL supplied medicines in the Jan Aushadhi Scheme (A novel scheme by Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, Gol), Free distribution scheme (Like for Govt. of Rajasthan), NRHM, NVBDS, Antimalarial programmes etc. We always emerged as contingent medicine provider to Governments and institutions, for example we supplied medicines to in case of Surat (Gujrat) plague epidemic, Latur (Maharastra) & Bhuj (Gujrat) earthquakes and now we are supplying medicine for Swine flu to various states.

#### Sickness and Revival, if any:

Currently no sickness, but reported loss first time during 2013-14.

Plant Machinery and Capacity recognition:

Capacity utilization of RDPL was as follows:

- RDPL is a formulation unit engaged in production of dosage forms Tablets, Capsules (Beta-Lactums & Non Beta-Lactums), Liquid - Orals & Externals, ORS Powder & Ophthalmic medicines in a Schedule 'M' compliant facility.
- I. The company, under the quality management, has a wellequipped laboratory with modern equipments.

#### **Popular Brands:**

Currently RDPL is not in ethical i.e. trade business so do not have any popular brands but RDPL shall start this in financial year 2015 – 16. Premium products by sale value in year 2013-14 was as under:

- Ciprofloxacin Tablets : 30.83 %
- Azithromycin Tablets : 30.81 %
- Omeprazole Capsules : 11.39 %
- Oral Rehydration Salts: 7.07 %
- Amoxycillin Capsules : 6.03 %

RDPL do not have any monopoly or established brand since RDPL currently do not have trade sales.

#### Manpower:

No. of manpower employed as on 31.03.2014 are as under:

Managers	: 40
Officers & Supervisors	: 40
Workers & Staff	: 207
Total	: 287

Product Group	Unit	Installed	Capacity Utilization (In Units & % of installed)					
			(2011-12)		(2012-13)		(2013-14)	
			Units	%	Units	%	Units	%
Tablets	Millons / 2 Shift	720.00	630.76	87.61	450.32	62.54	318.00	50.49
Capsule	Millons / Shift	144.00	129.61	90.00	165.75	115.10*	93.90	65.23
Liquids	K L / Shift	300.00	336.39	112.13*	275.20	91.73	239.40	79.80
Powder	M Ton/ Shift	226.80	181.47	80.01	156.25	68.89	90.39	39.85
Eye Drops	Vials Lacs / Shift	14.40	3.90	27.08	1.72	11.94	2.46	17.10

\* Sometimes section run on double shift basis because of additional orders.

Modernisaton of Plants (Government assistance projects and status):

Year	Project	Scheme	Funds Released	Status of Project
2013-14	Expansion, Modernisaton, Schedule – M & WHO-cGMP project	Project based support is given by the Dept. of Pharm., Ministry of Chem. & Ferti. , Gol	Rs. 455.00 Lacs received as first installment out of total sanctioned Rs.1139.00 lacs.	Project is under progress.

## 24 Product Profile and Range:

The Company has been manufacturing and marketing total 190 products in following therapeutic category range:

- Anti-Infectives, Anti-Malarial, NSAIDS, Antacids, Analgesic, Anti-Pyretics& Anti-Inflammatory, Anti-Emetics, Anti-Spasmodics, Anti-Diarrhoeal / Anti-Amoebic, Anti-Allergic, Anti-Bacterials, Anti-Fungal,
- Cough ExpectorantsVitamins & Minerals
- Opthalmic Preparations
- Oral Rehydration Salt (ORS).

#### Distribution Network, if any:

Distribution network for medicines can be depicted as under:





#### **Performance:**

Production / Turnover and Profit / Loss:

				(Rs. In Lakhs)
Years	Total Production* (Own + Loan Licence)	Gross Turnover	Profit Before Tax (PBT)	Profit After Tax (PAT)
2009-10	7612.76	8535.46	118.52	99.15
2010-11	8379.71	8067.37	150.07	119.86
2011-12	8225.85	8271.89	174.59	144.77
2012-13	8622.03	8567.27	77.49	79.87
2013-14	5493.36	4350.55	(-1943.52)	(-1939.73)

#### Marketing: Share of institutions and retail:

% Share of distribution of total sale was as under for the year 2013-14-



#### **New products:**

In year (2013-14), RDPL added two new products:

- Amlodipine & Atenolol Tablets
- Losartan Potassium Tablets

#### Future projects:

a. RDPL is going to diversify its business in Ayurveda and Veterinary segment. In Ayurveda RDPL has good exposure of marketing and achieved a sale of Rs. 8.50 crore (Approximate) by product manufactured on loan licence basis. Now RDPL is planning to set up in house manufacturing facility for manufacturing facility in RDPL premises for Tablets & Powder dosage forms in year 2015-16 with support of Dept. of Pharmaceuticals.Similarly RDPL wants to set up a facility to manufacture the Veterinary Products in RDPL premises in year 2015-16 with support of Dept. of Pharmaceuticals.

b. To complete the ongoing Expansion, Modernisaton, Schedule
– M and WHO-cGMP project.

#### Targets for Year 2015-16:

The targets for year 2015 - 16 shall be as follows-

- a. As per MOU of RDPL submitted to DPE Sales Projection Estimates for year 2015- 16 shall be Rs. 55 Crore.
- b. To achieve ISO 9001-2008 certification.
- c. To set up inhouse facility for manufacturing of Ayurveda Tablets & Powder dosage forms.
- d. To start Agrovet marketing division.
- e. To start manufacturing of Veterinary and Feed supplements.



c. Photographs:



'A view of RDPL office & plant'



Visit of Dr. M. Ariz Ahammed, Joint Secretary, Department of Pharmaceuticals to RDPL

#### HINDUSTAN ANTIBIOTICS LIMITED (HAL), PIMPRI, PUNE

#### **Background and Past achievements**

Hindustan Antibiotics Ltd (HAL) is wholly owned Government company engaged in the Manufacturing & Marketing of Life Saving Drugs. HAL was established in 1954 with WHO / UNICEF assistance. HAL is the first Company to Manufacture the Antibiotics like Bulk drugs Penicillin, Streptomycin and Gentamycin.

HAL has rare distinction of inventing two new molecules viz. Hamycin and Aureofungin

HAL has been instrumental in ensuring the availability of life saving drugs at affordable prices in the Country.

#### **Sickness and Revival**

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HAL was referred to BIFR in 1997. Rehabilitation Scheme was approved by BIFR on 5<sup>th</sup> June 2007 after series of hearings.

As the Rehabilitation Scheme was not fully implemented, IFCI Ltd. was engaged in 2011 to evaluate the performance in implementation of sanctioned scheme, identifying reasons to achieve performance, suggest business plan for the company with future corporate strategy to make HAL's operation viable. HAL has prepared Business Plan based on recommendations of IFCI with following features:-

- > Focus only on formulation business.
- > Drastic cost cutting measures including VRS
- > New utility set-up for Formulation

#### Second Rehabilitation package

HAL had prepared Rehabilitation Scheme as directed and submitted to Ministry in June'12. This scheme has undergone changes many times and company has submitted revised scheme in Jan.'15 covering liabilities upto March.'14 This scheme is under consideration Features of the scheme are as under:-

- i. Liabilities were covered upto March.'14.
- ii. VRS for 500 persons
- iii. Capital investment of Rs. 111.50 crores
- iv. Outsourcing of the non-core area
- v. Cost of scheme was as follows:-

#### Cost of Scheme

S. No	Particulars	Estimated Cost ( Rs. Crores)
1.	Capital Expenditure	111.50
2.	VRS cost – 500 employees	104.95
3.	Employee related dues	100.04
4.	Statutory dues	73.38
5.	Working capital requirement	44.00
6.	Bank loan	178.14
7.	ONGC loan	17.05
8.	Other Pressing Creditors	13.22
9.	Provision of contingencies	28.18
	Total	670.46

#### **Means of Finance**

S. No	Particulars	Estimated Cost (Rs. Crores)
1.	Sale proceeds from the vacant land	670.46
	Total	670.46

#### **Plant Machinery and Capacity**

HAL's product category has following installed capacities:

S. No.	Product Category	Unit	Installed Capacity (Annual)
1.	Cephalosporin Powder Injectables	Lac Nos.	450
2.	Penicillin Powder Injectables	Lac Nos.	450
3.	Penicillin & Non-Penicillin Tablets	Lac Nos.	2400
4.	Capsules (Penicillin)	Lac Nos.	2400
5.	IV Fluid	Lac Nos.	120
6.	Agro Chem	Lac Nos.	72



#### Modernization of the plants (Govt. assistance projects and status)

Sr. No.	Projects	Scheme	Funds released ( Rs. Crores)	Status of the project
1.	Upgradation of existing I V Fluid plant to WHO-GMP	Plan Funds for Project	6.28	Project under implementation
2.	Agro-vet upgradation & expansion	Plan Funds for Project	6.00	Project under implementation
3.	Utility set-up for formulation	Plan Funds for Project	8.41	Project under implementation
4.	ERP System			Provision of Funds in the Rehabilitation
5.	Expanding the capacity of Large Volume Parenteral			do
6.	Upgradation of Non-parenteral plant			do
7.	Provision for replacement & renewals of old machineries & facilities			do
8.	Provision for new products know-how & technology			do
Total			20.69	

#### **PRODUCT PROFILE AND RANGE**

#### **MAJOR PRODUCTS**

a) Cephalosporin Power Injectable Products

i) Cefotaxime Sodium, ii) Ceftriaxone, iii) Cefaparazone & iv) Ceftazidime

b) Betalactum Injectables

i) Benzyl Penicillin, ii) Meropenem & iii) Sodium Ampicillin

c) Non-Parenteral Tablets

i) Ciprofloxacin, ii) Norfloxacin, iii) Lecofloxacin & iv) Erythromycin

d) Penicillin Tablets

i) Penicillin V. Tabs, ii) Ampicillin Tabs & iii) Cefixime Tabs

e) Penicillin Capsules

i) Ampicillin, ii) Amoxycillin & iii) Cephalexin

f) Large Volume Parenteral – IV Fluids

i) Dextrose 5 %, ii) Normal Saline, iii)Sodium Chloride with Dextrose, iv) Mannitol, v) Ciprofloxacin, vi) Metronidazole, vii) Levofloxacin & viii) Plasma Volume Expander (Polygeline)

g) Agro Products

i) Streptocycline, ii) Aureofungin, iii) Azotomeal, iv) Phosphomeal & v) Humaur

#### Manpower

Present manpower strength is 1058

#### Distribution network if any

HAL has its own Marketing network with C&F agents throughout the country.

		Performance	Rs. in Crores)
Sr. No.	Particulars	2014-15 (upto Jan. 2015) (Provisional)	
1.	Production	14.88	
2.	Sales Turnover	13.92	
3.	Net profit / loss	(-) 75.35	
4.	DPE rating	Poor for year 2013-14	
5.	Marketing share	100% pharma products sale institutions and in Agro sector trade. Share of Institutional sa 2014-15 is 48.48% and trade sa	100% sale is in le for the year
6.	New products	Potassium Iodate Tab. and Norr glycerin introduced in the year	

#### Target for the year 2015-16

#### Rs. in Crores

27

Particulars	2015-16
Production	100.00
Sales Turnover	100.00
Net profit / loss	(-) 52.92
	Production Sales Turnover





'Visit of Hon'ble Union Minister of State for Chemicals & Fertilizers Shri Hansraj Gangaram Ahir to Cepholosporin Plant, HAL, Pimpri, on 7th Jan. 2015



Visit of Parliamentary Committee of Chemicals & Fertilizers headed by Chairman Shri Anandrao Adsul, M.P. along with his team to HAL, Pimpri, on 10th Jan. 2015

#### BENGAL CHEMICALS & PHARMACEUTICALS LTD.(BCPL)

#### BACKGROUND

Bengal Chemicals and Pharmaceuticals Limited (BCPL), erstwhile Bengal Chemical and Pharmaceutical Works Limited (BCPW) was set up 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 production and selling 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. The Company currently has four factories, eleven Sales Outlets and ten C&F Agencies spread across the country.

#### **Manufacturing Locations:**

The registered and corporate offices of BCPL are located in Kolkata. 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 & Cephaphosporin Blocks) and modernisation of Ointment block that were initiated as envisaged in the plan and will be commissioned by April 2015.

#### Panihati Unit

Panihati unit, located near Kolkata, primarily produces Alum and products like Pheneol, Naphthalene Balls, and other disinfectants. Commercial production in most of the renovated productionblocks such as Alum, Pheneol, Napthalene 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, if any:

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:

SI. No	PRODUCTS	UNIT	INSTALLED CAPACITY/ YEAR	ACTUAL PRODUCTION UPTO JAN 2015	% OF CAPACITY UTILISATION
1.	ALUMINA	MT	8000.00	4314.45	64.7%
2.	SPIRITUOUS (AGURU)	KL	300.00	34.848	348.48%


SI. No	PRODUCTS	UNIT	INSTALLED CAPACITY/ YEAR	ACTUAL PRODUCTION UPTO JAN 2015	% OF CAPACITY UTILISATION
3.	TABLET	CR	15.00 (yetto be commissiond)	1.775	14.20%
4.	CAPSULE	CR	5.00 (yet to be commissiond)	0.566	13.584%
5.	OINTMENT	MT	60.00	48.533	97.066%
6.	HAIR OIL	KL	800.00	262.66	97.066%
7.	PHENEOL	KL	3000.00	1341.32	53.6528%
8.	NAPTHALENE	MT	450.00	142.92	38.112%
9.	DISINFECTANTS	KL	1200.00	244.89	24.489

(Rs.in Crores)

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

	( )
Projects	Cost on completion
Ointment & Common items – Maniktala	29.57
Betalactam Block-Maniktala	30.39
Cephalosporin Block- Maniktala	29.75
Panihati Project	27.95
OSD project at Kanpur	34.44
ASVS - Maniktala	29.64
Project salary, & Other common expenses	17.07
Total	198.81

### STATUS OF IMPLEMENTATION OF PROJECTS:

Particulars	Status			
Panihati: Civil Construction, plant& machinery, utilities ETP, Roads, drains, Stores, Admn. Office.	Completed. Commercial production commenced.			
Maniktala:				
Stores Building	Completed.			
Utilities, ETP, Roads, drains etc.	Completed.			
Ointment Block	Commissioning progressing			
Betalactum & Cephalosporin Block	Commissioning is in progress.			
ASVS Section	To be taken up in 2015-16			
Kanpur:-	QA Block, Utilities,			
Tablet, ORS, renovation /up gradation of existing blocks, QA, Utilities, amenity, Sterile Block etc.	Amenities, ETP completed. Civil construction of OSD almost completed. HVAC, electrical work, utilities etc.			

# not completed.

### Product profile and range:

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

### **Division wise Product Segmentation**

Division	Description	
Division I	Ferric Aluminium Sulphate (Alum)	
Division II	Tablets	
	Capsules	
	Liquid Preparation	
	Ointment	
	Antiseptic Liquid	
	Injectables	
	Aqua Ptychotis	
	• Eutheria	
	Kalmegh	
Division III	Pheneol	
	Bleaching Powder	
	Klin Toilet	
	• Lysol	
	Cantharidine Hair Oil	
	Naphthalene Balls	
	Liquid Soap (For Industrial Use)	
	White Tiger (Floor Cleaner)	
	Aguru (Essence)	

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

### Manpower as on 01.02.2015:

Particulars	01.02.2015
	Nos.
EXECUTIVES	68
SUPVERVISORS	94
Workers	255
Grand Total	417

### Distribution network if any:

The company has a strong distribution network pan India with 11 Depots and 7 C&F Agencies .

### Performance:

Details of Production & Sales of BCPL from 2010-11 onwards are as under:





(Rs. in Crore)

Particulars	2010-11	2011-12	2012-13	2013-14	2014-15 Upto Dec'14
	Actual	Actual	Actual (Prov.)	Actual (Prov.)	Actual (Prov.)
Production	80.4	51.7	36.32	19.7	46.79
Sales	54.85	48.25	27.37	16.87	31.90
Profit/Loss	(10.70)	(18.23)	(17.94)	(33.82)	(8.82)

Marketing: Share of Institutions and retail

SI. 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
	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

Targets for 2015-16

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	Rs. in Cr.
Production	72.00
Turnover	60.00
Net profit / loss	(23.42)

Maniktala Factory after Renovation



Quality Control Laboratory- Maniktala



Panihati Factory after Renovation







Pheneol Filling Block

### 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 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 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 to1968 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 for supplying 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 fulfill 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 October1996 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 10.2.2002 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 op[ined 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 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 CDRA 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 DRS of IDPL is self-financing in nature in other words no fund will be sought from the Govt rather the present assets will be sold off and the fund released will be used to payoff secured creditors.

### **IDPL WHOLLY OWNED SUBSIDIARIES**

### A) 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 plant and engaging in manufacture of pharmaceuticals formulations. The production achieved for the F.Y. 2013-14 was Rs. 12.00 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.

# C) 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 Corporate 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.

The 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. 2013-14 was Rs. 14.70 crores which is the highest ever achieved by ODCL.

IDPL TODAY - Presently IDPL is engaged in manufacturing formulations only.In-house production of formulation during the year 2013-14 was Rs.62.83 crores, items-wise details 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. Schedule 'M' GMP compliant plants are Rishikesh, Rishikesh Plant is WHO-GMP compliant now whereas in Gurgaon Plant, Schedule-M is progressing. IDPL will restart its Hyderabad Formulation Unit during the year 2015-16.

Year	Project	Scheme	Funds released (In crs)	Plant's Allocation	Status of Project
2010-11	Sch-M Work	Loan to IDPL	4.45	1.70-Rishikesh 1.00- Gurgaon 1.75- Chennai	Rishikesh & Chennai Plant -made Sch-M compliant. Sch-M work of Tab. Section of Gurgaon Plant -likely to be completed.
2011-12			3.40	0.80-Rishikesh 2.05- Gurgaon 0.55- Chennai	
2012-13	Re-starting Formulation Work		5.00	Hyderabad Plant	Work in progress
2014-15			5.00		
2011-12	Sch-M Work	Loan to ODCL	1.21	ODCL	Inj. , ORS & non-beta Tab. Section
2012-13			1.22		made Sch-M compliant. Beta Lactum Tab. & Cap. Section is in progress of
2013-14			1.80		Sch-M work.

### **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 /Antiinfective, Analgestic / Antiinflammatory, Gastrointestinal, Respiratory Tract, Contraceptive, Vitamins / Mineral, Anti allergic, Anti fungal Anti malarial Anti diabetic Cardiovascular.

Popular Brands: Deacos, 110 ml, Sukcee Tab, Cebxin Z are popular brands of IDPL.

### Manpower-

Presently IDPL has 88 regular employees and 106 on contract in different location of the Company including 100% wholly owned Subsidiaries Company. The company has not been permitted to go for regular hiring 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&FA) 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 (Prov)	2014-15 (up to Jan 2015)
Production	50.78	58.71	62.83	52.99
Sales	50.69	59.47	60.18	46.00
Profit/ loss(EBIDTA)	-7.91	-3.95	-2.25	
Net Profit/loss	-251.32	-173.21	-171.56	
DPE Rating	Good	Very 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.

