सत्यमेव जयते

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare

Government of India

Annual Report 2014-15

CONTENTS

MISSION, VISION AND OBJECTIVES OF IPC

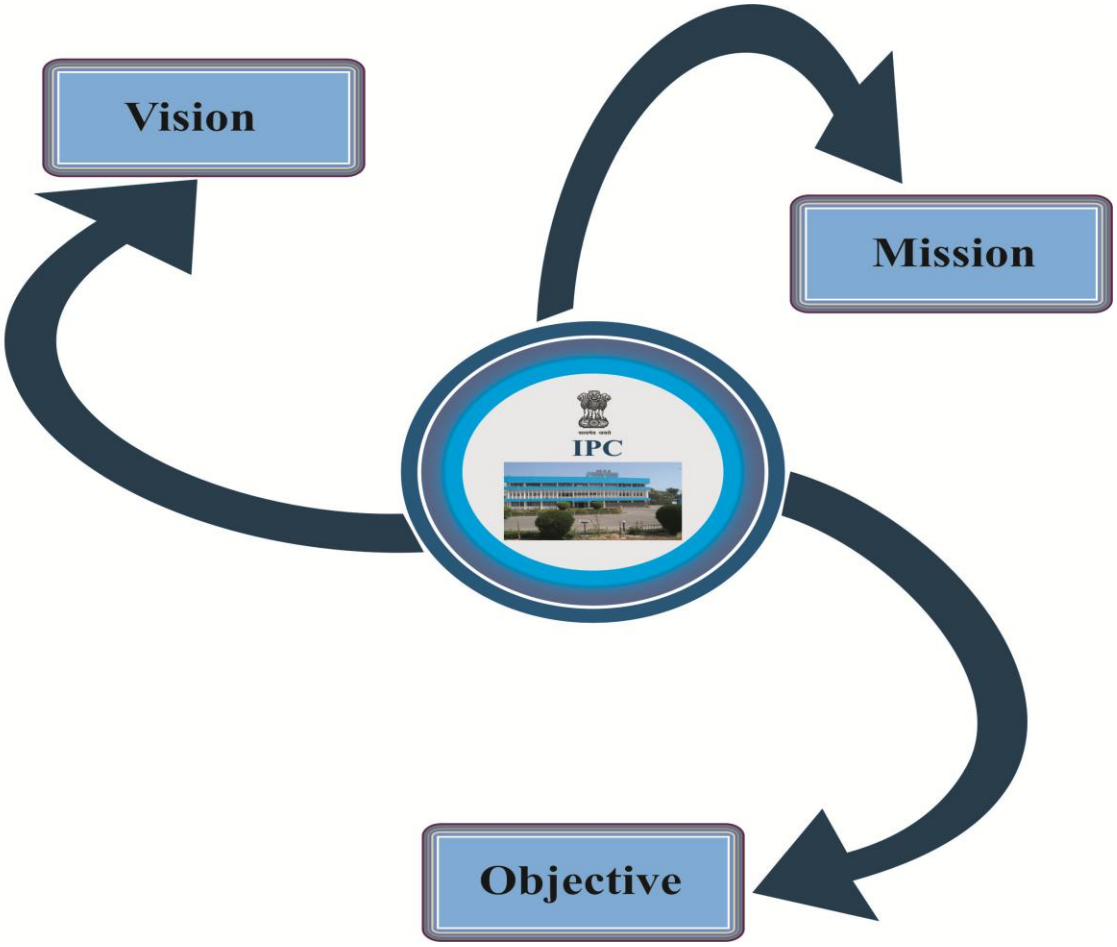


Figure: Functions of IPC

MISSION: To protect and promote public health by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients, dosage forms and medical devices for use by healthcare professionals, patients and consumers.

VISION: To promote the highest standards for drugs for use in humans and animals within practical limits of the technologies available for manufacture and analysis.

OBJECTIVES: To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, excipients and dosage forms as well as medical devices, and to keep them updated by reviews and revisions on a regular basis.

- To accord priority to monographs of drugs included in the National Essential Drugs List and their dosage forms.

- To prepare monographs for products that have normally been in the market for not less than 2 years except for certain special categories of new drugs like antiretrovirals, antituberculosis and anticancer drugs and their formulations introduced more recently needing priority attention.

- To give special attention to the methods of manufacture used by the indigenous industry in selecting the pharmacopoeial tests for monitoring the toxic impurities as applicable to such drugs.

- To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.

- To accelerate the processes of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products required.

- To collaborate with other Pharmacopoeia Commissions like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing the national standards with global standards without harming the National interests and concerns.

- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/ materials.