(Rs in Crore)

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New Products launched .– Cefexime 100 mg, & 200 mg., Cefuroxime Axetil 250mg & 500mg., Aceclofenac 100mg, Aceclofenac 100mg. + Paracetamol 500mg, Calcium+Vitamin D3 500mg

### Future Projects:-

To make all IDPL Plants s WHO-GMP compliant.

### Targets for 2015-16:

Production	:	Rs
Sale	:	Rs

Rs 70 Crore Rs 72 Crore



Blister Packing Machine -Rishikesh



Microbiology Lab- Rishikesh

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HPLC Lab-Rishikesh

### **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, Earthquake etc. Recently in Odisha, Uttrakhand and J&K floods. IDPL contributed significantly by providing life saving medicines on time.

### Archive Room-Rishikesh



ODCL Bhubaneswar



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	2012-13
Rajasthan Drugs & Pharmaceuticals Limited	2012-13
Hindustan Antibiotics Limited	2012-13
Indian Drugs & Pharmaceuticals Limited	2010-11
Bengal Chemicals & Pharmaceuticals Limited	2010-11
Bengal immunity Limited	2005-06



### 5.3 JAN AUSHADHI SCHEME

### **NEED FOR JAN AUSHADHI SCHEME**

Making available quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons. For example, some of the comparative prices illustrated here would show that there is a big difference in prices between the branded medicines sold in the market and generic medicines having the same efficacy being sold in Jan Aushadhi Outlets. In view of the above, ensuring availability of quality medicines at affordable prices to all has been one of the key objectives of the Department of Pharmaceuticals, Government of India. With a view to achieve this objective the Government has been taking several regulatory and fiscal measures from time to time. In order to provide further relief to the common man in the area of healthcare, a countrywide Campaign for ensuring availability of generic medicines at affordable prices to all, in the name of "Jan Aushadhi Campaign", was launched by the Department of Pharmaceuticals, in November, 2008 in collaboration with the

SI. No.	Product Name	Strength of Pack of 10	Ceiling Price*/Average Price of leading Brands#	Price of Jan Aushadhi	Price Difference of Branded Medicines V/s Jan Aushadhi Medicines
			Analgesic Anti-Inflammatory		
1	Diclofenac	100mg	39.73	4.43	9 times
2	Paracetamol*	500mg	10.00	5.60	2 times
3	Nimesulide	100mg	33.93	3.42	10 times
4	Tramadol*	50mg	65.10	3.94	16 times
			Antibiotics		
1	Ciprofloxacin	250mg	47.37	16.54	3 times
2	Amoxycillin*	500mg	64.70	37.00	2 times
3	Azithromycin*	500mg	218.10	105.09	2 times
4	Cefixime*	100mg	81.80	30.12	3 times
5	Ofloxacin*	200mg	52.10	17.13	3 times
			Gastro-Intestinal Tract/Anthelmin	ntics	
1	Domperidone*	10mg	24.00	3.29	7 times
2	Pantaprazole*	40mg	50.96	7.72	7 times
3	Albendazole*	400mg	97.00	20.31	5 times
4	Aceclofenac + Paracetamol +	100mg+500mg	36.67	11.22	3 times
5	Rabeprazol	20mg	57.84	6.12	9 times
			Cardio-Vascular/Diuretics		
1	Atenolol*	50mg	22.00	3.07	7 times
2	Amlodipine*	5mg	30.10	2.51	12 times
3	Atorvastatin	20mg	174.85	10.32	17 times
4	Enalapril*	5mg	31.50	6.60	5 times
5	Losartan Potassium*	50mg	45.70	6.99	7 times
			Anti Diabetics		
1	Glimperide	2mg	54.00	3.11	17 times
2	Metformin HCL*	500mg	16.60	4.80	3.5 times
			Respiratory System and Anti Alle	rgic	
1	Cetrizine*	10mg	19.20	3.09	6 times
2	Cough Syrup	110ml	29.33	19.48	1.5 times

Price Comparison

\* Product with Ceiling prices as fixed by NPPA

# Source : IDR

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State Governments, as a direct market intervention strategy.

### II The Original Jan Aushadhi Scheme

- TARGET OF THE SCHEME -- Under this campaign, it was proposed to open, initially, at least one store in each of the 630 districts of the country.
- (2) PROVISIONS OF THE ORIGINAL SCHEME:
- (i) AGENCY WHO WOULD IMPLEMENT THE SCHEME: BPPI (Bureau of Pharma PSUs of India)
- (ii) ELIGIBILITY TO OPEN JAN AUSHADHI STORES: Under the campaign, NGOs / Hospitals / Charitable / Cooperative / Government Bodies having minimum of three years experience and good track record, experience of working with Central/State Governments, ability/resources to furnish the allotted space as per the design/layout provided by the BPPI, capable of meeting all Legal/Statutory/Regulatory requirements for running the stores and whose applications were recommended by the State Governments (Health Department) were eligible to open such Jan Aushadhi Stores. Individuals and commercial organizations were, however, not allowed to open the stores under this campaign.
- (iii) LOCATION OF JASs : In the premises of Govt Hospitals
- (iv) AUTHORITY WHO DECIDED THE OPERATING AUTHORITY OF THE JAN AUSHADHI SHOPS: State Govts recommended the operating agencies and allocate space within state govt hospital premises. Based on recommendations of the State Government, BPPI appointed the operating authority to run the JAS.
- (v) NO OF MEDICINES SOLD AT JAS: 319 medicines were to be sold in the JAS.
- (vi) MEDICINES TO BE SUPPLIED BY: 5 CPSUs under the Department of Pharmaceuticals.
- (vii) FIXING OFRATES OF MEDICINES: Medicines were sold at PPP rates (fixed by the NPPA) minus 10% plus retailer margin plus local VAT.
- (viii) SUPPLY CHAIN OF MEDICINES:CPSUs supplied to their C&F Agents who supplied to Stockists. Stockists supplied to JAS.
- (ix) GRANT TO JASs: Rs. 2.5 lakhs to each JAS for infrastructure etc.

# 36 ACHIEVEMENTS/SHORTCOMINGS OF THE ORIGINAL SCHEME

The poor performance of the Scheme was quite evident from the fact that, as against the target of opening one JAS in each of the 630 districts, only 157 JASs could be opened till September, 2013. Of these, only 97 JASs were operational. The Public Health Foundation of India (PHFI) was asked to study the Scheme and suggest remedial measures. Based on the Report of PHFI and ground level observations it was found that the following were mainly responsible for the scheme not being successful.

- (a) Over dependence on support from State Government
- (b) Poor Supply Chain management:

- (c) Non-prescription of Generic Medicines:
- (d) State Governments launching free supply of generic drugs:
- (e) Lack of awareness among the Public:

### III. A NEW BUSINESS PLAN – TO OVERCOME SHORTCOMINGS OF ORIGINAL SCHEME

With a view to remove the shortcomings noticed in the original Jan Aushadhi Scheme a revised New Business Plan has been worked out. The New Business Plan was approved in August, 2013. The new Business Plan takes care of major bottlenecks in implementation of the scheme so far. The proposed changes in the scheme under the New Business Plan are listed below:-

(i) Relaxation of eligibility conditions for Operating entities: Jan Aushadhi Stores may be opened outside the premises of hospitals also. Moreover, any NGO/ charitable society/ institution/ Self Help group with experience of minimum 3 years of successful operations in welfare activities, supported by three years audited accounts, will be eligible for applying for opening of drug store. As far as individuals are concerned, unemployed pharmacists/ doctors/registered medical practitioners would be given preference for running the stores. The applicants have to approach BPPI with a complete application along with the following particulars;

- a) Own space or hired space duly supported by proper lease agreement
- b) Minimum required space conforming to standards as approved by the BPPI.
- c) Sale license from competent authority.
- d) Proof of securing a pharmacist.
- e) Financial capacity to run the store (bank statements/ audited accounts for the last three years/ a sanction letter from bank for extending loan).
- (ii) Coverage of the Scheme:

In the consolidation phase, it is proposed to establish a complete supply chain in the States where Jan Aushadhi Scheme has a substantial presence. Efforts would be made to open as many stores as possible in these States such as Punjab, Haryana, Delhi, Uttarakhand, Jharkhand, Himachal Pradesh, Maharashtra, Madhya Pradesh, Andhra Pradesh, West Bengal, Uttarakhand, Chandigarh, Jammu & Kashmir, Tripura, Uttar Pradesh and Odisha. North Eastern States would be given special attention to popularize the scheme. Later, the scheme will be extended to other States depending on the response from them. It is proposed to start a minimum of 3000 stores over a period of four years.

(iii) Review of existing list of medicines:

Under the original Scheme only 319 medicines were listed for sale at the Jan Aushadhi stores. There was a need to review this list to provide maximum coverage to the newer molecules in demand, and also products under the NLEM. With this in view, a revised list of 361 medicines has been prepared, covering almost all therapeutic categories of drugs.

(iv) Supply Chain Management:

More suppliers of medicines are being roped in from other Public Sector Undertakings (PSUs) as well as private manufacturers. Procurement of drugs from private manufacturers is also necessitated by the fact that CPSUs have in-house capacity to manufacture only 138 products.

An IT based Management Information System is to be used to ascertain availability of medicines in stores on a real time basis, and accordingly trigger supply of medicines through a transparent procurement process and supply chain, patterned almost on the model of Tamil Nadu Medical Services Corporation (TNMSC).

- (v) Sourcing of drugs :
- (a) As mentioned earlier, the list of products (138 Nos), reserved for CPSUs, has been finalized in consultation with them based on their in-house manufacturing capability. In respect of these drugs, CPSUs shall have the first claim to supply. To ensure regular and adequate supply of medicines, apart from procurement of medicines from the CPSUs, BPPI is to supplement supply by direct purchase of medicines from private sector companies through open tender process, as per the guidelines issued by Central Vigilance Commission. The list includes 276 items out of the earlier list of 361 items identified for supply from Jan Aushadhi Stores and also top selling medicines belonging to 6 Therapeutic groups namely; (a) Anti-diabetic (b) Cardiac, (c) Gastro (d) anti-infective (e) Analgesic (f) Respiratory and Vitamins. All efforts are being made to make available the supplies within a few months time

As and when infrastructure for in-house manufacture of drugs is created in CPSUs, the private sector will be gradually phased out.

Even in respect of drugs reserved for CPSUs, these drugs may be procured from private sector or other PSUs in case the respective CPSU fails to supply medicines on time. It is to be kept in mind that stock-out situations for any drug should be avoided at any cost.

### (vi) Quality Control:

BPPI would ensure that only quality drugs are supplied through the Jan Aushadhi stores. To ensure this, it is essential that manufacturers of drugs are selected carefully and after due inspection of their facilities to ensure that they conform to required standards i.e. WHO-GMP compliance. Further, samples should be sent for testing on a regular basis. Any failure on the part of suppliers to comply with quality standards should trigger initiation of stringent actions, in addition to blacklisting the firms against future contracts. Though BPPI would ensure quality control through its own channels, the ultimate responsibility to ensure quality of medicines would rest with the manufacturers.

### (vii) Pricing of Drugs:

Out of the proposed list of 361 medicines, MRPs for 138 medicines, manufactured and supplied by the CPSUs, have already been fixed in consultation with NPPA. In respect of medicines procured from private manufacturers or other PSUs, MRP will be fixed on the basis of rates arrived through tender process plus trade margins and other incidental costs (including excise duty, if any, and VAT component).

As mentioned earlier, MRPs of the medicines will be decided by BPPI after taking into consideration the wholesalers' margin of 8% and retailers' margin (Jan Aushadhi stores) of 16% for medicines under DPCO'95 and 10% for wholesalers and 20% for retailers for the non-DPCO medicines. Similarly, MRPs of surgicals and consumables will be worked out based on the procurement rates including distribution costs.

Beyond the 12<sup>th</sup> Plan period, an additional margin not exceeding 2% will also be collected to meet administrative expenses of BPPI. As the BPPI has to be run on 'no profit no loss' basis, the exact percentage would be worked out based on the volume of turnover at that time.

IV. Directions of the EFC

The EFC under the Chairmanship of the then Secretary Pharmaceuticals, after detailed deliberations, approved the new Business Plan with an estimated cost of Rs. 148.82 crores, subject to the condition that no expenditure shall be made for new JAS from the present allocation till;

- A full-fledged procurement system is put in place and rate contracts finalized and;
- (ii) IT-based supply chain management solution isoperationalized on pilot basis and;
- (iii) All the necessary arrangements such as warehouses, stockists, required manpower etc. are put in place to manage supply chain.

As on date, 176 JAS have been opened out of which only 96 are functional. No. of stores opened during various years is as under:

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### Details of JAS opened financial year wise as on 19.02.2015

Financial Year	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
Number of Stores Opened	07	36	54	20	37	8	14
Table Number of shares opened till 10.02.2015 177							

Total Number of stores opened till 19.02.2015 = 176





- /. Progress made in implementation of new business plan
  - (i) Availability of medicines:
  - Procurement of medicines has been started from private manufacturers also, in addition to CPSUs after following the normal tender process and entering into agreements with them.
  - Rate of medicines, both for CPSUs and Private Suppliers has been finalized/are being finalized.
  - (ii) Creation of Central ware House: A Central Ware House has been in the IDPL Complex at Gurgaon which has started functioning in the month of May, 2014.
  - (iii) Management of Supply Chain: An IT based management information system software is being introduced to ascertain availability of medicines in Jan Aushadhi stores and supply of medicines through a transparent procurement process & supply chain on a real time basis.
  - (iv) Quality Control: 8 NABL approved laboratories have been empanelled after following the normal tendering process for testing of samples of each batch of drugs to be procured. Medicines received in the warehouse are dispatched to Super stockists / Jan Aushadhi Stores only after getting the Passed reports from the NABL approved laboratories.
  - (v) Appointment of Super Stockist/ C&F Agents: Forsupply of medicines to Jan Aushadhi stores, 06 super stockists in various states have been appointed. More Super stockists would be appointed as per the requirement.
  - (vi) Opening of new Jan Aushadhi stores: Expression of Interest from interested parties for opening of Jan Aushadhi Stores in the States of Orissa, Uttar Pradesh, Madhya Pradesh, Assam, Bihar and Chhattisgarh were called for. In addition, the State Govt. of Chhattisgarh, Tripura and J&K have proposed to open more Jan Aushadhi Stores. Expression of Interest are being invited in respect of some other states.

(vii) Publicity campaign: It is proposed to launch massive media campaign for educating people about use of generic medicines and the benefits of the Jan Aushadhi Campaign, especially in those States where the Jan Aushadhi Scheme has already been started so that people take full advantage of the availability of generic medicines at affordable prices at the Jan Aushadhi Stores. A beginning has been made by giving a full page color advertisement in all the newspapers in the state of Orissa. The details are being worked out in consultation with DAVP agencies.

### VI. STRATEGIC ACTION PLAN:-

Given the unsatisfactory performance of the Jan Aushadhi Scheme - which has been operational since 2008, the Department is revisiting the scheme plan and formulating a strategic Action Plan 2015 with a paradigm shift to make quality medicines accessible through affordability and availability. The Strategic action plan includes (i) New Distribution System: Expansion beyond the exclusive JAS stores in retail markets through retailers and franchisee with signage exclusivity (ii) Enlargement of medicines basket, (iii) Team building with all stakeholders -Prescribers (Doctors), Doctors Associations, Medical Council of India, Chemists & Druggists Association, Consumer Association, State Governments, Regulators and all others by addressing their respective concerns (iv) Advocacy and perception management on quality of JAS medicines for brand building (v) Strengthening Bureau of Pharma Public Sector Undertakings of India (BPPI) (vi) improved Supply Chain Management (vii) Value Added Services in partnership other service providers – online/home delivery, post offices, co-operatives, insurance agencies etc. (viii) Recognition of Doctors, Distributors and retailers and NGOs actively engaged in generics.

Under the Strategic Action Plan 2015, a pilot initiative will be launched during 2015-16 to reach out all sections of society with results and will be expanded across the country in the coming 3 years covering all therapeutic groups.



NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs)





# CHAPTER-6 NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPER), S.A.S NAGAR, MOHALI

NIPER, SAS Nagar, Mohali was initially registered as a society under the Societies Act. The faculty for the institute was appointed in 1994. In 1998, Parliament enacted National Institute of Pharmaceutical Education and Research Act, 1998. NIPER was declared as an "Institute of National importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities.

The main objectives of the Institute:

- 1. Nurture and promote quality and excellence in pharmaceutical education & research.
- 2. Toning up the level of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession.
- Creation of National Centers to cater to the needs of the pharmaceutical industry and other research and teaching institutes.
- Collaboration with Indian industry to help it meet global challenges.
- 5. National/International collaborative research.
- Study of sociological aspects of drug use and abuse and rural pharmacy etc.
- 7. Running programmes in drug surveillance, community pharmacy and pharmaceutical management.

### **NIPER has ten Departments:**

- 1. Medicinal Chemistry
- 2. Pharmaceutics
- 3. Natural Products
- 4. Pharmacology & Toxicology
- 5. Pharmaceutical Analysis 6. Biotechnology
- 7. Pharmaceutical Technology 8. Pharmacy Practice
- 9. Pharmaceutical Management 10. Pharmacoinformatics

### **Disciplines:**

The first batch of students was admitted in 1998. The NIPER offers Masters' and Ph.D. degrees n15 streams and caters to the various needs of pharmaceutical industry:

- 1. Medicinal Chemistry
- 2. Natural Products
- 3. Traditional Medicine
- 4. Pharmaceutical Analysis
- 5. Pharmacology & 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

### Infrastructure:

NIPER conducts regular education programmes for academia and industry in various disciplines and helps the Indian Pharmaceutical Industry in solving their R&D related requirements. NIPER has upgraded facilities for achieving the highest level of efficiency in imparting education and events. There are state-of-art classrooms with installation of TV panels and laptop systems. NIPER laboratories are fully equipped with modern equipments that are equivalent to other state-of-the-art laboratories in the world. All the available facilities are of international level and standards. A Technology Development Centre has also been set up. In addition, there has been significant improvement in research infrastructure as several high value sophisticated instruments have been added which has helped in increased thrust in R&D activities.

### **Central Research Facilities:**

Following central facilities provide support to the research groups within the Institute as well as from outside:

- 1. Central Instrument Laboratory
- 2. Computer Centre
- 3. Library and Information Centre
- 4. Central Animal facility
- 5. National Toxicology Centre (GLP compliant)
- 6. Technology Development Centre
- 7. National Bioavailability Centre (WHO accredited)
- 8. Impurity Profiling & Stability Testing Laboratory
- 9. Pharmacological & Toxicological (GLP compliant) Screening Facilities

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### Seats for admission to P.G. Courses, Ph.D in NIPER, S.A.S. Nagar:

Since 2010, NIPER, S.A.S. Nagar, has increased seats for admission to postgraduate courses and Ph.D. Programme

Courses	Students admitted in year 2014
Ph.D	27
M.S.	196
M.B.A.	39
Total	262



In July 2014, 256 Masters' students [including M.S. (Pharm.), M. Pharm. and M.Tech.(Pharm.)] and 63 M.B.A. (Pharm.) students graduated from the Institute.

Academic excellence: During 2014 the Institute has published 136 articles in journals of repute. NIPER has filed 7 patents in 2014. Since the inception of academic programme, 2227 students have passed out (Masters 1615, MBA 421 & Ph.D.191).

International collaborations: The Institute entered into several International collaborations and a number of visitors from abroad and within the country visited the Institute, thus highlighting the ever-rising status of the Institute. NIPER started conducting training programs at the newly established Small and Medium Pharmaceuticals Industry Centre (SMPIC) for Small and Medium Pharmaceuticals industry on the aspects of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), Instrumental analysis and manufacturing of APIs and Formulations. The centre also provides a focal point to industry academia interaction.

# RECENT DEVELOPMENTS AT NIPER, S.A.S. NAGAR

### (GENERAL)

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- 1. The Institute has played mother role to all the new NIPERs started in different parts of the country by helping them in variety of ways including centralized admissions.
- 2. A Technology Development Centrehas been set up in the NIPER, S.A.S. Nagar.
- 3. The WHO accredited National Bioavailability Centrehas been established with support of Deptt. of Science & Technology, Govt. of India, which is one of the two centers of the world to conduct the bioavailability studies for oral fixed-dose combination of anti-tubercular drugs. Inspection of the facility for renewal of approval was conducted by a team of DCGI on 23/12/2014.
- 4. The Institute has also set up the Good Laboratory Practices (GLP) compliant National Toxicology Centre, National Centre of Pharmacoinformatics, National Centre for Safety Pharmacology and Centre for Nanotechnology with the support of Department of Science & Technology (DST) under Pharmaceutical Research & Development Support Fund (PRDSF programme).
- 5. NIPER, S.A.S. Nagar, has now started training programmes for Small and Medium Pharmaceutical industry on the aspects of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), Instrumental analysis and manufacturing of APIs and Formulations. An important aspect of the training programs is the demonstration in the Technology Development Center (TDC), Central Instrument Laboratory (CIL), and Central Animal Facility (CAF), etc. Separate handson training modules are available for High Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), and Atomic Absorption Spectroscopy (AAS).
- 6. NIPER has more than 1840 publications, most of them in reputed, peer-reviewed, international journals.

- 7. The EFC documents for two plan proposals for Rs. 253.4 cr for the remaining period of XII five year plan have been submitted to Deptt. of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India.
- 8. Non-Plan budget proposal of Rs. 47.93 cr has been submitted out of which Rs. 12.77 cr has been released by the Ministry for meeting the expenses till the third quarter for the year 2014-15.
- 9. New projects worth Rs. 0.55 cr were sanctioned till date by various funding agencies to NIPER. In addition, the Department of Pharmaceuticals has funded three proposals on (i) Target specific drug discovery research against kala azar, (ii) Target specific new drug discovery of antituberculosis agents, (iii) Studies on molecular approaches to TB-determination of the prevalence of MDR and XDR strains, drug susceptibility testing and development of new diagnostic tests (collaborative project with AIIMS, New Delhi)

### (Research)

- 1. Neglected diseases
  - Some multifunctional proteins have been identified as virulence factors in *Mycobacterum tuberculosis*.
  - The role of different residues in the conserved motif of acetyl CoA synthetase (AceCS) from *Leishmania donovani* has been studied with a view to identify molecular targets on which to base future treatment strategies.
  - A series of twenty six structurally diverse α-aminophosphonates have been synthesized and evaluated for in vitro anti-leishmanial activity and cytotoxicity. Seven compounds exhibited anti-leishmanial potency against the *L. donovani* promastigote with IC50 values in the low micromolar range.
  - Of a total of 35 S-benzylatedguanylthiourea derivatives synthesized, one was found to be curative and five more compounds showed promising pharmacological profile on *Plasmodium berghii* in mice.
  - Two pentamidine-heterocyclic hybrids were found to exhibit potent antileishmanial activities in promastigote assay, comparable to pentamidine (a clinically used antileishmanial drug). They were found to be significantly less cytotoxic than pentamidine for human monocytic cell line and macrophages.
  - A combined structure and ligand based pharmacophore modeling, shape based virtual screening, docking and MD simulation for *Mtb*-ASADH (aspartate β-semialdehyde dehydrogenase) was performed to identify potent inhibitors of the enzyme. Best screened hits have the characteristics of highly electronegative functional groups (-COOH and -NO2) on both sides and exhibited the H-bonding interactions with highly conserved residues Arg99, Arg249 and His256.

- 2. Other diseases
  - CCR2 binds to the monocyte chemotactic protein MCP-1, a CC chemokine, produced at the sites of inflammation and infection. Homology modeling and subsequent molecular modeling studies proved successful in probing the structure of human CCR2 chemokine receptor for the structure-based virtual screening and predicting the binding modes of CCR2 antagonists.
  - Structural modifications of scaffolds such as β-carboline and isoquinoline were designed to synthesize and to generate structure-activity relationship for anti leishmanial activity and cytotoxic potential against various human cancer cell lines.
  - Extracts of *Ferula asafoetida* were evaluated for their pancreatic lipase enzyme inhibition activity.
  - The metabolic profile of Itraconazole (associated with serious idiosyncratic adverse reactions of theskin like Steven-Johnson syndrome, Lyell's syndrome and photosensitivity) in rat skin S9 fractionusing LC-MS tools resulted in identification of a direct covalent adduct of the drug with GSH (drug- GSH) and a total of six metabolites (M1-M6). The study revealed that skin toxicity of itraconazole may be associated with its GSH adduct or metabolites M2, M4 and M5 (as predicted by TOPKAT).
  - Age- and gender-specific differences in experimental model of global cerebral ischemia/reperfusion injury showed significant effect on locomotor hyperactivity and Y-maze spontaneous alternations behavior indicating that age and gender might have a significant role in the behavioral (functional and cognitive) outcomes of global cerebral ischemia.
  - Study of the effect of high glucose and insulin in breast cancer cells provided the first evidence that high glucose and insulin promotes proliferation of these cells by differential alteration of GSK-3β, NF- κB, and ERα expression and histone H3 modifications, which may directly or indirectly modulate the expression of genes involved in its proliferation.
  - Chemotherapy with agents like cyclophosphamide caused decrease in the zinc levels both in the serum and testes of the treated rat. Zinc supplementation was shown to be beneficial to those rats under chemotherapeutic agents; it has improved several of the reproductive damages caused by the anticancer agent.
- 3. Drug development and formulation
  - Understanding kinetic and thermodynamic events is paramount for design of stable amorphous pharmaceutical systems. Taking Celecoxib as a model drug, (i) differences in molecular interactions incrystalline and amorphous state, (ii) thermodynamic events associated with amorphous state, (iii) nature of



interactions in the binary systems, and (iv) solubility benefits associated with the amorphous systems, have been demonstrated.

- Co-encapsulation of antioxidant with anticancer drugs for improving oral bioavailability, synergistic anticancer efficacy and reduced toxicity has been attempted.
- Platforms are being designed for oral insulin delivery using nanocarrier systems.
- 4. Other areas
  - Chemo-enzymatic synthesis of drugs (Ranolazine, Lebulozole, Dropropizine) using lipase as biocatalyst was carried outsuccessfully. Oxidoreductase systems from various microorganisms were utilized for the stereoinversion of (RS)-Linezolide, (RS)-methyl pyridine methanol, DL-phenyl lactic acid, etc.
  - A palladium-catalyzed regio- and chemoselective direct benzylation of primary benzamides with 2bromobenzyl bromides under a mild basic condition has been developed affording various substituted diarylmethanes in good yields. Utilizing the above protocol, the synthesis of the two marketed drugs Xyzal® and Femara® are currently underway.
  - Monograph on anti-inflammatory Abhaya vati was developed.
  - Study of the effect of RNA aptamers on stabilization of misfolded proteins involved in Huntington's disease was studied. This showed improved solubilization and enhanced viability of cells expressing the protein and the selected aptamers.
  - Using rational (site-directed mutagenesis) and random (random mutagenesis) approaches, the process of generating variants of recombinant human PON1 enzyme having enhanced activity towards desirable substrate(s) is being optimized.
  - Assessment of an appropriate and reliable method to diagnose neuropathic pain including translation of screening questionnaires in local languages and validating them in Indian population has been initiated.

### (Events and Activities)

- 1. The following awards have been granted to the Institute:
  - a. Two Ranbaxy Science Scholar Awards
  - b. In addition, students have received awards at various national and international symposia, in recognition of the work carried out by them.
- 2. The following events were conducted by the Institute:
  - SMPIC dissolution and solubility enhancement technology in pharmaceutical formulations on 5<sup>th</sup> September, 2014
  - b. International symposium on recent advances in medicinal chemistry on 8-10 September, 2014

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- Indo US conference on molecular modeling and informatics in drug design (M2ID2) on 3-6 November, 2014
- d. Hindi Pakhwada from 15-30 September, 2014
- e. 4th Biennial International conference on New developments in drug discovery from natural products and traditional medicines (DDNPTM) on 20-22 November, 2014
- f. ITEC/SCAAP training program from 24th November-4th December, 2014
- g. 7th International symposium on drug metabolism and pharmacokinetics (DMPK-2015) from 18th – 21<sup>st</sup> February, 2015
- h. Pledge being administered to employees and students of NIPER, S.A.S. Nagar at the Swachchh Bharat Abhiyan on Oct. 2, 2014

### **ESTABLISHMENT OF NEW NIPERS:**

In terms of the amended National Institute of Pharmaceutical Education and Research (NIPER) Act, 1998, the Government of India has set up six new NIPERs at **Hyderabad**, **Hajipur**, **Ahmedabad**, **Rae Bareli**, **Guwahati and Kolkata**. These New NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained man power for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, new NIPERs are functioning with the assistance of the Mentor Institutes.

1.	New NIPERs	Mentor Institute
2.	Ahmedabad	B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre, Ahmedabad.
3.	Hajipur	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna.
4.	Hyderabad	Indian Institute of Chemical Technology (IICT), Hyderabad.
5.	Guwahati	Guwahati Medical College and Hospital (GMCH), Guwahati.
6.	Kolkata	Indian Institute of Chemical Biology (IICB), Kolkata.
	Rae Bareli	Central Drug Research Institute (CDRI), Lucknow.

### Starting of Classes at New NIPERs:

Pursuant to the approval of the Cabinet to the setting up of six new NIPERs, classes were started from the academic Session 2007-08 with the help of Mentor Institutes at Ahmedabad, Hyderabad, Kolkata and Hajipur. The classes were started at NIPER, Guwahati and Rae Bareli in 2008-09.

The students are selected through Common Admission Test conducted by NIPER, SAS Nagar, Mohali in association with these new NIPERs.

An Apex Committee under the chairmanship of Secretary (Pharma) has been formed to oversee the smooth functioning of new NIPERs

till the Board of Governors of each new NIPER is formed. Likewise, State level Coordination Committee under the Chairmanship of an officer of the level of Principal Secretary of the concerned State Government has been formed for each NIPER to oversee the functioning of the new NIPERs.

### NIPER-HYDERABAD

### VISION

To serve as a leading global institution in the field of higher learning and research in Pharmaceutical Sciences

### MISSION

To strive towards excellence in the field of Higher Education and Research in Pharmaceutical Sciences & Management.

### **OBJECTIVES**

- Enhancement of creativity, motivation, drives and inculcates professionalism.
- To bring synergy between academic, R & D, technology and industry through training and exposure for such environment
- Bridging collaborations between pharmacy, biotechnology, information technologies and preparing for meeting global challenges
- Create a world class institute of teaching and research in the field of pharmaceutical sciences
- Develop and practice e-learning for the professionals and training for teachers, researchers, regulators in the respective field
- Expand research activities in new avenues and emerging segments
- Explore national and international collaboration in pharmaceutical sciences

### **GENERAL**

- NIPERs are autonomous bodies and established under the aegis of Ministry of Chemicals & Fertilizers as a centre of excellence for higher education, research and development in pharmaceutical sciences. These institutes have been declared as an "Institutes of National Importance" by Government of India through an Act of Parliament (NIPER ACT 1998 & NIPER Amendment ACT 2007).
- Maintains interactions and research collaborations with various Pharma Industries and Academic Institutions
- Qualified and well experienced faculty has been inducted into NIPERs & Mentor Institute Scientists' render their services or expertise to NIPERs.
- Students get admitted to NIPERs through two National wide Open Entrance Examinations (GPAT & NIPER-JEE)
- Good number of students were placed in Pharmaceutical Industries and some more were in Research Institutes or Universities for pursuing Ph.D. in India as well as abroad.



### **Programmes Offered**

NIPER-Hyderabad offers M.S.(Pharm.), M.Tech(Pharm.) and MBA (Pharm.) in following disciplines :

Discipline	Admitted in the Academic Year	Proposed in the Academic Year
	2013-14	2014-2015
M.S. (Pharm)		
Medicinal Chemistry	30	30
Pharmaceutical Analysis	16	16
Pharmacology & Toxicology	15	15
Pharmaceutics	15	15
Regulatory Toxicology	08	08
M.B.A.(Pharm)		
Pharmaceutical Management	20	20
M.Tech.(Pharm)		
Pharmaceutical Technology (Process Chemistry)	08	08
Total MS Students	112	112
Ph.D		
Medicinal Chemistry	6	5
Pharmaceutical Analysis	1	3
Pharmacology & Toxicology	2	2
Pharmaceutics	2	2
Total Ph.D Students	11	12

### **Research Areas**

- Drug Discovery: Synthesis of New Chemical Entities (NCEs) for
  - o Anti-Cancer
  - o Anti Inflammation
  - Anti Microbial
  - Metabolic disorders
- Peptidomimetics as therapeutic agents and Drug Delivery Systems
- Computer Aided Drug Design (CADD)
- Impurity Profiling
- Analytical Method Development
- Standardization of Herbal drugs
- Stability Improvement Methods
- In vitro and In vivo Screening of New Chemical Entities (NCEs) for various activities like Antidiabetic, Antiarthritis, Anticancer, Analgesic and Anti inflammatory activity
- Drug Metabolism and Pharmacokinetic studies (DMPK)
- Therapeutic drug monitoring, adverse drug reaction and Drug-Drug interactions studies
- Novel Drug Delivery Systems
- Nano Particle Technology

- Improvement in Bioavailability
- Application of QBD in Formulation Design and Processing
- Stability Improvement Methods

Achievements & Research Accomplishments

- Third Convocation :Total No. of M.S.(Pharm.) Degrees Awarded in the Third Convocation is 73, which was held on 19<sup>th</sup> October, 2013.
- Awards: The faculty is honored with OPPI Scientist; OPPI Young Scientist and IDMA Young Pharmaceutical Analyst Awards for their research contribution.
- Research Publications: 54 Peer reviewed International / National Publications were published.
- Poster Presentations: About 35 Posters were presented at different Conference / Symposia by the faculty and students
- Recent Conference / Workshops organized:
  - International Conference on Drugs for the Future : Infectious Diseases (DFID)
  - Drug Discovery from Toxins (Dec, 2013)
  - Recent Scenario on Rare Diseases & Disorders (Sept, 2013)
  - Export Business Opportunities for Pharma Products in Africa (May, 2013)
  - Dietary Restrictions in Therapeutics (April, 2013)

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- MoUs :NIPER-Hyderabad has entered into Memorandum of Understanding (MoUs) and Research agreements with several Academic and Industrial Collaborations (8 Nos.) to pursue advanced research in the areas of mutual interest and to encourage student/faculty exchange programmes.
- Grants / Projects : NIPER-Hyderabad faculty got Grants / Projects (9Nos.) with DBT, ICMR, DST and UKIERI, SERB, YISSUM, etc.

### Infrastructure & Research Facilities (NIPER-Hyderabad)

- Library and Information Center, Central Computer Facility, MM / CADD facility, Animal House.
- World Class Institutional facilities of CSIR-IICT are extended to NIPER-Hyderabad.
- Upcoming Facility (NCRDBD):National Centre for Research & Development in Bulk Drugs is being set up in NIPER to start Pharma-oriented R&D center across the country, tailored to the requirements of specific sub-segments such as bulk drug industry, formulations industry etc.

### Placements

- >75% of students are placed every year in Pharma Industries
- Some students get Ph D positions in India and abroad

### NIPER-AHMEDABAD

The National Institute of Pharmaceutical Education and Research (NIPER) has been established under the aegis of Ministry of chemicals and fertilizers, Government of India, Dept. of Pharmaceuticals, as a centre of excellence in imparting higher education, research and development in pharmaceutical sciences and is first of its kind in the country. The Institute was declared as an Institute of National importance by Government of India through an Act of Parliament, notified on 26th June 1998. The institute is a member of Association of Indian Universities and Association of Commonwealth Universities.

### Vision

To be a Nationally and Internationally recognized premier Centre of Excellence in Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and Biomedical Technology

### Mission:

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- To ensure that departmental and administrative associates are provided with necessary resources to excel in learning, research, teaching and administration
- To establish National Centre of Medical Devices (NCMD) for contributing for medical technology education through collaborative programmes of mutual interest
- To evolve medical technology clusters with common facilities for creating an ecosystem for the benefit of SME's focusing on medical technology
- Development of human resources by skill up-gradation of students through specialized courses and training

- To encourage students for innovative translational research through interdisciplinary research team
- To promote national and international collaboration with Pharmaceutical Industries, Medical Centres and Universities
- To facilitate international student and faculty exchange programmes to enhance the diversity on the campus
- To organize International and National conferences and structured workshops for the benefit of students and professionals

### **ACADEMIC ACTIVITIES**

The students for M.S. (Pharm.) and Ph. D programme are admitted through a nationwide open competitive entrance examination (NIPER-JEE) conducted by NIPER Mohali. The prerequisite to appear for this examination is undergraduate degree and GPAT/GATE qualification. During their entire tenure students are groomed to bridge a link between academia and the industry.

NIPER-Gn offers M.S. (Pharm.) and Ph. D programme in following disciplines

- Biotechnology
- Medical Devices
- Medicinal Chemistry
- Natural Products
- Pharmaceutical Analysis
- Pharmaceutics
- Pharmacology & Toxicology

### Admission of students to M.S.(Pharm.) in 2014-2015

NIPER-Gandhinagar entered into eighth academic year of its existence, from July 2014. The institute has Masters level programme in seven different disciplines in the eighth academic year, leading to M.S.(Pharm.) in Pharmaceutics, Natural Products, Biotechnology, Pharmaceutical Analysis, Medicinal Chemistry, Pharmacology & Toxicology and Medical Devices streams. The institute has currently 31 students from Batch 2013-15 and in the eighth academic year, 34 students were admitted to seven streams (Batch 2014-16).

### Teaching schedule for the Academic Year 2013-14

### **1st Semester**

Teaching started with the orientation week in last week of July 2014, wherein Experts from industry were called to orient the students. Regular teaching schedule was followed the week after. Weekly, two seminars were scheduled for the first semester students. The Mid-term exams were scheduled from 6 to 10th October 2014 and the Final Exams were scheduled from 15th to 26th December 2014.

### **3rd Semester**

Third Semester started from the second week of May 2014. The students submitted their Project Proposals and literature survey summary in the first week of June 2013 followed by the Project

Proposal Defense. The Project Progress presentation was held in presence of SRC members from January 5-9, 2015.

	No. of Students admitted		
Discipline	(Batch 2013-15)	(Batch 2014-16)	
Natural Products	4	3	
Pharmaceutics	6	7	
Biotechnology	5	5	
Pharmaceutical Analysis	5	5	
Medicinal Chemistry	3	5	
Pharmacology and Toxicology	3	4	
Medical Devices	5	5	

### Ph. D. Programme

Currently six Ph. D. fellows are pursuing their PhD programmes at NIPER-Gandhinagar. All of them have successfully completed their coursework and are currently continuing with their laboratory experimental work. A review of their research work was recently held (six monthly evaluation) to assess the progress of their work, in presence of external examiner.