COMPOSITION OF THE INDIAN PHARMACOPOEIA COMMISSION

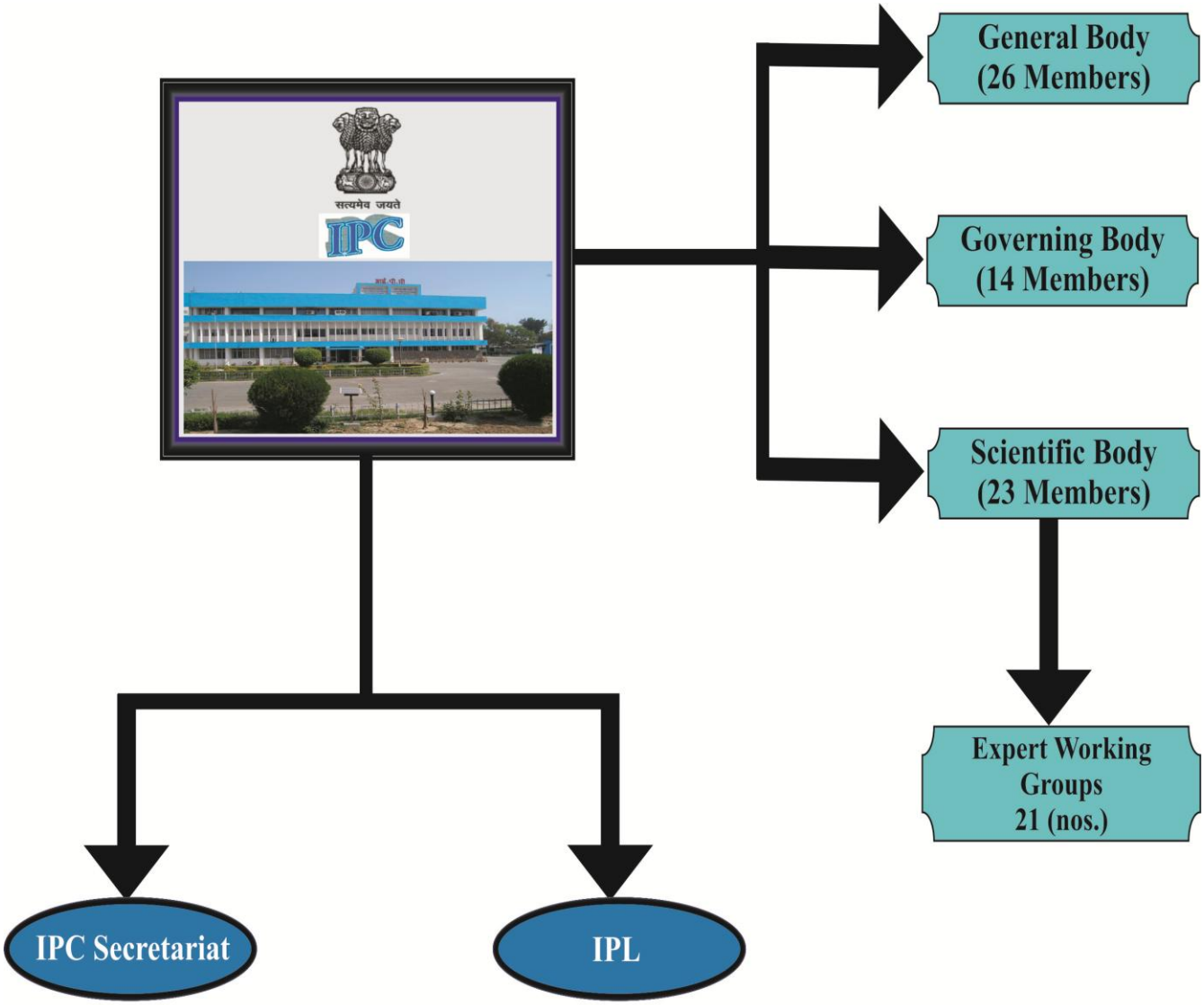


Figure: Structure of IPC

Bodies of the IPC:

Governing Body: The composition of the Governing Body is given below:

S. No.	Position	Name & Address
1.	*Chairman (ex-officio)*	Shri Bhanu Pratap Sharma Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
2.	*Co-Chairman*	Professor B. Suresh Vice-Chancellor, J.S.S. University JSS Medical Institution Campus Sri Shivarathreeshwara Nagara Mysore-570 015
3.	*Member (ex-officio)*	Dr. Jagdish Prasad Director General (DGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011
4.	*Member (ex-officio)*	Shri K. B. Agarwal Additional Secretary (Food & Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011
5.	*Member (ex-officio)*	Ms. Vijaya Srivastava Addition Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
6.	*Member (ex-officio)*	Shri K. L. Sharma Joint Secretary (Regulation) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
7.	*Member (ex-officio)*	Shri Shambhu Kallolikar Joint Secretary Department of Pharmaceuticals Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi-110011
8.	*Member (ex-officio)*	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011

9.	*Member (ex-officio)*	The Drugs Controller General (I) Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road New Delhi-110002
10.	*Member (ex-officio)*	Dr. Surinder Singh Director National Institute of Biologicals A-32, Sector-62, Institutional Area Noida-201 309
11.	*Member*	Professor (Dr.) Lalji Singh Former Vice-Chancellor Banaras Hindu University Varanasi -221 005 (U.P)
12.	*Member*	The President Pharmacy Council of India Combined Councils Building Kotla Road, Aiwan-E-Ghalib Marg Post Box No. 7020 New Delhi-110 002
13.	*Member*	Dr. Kiran Mazumdar Shaw C&MD Biocon Limited 20th KM, Hosur Road Electronics City, P.O., Hebbagodi Bangalore- 560 100
14.	*Member-Secretary (ex-officio)*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

General Body: The composition of the General Body is given below:

S. No.	Position	Name & Address
1.	*Chairman (ex-officio)*	Shri Bhanu Pratap Sharma Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
2.	*Co-Chairman*	Professor B. Suresh Vice-Chancellor, J.S.S. University JSS Medical Institution Campus Sri Shivarathreeshwara Nagara Mysore-570 015

3.	*Member* *(ex-officio)*	Dr. Jagdish Prasad Director General (DGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011
4.	*Member* *(ex-officio)*	Shri K. B. Agarwal Additional Secretary (Food & Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011
5.	*Member* *(ex-officio)*	Ms. Vijaya Srivastava Addition Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
6.	*Member* *(ex-officio)*	Shri K. L. Sharma Joint Secretary (Regulation) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
7.	*Member* *(ex-officio)*	Shri Shambhu Kallolikar Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi-110011
8.	*Member* *(ex-officio)*	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
9.	*Member* *(ex-officio)*	The Drugs Controller General (I) Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road New Delhi-110002
10.	*Member* *(ex-officio)*	Dr. Surinder Singh Director National Institute of Biologicals A-32, Sector-62, Institutional Area Noida-201 309
11.	*Member*	Professor (Dr.) Lalji Singh Former Vice-Chancellor Banaras Hindu University Varanasi -221 005 (U.P)
12.	*Member* *(ex-officio)*	The Director Central Drugs Laboratory 3, Kyd Street