### **RESEARCH ACTIVITIES IN DIFFERENT DEPARTMENTS**

### Department of Biotechnology

- Generation of induced Pluripotent Stem Cells (iPSCs) using non viral methods and its redifferentiation
- Pharmacogenetics studies and population based genome analyses like genomic alteration in oral cancer, diabetes, tuberculosis
- Proteomics and genomics biomarkers for diabetes and its secondary complications
- Cancer research including targeted drug delivery to cancerous cells usingnanoparticles, to overcome chemoresistance and prevention of relapse by Cancer tem Cells (CSCs) redifferentiation
- Expression of therapeutic protein through various expression systems, including bacterial, plants and mammalian cells
- Plant tissue culture and identification of molecular markers
- Development of novel vaccine against infectious diseases
- Gene silencing through siRNA and shRNA

### **Department of Pharmaceutics**

- Development of specialized delivery systems including Taste masked formulation, Pellets, Microneedle, Transdermal, SLN, NLC and SMEDDS
- Physical characterization of pharmaceuticals using rheology, thermal and texture analysis, imaging techniques,
- Identification and formulation of novel adjuvants and compatibility screening
- Formulation development and stability of biotherapeutic agents
- Targeted lymphatic delivery system for Cancer, Leishmaniasis and HIV

- Solubility enhancement using nanocrystallization, complexation and cocrystallization
- Nanotechnology based drug delivery system targeting brain
- Formulation development of solid orals using Quality by Design (QbD)

### **Department of Natural Products**

- Target Oriented Synthesis (TOS) based development of New Chemical Entities (NCEs) of natural scaffolds against Multi Drug Resistant Tuberculosis and its secondary complications
- Lead based design and development of NCEs of natural pharmacophores as antidiabetic and other autoimmune disease leads
- Diversity Oriented Synthesis (DOS) of small molecules as anti -HIV, anti-Alzhiemer's and anti-inflammatory leads
- Molecular docking and Structure Activity Relationship (SAR study) of NCEs
- Discovery of new natural products as anticancer and neuroprotective leads
- Development of National repository of secondary metabolites
- Development and standardization of herbal formulations

### **Department of 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 pharmacokinetics and

pharmacodynamic studies

- Computer aided drug designing and study of Structure activity relationship
- Design and synthesis of target compounds as anticancer and DPP-IV inhibitor agents
- Ionic liquid mediated C-C and C=C bond forming reactions
- Synthesis of Bax activating molecules to drag cancerous cells towards apoptosis

### **Department of 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



### **Department of Pharmacology and Toxicology**

- Development of immunosuppressive human xenograft mice model
- Neuroprotection against cerebral ischemia, traumatic brain injury, alzheimer's disease, stress disorders and multiple sclerosis
- Pharmacological screening of synthetic and herbal products for antidiabetic, anticancer, antiulcer and anti-inflammatory activity
- Behavioural studies on learning & memory, depression and anxiety
- Pharmacokinetics and Pharmacodynamics and bioavailability studies of herbal drugs
- Absorption Digestion Metabolism Excretion (ADME) and toxicological studies of herbal and chemical entities
- In-vitro and in-vivo correlation

### **Department of Medical Devices**

- Research on osteoconductive coating materials for bone tissue engineering
- Studies on anti-proliferative and antithrombotic coatings for polymeric and bare metal stents
- Development of polymer based implants for peripheral nerve regeneration
- Development of matrix for biosensor
- Surface modification of nanomaterials for biomedical applications
- Fabrication of artificial cornea and contact lens with newer approach
- Synthesis of 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

### **National Centre for Medical Devices**

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Medical device industry is multi-product industry with multipurpose use. India's medical device market is currently the fourth largest market in Asia with 700 medical device makers, and ranks among the top 20 in the world. The Indian medical device and equipment market is expected to grow \$ 7.8 billion by 2016, at a CAGR of 15.5 per cent. The Indian medical devices industry forms a very small part of the total manufacturing industry accounting for only 0.2 per cent of all certified facilities. Due pioneering efforts of NIPER-Gn, the India's first cutting edge interdisplinary department has been established in 2012. The main goal of this department is to combine the pharmacy aspects with engineering to produce indigenous products and innovations, in which India mainly depend on western outfit. It explores huge job and research opportunities in India, since we are importing 90% of devices from other countries.

### **CONFERENCE/WORKSHOP/ SEMINAR ORGANIZED**

• One Day Seminar series on "Concepts in Pharmaceutical Analysis", 12th September, 2014.

### **HONOURS/AWARDS**

- Best Poster Award: Bhavik Kansara, Anita Mahapatra, Y. Venkat Raju, Lakshmi S. Glucose uptake activation in muscle cell line (C2C12) by *Cassia auriculata*. National conference on Herbal drugs: opportunities and challenges 5-7 Nov, 2014
- Awarded Gufic prize: Dilawar Uphadhayay, Sheetal Anandjiwala, Harish Padh, Manish Nivsarkar. *In-vivo* pharmacokinetic and metabolism of Picroside I and II from Kutkin in rat plasma. at Indian pharmacological society conference 28-30 December, 2014

### PUBLICATIONS/PRESENTATIONS/PATENTS

### **Patents filed**

- 1. Neelam Chauhan, et al. Novel 2-substitued thaizole compounds, Indian Patent, July, 2014
- 2. Neelam Chauhan, et al. Minicircle DNA vector for inducing pluripotency in nucleated blood cells and other cell types and its re-differentiation for the use in regenerative medicine. Provisional Indian Patent, June 2014.
- Anita Mahapatra, Neelam Chauhan, et al. Synthesis of 1,4- naphthoquinone analogues as potential agents for antidiabetic and other autoimmune diseases, Provisional Indian Patent, June 2014.

### **Publications**

- Mahapatra A, Shah P, Jivrajani M and Nivsarkar M. Synthesis and blastocyst implantation inhibition potential of lupeol derivatives in female mice. Records of Natural Products, accepted, under Revision (2014) [Impact Factor: 1.560].
- Mahapatra A, Maheswari V, Kalia NP, Rajput VS and Khan IA. Synthesis and antitubercular activity of berberine derivatives. Chemistry of Natural Compounds, 50(2), 321-325 (2014) [Impact Factor: 0.599].
- Mahapatra A, Chauhan N, Patel DR, Kalia NP, Rajput VS and Khan IA. Synthesis and anti-tubercular activity of oleanolic acid analogues. Pharmaceutical Chemistry Journal, 48(1), 39-43 (2014) [Impact Factor: 0.320].
- Chauhan N, Padh H. Intra and inter ethnic variations for NAT2 polymorphisms. African Journal of Biotechnology 13: 4639-46 (2014) [Impact Factor: 0.57].
- Jansari S, Devashri N, Dhanani A, Chauhan N. Differentiation of stem cells into pancreatic β-cells: regenerative medicine for diabetes. International Journal of Biological and Pharmaceutical Research, 5: 901-9 (2014) [Impact Factor: 1.34].
- Bhatt D, Chauhan N, Sharma A, Dhawan D, Bhatt R, Phatak S and Padh H. Plasma glucose concentration as a phenotypic

marker for *CYP2C9* genetic variants in diabetic population of Gujarat. Indian Journal of Pharmaceutical Sciences, 76: 72-77 (2014) [Impact Factor: 0.63].

- Shah BM, Misra M, Shishoo CJ and Padh H. Nose to brain microemulsion-based drug delivery system of rivastigmine: formulation and ex-vivo characterization. Drug Delivery, 1-13 (2014).
- Pathak R, Dash RP, Misra M and Nivsarkar M. Role of mucoadhesive polymers in enhancing delivery of nimodipine microemulsion to brain via intranasal route. Acta Pharmaceutica Sinica, 4(2):151-160 (2014).
- Kalavadia S, Dash RP, Misra M and Nivsarkar M. Design and *in vivo* evaluation of gastrointestinal mucoadhesive patch system (Gmps) loaded with chitosan nanoparticles. International Journal of Pharmaceutical Development & Technology, 4 (3) (2014).
- Dokania S and Joshi AK. Self-microemulsifying drug delivery system (SMEDDS) – challenges and road ahead. Drug delivery, Informa healthcare (2014)

### **PLACEMENT ACTIVITIES**

 To provide placement to students at reputed Pharma companies, a placement Cell (including the faculty members as well as the students of NIPER-A) has been created which is responsible for publishing a placement brochure and sending it to various Pharma companies.



- Various companies have been visiting our organization for Campus Interviews.
- For the present 2013-2015 Batch, placement activity has already been initiated and so far 4 companies have requested students brief profile for initial screening at their level. This activity is expected to pick up momentum in coming months.

### For 2012-2014 Batch:

For campus recruitment total 15 companies contacted placement cell for placement related activities for different stream of students. Some of them visited us while remaining called students at their premises for further interviews and screening. Some of the companies which contacted us for placement includes Troikaa Pharmaceuticals Ltd, Indigene Pharma, Macleods pharma , Zydus Cadila, oxygen, Envision scinetific, RELYSYS, S3V- vascular technologies, Alembic Pharmaceutical Ltd, Piramal discovery, Intas Biopharma, Amneal Pharma, Naticon Inc, Sun pharma etc. Out of total 52 students, 46 students opted for placement, in which 14 students were placed in campus, while 24 students were placed post submission of thesis. The pay package offered by different companies ranged in between 3.25- 1.8 lakhs Per annum. As on date all the students of 2012-2014 batch have got placements in different companies except few students who have opted for higher studies.

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
Total	52	46	14	10	24



### **NIPER-KOLKATA**

The National Institute of Pharmaceutical Education & Research-Kolkata (NIPER-Kolkata) was established as an Institute of National Importance by the Government of India through Act of Parliament (NIPER Act 1998 & NIPER amendment Act 2007). The Institute is presently housed at the Indian Institute of Chemical Biology (IICB) which is the Mentor Institute – a premier Institute of the Council of Scientific & Industrial Research (CSIR), India,

Objectives: The main objectives of NIPER-Kolkata are:

- To tone up the level of pharmaceutical education and research.
- To produce leaders in the field and provide opportunities for training of future teachers and research scientists for the industry and the profession.
- To be a centre for innovation in pharmaceutical sciences and technology.
- To encourage research and studies in new and emerging areas like discovery of pharmacologically active molecules, cellular and molecular biology, immunology and immunodiagnostics, recombinant DNA technology and monoclonal antibody technology, novel drug delivery systems, chemical and biochemical process technology, etc.
- To provide scientific basis for traditional medicines.

NIPER-Kolkata was inaugurated on November 05, 2007. Since its inception the Institute has been conducting Masters' level programmes in three different disciplines, Medicinal Chemistry, Natural Products and Pharmacoinformatics, leading to M.S. (Pharm.) degree.

### Admission of students in 2014-2015

Counselling for admission of students took place in NIPER-Mohali in the month of July, 2014.

Discipline	No. of students
Medicinal Chemistry	16
Natural Products	12
Pharmacoinformatics	14

The orientation programme for the students took place on 4<sup>th</sup> August, 2014 and the first year first semester classes commenced from 5<sup>th</sup> August, 2014.

### 50 Academic Programme

- Twenty nine Masters Students of the first batch who graduated in June, 2009 received their M.S. (Pharm.) degree scrolls in the first convocation held on 11<sup>th</sup> June, 2010.Thirty twoMasters Students of the second batch who graduated in June, 2010 and the third batch of 40 students who graduated in June, 2011 received their degree scrolls in the second convocation held on 18<sup>th</sup> May, 2012.
- The fourth batch of 49 students, who graduated in June, 2012 and the fifth batch of 47 students, who graduated in June, 2013 received their degree scrolls in the third convocation held on 25<sup>th</sup> October, 2013.
- The sixth batch of 37 students graduated in June, 2014.

- The seventh batch of 49 students is doing their 3<sup>rd</sup> semester and will complete their course in June, 2015.
- The eighth batch of 42 students is doing their 1<sup>st</sup> semester.
- A total of 500 books have been purchased by NIPER-Kolkata. The Institute subscribes for SciFinder.

### **Placement activities:**

- Most of the students of the first six batches 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.
- The placement activities for the seventh batch of students have been initiated and the placement brochure has already been brought out.

### **Events & activities:**

- a) A six week workshop was conducted for the second year students by British Council to improve their language skill.
- b) Each second year student is allowed to attend one scientific conference.
- c) A popular lecture on "Earthquake, Tsunami and preparedness" was delivered by Prof. (Dr.) Sugata Hazra, School of oceanographic studies, Jadavpur University, Kolkata-700032 on 19<sup>th</sup> September, 2014.

### Swachchh Bharat Abhiyan (Clean India Mission)

A program was initiated on 2<sup>nd</sup> October, 2014 at the Mentor Institute jointly by CSIR-IICH and NIPER-Kolkata to observe "Swachchh Bharat Abhiyan (Clean India Mission)".



### The faculty:

The faculty involved in teaching the M.S. (Pharm.) courses consists of visiting Teachers from Calcutta University, Jadavpur University, West Bengal State University at Barasat and West Bengal University of Technology and Scientists from Bose Institute, Central Research Institute of Ayurveda, Indian Association for the Cultivation of Science, Indian Institute of Chemical Biology, Institute of Post Graduate Medical Education & Research, and Saha Institute of Nuclear Physics and industries like TCG Life Sciences.



### Staff and Officers:

NIPER-Kolkata does not have any permanent staff and officers. Retired persons have been appointed on contract basis for running the academic programme, administration, examination activities, and placement of students, students' hostel and other activities.

Library: A total number of 922 books are available for NIPER students. All scientific journals are available online to NIPER students from the Mentor Institute library.



Library

### Library

Hostel accommodation and facilities: At present the NIPER-Kolkata students (total 91) are accommodated in the CSIR Scientists Apartment, 428 Prince Anwar Shah Road, Kolkata-700045. The hostels are self-sufficient with canteens, common rooms, facilities and desktop computers with wireless Internet service enabling access to all International and National Journals.

### **Games & Sports activities**

a) Facilities have been provided in the Hostel campus for outdoor games like Cricket, Badminton and Volleyball and indoor games like carom and chess. The annual sports and games of NIPER-Kolkata are held in January every year. During this period facility has been provided for Gym in the hostel.

### NIPER, RAEBARELI

### **ACADEMIC ACTIVITIES:**

The National Institute of Pharmaceutical Education and Research (*NIPER*), Raebareli was created on November 14, 2008 under the mentorship of CSIR-Central Drug Research Institute,Lucknow. Currently NIPER Raebareli is offering M.S. (Pharm.) courses in three disciplines Medicinal Chemistry, Pharmaceutics and Pharmacology and Toxicology. The 7<sup>th</sup> Batch (2014-16) students are pursuing their 1<sup>st</sup> Year (I & II Semester) course work in NIPER, Raebareli campus and the 6<sup>th</sup> batch students after completing their 1<sup>st</sup> Year (I & II Semester) course work in NIPER, Raebareli campus are now pursuing their 2<sup>nd</sup> Year (III & IV Semester) project work under the able supervision of different scientists of CSIR-CDRI. The stream wise present status of students is given below:

Courses	No. of students in 6 <sup>th</sup> Batch (2013-15)	No. of Students in 7 <sup>th</sup> Batch (2014-16)
M.S. (Pharm.) Medicinal Chemistry	18	19
M.S. (Pharm.) Pharmaceutics	15	13
M.S. (Pharm.) Pharmacology & Toxicology	6	6
Total	39	38

### **EVENTS:**

 6<sup>th</sup> NIPER (RBL)-CDRI SYMPOSIUM (20<sup>th</sup> - 22<sup>nd</sup> FEBRUARY, 2014):

Indian pharma industry has to focus more on R&D, so as to enable India to maintain its status in the world pharma market and move ahead to become a global leader. Keeping this in view NIPER, Raebareli initiated the series of NIPER (RBL) - CSIR-CDRI Symposium to groom its students with core competencies, ethics and values to evolve in rapidly changing scenario of the Pharma sector. This year the 6<sup>th</sup> symposium of the series was held on the topic "Current Scenario in Drug Discovery & Development" during February 20<sup>th</sup>-22<sup>nd</sup> 2014 in the new campus of CSIR– Central Drug Research Institute, Lucknow to enable the students in updating their knowledge and awareness about recent scientific developments.

The inaugural address was delivered by Prof. Y.K Gupta, Head, Department of Pharmacology, AIIMS, New Delhi on the topic 'Clinical Research in India". The inaugural function was presided over by Prof. B. N. Dhawan, Ex Director, CSIR-CDRI, Lucknow. About 85 posters were presented and the session was spread over two days where the students displayed their project based presentations. The best and the second best posters were suitably awarded.

• SECOND CONVOCATION (7<sup>th</sup> APRIL, 2014):

The second convocation of NIPER, Raebareli was held on April 7, 2014 in CSIR-CDRI, Lucknow. The occasion was graced by the eminent Scientist Professor Goverdhan Mehta, Padma Shri, FRS, FNA, FASc, FNASc, FTWAS, National Research Professor, School of Chemistry, University of Hyderabad, as the Chief Guest and Ms. Aradhana Johri, Secretary, Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, Government of India presided over the function. Academic excellence of students was rewarded with Gold & Silver medals. Chief Guest Professor Goverdhan Mehta delivered the key note address and Ms. Aradhana Johri delivered an inspiring speech with emphasis on proper employment of the pass out students.

A total of 89 students from three batches (2009-11, 2010-12 and 2011-13), received their degrees with great pride and honour. from Ms. Aradhana Johri, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers,



Govt. of India and Chairperson, Steering Committee, NIPER – Raebareli.

The Chief Guest Professor Goverdhan Mehta presented Gold & Silver Medals to the thirteen academic toppers from three batches (2009-11, 2010-12 and 2011-13).

PHARMACY DAY (27<sup>th</sup> SEPTEMBER, 2014):

Like previous years Rx Pharmacy Day, 2014 was successfully organized at NIPER, Raebareli on 27<sup>th</sup> September, 2014 as an anuual event. On this occasion a very informative lecture was delivered by Dr. Raja Roy (Professor, CBMR, Lucknow) on the topic "Use of NMR in Clinical Studies". The second lecture was delivered by Dr. Rishi Pal Astt. Professor, Department of Pharmacology, KGMU, Lucknow on the topic "Drug discovery & Development", which was lively, interactive and full of motivation for everyone.

SWACHH BHARAT ABHIYAN (2<sup>nd</sup> OCTOBER, 2014):

'Swachhta Abhiyan' was organised in NIPER, Raebareli on 2<sup>nd</sup> October, 2014 taking ahead the legacy and responding to the Nation's call by the Hon'ble Prime Minister, Mr. Narendra Modi followed by the communication of the same by Madam Smriti Irani, Minister of Human Resource Development, Government of India.

The campaign started with administering of pledge by Project Director to all the faculty & staff members and students to carry out the cleanliness drive and contribute voluntarily towards cleaning of institute campus and neighborhood.

• ANNUAL DAY CELEBRATION (14<sup>th</sup> NOVEMBER, 2014):

The 6<sup>th</sup> Annual Day celebration of NIPER, Raebareli was held on 14<sup>th</sup> November, 2014. The chief guest Dr. K.C. Gupta, Ex-Director, CSIR-Indian Institute of Toxicology Research (*IITR*), Lucknow delivered the very innovative lecture titled *"EnhancedTargeted Anticancer Activity of Doxorubicin Nanoparticle in Ehrlich's Ascites Tumors"*. The function was attended by eminent scientists, technologists and academia. Students were also given awards for their participation in various extracurricular activities held in the campus during the year.

PUBLICATIONS:

The students were ably inspired for scientific publication and presentation to bring NIPER, Raebareli on scientific research platform which led to publications in reputed journals with inputs from project work and presentation of papers in conferences. A total of 41 publications in research Journal and conferences were published and presented.



Releasing of 6<sup>th</sup> NIPER-RBL-CSIR-CDRI Symposium Souvenir (L-R): Dr. Neeraj Sinha, Senior Principal Scientist, CSIR-CDRI, Dr. S.K. Puri, Director, CSIR-CDRI, Chief Guest Dr. Y.K. Gupta, Prof. & Head, Dept. of Pharmacology, AIIMS, New Delhi), Dr. B.N. Dhawan, Ex-Director, CSIR-CDRI, Dr. P.K. Shukla, Project Director, NIPER-Raebareli.



NIPER, Raebareli student receiving Medal and degree receipentsat 2nd NIPER (RBL) from Prof. Goverdhan Mehta held on 7th April, 2014



Gold and Silver Medal Convocation Ceremony



Students, staff and faculty of NIPER (RBL) participating in "Swachata Abhiyan" organinsed at NIPER (RBL) on 2<sup>nd</sup> October, 2014



Laboratory at NIPER (RBL)



(L-R) Dr. Achint Jain, Lecturer, NIPER (RBL); Dr. P.K. Shukla, Project Director, (NIPER (RBL); Dr. K.C. Gupta, Ex-Director, IITR, Lucknow; Dr. S.K. Puri, Director, CSIR-CDRI, Lucknow with the winners of Annual Sports 2013-14 during 6<sup>th</sup> Annual Day Celebration held on 14<sup>th</sup> November, 2014.

### **NIPER HAJIPUR**

NIPER Hajipur has been established to meet the dual objectives i.e. to inspire and provide opportunities for top class Pharma education to the youth of Bihar and the country on the one hand and to supply skilled manpower to our fast growing Pharma industry on the other. It is heartening to see the students reaching and crossing the every-increasing standards of excellence in their academic pursuits as well as in research projects. With a view to impart cutting-edge science related to the pharmaceutical industries and pharma-regulatory bodies' requirements, NIPER Hajipur has started initially its inning with courses like Pharmacy Practice, Pharmaco-informatics and Biotechnology. A total of 36 students have been admitted this year, of which 15 are in Pharmacy Practice, 11 are in Pharmacoinformatics and 10 are in Biotechnology. Apart from Masters Program, 19 Ph. D. students have been admitted, of which 12 are in Biotechnology, 6 are in Pharmacoinformatics and 1 in Pharmacy Practice.

NIPER, HAJIPUR is undertaking applied and meaningful research in these areas. In coming years, NIPER, Hajipur is going to attain



greater heights and would be a leading seat of learning for the modern pharmaceutical science.

The main objectives of the Institute:

- Nurture and promote quality and excellence in pharmaceutical education & research.
- Toning up the level of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession.
- Creation of National centers to cater to the needs of the pharmaceuticals industry and other research and teaching institutes.
- Collaboration with Indian industry to help it to meet global challenges.
- National / International collaborative research.
- Study of sociological aspects of drug use and abuse and rural pharmacy etc.
- Running programme in drug surveillance, community pharmacy and pharmaceutical management.

### Departments

From the beginning NIPER Hajipur has been entrusted with the responsibility of teaching and research in the following three disciplines:

Biotechnology Pharmacy Practice Pharmacoinformatics

### Intake of the students:

Numbers of M Pharm. / MS. Pharm. students admitted and passed during 2009 to 2016 are as follows:

Year	Admitted	Passed	Left NIPER
2009-11	34	32	2
2010-12	42	40	2
2011-13	43	41	2
2012-14	21	19	-
2013-15	39	Continuing	
2014-16	36	Continuing	

### Number of students admitted in Ph.D. programme:

Year	Ph. D (Biotechnology)	Ph. D (Pharmacoinformatics)	Ph. D (Pharmacy Practice)
2011	3	2	-
2012	3	2	-
2013	3	2	-
2014	3	0	1





One day National seminar on Recent Trends in Cancer Research



Participants in National Seminar at NIPER, HAJIPUR



Chief Guest Dr D J Chattopadhyay, Pro Vice chancellor (Academics), Kolkata University

### **NIPER, GUWAHATI**

National Institute of Pharmaceutical Education and Research (NIPER) is the first national level institute in Pharmaceutical sciences with a proclaimed objective of becoming a 'Center of Excellence' for Advanced Studies and Research in Pharmaceutical Sciences'. The Government of India has declared NIPER as an 'Institute of National Importance'. NIPER, Guwahati was inaugurated on 16th September 2008 by the then Honorable Union Minister for Chemicals and Fertilizers and Steel, Shri Ram Vilas Paswan in the presence of several distinguished personals. The institute is completing 6 years of its establishment. The Central Plan outlay for 2012-13 for various projects, programmes and schemes and Central Assistance for State and Union Territory Plans has depicted that the expenditure earmarked for North Eastern Region (18.80 crore) is incurred from NIPER, Guwahati. The Government of Assam has provided approximately 89.0 acres of land for construction of new campus in Changsari, north of Guwahati city. The necessary formality to start the construction work has already been completed. Government Medical College and Hospital (GMCH) is the second largest hospital in India in respect of its bed strength and enjoys a prestigious status for its academic pursuits and patient care. It is also a tertiary care referral center for specialty and super specialty treatment. As a mentor institute, it is making all efforts to take NIPER to great heights. NIPER, Guwahati organized 1st Convocation on 6th September 2013 where degrees were awarded to the passed out students till the previous academic year since the first batch.

### Vision

- Enhancement of creativity, motivation, drives and professionalism.
- 2. To bring synergy between academics, R&D, Technology and Industries and exposure to such environment.
- 3. Bridging collaborations between pharmacy, biotechnology, information technology and prepare for meeting global challenges.
- 4. To prepare professionals to suit to the need of Pharmaceutical Industry.
- 5. National/International collaborative research.
- Exposure for the students and scholars to high-tech areas such as drug discovery, pharmacogenomics, toxicogenomics, RNA and DNA technology, bioinformatics, drug design and molecular modeling, molecular biology and herbal research etc.,
- Develop and practice learning for the professionals and training for teachers, researchers and regulators in the respective fields.
- 8. Create a world class institute for teaching and research in the field of Pharmaceutical sciences.
- 9. Running programmes in drug surveillance, community pharmacy and Pharmacovigilance and Haemovigilance.

The NIPER has three Departments:

- 1. Pharmacology & Toxicology
- 2. Biotechnology
- 3. Pharmacy Practice

### **Disciplines:**

The first batch of students was admitted in 2008. Besides catering to the various needs of pharmaceutical industry, the NIPER offers Masters degree in following 3 streams and Ph.D. degrees in 2 streams :

- 1. Pharmacology & Toxicology
- 2. Biotechnology
- 3. Pharmacy Practice

### Infrastructure:

NIPER conducts regular education programmes for academia and industry in various disciplines and helps the Indian Pharmaceutical

Industry in solving their R&D related requirements. National Institute of Pharmaceuticals Education & Research has upgraded facilities for achieving the highest level of efficiency in imparting education and events. NIPER laboratories are equipped with modern equipment's that are equivalent to other state-of-the-art laboratories in the World and students are utilizing facilities of mentor institute and others like IIT-Guwahati, State biotech hub, Gauhati university for those instruments which are not available in the institute.

### **Events and Activities:**

NIPER, Guwahati encourages the students to participate actively in conferences, seminars, trainings and workshopsStudents attended "National Seminar on Molecular Pathology of Cancer" on 10<sup>th</sup> January 2014 in Dr. B. Borooah Cancer Institute, Guwahati.



Students attended ICPS 2014 held at SGRR ITS Dehradun, Uttarakhand.



The students attended the "9th Annual Conference of Association of Oncologists of North East India" (AONEI), 2014 held on 1st and 2nd March 2014 in Guwahati. In the Paper presentation (Oral cum Poster) competition, students from NIPER, Guwahati were awarded the first and second prize for the papers "Evaluation of the anticancer and protective effects of morin hydrate in combination with cisplatin using peritoneal carcinomatosis models in mice" by Athira.K.V, Kasbe Prajapati, MangalaLahkar, Ranadeep Gogoi and 'Study of ras gene polymorphism in human multiple myeloma of Assam" byNityanand Bolshette, Swathisree Karaggi, Vinayak Jamdade, Ranadeep Gogoi,Mangala Lahkar, Jina Bhattacharyy, respectively





Twenty one students participated in the training program on "Basics of Good Clinical Practice", organized by Clinical Development Services Agency (CDSA), an extramural unit of Translational Health Science & Technology Institute (THSTI), Department of Biotechnology, Ministry of Science & Technology, Govt. of India held at NEIGRIHMS, Shillong, Meghalaya on 28th and 29thMarch 2014 under the leadership of Prof.B.K.Bezbaruah, Project Director.



- Further, students attended the "Academy of Clinical Experts (ACE)" meeting held in Mumbai on 26-27th July 2014. The Best Paper Award (Rs.50,000) was secured for "Toll like receptor expression pattern and polymorphism profiling in patients of multiple myeloma" by Nityanand Bolshette, Krishan Thakur, Ranadeep Gogoi, Mangala Lahkar, Jina Bhattacharyya of NIPER, Guwahati.
- Students also attended and presented paper in the first annual conference of the 'Association of Pharmacy Teachers of India' (APTI) Haryana state branch held at Kurukshetra University in Haryana on 22nd and 23rd August 2014. The theme of the conference was "Indian scenario of Pharmaceutical Education Challenges and Future Perspectives".



A report on the brilliant achievements of Mr. Parveen Kumar, first batch Ph.D Scholar, NIPER, Guwahati was published in 'Himachal Dustak', a daily newspaper of Himachal Pradesh 55





NIPER-Guwahati enthusiastically inaugurated the Swatch Bharat mission on October 2nd,2014 and continuing their activities in maintaining, cleanliness and spreading the knowledge of the role of cleaning since October 2nd, 2014.

Some of the Photographs taken during "Swachh Bharat Mission at NIPER-Guwahati" areas follows:





To commemorate the Birth anniversary of The Iron Man of India "Sardar Vallabhbhai Patel" "National Unity Day" was observed at NIPER-Guwahati on 31st October 2014.

### Rashtriya Ekta Diwas at NIPER-Guwahati

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### Present status and future prospects:

NIPER, Guwahati students are coming up with timely publications of their research work. The students of the institute are highly motivated towards all facets of academics, research as well as their careers.

Amongst the passed out students of 2014, few are admitted in Ph.D programs in different national institutes, including NIPERs, IIT. Few students got absorbed in various pharmaceutical companies and consultancy firms, including TCS, Cognizant. The rest are establishing their careers in academics and industry.

Running a national institute under a mentor institute is itself a challenging task. However, the mentor institute, GMCH is putting its extra energy, devotion and motivation in establishing NIPER, Guwahati as a center of excellence. The management committee of NIPER, Guwahati is striving hard for the growth of the institute by developing more infrastructure and facilities and by providing more guidance in academics and orientation in research. It is hoped that the forthcoming year would unfold its unlimited achievements in every field.



# 7

# Chapter

### NEW INITIATIVES

- 7.1 Cluster Development Programme for Pharma Sector" (CDP-PS)
- 7.2 New Initiatives Taken by National Pharmaceutical Pricing Authority (NPPA)
- 7.3 National Center for Research & Development in Bulk Drugs at National Institute of Pharmaceuticals Education & Research, Hyderabad
- 7.4 Collaborative TB and Kala Azar Research Project of NIPER, Mohali



# Chapter - 7 New Initiatives

### 7.1 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 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.

- 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 lessforcreation f common facilities. Some of the indicative activities under the Common facilities are:
  - Common Testing Facilities
  - TrainingCentre
  - EffluentTreatmentPlant
  - R&D Centres
  - CommonLogistics Centre

7.1.2 Setting up of Task Force on Enabling the Private Sector to lead the growth of Pharmaceutical Sector. A Task Force comprising representatives from Government Departments/Institutions and Industry Associations has been set up in the Department with the following Terms of Reference (ToRs):

- Identifying the challenges before the Indian Pharmaceutical Industry pertaining to various government departments and agencies.
- Identifying ways to ensure better coordination among various Government Departments and Industry to facilitate the industry.
- (iii) Identifying areas of duplication, if any, among different Government agencies and departments on issues relating to Pharmaceutical Industry including research.
- (iv) Suggesting suitable changes in the administrative arrangements or administrative mandate of Government agencies and Departments to enable better and coordinated facilitation and support to the industry.
- Exploring the possibility of having a single window clearance type of facilitation for the industry for the required regulatory approvals.

- (vi) Working out the mechanism for a regular and institutionalized forum for Government Industry partnership where the industry issues can be redressed periodically and in a time bound manner.
- (vii) Exploring the possibility of linking the Indian Pharmaceutical Industry with various educational and research Institutions in the Government Sector like NIPERs, Research Institutes under Department of Health Research, Department of Bio Technology, Department of Science and Technology and others.

The Task Force to submit its report in three months.

7.1.3 Setting up of Task Force to identify issues relating to the promotion of domestic production of high end Medical Devices and Pharmaceutical Manufacturing Equipment in the Country. A Task Force comprising representatives from Government Departments/Institutions and Industry Associations has been set up in the Department with the following Terms of Reference (To Rs):

- Ascertaining the present status and share of domestic production and imports in different categories of medical devices and equipments used in the manufacture of Pharmaceuticals.
- (ii) The impediments that exist in making India self-reliant in domestic production of medical devices and equipments used in manufacture of pharmaceuticals.
- (iii) The steps necessary for promotion of domestic production of high end medical devices and pharmaceutical manufacturing equipments.

The Task Force will submit its findings in three (3) months.

7.1.4 Setting up of Task Force for development of manufacturing capabilities in each medical vertical in Pharmaceutical production. A Task Force comprising representatives from Government Departments/Institutions and Industry Associations has been set up in the Department with the following Terms of Reference (ToRs):

- Identifying focus areas for development of manufacturing capabilities in each medical vertical keeping in mind the specificities of each medical discipline.
- (ii) Identifying the gaps in domestic manufacturing in these verticals and suggesting ways to overcome these.
- (iii) Identifying the issues and support required from different government agencies and departments for achieving the manufacturing capabilities and filling the gap areas, if any, in each medical vertical.
- (iv) Any other related issues which may come up during the Task Force meetings and which the Task Force may also like to include as a Term of Reference.



The Task Force will submit its findings in three (3) months

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

### (I) Integrated Pharmaceutical Database Management System (IPDMS)

With the help of NIC, a web-enabled application called Integrated Pharmaceutical Database Management System (IPDMS) is being developed to facilitate online submission Form-II, III and V of DPCO, 2013 by all drug manufacturers. The objective is to fix/ revise prices of scheduled formulations/ new drugs on the basis of data provided by manufacturers themselves; monitor availability of Scheduled Formulations in every part of the country; regulate and monitor the price rise of Scheduled and non-Scheduled Formulations; enforce notified price; detect price rise violation; and recover overcharged amount along with interest from the company. Further, an ICT (Information Communication & Technology) enabled workflow system will be developed to facilitate all its functions as stated above.

The IPDMS would (i) facilitate Online submission of all DPCO forms by the companies at regular intervals; (ii) creation of uniform structure of data-base for all the companies and to build good authentic database of medicine market prices and other details; (iii) facilitate processing of forms at NPPA level with a pre-defined workflow in transparent manner; (iv) generating a large number of analytics and reports on database for supporting decision making; and (v) facilitate public awareness on availability of medicines and market price comparison on database through different information dissemination methods.

After getting security clearance from NIC, the registration process was launched on 18.09.2014. Till 13.02.2015, 351 pharma companies have already registered and 449 pharma companies are in the process of registration with the online system. So far 21,571 products have been registered and another 8053 are under process. This system would be beneficial to all stake holders, i.e., NPPA, the pharma industry and the consumers at large, in resolving the various problems being faced in the past. Industry will benefit from a user-friendly online reporting mechanism; NPPA will benefit from reliable database based on self-disclosure by companies, and consumers will benefit from access to comprehensive price database of medicines. The issue of overpricing/overcharging will also be effectively addressed by way of self-regulation by companies and a non-discretionary objective mechanism for proceeding against overcharging. It will bring about efficiency in implementation of DPCO 2013 with greater transparency.

### (II) Pharma Jan Samadhan

Pharma Jan Samadhan (PJS) is a web enabled system developed by National Pharmaceutical Pricing Authority (NPPA) with the assistance of National Informatics Centre (NIC). The primary objective of PJS is to put in place a speedy and effective complaint redressal system with respect to availability and price of medicine. PJS serves as a robust e-governance tool for protection of consumer interest through effective implementation of the Drugs (Price Control) Order 2013. PJS replaces the earlier online Complaint Submission and Redressal System (CSRS) that was developed with respect to DPCO 1995.

Under PJS, Consumers, NGOs, dealers and enforcing agencies can register complaints related to:

- (i) Overpricing of Medicine
- (ii) Non-availability or Shortage of any medicine
- (iii) Sale of New Medicine without prior price approval of NPPA
- (iv) Refusal of supply or sale of any medicine without good and sufficient reason

Consequent upon registration of a complaint by the complainant, the same reaches the designated officer of NPPA who verifies the complaint and initiates appropriate action for resolving it in a time bound manner.

### (III) Consumer Awareness and Publicity Through Print, Electronic and other media:

Plan Scheme of Consumer Awareness and Publicity through Print, Electronic and Other Media is an on-going joint publicity campaign programme of the NPPA and Department of Consumer Affairs (DCA) on a 50:50 cost sharing basis. The modus operandi of the Scheme are:

- Print Media Issue of Advertisement through National/ Regional newspapers on bi-monthly basis as per media plan of DAVP to create public awareness.
- Publicity through Mobile Outdoor Media covering through Outer Panels of EMU/MEMU/DMU Trains moving in and out in various States for spreading the NPPA message- Installation of panels creating general awareness while purchasing medicine.
- Display of Vinyl Boards/ Hoarding in Govt. and Pvt. Hospitals
  Permanent installation of vinyl boards in hospitals about the availability of medicines at reasonable price.

The Department of Consumer Affairs, which had earlier regretted to part finance their share for the above two components, has now agreed to the joint publicity campaign on 50:50 cost sharing basis. An amount of Rs. 2.0 crore is earmarked under Plan Head for the year 2014-15 for this purpose. NPPA has already published one advertisement in various national and regional newspapers on 08.1.2015. Another advertisement is planned to be released by March, 2015.

# (IV) Compendium of Notified Ceiling Prices of Scheduled Drugs under DPCO 2013.

NPPA has prepared Compendium of Notified Ceiling Prices of Scheduled Drugs under DPCO 2013 as on 31.01.2015, which is available on NPPA's website. Printed copies are being distributed to State Drug Controllers and other stakeholders for information dissemination / enforcement.