		Kolkata-700016
13.	*Member (ex-officio)*	From Regulatory Bodies Central Drugs Standard Control Organisation Directorate General of Health Services FDA Bhawan, Kotla Road New Delhi
14.	*Member (ex-officio)*	Prof. K. K. Bhutani Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062
15.	*Member (ex-officio)*	Commissioners in-charge of Drug Control Administration, Andhra Pradesh
16.	*Member (ex-officio)*	Commissioners in-charge of Drug Control Administration Sikkim
17.	*Member (ex-officio)*	Commissioners in-charge of Drug Control Administration Gujarat
18.	*Member (ex-officio)*	Commissioners in-charge of Drug Control Administration Uttar Pradesh
19.	*Member (ex-officio)*	Commissioners in-charge of Drug Control Administration Himachal Pradesh
20.	*Member (ex-officio)*	The President Indian Drug Manufacturers Association (IDMA) 102-B, Poonam Chambers, Wing -A Dr. Annie Besant Road, Worli Mumbai 400018
21.	*Member (ex-officio)*	The President Organization of Pharmaceutical Producers of India (OPPI) Peninsula Corporate Park, Peninsula Chambers Gr. Floor, Ganpatrao Kadam Marg Lower Parel Mumbai-400 013
22.	*Member (ex-officio)*	Dr. Rao V. S. V. Vadlamudi President Indian Pharmaceutical Alliance (IPA) Mumbai
23.	*Member (ex-officio)*	Dr. C. Adithan Director-Professor Department of Pharmacology Jawaharlal Institute of Postgraduate Medical

		Education and Research Pondicherry-605 006
24.	*Member* *(ex-officio)*	The President, Pharmacy Council of India Combined Building Kotla Road, Aiwan-E-Ghalib Marg Post Box No. 7020 New Delhi-110 002
25.	*Member*	Dr. Kiran Mazumdar Shaw C&MD, Biocon Limited 20th KM, Hosur Road Electronics City, P.O., Hebbagodi Bangalore- 560 100
26.	*Member-Secretary* *(ex-officio)*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

Executive Committee: The composition of the Executive Committee is as follows:

S. No.	Position	Name & Address
1.	*Chairman*	Professor B. Suresh Vice-Chancellor, J.S.S. University JSS Medical Institution Campus Sri Shivarathreeshwara Nagara Mysore-570 015
2.	*Member-Secretary*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002
3.	*Member*	Professor (Dr.) Lalji Singh Former Vice-Chancellor Banaras Hindu University Varanasi -221 005 (U.P) India

Scientific Body: The composition of the Scientific Body is as follows:

S. No.	Position	Name & Address
1.	*Chairman*	Prof. B. Suresh Vice-Chancellor J. S. S. University JSS Medical Institution Campus Sri Shivarathreeshwara Nagara, Mysore-570 015
2.	*Member*	Professor Praveen Aggarwal Professor in-charge Department of Emergency Medicine All India Institute of Medical Sciences (AIIMS) Ansari Nagar, New Delhi-110029
3.	*Member*	Mr. Vinod Arora Former-Vice President (Pharma Research) Ranbaxy Research Laboratories S-340 second floor Uppal southend , Sector 48 Sohna Road, Gurgaon 122101
4.	*Member*	Dr. Manish Gangrade Head-Analytical Development Lab CIPLA Limited L.B.S. Marg, Vikhroli (W), Mumbai-400 083
5.	*Member*	Professor Y. K. Gupta Head Department of Pharmacology All India Institute of Medical Sciences (AIIMS) Ansari Nagar, New Delhi-110029
6.	*Member*	Dr. S. S. Jadhav Executive Director Quality Assurance & Regulatory Affairs Serum Institute of India Ltd. 212/2, Hadapsar, Pune-411 028
7.	*Member*	Dr. Prasad V. Kanitkar Former Director, Plant Operations Pfizer Global Manufacturing Pfizer Limited, Thane Belapur Road K.U. Bazar Post, Turbhe, Navi Mumbai-400 705
8.	*Member*	Dr. H. G. Koshia Commissioner Food & Drugs Control Administration Government of Gujarat Block No. 8, 1st Floor, Dr. Jivraj Mehta Bhavan Gandhinagar-382 010

9.	*Member*	Dr. J. P. Mehta Plant Manager Franco-Indian Pharmaceuticals Pvt. Ltd. 20, Dr.E. Moses Road Worli, Mumbai-400 011
10.	*Member*	Dr. S. M. Mudda Executive Director Technical & Operations Micro Labs Limited 27, Race Course Road, Bangalore-560 001
11.	*Member*	Dr. D. B. Anantha Narayana Former Director Hindustan Lever Research Centre #15 (Old No 1101/927) 1 "F" Main Road, 2nd Stage Giri Nagar, Bangalore – 560085
12.	*Member*	Dr. Vinay G. Nayak President Technical Operations Emcure Pharmaceuticals Ltd. Plot No. P-2, IT-BT Park, Phase II MIDC, Hinjwadi, Pune-411 057
13.	*Member*	Dr. S. Y. Pandey Director Chemistry and Business Development Jai Research Foundation Daman Ganga Bridge, N.H. No. 8 Valvada - 396 108 Dist. Valsad, Gujarat
14.	*Member*	Joint Commissioner (Testing) Food & Drugs Laboratory Near Polytechnic Baroda – 390 002 (Gujarat)
15.	*Member*	Dr. G. N. Qazi Vice Chancellor Jamia Hamdard Hamdard University, 'A' Category – NAAC Hamdard Nagar, New Delhi-110 062
16.	*Member*	Dr. Anurag S. Rathore Professor Department of Chemical Engineering Indian Institute of Technology Hauz Khas, New Delhi-110 016
17.	*Member*	Prof. Rakesh Kumar Sharma Additional Director and Head CBRN Defence Institute of Nuclear Medicine and Allied Sciences (INMAS)

		Brig SK Mazumdar Marg, Delhi 110 054
18.	*Member*	Professor (Dr.) Lalji Singh Bhatnagar Fellow (CSIR) Former Vice-Chancellor Banaras Hindu University, Varanasi – 221005
19.	*Member*	Mr. R. Sridharan Former Sr. Vice President Corporate Quality Assurance Lupin Limited 603, Sarangi Lokpuram, Thane (W) – 400 610
20.	*Member*	Dr. N. Udupa Principal Manipal College of Pharmaceutical Sciences Madhav Nagar Manipal-576 104 (Karnataka)
21.	*Member*	Dr. P. V. Venugopal WHO Temporary Advisor A-11, Sarvodaya Enclave, New Delhi-110 017
22.	*Member*	Professor M. R. Yadav Head, Pharmacy Department Faculty of Technology and Engineering The M. S. University of Baroda Vadodara– 390 001 (Gujarat)
23.	*Member-Secretary (ex-officio)*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

Special Invitees:

Special Invitee	Dr. B. R. Jagashetty Former Drugs Controller of Karnataka Flat No. 702/402, Ram Sridhar Apts BTM 2nd Stage, 16th Main Aicoboonagar, Bangalore – 560076
Special Invitee	Mr. S. S. Venkatakrishnan Former Drugs Controller of Kerala 12/548, (GNRA 47), Dhanyasree Vrindavanam Gardens, Old P O Lane Kodunganoor, Thiruvananthapuram-695013

National Consultative Committee (NCC) of IPC

Composition of the National Consultative Committee (NCC) of the Indian Pharmacopoeia Commission, Ghaziabad is as follows:

S. No.	Position	Name and Address
1.	*Chairman (ex-officio)*	Secretary to the Govt. of India (DHR), and Director General Indian Council of Medical Research Ramalingaswamy Bhawan Ansari Nagar, New Delhi-110 029
2.	*Co-Chairman (ex-officio)*	Shri K. B. Agarwal Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
3.	*Member (ex-officio)*	Dr. Surinder Singh Director National Institute of Biologicals B-62, Institutional Area Noida-201 307
4.	*Member*	Professor (Dr.) Lalji Singh Former Vice-Chancellor Banaras Hindu University Varanasi -221 005 (U.P)
5.	*Member*	Prof. B. Suresh Vice-Chancellor J. S. S. University JSS Medical Institution Campus Sri Shivarathreeshwara Nagara Mysore-570 015
6.	*Member*	Professor C. K. Kokate Vice-Chancellor KLE University Belgaum
7.	*Member*	Dr. G. N. Qazi Vice Chancellor Jamia Hamdard Hamdard University, 'A' Category – NAAC Hamdard Nagar, New Delhi-110 062
8.	*Member*	Professor Y. K. Gupta Head, Department of Pharmacology All India Institute of Medical Sciences (AIIMS) Ansari Nagar, New Delhi
9.	*Member*	Dr. P. V. Appaji Executive Director

		Pharmaceuticals Export Promotion Council (Pharmexcil) 101, Aditya Trade Centre Ameerpet, Hyderabad-500 038
10.	*Member*	Mr. M. Ayyapan C&MD HLL Mahilamandiram Road Poojappura Thiruvananthapuram-695 1012
11.	*Member* *(ex-officio)*	Drugs Controller General (I), Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road New Delhi
12.	*Member*	Dr. B.E. Rao WHO Consultant and Ex-CMD, IDPL 906, Amsri, Central Court (Old Lancer Road) Secunderabad- 500 025
13.	*Member*	Dr. M. Bamji Former Director Grade Scientist National Institute of Nutrition 211 Sri Datta Sai Apartments RTC Cross Road Hyderabad-500 020
14.	*Member*	Mr. Pankaj Patel C&MD Cadila Health Care Zydus Tower Satellite Cross Road Ahmedabad- 380 015
15.	*Member*	Dr. Sudershan Arora Former President, Ranbaxy Research Laboratory Plot No. 20, Sector 18 Udyog Vihar, Gurgaon
16.	*Member-Secretary* *(ex-officio)*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

Expert Committees and Working Groups:

1. **Review of IP Work**
   Mr. J. L. Sipahimalani (*Chairman*), Members, Mr. R. Raghunandanan, Mr. R. Sridharan.

2. **Sub-Group for Reviewing IP Work**
   Dr. R. A. Singh, Mr. Arvind Kukrety, Mr. Gaurang Oza, and Mr. S. L. Jat.

3. **IPRS Review Committee**
   Dr. V. G. Nayak (*Chairman*)*;* Dr. Raman Mohan Singh, Dr. P. K. Guha, Dr. K. V. Jogi, Prof. Sanjay Singh, Dr. K. K. Singh, Dr. Girish Juneja, and Mr. S. K. Mishra.

4. **Anti-Cancer**
   Dr. K. V. Jogi (*Chairman*), Dr. B. Nagaraju, Dr. N. Padmaja and Dr. Mohan Jain.

5. **Anti-Retroviral**
   Dr. Manish Gangrade (*Chairman*), Dr.Antony Raj Gomas, Ms. Rashmi Srivastava, and Dr. Suryanarayana Mulukutla.

6. **Radiopharmaceuticals**
   Dr. Rakesh Kumar Sharma (*Chairman*), Dr. M. G. R. Rajan, Dr. Anil Kumar Mishra, Dr. Grace Samwel, Dr. N. Shivaprasad, Dr. Aruna Korde, and Dr. Sanyog Jain.

7. **Biologics**
   Dr. Surinder Singh (*Chairman*), Dr. Anurag S. Rathore and Dr. S.S. Jadhav.

8. **Excipients**
   Dr. P.V. Kanitkar (*Chairman*), Mr. Subodh Priolkar, Dr. D.B.A. Narayana and Dr. Shailesh Nagarsenkar.

9. **General Chapters**
   Dr. Vinay G. Nayak (*Chairman*), Dr.Sunil S.Nadkarni, Mr. Antony R. Gomes, Dr. Vinay Aroskar, Dr. Pramod Dalvi, Dr. Sundara Kalyana Balaji, Mr. Kundan D. Patil, Mr. Deepak Jakate, Mr. Sanjay Despandey, Dr. V. B. Malkar, Mr. Mohan Jain, Dr. Luis Coutinho.