### (V) Consultation with Stakeholders

NPPA has also initiated detailed consultations with stakeholders including civil society organizations, public health experts, State

Drug Controllers and representatives of Pharma industry & trade. Details of consultations are given below:

SI No.	Consultation with	Held on
1.	Civil Society & Public Health Experts at Delhi	27.8.2014
2.	State Drug Controllers at Delhi	3.9.2014
3.	Trade Associations and representatives of FICCI and CII at Delhi.	17.9.2014
4.	Pharma Industry Associations at Delhi	30.9.2014.
5.	Regional Meeting with SDCs at Delhi	29.12.2014
6.	Workshop on affordable medicines for all at Bhubaneshwar	22.1.2015
7.	Meeting with officers of Maharashtra Drug Controller, DOP, Public Health Experts, reps of AIDAN Network regarding Pharmaceutical Pricing at Nagpur.	1.2.2015

### 7.3 NATIONAL CENTER FOR RESEARCH & DEVELOPMENT IN BULK DRUG (NCRDBD)

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 ecofriendly 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.



### 7.4 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 instalment of Rs. 1.22 crore for both the projects was made in 2014. Based on the demand from the implementation agency, additional releases have been made during current fiscal year as well.



Shri Ananth Kumar, Hon'ble Minister for Chemicals& Fertilizers, Shri Hansraj Gangaram Ahir, Hon'ble Minister of State for Department of Pharmaceuticals, Dr. V.K Subburaj, Secretary Department of Pharmaceuticals , Shri Sudhansh Pant, Joint Secretary Department of Pharmaceuticals and Shri Jayant Tagore, President, Bulk Drugs Manufacturer Association (BDMA) on the occasion of release of Agenda for Pharmaceutical Industry in India on 25<sup>th</sup> February, 2015, New Delhi.

Sanda III



IMPLEMENTATION OF RAJBHASHA




### CHAPTER 8 IMPLEMENTION OF RAJBHASHA

### Hindi Prayog Protsahan Pakhwara

Hindi Prayog Protsahan Pakhwara was observed in the Department from 13<sup>th</sup> to 27<sup>th</sup> September, 2014 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 and winners were awarded cash prizes.

### 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 wasmade 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 2014-15,

### Official Language inspection of the sections in the Department of Pharmaceuticals to increase the use of official language in official work

To assess the status of the use of Hindi in the Department, OL inspection of 7 sections was conducted during the year 2014-15. Letters were written to the sections to take measures to remove the deficiencies found during the inspection.

Sanda III



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.

The Department is headed by Secretary to the Government of India who is assisted by two Joint Secretaries and one Economic Adviser.

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 / Physically handicapped in the main Secretariat of the Department of Pharmaceuticals, as on 31.12.2014 is as under:-

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.

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	Scheduled Castes	Scheduled Tribes	Other Backward Castes	Physically Handicapped
А	30	2	4	1	-
В	48	4	-	2	-
С	25	8	-		-
Total	103	14	4	3	







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### 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 isas 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.
- 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 pharmaceuticals 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 consulations 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.

Sanda III

## Chapter 11

INFORMATION AND COMMUNICATION TECHNOLOGY

- 11.1 Local Area Network (LAN)
- 11.2 IT Infrastructure
- 11.3 Website
- 11.4 Video Conferencing
- 11.5 File Tracking System
- 11.6 E-Governance
- 11.7 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, 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 INFRASTRUCTURE

Department of Pharmaceuticals in close association with NIC has focused on building up the IT infrastructure within the Ministry with the following objectives:

- Improve workflow, work management and monitoring.
- Assist in analyzing, decision making and scheduling through Management Information Systems (MIS).
- Storage of data, analysis and handling of databases.
- Provide Graphical User Interface (GUI) based environment.
- LAN for sharing the resources among users.
- Simplify dissemination of information to public and make it interactive.
- Train all personnel in making most of this technology.

### 11.3 WEBSITE AND SOCIAL MEDIA

As Website is an electronic medium to provide information and enhance government citizen interaction, a Web Site in English and in Hindi has been launched by the Department (http://pharmaceuticals.gov.in) and is hosted at NIC to ensure maximum reach of information and services to the citizens. It provides details of organizational set up of the department, its functions, subordinate offices, policies, publications, statistical data/information on functional parameters. Steps are being taken to redesign the website to make it more vibrant and interactive. 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. Various posts to create awareness regarding generic medicines, Educational and Research institutes NIPERs, etc. is posted on Facebook and twitter pages of Department.

### 11.4 VIDEO CONFERENCING

Video Conferencing facility is operational for Joint Secretary and above level Officers. 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. Executive Video Conferencing System (EVCS) is also installed at Secretary Desk to connect to Cabinet Secretary and Secretaries of other Ministries/Departments.

### 11.5 FILE TRACKING SYSTEM

Department has implemented a web based File Tracking system (FTS) to keep record of its receipts being received at various locations in the department and to maintain a consistent watch over the movement of various important Files and Receipts at different levels in the process of decision-making. The system is used as a tool to curb down pendency at all levels in the Department.

### 11.6 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. The 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.
- 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 off 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 and Result Framework Management System are functional in the Department to facilitate various sections.

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

- E-Office 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. Implementation of e-Office reduces duplicity of work, increases transparency and efficiency and reduces paper work.
- Parliament Questions and Assurances System Repository of Parliament Questions and reminder system of Assurances is being 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.

### **11.7 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 and 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 higher 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 Organization	ons)
Annexure – II	(Organizational Chart of NPPA)	
Annexure – III	(Result Framework Document 2013-14)	



### 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, Maharahstra.
- 3. Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore-560010.
- 4. Bengal Chemicals & Pharmaceuticals Ltd, Kolkata, West Bengal.
- 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.





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

SI. 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 (KAPL), Banglore-700013	Shri K.M. Prasad	Managing Director
4.	Bengal Chemicals & Pharmaceuticals Limited (BCPL), Kolkata-700013	ShriE.A. Subramanian	Managing Director
5.	Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Road No. 12 V.K.I Area Jaipur-302013	Shri S.B. Bahdrannavar	Managing Director



### ANNEXURE 1 [C]

### List of Responsibility Centers and Subordinate Organizations

Address	SAS Nagar, NIPER Mohali, Punjab - 160062	B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre, Sarkhej Gandhinagar Highway, Thaltej, Ahmedabad-380054	NIPER, Hyderabad IDPL Township, Balangar, Hyderabad-500007	Rajendra Memorial Research Institute of Medical Science (RMRIMS), Agam Kuan Patna-800 007 (BIHAR)	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.)	NIPER Guwahati, Guwahati Medical College & Hospital Guwahati-781032	NIPER Raebareli, Central Drug Research Institute Chatter Manzil P.O. Box 173, Lucknow-226001
Mobile Number	09417203802	09824335881	09440802784	09431012380	09831036984	09864066772	09335866066
Email	director@niper.ac.in	kirankalia@gmail.com	projectdirector@niperhyd.ac.in	drpradeep.das@gmail.com	Chitra_mandal@yahoo.com	niperghy@gmail.com	pk_shukla@cdri.res.in
Landline Number	0172-2214690	079-27439375	04057193157	0612-2636651	03324735368	03612132751	05223290093
Responsibility Centers and Subordinate	Dr. K.K. Bhutani, (Officiating Director)	Dr. Kiran Kalia, (Director)	Dr. Ahmed Kamal, (Project Director)	Dr. Pradeep Das, (Project Director)	Dr. Chitra Mandal, (Project Director)	Prof (Dr) B.K. Bezbaruah (Project Director)	Dr. P Shukla
SI. No.	÷	2.	с.	4.	ц	9.	7.



### **Organisational Chart of NPPA**

		Overcharging-II Legal	<ul> <li>All overcharging cases/files</li> <li>All overcharging cases/files</li> <li>for the period from 2005 to 2007 under DPCO 1995.</li> <li>DPCO 2013 and related 2 work</li> <li>2007 under DPCO 2013 and related 2 bero 2013 and related 2 bero 2013 and related 1 bero 2013 and related 1 bero 2013 bero 2013 and related 1 bero 2013 bero 2013 and related 1 bero 2 be</li></ul>
	Advisor	Pricing	<ol> <li>Fixation/Revision of prices of 1. NLEM formulations.</li> <li>NLEM formulations.</li> <li>Working out factors/ norms related to pricing formula given in DPCC. 2013 and its revision from time to time.</li> <li>Collection of market based 2 collection of market based on NLEM formulations for which 3. UNEM formulations based on NNPI on or after 1st April, every year.</li> <li>Annual revision of prices when-ket structure in respect of 5. Annual revision of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixation of prices in the official Gaztte and on NLEM formulations</li> <li>Price fixatter of an on NLEM formulations</li> <li>Annual exercise in respect of an on the price data of NLEM formulations</li> <li>Annual exercise in respect of an on the price of an on on on the price of an on on on on on on the price data of NLEM formulations wherever and an on the price data of NLEM formulations wherever and an on on</li></ol>
Chairman NPPA	Member Secretary	Overcharging-I	<ol> <li>All overcharging cases/ files w.e.f. 01.01.2008 onwards under DPCO 1995, and related work.</li> <li>Issue notice to the com- panies for overcharging and subsequent follow up.</li> <li>Issue show cause no- tice, working out the overcharged amount and raise demand for recovery of the over- charged amount.</li> <li>Recovery of over- charged amount.</li> <li>Grant personal hearing and pass speaking/ rea- soned order whenever needed.</li> <li>Examination of other is- sues related to over- charging under DPCO, 1995 for recovery of the overcharged amount.</li> <li>Providing input to Legal Division for court cases.</li> <li>Related Parliament Questions/matters.</li> </ol>
	ž	Mon.& Enf. Division-III	<ol> <li>Enforcing and implementation of the prices of NLEM formulations fixed by NPPA.</li> <li>Monitoring of the price movement of non-NLEM for- mulations based on monthly reports of IMS and ac- tion thereof, if found more than 10%.</li> <li>Processing of SDCs reports received in respect of non-implementation of the prices of NLEM formula- tions and other DPCD related matters.</li> <li>Complaints received from individuals. NGOs, institutes related to pricing/ marketing at prices higher than the price fixed by NPPA or price increase more than 10%.</li> <li>Sending reports to Overcharging Division for recov- ery of overcharged amount.</li> <li>Sending reports to Pricing Division to fix the prices in respect of NLEM formulations, if price is not fixed.</li> <li>Interaction/ correspondence with State Drugs Con- trollers in the matter related to enforcement of DPCO provisions.</li> <li>Shortage and availability of NLEM and non-NLEM formulations.</li> <li>Policy matter related to new DPCO.</li> <li>Policy matter related to new DPCO.</li> <li>Policy matter related to new DPCO.</li> <li>Of cases relating to Bulk Drugs &amp; Formula- tions.</li> <li>Storage &amp; Preservance of IMS Data and providing inputs to the concerned Divisions of NPPA.</li> <li>Storage A Preservance of IMS Data and providing inputs to the concerned Divisions of NPPA.</li> <li>Nork relating to Bulk Drugs</li> <li>RTI work.</li> <li>RTI work.</li> <li>Work relating to RFD</li> </ol>
		Admn. Division	<ol> <li>Establishment matters</li> <li>General Admn.</li> <li>General Admn.</li> <li>General Admn.</li> <li>General Admn.</li> <li>Cash/Budget</li> <li>Cash/Budget</li> <li>Nork related to be Vigilance</li> <li>Vigilance</li> <li>Vork related to parliament Com- mittees</li> <li>Sonsolidation</li> <li>Parliament Com- matters.</li> <li>ISO Audit</li> <li>ISO Audit</li> <li>ISO Audit</li> <li>NPPA's website.</li> </ol>

### ANNEXURE - III



### Section 1: Vision, Mission, Objectives and Functions

### 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 India4. Encourage environmentally sustainable development of Pharmaceutical Industry5. 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.

### Objectives

- 1 Disposal of review application as per the provisions of DPCO' 95
- 2 Enforcement of price control measures
- 3 Facilitate growth of Central pharma PSUs with required support
- 4 Jan Aushadi Campaign setting up of Jan Aushadhi Stores
- 5 Develop Pharma Human Resources through M.Pharma and Ph.D programmes in NIPERS
- 6 Setting up of New NIPERs
- 7 Develop Infrastructure for Pharma R &D
- 8 Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation
- 9 Promotion of Research at NIPERs
- 10 Scheme on Cluster Development Programme for Pharma Sector
- 11 Promotion of Indian Pharmaceuticals Products / Industry
- 12 Capacity building of Indian Pharma Industry
- 13 Creation of IPR Facilitation center at Pharmexcil
- 14 Scholarship Scheme at NIPERs for students from foreign countries

### **Functions**

- 1 Matters relating to Pharmaceuticals and Drugs, excluding those specifically allotted to other departments.
- 2 Planning, development and control of, and assistance to, all industries dealt with by the Department







### Section 1: Vision, Mission, Objectives and Functions

- 3 Promotion of public private partnership in pharmaceutical related areas.
- 4 Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
- 5 Technological up-gradation of the pharmaceutical industry to enable them to compete in the world market and to provide better quality drugs in the indigenous market
- 6 Matters related to making available drugs at reasonable prices as per the provisions of extant rules and instructions, monitoring of prices and their enforcement, etc.
- 7 Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector.
- 8 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.
- 9 International co-operation for developing and promoting pharmaceuticals industry, investment, research, including work related to international conferences in related areas in India and abroad.
- 10 Technical support for dealing with national hazards in pharmaceutical sector.
- 11 All matters related to following Acts, Rules and Orders: (i). The National Institute of Pharmaceuticals Education and Research Act, 1998 and amendments thereto. (ii). Drug Pricing Control Orders.
- 12 Matters relating to the following Central Public Sector Enterprises and their subsidiaries: (i) Bengal Chemicals and Pharmaceuticals Limited (BCPL). (ii) Hindustan Antibiotics Limited (HAL). (iii) Indian Drugs and Pharmaceuticals Limited (IDPL). (iv) Karnataka Antibiotics and Pharmaceuticals Limited (KAPL). (v) Rajasthan Drugs and Pharmaceuticals Limited (RDPL).
- 13 Matters relating to the following autonomous organizations: (i) National Institute of Pharmaceutical Education & Research (NIPER), SAS Nagar, Mohali. (ii) National Institute of Pharmaceutical Education & Research, Hyderabad. (iii) National Institute of Pharmaceutical Education & Research, Ahmedabad. (iv) National Institute of Pharmaceutical Education & Research, Kolkata. (v) National Institute of Pharmaceutical Education & Research, Kolkata. (v) National Institute of Pharmaceutical Education & Research, Raebareli. (vii) National Institute of Pharmaceutical Education & Research, Raebareli. (vii) National Institute of Pharmaceutical Education & Research, Raebareli. (vii) National Institute of Pharmaceutical Education & Research, Raebareli. (vii) National Institute of Pharmaceutical Education & Research, Raebareli. (vii)
- 14 Matters relating to an Attached office (i). National Pharmaceutical Pricing Authority (NPPA)

									_	
	Poor	60%	110	2000	31/03/2014	28/02/2014	15/09/2013	28/02/2014	31/03/2014	31/03/2014
/alue	Fair	70%	105	3000	22/03/2014	15/02/2014	15/08/2013 31/08/2013 15/09/2013	15/02/2014	22/03/2014	28/02/2014 15/03/2014 31/03/2014
Target / Criteria Value	Good	80%	100	4000	15/03/2014	31/01/2014	15/08/2013	31/01/2014	15/03/2014	
Target /	Very Good	%06	66	5000	07/03/2014 15/03/2014 22/03/2014 31/03/2014	15/01/2014 31/01/2014 15/02/2014 28/02/2014	30/07/2013	15/01/2014 31/01/2014 15/02/2014 28/02/2014	07/03/2014 15/03/2014 22/03/2014 31/03/2014	15/02/2014
	Excellent	100%	06	5500	28/02/2014	31/12/2013	15/07/2013	31/12/2013	28/02/2014	31/01/2014
	Weight		5.00	3.00	1.50	1.50	3.00	1.50	1.50	2.00
	Unit		days from the date of receipt	.ou	Date	Date	Date	Date	Date	Date
c	Success Indicator		[1.1.1] Issue of review order after approval of the Competent Authority and uploading on the Departments website.	[2.1.1] No. of Test Purchases made by NPPA/ State Drug Controllers	[3.1.1] Sending proposal to the Cabinet	[3.2.1] Sending draft Cabinet Note to the Cabinet	[3.3.1] Sending proposal to Cabinet	[3.4.1] Obtaining approval of Competent Authority	[3.4.2] Release of funds	[4.1.1] Approval of the Competent Authority
	Action		<ul> <li>[1.1] Processing of review applications under DPCO, 1995, for orders by the competent authority for disposal in 90 days of receipt of Review Application in the Department</li> </ul>	[2.1] Monitoring and Enforcing prices	[3.1] Revival of IDPL	[3.2] Second Rehabilitation of HAL	[3.3] Extension of Purchase Preference Policy	[3.4] Project based support to PSUs for WHO-GMP compliance under Critical Assistance Scheme (WHO-GMP Compliance in various PSUs/RDPL)		[4.1] Modification of Jan Aushadhi Scheme based on the Revised Business Plan
	Weight		5.00	3.00	9.00					4.00
	Objective		[1] Disposal of review application as per the provisions of DPCO' 95	[2] Enforcement of price control measures	<ul><li>[3] Facilitate growth of Central pharma PSUs with required support</li></ul>					<ul> <li>[4] Jan Aushadi Campaign - setting up of Jan Aushadhi Stores</li> </ul>

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	1.1.1									
	Poor	60%	31/03/2014	09	60	31/03/2014	31/03/2014	31/03/2014	31/03/2014	31/03/2014
alue	Fair	70%	22/03/2014	02	70	28/02/2014	28/02/2014	15/03/2014	15/03/2014	31/12/2013 14/02/2014 31/03/2014
Target / Criteria Value	Good	80%	15/03/2014	8	80	01/02/2014	01/02/2014	28/02/2014	28/02/2014	31/12/2013
Target / (	Very Good	90%	07/03/2014 15/03/2014 22/03/2014 31/03/2014	6	06	15/01/2014 01/02/2014 28/02/2014 31/03/2014	15/01/2014 01/02/2014 28/02/2014 31/03/2014	15/02/2014 28/02/2014 15/03/2014 31/03/2014	15/02/2014 28/02/2014 15/03/2014 31/03/2014	31/10/2013
	Excellent	100%	28/02/2014	100	100	31/12/2013	31/12/2013	31/01/2014	28/01/2014	30/09/2013
	Weight		2.00	4.00	1.00	2.00	2.00	3.00	3.00	3.00
	Unit		Date	%	%	Date	Date	Date	Date	Date
	Success Indicator		[4.1.2] Issue of Order	[5.1.1] No. of Admission during the year	[5.2.1] Total placement of NIPER's students	[6.1.1] Commencement of construction work	[6.2.1] Commencement of construction work	[7.1.1] Receipt of Project Reports from the consultant	[7.2.1] Receipt of Project Reports from the consultant	[7.3.1] Approval of the Competent Authority
	Action			<ul> <li>[5.1] Intake of students for</li> <li>[5.1] Intake of students for</li> <li>Masters and Ph. D degrees</li> <li>NIPER, Mohali</li> <li>Ph. D – 50, MS-250, MBA-</li> <li>61 Other NIPERs</li> <li>Ahmedabad – 53 (6)</li> <li>Guwahati – 41 (4)</li> <li>Hajbur – 21 (5)</li> <li>Hyderabad – 96 (12)</li> <li>Kolkata – 42 Rae Bareli –</li> <li>39</li> </ul>	[5.2] Placement of sucessful students of NIPER. Mohali in job/Research	[6.1] Construction of campus at [ Guwahati	[6.2] Construction of campus at [1 Gandhinagar	[7.1] Setting up of GLP Compliant labs - Chemical & Biological in PPP mode.	[7.2] Setting up of GLP Compliant Large Animal House in PPP mode.	[7.3] Establishing National Centre for R&D in Bulk Drugs (NCRDBD) at NIPER, Hyderabad to strengthen advance research in Bulk drugs.
	Weight			9.00		4.00		12.00		
	Objective			<ul> <li>[5] Develop Pharma Human Resources through M.Pharma and Ph.D programmes in NIPERS</li> </ul>		[6] Setting up of New NIPERs		[7] Develop Infrastructure for Pharma R &D		