10. **General Chapters & Dosage Forms**
    Mr. Vinod Arora (*Chairman*), Dr. Prashant Dixit.

11. **Herbal Products**
    Dr. D. B. Anantha Narayana (*Chairman*), Dr. Amit Agarwal, Dr. G. Patani, Dr. Pulok Mukherjee, Dr. M. N. Nanjan, and Dr. C. K. Katiyar.

12. **Sub Group on "Essential Oils" for the IPC**
    Mr. Ramakant Harialka, Mr. B. Murali, Dr. Rahul Singh, Ms. Bhuvana Nageswaran, and Dr. Hema Lohani.

13. **Inhalation Products**
    Mr. R. Sridharan (*Chairman*), Mr. Satish Sharma, Mr. Sanjay Gupta, Mr. Nagesh Shenoy, Mr. Ganadish Kamat, Mr. Amit Sule, and Mr. S. G. Belapure.

14. Medical Devices

Dr. S. Eswara Reddy (*Chairman*).

15. Microbiology (General)

Dr. J. P. Mehta (*Chairman*), Mr. C. Hariharan, Dr. Gopa Ghosh, Mr. S. N. Chavan, Dr. Jadhav, Mr. A. P. Mohan, Dr. P. K. Chitnis, Dr. Suhas Mangaonkar, Mr. Om Prakash Verma and Mr. Ashok Desai.

16. Ophthalmics

Dr. S.M. Mudda (*Chairman*), Mr. V. Shiv Kumar, Ms. Shakila S. Pai, Mr. R.T. Arasu, Mr. Navneet V. Mehta, Ms. S. Asha, Mr. P. Venkata Reddy and Ms. Aditi Panandikar.

17. Parenteral Preparations (General)

Mr. Satish R. Kulkarni (*Chairman*), Mr. Hemal Patel, Mr. Vijay V. Kshirsagar, Mr. H. T. Nazare, Mr. S. L. Jat, Mr. Sudhir Pandya.

18. Veterinary Products

Dr. Rishendra Verma (*Chairman*)

19. Vaccines

Mr. S.S. Jadhav (*Chairman*), Dr. Arun Bhardwaj, Dr. A. Ramkrishan, Dr. Sumant Sharachchandra Karnik, Dr. Sunil Gairola, Dr. Mahesh Bhalgat, Mr. Anil Sood, Mr. P.M. Patel, Mr. Parag P. Nagarkar and Dr. K. Anand Kumar.

20. Biologicals and rDNA products

Dr. Anurag Rathore (*Chairman*), Dr. S.S. Jadhav, Dr. Venkata Ramana, Dr. Sriram Akundi, Mrs. Kinnari Vyas, Mr. Arvind Kukrety, Dr. SAmir Sangitrao, Dr. Renu Jain, Dr. Rahul Kulkrni, Dr. Himanshu Gadgil, Dr. Satyanarayana Subrahmanyam, Ms. Seema Shimpi, Dr. Mahesh K. Bhalgat, Dr. Jayasheel B.G. and Ms. Meenu Batolar.

21. Website Development

Dr. D. B. Anantha Narayana (*Chairman*), Dr. P. V. Venugopal, Mr. G. S. Bedi.

SCIENTIFIC ACTIVITIES & ACHIEVEMENTS

AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT

Indian Pharmacopoeia (IP) related work:

Preparation of Manuscript of Addendum 2015 to IP 2014 and work for IP Addendum 2016 is under process:

The following admissions, upgradations, changed titles and omissions were made as per the suggestions received from various stakeholders, subject experts and the concerned committees. The final manuscript of Addendum 2015 to IP 2014 was checked by the subject experts and Technical Secretariat of IPC and handed over to NISCAIR New Delhi, for printing. Whereas, the final manuscript of Addendum 2016 to IP 2014 is under review.

Admissions

The following General Chapters, Monographs on drug substances, dosage forms, and pharmaceutical aids, New Drug Substances Monographs, Antibiotic Monographs, Radiopharmaceutical Monographs, Herbal Monographs, Human Vaccines, Insulin Products, Biotechnology Products, Veterinary Non-Biological Monographs, Veterinary Biological Monographs, Veterinary Diagnostic Monographs, Veterinary Immunosera Monographs, Veterinary Surgical Monographs were admitted. **(See Annexure-I)**

Omissions

The following monographs were omitted. **(See Annexure II)**

Errata 003 and 004 to IP 2014

Worked on the queries/suggestions received from different stakeholders including pharma industries and after discussing and taking views of the subject expert group for IP, the same is finalized and put up on website for appropriate time and released on 09.01.15 and 10.03.15 by the Secretary-cum-Scientific Director of IPC. Total more than 100 amendments taken place in the following monographs/tests. **(See Annexure III).**

New Monographs Drafted for next Addendum 2016 to IP 2014

Following 63 new chemical monographs were drafted during this period for next addendum 2016 to IP 2014 and put up on the website for stakeholders comments. **(See Annexure IV)**

IP related Queries (As Technical Secretariat)

The AR&D team has examined more than 500 queries received from different stakeholders related to IP chemical & excipient monographs having upgradation of the tests, technical and typographical errors. Dr. S.C. Mathur of AR&D have worked as Technical

Secretariat team also during this period and action taken on all technical matters referred through Scientific Director of IPC.

Verification of Analytical methods for IP

The AR&D team is vigorously involved in analytical verification of various tests in the existing monographs of IP-2014 and the monographs drafted for addendum 2015 and 2016 of IP 2014. Carried out verification of analytical method for drugs samples received from various stakeholders in the AR&D Division for verification of different tests of IP monographs. During this period following tests in mentioned samples were verified.