											-
	Poor	60%	31/03/2014	31/03/2014	28/02/2014	31/03/2014	31/03/2014	0	F	100	N
/alue	Fair	70%	14/03/2014	15/03/2014	31/01/2014	15/03/2014	21/03/2014	-	-	110	m
Target / Criteria Value	Good	80%	14/02/2014 14/03/2014	15/02/2014	31/12/2013	28/02/2014	14/03/2014	7	2	120	4
Target /	Very Good	90%	31/12/2013	31/01/2014 15/02/2014 15/03/2014 31/03/2014	30/11/2013 31/12/2013 31/01/2014 28/02/2014	15/02/2014 28/02/2014 15/03/2014 31/03/2014	07/03/2014	т	ю	150	ω
	Excellent	100%	31/10/2013	31/12/2013	31/10/2013	31/01/2014	01/03/2014 07/03/2014 14/03/2014 21/03/2014 31/03/2014	4	4	155	ω
	Weight		3.00	3.00	3.00	8.00	3.00	1.50	1.50	3.00	3.00
	Unit		Date	Date	Date	Date	Date	No.	No.	NO.	No.
	Success Indicator		[7.4.1] Approval of the Competent Authority	[8.1.1] Release of Funds	[8.2.1] Approval of the Scheme.	[8.3.1] Submission of the proposal to the Cabinet Committee on Economic Affairs (CCEA)	[8.4.1] Receipt of in- principle approval of the Planning Commission	[9.1.1] No.of Patents to be filed during the year	[9.1.2] No. of Patents commercialized during the year	[9.2.1] No. of Publication in the International Journals during the year	[9.3.1] No. of Publications in the International Journals
	Action		[7.4] Setting up of Incubator Facilities at NIPER, Mohali	[8.1] Development of new drugs for TB & Kalazar by NIPER	[8.2] Preparation of Schemes for approving R&D Projects of all NIPERs	<ul> <li>[8.3] Pharmaceuticals</li> <li>Technology Upgradation Assistance Scheme(PTUAS) for Pharma Medium</li> </ul>	[8.4] Setting up of Venture Fund [8.4.1]	[9.1] Getting Patents at NIPER, Mohali during the year.		[9.2] Publication of Papers in international journals by NIPER, Mohali	[9.3] Publication of Papers in international journals by NIPER, Hyderabad Kolkata Rae Bareli Hajipur Guwahati
	Weight			17.00				9.00			
	Objective			[8] Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation				[9] Promotion of Research at NIPERs			

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		1.00								
		Poor	60%		30/10/2013	31/12/2013	31/03/2014	100	31/03/2014	31/03/2014
/ol-10	/alue	Fair	70%		30/09/2013	30/11/2013	28/02/2014	200	15/02/2014 28/02/2014 31/03/2014	28/02/2014
	arget / Unterta value	Good	80%		31/08/2013	31/10/2013	31/01/2014	300	15/02/2014	14/02/2014
Tossot /	l arget /	Very Good	90%		31/07/2013 31/08/2013 30/09/2013 30/10/2013	30/09/2013 31/10/2013 30/11/2013 31/12/2013	31/12/2013 31/01/2014 28/02/2014 31/03/2014	400	31/01/2014	31/01/2014 14/02/2014 28/02/2014 31/03/2014
		Excellent	100%		30/06/2013	31/08/2013	30/11/2013	200	31/12/2013	31/12/2013
Ī		Weight			3.00	3.00	5.00	5.00	1.00	3.00
		Unit			Date	Date	Date	No. of Personn el trained	Date	Date
	¢	Success Indicator			[10.1.1] Submission of the draft scheme to Planning Commission	[10.2.1] Appraisal of the proposed scheme by EFC	[11.1.1] Implementation of two finalized proposals – (i) Seminars/ workshops on the Regulatory framwors in African countries (ii) Seminar on Potential of Indian Pharma Sector in	[12.1.1] Seminars/workshop Renur Centres on WHO-GMP Standards compliance	[13.1.1] Timely release of funds	[14.1.1] Approval of the scheme by the Competent Authority
		Action		Gandhinagar	[10.1] Approval of the the draft scheme by Planning Commission	[10.2] Approval of the Scheme by EFC	[11.1] Follow Up Action of Third India Pharma Summit held in November 2012	[12.1] Training of Industry Personnel for complaince to WHO-GMP Standards	[13.1] Dissemination of information on IPRs and related issues to the Pharma Industry by Pharmexcil.	[14.1] Scholarship scheme for students of other countries with a focus on those countries
		Weight			6.00		2.00	5.00	1.00	3.00
		Objective			[10] Scheme on Cluster Development Programme for Pharma Sector		[11] Promotion of Indian Pharmaceuticals Products / Industry	[12] Capacity building of Indian Pharma Industry	[13] Creation of IPR Facilitation center at Pharmexcil	[14] Scholarship Scheme at NIPERs for students from foreign countries



							Target /	Target / Criteria Value	/alue	
Objective	Weight	Action	Success Indicator	Unit	Weight	Excellent	Very Good	Good	Fair	Poor
						100%	90%	80%	70%	60%
		which are major export markets for Indian Drug Industry								
* Efficient Functioning of the RFD System	3.00	Timely submission of Draft RFD 2014-15 for Approval	On-time submission	Date	2.0	05/03/2014	06/03/2014	07/03/2014	06/03/2014 07/03/2014 08/03/2014 11/03/2014	11/03/2014
		Timely submission of Results for 2012-13	On-time submission	Date	1.0	01/05/2013	02/05/2013	03/05/2013	02/05/2013 03/05/2013 06/05/2013 07/05/2013	07/05/2013
* Transparency/Service delivery Ministry/Department	3.00	Independent Audit of implementation of Citizens/Clients' Charter (CCC)	% of implementation	%	2.0	100	06	80	70	60
		Independent Audit of implementation of Public Grievance Redressal System	% of implementation	%	1.0	100	06	80	70	60
* Administrative Reforms	6.00	Implement mitigating strategies for reducing potential risk of corruption	% of implementation	%	1.0	100	<u> </u>	06	85	80
		Implement ISO 9001 as per the approved action plan	% of implementation	%	2.0	100	<u> 9</u> 6	06	85	80
		Identify, design and Implement major innovations.	Timely submission of Action Plan for enabling innovation	Date	2.0	15/05/2014	16/05/2014	19/05/2014	16/05/2014 19/05/2014 20/05/2014 21/05/2014	21/05/2014
		Identification of core and non- core activities of the Ministry/Department as per 2nd ARC recommendations	Timely submission	Date	1.0	24/03/2014	25/03/2014	26/03/2014	25/03/2014 26/03/2014 27/03/2014 28/03/2014	28/03/2014
<ul> <li>Improving Internal Efficiency/Responsiveness.</li> </ul>	2.00	Update departmental strategy to align with 12th Plan priorities	Timely updation of the strategy	Date	2.0	10/09/2013	17/09/2013	24/09/2013	17/09/2013 24/09/2013 01/10/2013 08/10/2013	38/10/2013
<ul> <li>Ensuring compliance to the Financial Accountability Framework</li> </ul>	1.00	Timely submission of ATNs on Audit paras of C&AG	Percentage of ATNs submitted within due date (4 months) from	%	0.25	100	06	80	70	60

\* Mandatory Objective(s)

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UE.	-10 -	5									
	Poor	60%		60				60		60	
alue	Fair	70%		20				20		70	
Target / Criteria Value	Good	80%		80				80		80	
Target / (	Very Good	80%		06				06		06	
	Excellent	100%		100				100		100	
	Weight			0.25				0.25		0.25	
	Unit			%				%		%	
(	Success Indicator		date of presentation of Report to Parliament by CAG. during the year.	Percentage of ATRS submitted within due date (	6 months) from date of	Parliament by PAC .during	the year.	Percentage of outstanding ATNs disposed off during	the year.	Percentage of outstanding ATRS disposed off during	the year.
	Action			Timely submission of ATRs to the PAC Sectt. on PAC Reports.				Early disposal of pending ATNs on Audit Paras of C&AG Reports	presented to Parliament before 31.3.2013.	Early disposal of pending ATRs on PAC Reports presented to	Parliament perore 31.3.2013
	Weight		<b></b>								
	Objective										

\* Mandatory Objective(s)



### Section 3: Trend Values of the Success Indicators

Projected Value for FY 15/16	1	1	1	1	1	1	1	I
Projected Value for FY 14/15	1	1	I	1	1	1	I	ł
Target Value for FY 13/14	с б	5000	07/03/2014	15/01/2014	30/04/2013	15/01/2014	07/03/2014	15/02/2014
Actual Value Actual Value Target Value for for FY 11/12 FY 12/13 FY 13/14	1	1	I	I	1	1	1	-
Actual Value for FY 11/12	1	1	1	1	I	1	ł	1
Unit	days from the date of receipt	OL	Date	Date	Date	Date	Date	Date
Success Indicator	[1.1.1] Issue of review order after approval of the Competent Authority and uploading on the Department's website.	[2.1.1] No. of Test Purchases made by NPPA/ State Drug Controllers	[3.1.1] Sending proposal to the Cabinet	[3.2.1] Sending draft Cabinet Note to the Cabinet	[3.3.1] Sending proposal to Cabinet	[3.4.1] Obtaining approval of Competent Authority	[3.4.2] Release of funds	[4.1.1] Approval of the Competent
Action	<ul> <li>[1.1] Processing of review applications under DPCO, 1995, for orders by the competent authority for disposal in 90 days of receipt of Review Application in the Department</li> </ul>	[2.1] Monitoring and Enforcing prices	[3.1] Revival of IDPL	[3.2] Second Rehabilitation of HAL	[3.3] Extension of Purchase Preference Policy	[3.4] Project based support to PSUs for WHO-GMP compliance under Critical Assistance Scheme (WHO-GMP Compliance in various PSUs/RDPL)		[4.1] Modification of Jan Aushadhi Scheme
Objective	<ul> <li>[1] Disposal of review application as per the provisions of DPCO' 95</li> </ul>	<ul><li>[2] Enforcement of price control measures</li></ul>	<ul><li>[3] Facilitate growth of Central pharma PSUs with required support</li></ul>		<u> </u>			[4] Jan Aushadi Campaign - setting up of Jan Aushadhi

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Projected Value for FY 15/16		-	1		I	I	1	1
Projected Value for FY 14/15		-	1	1	I		I	I
Target Value for FY 13/14		07/03/2014	6	06	15/01/2014	15/01/2014	15/02/2014	15/02/2014
Actual Value Actual Value Target Value for for FY 11/12 FY 12/13 FY 13/14		I	1	1	I	I	I	I
Actual Value for FY 11/12		1	:	1	1	-	1	1
Unit		Date	%	%	Date	Date	Date	Date
Success Indicator	Authority	[4.1.2] Issue of Order	[5.1.1] No. of Admission during the year	[5.2.1] Total placement of NIPER's students	[6.1.1] Commencement of construction work	[6.2.1] Commencement of construction work	[7.1.1] Receipt of Project Reports from the consultant	[7.2.1] Receipt of Project Reports from the consultant
Action	based on the Revised Business Plan		<ul> <li>[5.1] Intake of students for Masters and Ph. D degrees NIPER, Mohali: PD – 50, MS-250, MBA-61 Other NIPERs Ahmedabad – 53 (6) Guwahati – 41 (4) Hajipur – 21 (5) Hyderabad – 96 (12) Kolkata – 42 Rae Bareli – 39</li> </ul>	[5.2] Placement of sucessful students of NIPER. Mohali in job/Research	[6.1] Construction of campus at Guwahati	[6.2] Construction of campus at Gandhinagar	[7.1] Setting up of GLP Compliant labs - Chemical & Biological in PPP mode.	[7.2] Setting up of GLP Compliant Large Animal House in PPP mode.
Objective	Stores		[5] Develop Pharma Human Resources through M.Pharma and Ph.D programmes in NIPERS		[6] Setting up of New NIPERs		<ul><li>[7] Develop Infrastructure for Pharma R &amp;D</li></ul>	



### Section 3: Trend Values of the Success Indicators

								1
Projected Value for FY 15/16	1	I	I	I	1	I	I	1
Projected Value for FY 14/15	1	I	1	1	1	1	1	1
Target Value for FY 13/14	31/10/2013	31/12/2013	31/01/2014	30/11/2013	15/02/2014	07/03/2014	3	3
Actual Value for FY 12/13	1	I	1	1	1	1	1	1
Actual Value Actual Value Target Value for for FY 11/12 FY 12/13 FY 13/14	1	I	1	1	1	I	I	-
Unit	Date	Date	Date	Date	Date	Date	No.	No.
Success Indicator	(7.3.1) Approval of the Competent Authority	[7.4.1] Approval of the Competent Authority	[8.1.1] Release of Funds	[8.2.1] Approval of the Scheme.	[8.3.1] Submission of the proposal to the Cabinet Committee on Economic Affairs (CCEA)	[8.4.1] Receipt of in-principle approval of the Planning Commission	[9.1.1] No.of Patents to be filed during the year	[9.1.2] No. of Patents commercialized
Action	[7.3] Establishing National Centre for R&D in Bulk Drugs (NCDBD) at DrUPER, Hyderabad to NIPER, Hyderabad to strengthen advance research in Bulk drugs.	[7.4] Setting up of Incubator Facilities at NIPER, Mohali	[8.1] Development of new drugs for TB & Kalazar by NIPER	[8.2] Preparation of Schemes for approving R&D Projects of all NIPERs	[8.3] Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS) for Pharma Medium Enterprises	[8.4] Setting up of Venture Fund	[9.1] Getting Patents at NIPER, Mohali during the year.	
Objective			<ul> <li>[8] Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation</li> </ul>				[9] Promotion of Research at NIPERs	

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Projected Value for FY 15/16		1	1	1	1	1
Projected Value for FY 14/15		1	1	I	1	1
Target Value for FY 13/14		150	Q	31/07/2013	30/09/2013	31/12/2013
Actual Value Actual Value Target Value for FY 11/12 FY 12/13 FY 13/14		I	1	I	1	1
Actual Value for FY 11/12		I	1	I	1	1
Unit		Ö	Ö	Date	Date	Date
Success Indicator	during the year	[9.2.1] No. of Publication in the International Journals during the year	[9.3.1] No. of Publications in the International Journals	[10.1.1] Submission of the draft scheme to Planning Commission	[10.2.1] Appraisal of the proposed scheme by EFC	[11.1.1] Implementation of two finalized proposals – (i) Seminars/ workshops on the Regulatory frameworks in African countries (ii) Seminar on Potential of Indian Pharma Sector in R&D
Action		[9.2] Publication of Papers in international journals by NIPER, Mohali	[9.3] Publication of Papers in international journals by NIPER, Hyderabad Kolkata Rae Bareli Hajipur Guwahati Gandhinagar	[10.1]Approval of the the draft scheme by Planning Commission	[10.2]Approval of the Scheme by EFC	[11.1]Follow Up Action of Third India Pharma Summit held in November 2012
Objective				[10] Scheme on Cluster Development Programme for Pharma Sector		[11] Promotion of Indian Pharmaceuticals Products / Industry



### Section 3: Trend Values of the Success Indicators

Objective	Action	Success Indicator	Unit	Actual Value for FY 11/12	Actual Value Actual Value Target Value for FY 11/12 FY 12/13 FY 13/14	Target Value for FY 13/14	Projected Value for FY 14/15	Projected Value for FY 15/16
[12] Capacity building of Indian Pharma Industry	[12.1]Training of Industry Personnel for complaince to WHO-GMP Standards	[12.1.1] Seminars/workshop at four Centres on WHO- GMP Standards compliance	No. of Personnel trained	1	645	400	1	1
[13] Creation of IPR Facilitation center at Pharmexcil	[13.1]Dissemination of information on IPRs and related issues to the Pharma Industry by Pharmexcil.	[13.1.1] Timely release of funds	Date	1	-	31/01/2014	1	1
[14] Scholarship Scheme at NIPERs for students from foreign countries	[14.1]Scholarship scheme for students of other countries with a focus on those countries which are major export markets for Indian Drug Industry	[14.1.1] Approval of the scheme by the Competent Authority	Date	1	1	31/01/2014	:	1
<ul> <li>Efficient Functioning of the RFD System</li> </ul>	Timely submission of Draft RFD 2014-15 for Approval	On-time submission	Date	1	07/03/2012	06/03/2014	1	1
	Timely submission of Results for 2012-13	On-time submission	Date	1	1	02/05/2013	1	1
<ul> <li>Transparency/Service delivery Ministry/Department</li> </ul>	Independent Audit of implementation of Citizens/Clients' Charter	% of implementation	%	I	1	95	1	I
	Independent Audit of implementation of Public Grievance Redressal System	% of implementation	%	1	1	95	1	1
* Administrative Reforms	Implement mitigating strategies for reducing	% of implementation	%	1	:	95	1	1
* Mondatony Objective/c)								

\* Mandatory Objective(s)

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								An	nual R	e
Projected Value for	FY 15/16		1	I	1	I	1	1	-	
Projected Value for	FY 14/15		1	I	1	1	1	1	1	
Target Value for	FY 13/14		95	95	15/10/2013	17/09/2013	6	6	06	
Actual Value Actual Value Target Value for	FY 12/13		1	I	I	I	1	1	1	
Actual Value for	FY 11/12		I	1	I	1	1	1	-	
Unit			%	Date	Date	Date	%	%	%	
Success Indicator			% of implementation	Timely submission of Action Plan for enabling innovation	Timely submission	Timely updation of the strategy	Percentage of ATNs submitted within due date (4 months) from date of presentation of Report to Parliament by CAG. during the year.	Percentage of ATRS submitted within due date (6 months) from date of presentation of Report to Parliament by PAC. during the year.	Percentage of outstanding ATNs disposed off during the year.	
Action		potential risk of corruption	Implement ISO 9001 as per the approved action plan	Identify, design and Implement major innovations.	Identification of core and non- core activities of the Ministry/Department as per 2nd ARC recommendations	Update departmental strategy to align with 12th Plan priorities	Timely submission of ATNs on Audit paras of C&AG	Timely submission of ATRs to the PAC Sectt. on PAC Reports.	Early disposal of pending ATNs on Audit Paras of C&AG Reports presented to Parliament before 31.3.2013.	
Objective						<ul> <li>Improving Internal Efficiency/Responsiveness.</li> </ul>	<ul> <li>Ensuring compliance to the Financial Accountability Framework</li> </ul>			* Mandatory Objective(c)



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cted e for 5/16	1
Projected Value for FY 15/16	
Projected Value for FY 14/15	1
Target Value for FY 13/14	6
Actual Value Actual Value Target Value Projected for for FY 11/12 FY 12/13 FY 13/14 FY 14/15	1
Actual Value for FY 11/12	1
Unit	%
Success Indicator	Percentage of outstanding ATRS disposed off during the year.
Action	Early disposal of pending ATRs on PAC Reports presented to Parliament before 31.3.2013
Objective	

\* Mandatory Objective(s)

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### Section 4: Acronym

Description	Conducting hearing is a quasi-judicial process for giving an opportunity to the aggrieved party (pharma company) which is also attended by officials of NPPA and pharma/ technical experts of the Department. The PH is being presently given by the concerned Deputy Secretary handling the DPCO matters. The record note of discussion of the PH is prepared and signed by the representative of the company, NPPA and the concerned DS and copy thereof is also handed over to the representative of the company, NPPA and the concerned party.
Acronym	Ha
SI.No	-

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Section 4:	Description and Definition of Success Indicators and Proposed Measurement Methodology
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General Comments		
Measurement		Purchase of Drug samples (i.e. scheduled and non-scheduled drugs) is one of the market surveillance devices
Definition		Monitoring and Enforcing Prices
Description	The Review order is prepared and issued after approval of Minister (C&F) and also sent for updating the same on the website of the department.	Purchase of Drug samples (i.e. scheduled and non-scheduled drugs) is one of the market surveillance devices to monitor the implementation of prices of drugs fixed by NPPA and to ensure enforcement of such prices by the Pharma companies in general.
Success indicator	[1.1.1] Issue of review order after approval of the Competent Authority and uploading on the Department's website.	[2.1.1] No. of Test Purchases made by NPPA/ State Drug Controllers
SI.No	-	2





Section 5 : Specific Performance Requirements from other Departments

What happens if your requirement is not met.	The effective control on monitoring and enforcement will be termed as "not satisfactory" as per the provisions of DPCO.	
Please quantify your What happens if requirement from your requirement is this Organisation not met.	600 samples	
Justification for this requirement	This is a barometer for measuring compliance of DPCO provisions of price control.	
What is your requirement from this organisation	NPPA is fully responsible for taking action in this regard in coordination with State Drug Controllers	
Relevant Success Indicator	[2.1.1] No. of Test Purchases made by NPPA/ State Drug Controllers	[1.1.1] Issue of review order after approval of the Competent Authority and uploading on the Department's website.
Organisation Type	National Pharmaceuticals Pricing Authority (NPPA)	
Organisation Type	Responsibility Centre / Attached office	
State		
Location Type	Central Government	



Section 6:	Outcome/Impact of Department/Ministry
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FY 15/16					006	1350
FY 14/15					006	006
FY 13/14				3.67	303	450
FY 12/13	9.38			2.38	30	281.76
FY 11/12	18.65			1.17	20	287.93
Unit	%	ÖZ	ÖZ	%	Ňo	Amount
Success Indicator	Growth of Pharmaceuticals Production in the Country	Vector borne diseases and Parasitic Diseases for which Drugs are not available	Quantity of Spurious drugs detected in the market by the inspectors	Price Index of 115.4 Pharmaceuticals Medicines in the Country (Comparison vis a vis previous year will reveal the trends)	No. of Stores opened	Sales of medicines (Rs. in lakhs)
Jointly responsible for influencing this outcome / impact with the following department (s) / ministry(ies)		Ministry of Health and Family Welfare	Ministry of Health and Family Welfare		State Government /BPPI	State Government /CPSEs/BPPI
Outcome/Impact of Department/Ministry	<ol> <li>Higher growth of Pharmaceuticals Industry in the Country</li> </ol>	2 Greater availability of Drugs for endemic diseases, Vector borne and parasitic diseases for which indigenous and effective drugs are not available	3 Reduction in Spurious Drugs 1	4 Availability of Pharmaceuticals at reasonable/Lower price in the country	5 Setting up of Jan Aushadi Stores	6 Supply of Generic Medicines to JAS





## Section 6: Outcome/Impact of Department/Ministry

	10				An
FY 15/16	Ą	AN			
FY 14/15	ЧN	NA	600	100	
FY 13/14	As per tgt	As per tgt	550	100	30/06/2013
FY 12/13	As per tgt	NA	590	120	
FY 11/12	95-100	NA	559		
Unit	%	%	Nos.	days from the date of	Date
Success Indicator	Admission of students	Success of specific schemes	No. of Test Purchases/Sample of Drugs (Scheduled and Non-Scheduled) and NNPA/State Drug Controllers	Processing of review applications under DPCO, 1995, for orders by the competent authority for disposal in 90 days of receipt of Review Application in the Department	Approval of the Planning Commission
Jointly responsible for influencing this outcome / impact with the following department (s) / ministry(ies)	NIPERs		ИРРА	Aqu	Planning Commission for approval
Outcome/Impact of Department/Ministry	7 Creation of HR professional h for Pharmaceutical Industry	8 Assistance to R&D in pharma NIPERs/ Private sector sector	9 Implementation of Notified Prices/ Enforcement of the Provisions of DPCO/95	10 Ensure reasonableness of pricing of drugs as per provisions of DPCO,95	<ol> <li>Provision of financial support F for growth of Pharma Medium Enterprises (MEs)</li> </ol>





Performance	5	Score	5.0	0.0	N/A	N/A	0.0	N/A	N/A	2.0	2.0	0.0
Perforr	Raw	Score	100.0	0.0	N/A	N/A	0.0	N/A	N/A	100.0	100.0	0.0
	Achiev-	CIICIL	06	1425			31/08/2013 15/09/2013 09/10/2013			15/02/2014 28/02/2014 15/03/2014 31/03/2014 20/08/2013	22/03/2014 31/03/2014 26/08/2013	53.75
	Poor	60%	110	2000	31/03/2014	15/02/2014 28/02/2014	15/09/2013	28/02/2014	31/03/2014	31/03/2014	31/03/2014	60
Value	Fair	70%	105	3000	22/03/2014 31/03/2014	15/02/2014	31/08/2013	15/02/2014 28/02/2014	22/03/2014	15/03/2014	22/03/2014	70
Target / Criteria Value	Good	80%	100	4000	07/03/2014 15/03/2014	15/01/2014 31/01/2014	30/07/2013 15/08/2013	15/01/2014 31/01/2014	07/03/2014 15/03/2014 22/03/2014 31/03/2014	28/02/2014	07/03/2014 15/03/2014	8
Target	Very Good	90%	6 0	5000	07/03/2014	15/01/2014	30/07/2013	15/01/2014	07/03/2014	15/02/2014	07/03/2014	06
	Excellent <sup>1</sup>	100%	6	5500	28/02/2014	31/12/2013	15/07/2013	31/12/2013	28/02/2014	31/01/2014	28/02/2014	100
	Weight		5.00	3.00	1.50	1.50	3.00	1.50	1.50	2.00	2.00	4.00
	Unit		days from the date of receipt	no.	Date	Date	Date	Date	Date	Date	Date	%
	Success Indicator		Issue of review order after approval of the Competent Authority and uploading on the Department's website.	No. of Test Purchases made by NPPA/ State Drug Controllers	Sending proposal to the Cabinet	Sending draft Cabinet Note to the Cabinet	Sending proposal to Cabinet	Obtaining approval of Competent Authority	Release of funds	Approval of the Competent Authority	Issue of Order	No. of Admission during the year
	Action		Processing of review applications under DPCO, 1995, for orders by the competent authority for disposal in 90 days of disposal in 90 days of receipt of Review Application in the Department	Monitoring and Enforcing prices	Revival of IDPL	Second Rehabilitation of HAL	Extension of Purchase Preference Policy	Project based support to PSUs for WHO-GMP compliance under Critical Assistance Scheme (WHO-GMP Compliance in various PSUs/RDPL)		Modification of Jan Aushadhi Scheme based on the Revised Business Plan		Intake of students for Masters and Ph. D degrees NIPER, Mohali: Ph.D – 50, MS-250, MBA-
	Weight		5.00	3.00	9.00		1			4.00		5.00
	Objective		1 Disposal of review application as per the provisions of DPCO' 95	2 Enforcement of price control measures	3 Facilitate growth of Central pharma PSUs with required support					4 Jan Aushadi Campaign - setting up of Jan Aushadhi Stores		5 Develop Pharma Human Resources through M. Pharma and Ph.D programmes in NIPERS

Performance Evaluation Report

Report
Evaluation
Performance

			S. Toma	N.C.									
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	Performance		ted Score		0.0	N/A	N/A	N/A	N/A	N/A	N/A	1.84	N/A
l	Perfon	Raw	score		0.0	N/A	N/A	N/A	N/A	N/A	N/A	61.25	N/A
			CILICIT		51							29/03/2014	
		Poor	60%		60	31/03/2014	31/03/2014	31/03/2014	31/03/2014	31/03/2014	31/03/2014	31/03/2014	28/02/2014
	Value	Fair	70%		70	28/02/2014	28/02/2014	15/03/2014	15/03/2014	14/02/2014	14/03/2014	15/03/2014	31/01/2014
	Target / Criteria Value	Good	80%		80	01/02/2014			28/02/2014		14/02/2014	15/02/2014	31/12/2013
	Target	/ery Good	90%		06	15/01/2014 01/02/2014 28/02/2014 31/03/2014	15/01/2014 01/02/2014	15/02/2014 28/02/2014	15/02/2014 28/02/2014 15/03/2014 31/03/2014	31/10/2013 31/12/2013	31/12/2013 14/02/2014 14/03/2014 31/03/2014	31/01/2014 15/02/2014 15/03/2014 31/03/2014 29/03/2014	30/11/2013 31/12/2013 31/01/2014 28/02/2014
		Excellent Very Good	100%		100	31/12/2013	31/12/2013	31/01/2014	28/01/2014	30/09/2013	31/10/2013	31/12/2013	31/10/2013
		Weight			1.00	2.00	2.00	3.00	3.00	3.00	3.00	3.00	3.00
		Unit			%	Date	Date	Date	Date	Date	Date	Date	Date
		Success Indicator			Total placement of NIPER's students	Commencement of construction work	Commencement of construction work	Receipt of Project Reports from the consultant	Receipt of Project Reports from the consultant	Approval of the Competent Authority	Approval of the Competent Authority	Release of Funds	Approval of the Scheme.
		Action		61 Other NIPERs Ahmedabad – 53 (6) Guwahati – 41 (4) Hajipur – 21 (5) Hyderabad – 96 (12) Kolkata – 42 Rae Bareli – 39	Placement of sucessful students of NIPER. Mohali in job/Research	Construction of campus at Guwahati	Construction of campus at Gandhinagar	Setting up of GLP Compliant labs - Chemical & Biological in PPP mode.	Setting up of GLP Compliant Large Animal House in PPP mode.	Establishing National Centre for R&D in Bulk Drugs (NCRDBD) at NIPER, Hyderabad to strengthen advance research in Bulk drugs.	Setting up of Incubator Facilities at NIPER, Mohali	Development of new drugs for TB & Kalazar by NIPER	Preparation of Schemes for approving R&D Projects of all NIPERs
		Weight				4.00	<u>.</u>	12.00	1			17.00	1
		Objective				6 Setting up of New NIPERs		7 Develop Infrastructure for Pharma R &D				8 Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation	





Performance	13	Score	N/A	N/A	1.5	0.0	2.65	3.0	2.44	0.0	2.0
Perfon	Raw	score	N/A	N/A	100.0	0.0	88.33	100.0	81.29	0.0	100.0
	Achiev-				160	0	145	45	27/08/2013	21/01/2014	05/11/2013
	Poor	60%	31/03/2014	31/03/2014	0	-	100	7	30/10/2013	31/12/2013	31/03/2014
Value	Fair	70%	15/03/2014 3	21/03/2014	-	-	110	ĸ	30/09/2013 3	30/11/2013	28/02/2014 3
Target / Criteria Value	Good	80%	28/02/2014	14/03/2014	2	7	120	4	31/08/2013 (	31/10/2013	31/01/2014
Target.	/ery Good	90%	15/02/2014 28/02/2014 15/03/2014 31/03/2014	07/03/2014 14/03/2014 21/03/2014 31/03/2014	е С	ε	150	Q	31/07/2013 31/08/2013 30/09/2013 30/10/2013 27/08/2013	30/09/2013 31/10/2013 30/11/2013 31/12/2013 21/01/2014	31/12/2013 31/01/2014 28/02/2014 31/03/2014 05/11/2013
	Excellent Very Good	100%	31/01/2014	01/03/2014	4	4	155	ω	30/06/2013	31/08/2013	30/11/2013
	Weight		8.00	3.00	1.50	1.50	3.00	3.00	3.00	3.00	2.00
	Unit		Date	Date	No.	ÖN	No	Ö	Date	Date	Date
	Success Indicator		Submission of the proposal Date to the Cabinet Committee on Economic Affairs (CCEA)	Receipt of in-principle approval of the Planning Commission	No.of Patents to be filed during the year	No. of Patents commercialized during the year	No. of Publication in the International Journals during the year	No. of Publications in the International Journals	Submission of the draft scheme to Planning Commission	Appraisal of the proposed scheme by EFC	Implementation of two finalized proposals – (i) Seminars/ workshops on the Regulatory frameworks in African countries (ii) Seminar on Potential of Indian Pharma Sector in R&D
	Action		Pharmaceuticals Technology Upgradation Assistance Scheme(PTUAS) for Pharma Medium Enterprises	Setting up of Venture Fund	Getting Patents at NIPER, Mohali during the year.		Publication of Papers in international journals by NIPER, Mohali	Publication of Papers in international journals by NIPER, Hyderabad Kolkata Rae Bareli Hajipur Guwahati Gandhinagar	Approval of the the draft scheme by Planning Commission	Approval of the Scheme by EFC	Follow Up Action of Third India Pharma Summit held in November 2012
	Weight			<u> </u>	00.6				6.00		2.00
	Objective				9 Promotion of Research at NIPERs				10 Scheme on Cluster Development Programme for Pharma Sector		11 Promotion of Indian Pharmaceuticals Products / Industry

Performance Evaluation Report

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Performance	Weigh-	ted Score	5.0	1.0	A/N	2.0	1.0	0.0	0.79	1.0	0.0
Perfor	Raw	score	100.0	100.0	A/N	100.0	100.0	0.0	78.68	100.0	0.0
	Achiev-	CIIICIII	500	27/09/2013		05/03/2014	01/05/2013	53	78.68	100	0
	Poor	60%	100	31/03/2014	31/03/2014	11/03/2014	07/05/2013	60	60	80	80
Value	Fair	70%	200	28/02/2014 31/03/2014 27/09/2013	28/02/2014	08/03/2014	06/05/2013	02	02	85	85
Target / Criteria Value	Good	80%	300		14/02/2014	07/03/2014	03/05/2013	80	80	06	06
Target	Excellent Very Good	90%	400	31/01/2014 15/02/2014	31/01/2014 14/02/2014 28/02/2014 31/03/2014	06/03/2014 07/03/2014 08/03/2014 11/03/2014 05/03/2014	02/05/2013 03/05/2013 06/05/2013 07/05/2013 01/05/2013	06	06	95	95
	Excellent	100%	500	31/12/2013	31/12/2013	05/03/2014	01/05/2013	100	100	100	100
	Weight		5.00	1.00	3.00	2.0	1.0	2.0	1.0	1.0	2.0
	Unit		No. of Personn el trained	Date	Date	Date	Date	%	%	%	%
	Success Indicator		Seminars/workshop at four Centres on WHO-GMP Standards compliance	Timely release of funds	Approval of the scheme by the Competent Authority	On-time submission	On-time submission	% of implementation	% of implementation	% of implementation	% of implementation
	Action		Training of Industry Personnel for complaince to WHO-GMP Standards	Dissemination of information on IPRs and related issues to the Pharma Industry by Pharmexcil.	Scholarship scheme for students of other countries with a focus on those countries which are major export markets for Indian Drug Industry	Timely submission of Draft RFD 2014-15 for Approval	Timely submission of Results for 2012-13	Independent Audit of implementation of Citizens'/Clients' Charter (CCC)	Independent Audit of implementation of Public Grievance Redressal System	Implement mitigating strategies for reducing potential risk of corruption	Implement ISO 9001 as per the approved action plan
	Weight		5.00	1.00	3.00	3.00		3.00		6.00	
	Objective		12 Capacity building of Indian Pharma Industry	13 Creation of IPR Facilitation center at Pharmexcil	14 Scholarship Scheme at NIPERs for students from foreign countries	* Efficient Functioning of the RFD System		<ul> <li>Transparency/Service delivery Ministry/Department</li> </ul>		* Administrative Reforms	

\* Mandatory Objective(s)





Performance Evaluation Report



Ohiantiva	Weight		Success Indicator		Meicht	:	Target	Target / Criteria Value	Value	ſ	Achiev	Performance	lance
	vveigill	ACIION			- Niciuliii	Excellent	Excellent Very Good	Good	Fair	Poor	ement	Raw V	Weigh- ted
						100%	%06	80%	20%	60%			Score
		Identify, design and Implement major innovations.	Timely submission of Action Plan for enabling innovation	Date	2.0	15/05/2014	16/05/2014	19/05/2014	16/05/2014 19/05/2014 20/05/2014 21/05/2014	21/05/2014		N/N	N/A
		Identification of core and non-core activities of the Ministry/Department as per 2nd ARC recommendations	Timely submission	Date	1.0	24/03/2014	25/03/2014	26/03/2014	25/03/2014 26/03/2014 27/03/2014 28/03/2014	28/03/2014		N/A	N/A
Improving Internal Efficiency/Responsiveness.	2.00	2.00 Update departmental strategy to align with 12th Plan priorities	Timely updation of the strategy	Date	2.0	10/09/2013	17/09/2013 24/09/2013 01/10/2013 08/10/2013	24/09/2013	01/10/2013	08/10/2013		N/N	N/A
Ensuring compliance to the Financial Accountability Framework	1.00	1.00 Timely submission of ATNs on Audit paras of C&AG	Percentage of ATNs submitted within due date (4 months) from date of presentation of Report to Parliament by CAG during the year.	%	0.25	100	06	80	70	09	0	0.0	0.0
		Timely submission of ATRs to the PAC Sectt. on PAC Reports.	Percentage of ATRS submitted within due date ( 6 months) from date of presentation of Report to Parliament by PAC. during the year.	%	0.25	100	06	80	70	09	0	0.0	0.0
		Early disposal of pending ATNs on Audit Paras of C&AG Reports presented to Parliament before 31.3.2013.	Percentage of outstanding ATNs disposed off during the year.	%	0.25	100	06	80	70	60	0	0.0	0.0
		Early disposal of pending ATRs on PAC Reports presented to Parliament before 31.3.2013	Percentage of outstanding ATRS disposed off during the year.	%	0.25	100	06	80	70	60	0	0.0	0.0
* Mandatory Objective(s)													

Total Composite Score :

33.21