For IP Addendum 2015 to IP-2014:

1. Verified related substance test of Rabeprazole API.
2. Verified related substance of Paracetamol Oral Suspension.
3. Verified assay of Levotrigine Dispersible Tablets.
4. Verified uniformity of content of Indapamide Tablets.
5. Verified assay of Atorvastatin Tablets.
6. Verified related substance of Carbimazole Tablets.
7. Verified full monographs of Citicoline Tablets.
8. Verified related substance of Piroxicam API.
9. Verified full monograph of Torsemide API.
10. Verified related substance test of Cloxacillin Sodium.
11. Verified assay of Nevirapine Hemihydrate.
12. Verified assay of Albendazole Oral Suspension.
13. Verified full monograph of Dorzolamide API.
14. Verified assay & identification of Nandrolone Decanoate Injection.
15. Verified related substance of Atenolol.
16. Verified identification of Enoxaparin sodium.
17. Verified dissolution of Nifedipine SR Tablets.
18. Verified assay & uniformity of content of Cyproheptidine Tablets.
19. Verified assay of Thyroxine Sodium Tablets.
20. Verified assay of Gemifloxacin Tablets.
21. Verified related substance Pregabalin sample.
22. Verified assay of Clotrimazole Cream.
23. Verified pH of Xylometazoline HCl Nasal solution.
24. Verified solubility of Menthol.
25. Verified light absorption test of Hyaluronidase.
26. Verified assay of Nicotinamide, Oxazepam, Clonazepam.
27. Verified full monograph of Cisplatin Injection.
28. Verified Uniformity of content of Glibenclamide
29. Verified dissolution of Ormeloxifene HCl Tablets.
30. Verified assay of Lamivudine Tablets.
31. Verified full monographs of Sitagliptin Tablets.

32. Verified assay of Ranitidine Tablets.
33. Verified assay of Diacerein Tablets.
34. Verified full monograph of Raloxifene HCl Tablets.
35. Verified full monograph of Barium Sulphate.
36. Verified assay of Efanavir Capsules.
37. Verified related substance test of Amlodipine Tablets.
38. Verified of Misoprostol Tablets.
39. Verified full monographs of Brimonidine Tartrate.
40. Verified assay of Carvedilol Tablets.
41. Verified dissolution of Ursodiol Tablets.
42. Verified full monograph of Natamycin Sodium.
43. Verified related substance of Donepizol HCl.
44. Verified full monograph of Ranitidine Oral Solution.
45. Verified full monograph of Tadalafil Tablets.

For IP Addendum 2016 to IP-2014:

1. Verified full monograph of Paroxetine HCl Prolonged release Tablets
2. Verified full monograph of Abiraterone Acetate API
3. Verified full monograph of Bendamustin HCl API
4. Verified full monograph of Bendamustin HCl Injection
5. Verified full monograph of Duloxetine Tablets
6. Verified full monograph of Entecavir Tablets
7. Verified full monograph of Exemestane Tablets
8. Verified full monograph of Metoprolol Succinate Prolonged Release Tablets
9. Verified full monograph of Metronidazole Gel.
10. Verified full monograph of Zolmitriptan nasal spray Tablets
11. Verified related substance test of Rabeprazole Injection
12. Verified related substance test of Dobutamine HCl
13. Verified Dissolution test of Sertraline Tablets
14. Verified Dissolution test of Dutasteride Tablets
15. Verified Uniformity of content of Tadalafil Tablets
16. Verified Water content of Resedronate Sodium
17. Verified Uniformity of Content of Norethisterone Tablets
18. Verified assay test of Chlorthalidone tablets

WHO Work for International Pharmacopoeia

Participated regularly for the development of the monographs for the WHO/International Pharmacopoeia from time to time. Following drugs monographs were checked and commented upon during this period which was received from WHO, Geneva.

1. Albendazole Chewable Tablets
2. Atazanavir Capsule

3. Atazanavir Sulfate
4. Clindamycin Hydrochloride
5. Clindamycin Hydrochloride Capsule
6. Dexamethasone Sodium Phosphate
7. Dexamethasone Sodium Phosphate Injection
8. Dextromethorphan Hydrobromide
9. Fluconazole Capsule
10. Fluconazole Injection
11. Flucytosine
12. Flucytosine Infusion
13. Index pharmacopoeias
14. Levamisole Hydrochloride
15. Misoprostol
16. Pyrantel Embonate
17. Pyrantel tablets

Worked for Publication Division

Dr. D.K. Sharma, Scientific Officer, AR&D Division had coordinated the work for publication of IP through NISCAIR, New Delhi.

IP Reference Standards Developments:

Organized and co-ordinated for development of IPRS at Reference Standard Division by developing IPRS vial and their packing, cold room facility and for making availability of candidate material from the stakeholders. Co-ordinated the analysis of these candidate material in Reference Standard Division. The list of available IPRS is reached upto 250.

Expert Member of European Pharmacopoeia (EDQM)

The European Directorate for the Quality of Medicines & Health Care (EDQM), Strasbourg (France) has specific offered to Dr. Raman Mohan Singh **as Expert of the European Pharmacopoeia since last 05 years and continued for this year also.**

Expert Member of United States Pharmacopoeia (USP)

Dr. Raman Mohan Singh, PSO was the expert member from IPC for the collaborative work with USP. Attended all the meetings/Telecon conference meetings held during this period.

Member of Bureau of Indian Standard (BIS), New Delhi

Dr. Raman Mohan Singh, PSO & Dr. S.C. Mathur, SSO are the member of different committees of Bureau of Indian Standards (BIS), New Delhi. Attended all referred correspondence and meetings of BIS from time to time.

1. Medical Equipment and Hospital Planning Council;
2. Cosmetic Sectional Committee, PCD 19;
3. Herbal Cosmetic Subcommittee, PCD 19:6;

4. Natural and Synthetic Fragrance Materials Sectional Committee, PCD-18;
5. Food Additive Selective committee
6. Rubber and Rubber Products Sectional Committee, PCD 13.

Training to Students/Scientists

Provided training to graduates, postgraduate students and scientific staff of various pharmacy colleges affiliated with different Universities and of different private and Govt. drugs testing laboratories.

BIOLOGICS SECTION

a) Biotechnology Derived Products

Biotechnology derived products encompass all products that are biologically sourced or derived using biological systems in their manufacturing. These include recombinant molecules such as monoclonal antibodies, fusion proteins and other therapeutic proteins. Compared to small molecule drugs, these biologics are highly specific and complex. They revolutionized the various treatments such as solid tumors or hematological cancers, immune-mediated disorders and neurological diseases. These products gained the momentum and are an emerging industry in India. In view of this, efforts have been made for the inclusion of the monographs of biotechnology derived products in IP. The monographs contain information including the definition of the Biotechnological Products ingredient relative to the monograph title followed by specifications.

Revised monographs and General Chapter in Addendum 2015 to IP 2014:

Revised Monographs

- Erythropoietin Injection
- Erythropoietin for Injection
- Filgrastim Injection
- Interferon Alpha 2b Injection
- Interferon beta 1a concentrated solution
- Recombinant streptokinase bulk solution
- Human Insulin
- Biphasic Isophane Insulin Injection
- Biphasic insulin aspart injection
- Biphasic Insulin Lispro injection

Revised General Chapter:

- Peptide mapping

New draft monographs in process for inclusion in Addendum IP 2016 to IP 2014: 08

a) Pegfilgrastim
b) Somatropin
c) Somatropin concentrated solution
d) Somatropin for injection
e) Menotropin
f) Menotropin for Injection
g) Insulin Glargine
h) Insulin glargine injection

New draft monographs in process (including verification of methods): 06

a) Rituximab DS & DP
b) Teriparatide DS & DP
c) Trastuzumab DS & DP
d) Follicle stimulating harmone DS & DP
e) Interferon beta 1a injection
f) Streptokinase Concentrated Solution

New draft general chapters are in process: 04

a) Glycoprotein and Glycan Analysis
b) Monoclonal Antibodies
c) Viral safety and viral clearance
d) Host cell protein and Host cell DNA

b) <u>Monographs on Human Vaccines</u>

A vaccine is a biological preparation containing antigens that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.

Pharmacopoeial vaccine monographs in IP contain information including the definition of the vaccine relative to the monograph title followed by specifications. The specifications cover the various tests for critical quality parameters of the vaccine, procedures and acceptance criteria.

New and amended vaccine Monographs and General chapters included in Addendum 2015 and to IP 2014 are:

Human Vaccines	
New Monographs: 03	**Revised Monographs :11**
BCG for Immunotherapy	Bacillus Calmette-Guerin Vaccine (Freeze dried)
Influenza vaccine human live attenuated	Cholera Vaccine(Inactivated, Oral)
Sterile water for Inhalation	Diptheria Vaccine (Adsorbed)
	Haemophilus Type b Conjugate Vaccine
	Hepatitis B Vaccine (rDNA)
	Inactivated influenza vaccine split virion
	Influenza vaccine (Human , Live attenuated)
	Measles, Mumps and Rubella Vaccine, (live)

	Group A meningococcal conjugate vaccine
	Meningococcal Polysaccharide A and C Vaccine
	Tetanus vaccine (Adsorbed)

Revised General Chapter: 02

- Test for Colony Forming Units (2.2.5)
- Particulate contamination

New draft monographs in process for Addendum 2016 to IP 2014 : 04

- Japanese Encephalitis Live Vaccine (Human)
- Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human)
- Typhoid Vi Conjugate Vaccine
- Pneumococcal Conjugated Vaccine

c) Monographs on Blood and Blood related products

Blood and blood products are used as biological medicines and as *in vitro* diagnostics. Blood products are basically any component of the blood which is collected from a donor for use in blood transfusion. These products constitute a key health concern and thus there is a need to develop their standards.

New draft monographs in process for Addendum 2016 to IP 2014

- Anti-AB Blood Grouping Reagent

PHARMACOLOGY DEPARTMENT

The content of NFI 2011 was revised in the light of existing medical and pharmaceutical literature and new chapters/drug monographs were also identified and content synthesized with expert inputs. The whole content was validated by the Experts through consultation meetings. Expert committee meetings were conducted in Department of Pharmacology, All India Institute of Medical Sciences (AIIMS) and at Nirman Bhawan, New Delhi for the preparation of 5th edition of NFI.

PHYTOPHARMACEUTICALS DIVISION

1. **Verification of Drafted monographs for IP Addendum 2016 to IP-2014:**
   Drafting and verification of 14 new herbal monographs of Ashoka, Cassia oil, Cinnamon bark oil, Cinnamon leaf oil, Ginkgo Dry Extract, Ginkgo Leaf, Ginkgo Tablet, Puskara, Jangali Haldi, Jatamansi, Kasni, *Morinda citrifolia*, Tea Tree oil, Nirgundi by HPLC/HPTLC/GC for IP Addendum 2016.
2. **Revision of Existing Herbal Monographs of IP 2014:**
   Revised the 20 monographs (Amaltas , Artemisia, Bala , Coriander Oil, Kaunch ,Lavender Oil , Nagakesar, Vidanga, Vijayasara, Asthisamhrta, Bassant, Birmi, Draksha Hingu, Mirch, Sahajana Leaf, Sahajana Stick, Shankhpushpi , Ginseng, Ginseng Dry Extract) of IP 2014 for incorporation in IP addendum 2016
3. **Development of a New General Chapter for Analysis of Herbal drugs:**
   HPTLC for Addendum 2016
4. **IP Related queries:**
   a) Addressed the Ginseng and Ginseng extract monograph related query of IP 2014.
   b) Addressed the coconut oil monograph related query of IP 2014.
5. **Good Pharmacopoeial Practices Guidelines :**
   Drafted the working document on Good Pharmacopoeial Practices – Herbal monographs and Analytical Methods for WHO Guidelines.
6. **Herbal Guidance Manual :**
   Prepared the "Guidance Manual for Monographs Development of Herbs and Herbal Products" with the help of Expert group members, stakeholders.
7. **Analysis of Drug Samples :**
   a) New drug sample of Ginkgo Dry Extract 120mg FCT Tablet.
   b) Analysis of samples of Opium received from Central Revenue Control Laboratory, New Delhi.
8. **Survey Samples :**
   Analyzed the Samples of Aspirin, Prednisolone, Carbamazepine, Ethambutol, Spironolactone, diiethylcarbamazine
9. **Trainings :**
   Given the training to Govt. analyst, Pharmacy students, Research scholars, and foreign delegates on followings topics:
   a) Evaluation of physiochemical parameters of herbal drugs.
   b) Extraction of Herbal Samples.
   c) Identification & Assay of Herbals Drugs by High Performance Liquid Chromatography (HPLC).
   d) Identification & Assay of Herbals Drugs by High Performance Thin Layer Chromatography (HPTLC).
   e) Macro-Microscopic analysis of Medicinal Plants
   f) Development of Botanical & Phytochemical Reference substances.

g) Identification & Assay of Herbals Drugs/Oils by Gas Chromatography (GC).

10. **Development of Botanical Reference substances (BRS)/ Phytochemical Reference substances (PRS) :**
    a) Developed 20 Botonical Reference substances (BRS) of Amra, Arjuna, Asthisamhrta, Bakuci, Bala, Birmi, Bhibhitaki, Bhringraj, Gokhru, Gudmar,Guduchi, Haridra, Kaunch, Lodhra, Mirch, Nagakesar, Pippali small, Punarnava, Shankhpushpi
    b) Developed 02 Phytochemical Reference substances (PRS) of Quercitin and Kaempferol.

MICROBIOLOGY DIVISION

The Microbiology Division is working on various parameters with respect to microbiological activities mentioned in Indian Pharmacopoeia (IP) and other microbial related areas. The major activities include upgradation and addition of IP General Chapters. IPRS analysis (Antibiotics), New Drugs analysis (NDS), Miscellaneous/Port Sample Analysis and Inter Laboratory Comparison (ILC). These activities are supporting to strengthen the IPC at various aspects. The progress report of Microbiology Division for the April 2014 to March 2015 is as under:

1. Analysed candidate reference material of IPRS (Amikacin sulphate, Erythromycin stearate etc.):
   - Microbiological Assay of Antibiotic : **05**
2. Analysed several New Drugs Samples (NDS) for various microbial tests/parameters:
   - Bacterial Endotoxin Test : **16**
   - Sterility Test : **20**
   - Test for Microbial Contamination : **49**
3. Analysed several Miscellaneous/Port Samples for various microbial tests/parameters:
   - Bacterial Endotoxin Test : **35**
   - Sterility Test : **30**
   - Test for Microbial Contamination : **07**
4. Inter Laboratory Comparison (ILC) of various drugs for Microbial bioassay, Microbial contamination test and Bacterial endotoxin test.
5. Worked for audit of NABL:

- Upgrade and revised 30 SOPs, 15 Log Books of instruments and 10 monitoring records related to Microbiology testing.
- Prepared other necessary documents required for NABL certification of Microbiology Division.
- Recalibrated all the required instruments through external agencies and In-house facility.

- Successfully faced the audit for NABL certification.
- Resolved all the NCs arose in the audit of NABL certification.

6. Activities for IP addendum 2015:

- New addition of General Chapter on "Drugs substances manufactured by cell culture/fermentation.
- Made amendments in general chapter and monographs related to microbiology.

7. Routine microbiological activities:

- Performing sub-culturing of microbial strains every 15 days for their preservation and maintain their every record and documents.
- Identification of sub-cultured microorganisms through morphological and biochemical method.
- Routine air monitoring of microbiology lab by Settle-plate method and maintain their records.
- Routine air monitoring of IPRS filling and storage area by Settle-plate method and maintain their records.
- Weekly fumigation of Microbiology lab and maintain their records.
- Activities such as temperature monitoring of Instruments (Incubators, Deep Freezers, Refrigerators, Hot air ovens etc) and temperature & relative humidity monitoring of microbiology lab are regularly performed. Their respective documents are prepared and maintained as per NABL norms.
- Addressed the different scientific quires raised by stakeholders.
- Studied and drafted initial reply of various scientific RTI queries.
- Various other works assigned by seniors.

8. Involved in arrangement and participated of hands on training of Government analyst from central/state drugs testing laboratories.

9. Augmentation of infrastructure and facility at Microbiology Division:

- Involved in the procurement of Air Sampler (Make-HiMedia) for Active Air Sampling of microbiology lab.
- Initiated for the procurement of Digital Zone Reader and Analytical Balance for Division.
- Involved in the procurement of appropriate microbiological media, reagents and chemicals for microbiological analysis.
- Convey the current status of Sterility Lab and its problems to higher authority and suggested the necessary development of new Sterility and Microbial Limit Test facility as per current clean room concept at IPC.
- Attended the several meeting on discussion regarding the new lab facility.
- Draw the layout of Sterility Room and Microbial Limit Test Room as per current clean room concept and prepared the requirements for the New Clean Room facility in Microbiology Division

10. Extraction of DNA from microbial cultures to optimization the RAPD and 16s rDNA amplification protocol for identification of microorganisms:

- DNA extraction from specified microbial cultures.
- DNA amplification through PCR and Gel electrophoresis.
- 16s rDNA sequencing of microbial culture's DNA from external agency.

11. Research activities:

- Developed and validated the microbial bioassay for quantification of Levofloxacin in pharmaceutical preparation.
- Prepared the research paper on the above topic and the paper have been published in Journal of pharmaceutical Analysis (Elsevier).

12. IP-Addendum 2015:

Made amendments in following veterinary monographs of IP 2014

a) Veterinery Diagnostics
b) Veterinary Vaccines
c) Febantel
d) Isoflupredone acetate
e) Avian Mycoplasma antigen
f) Avian Infectious Bronchitis vaccine, live
g) Bkackquarter vaccine
h) Duck plague vaccine, live
i) Fowl cholera vaccine, inactivated
j) Infectious avian encephalomyelitis vaccine, live
k) Infectious brusal disease vaccine, inactivated
l) Infectious chicken anemia vaccine, inactivated
m) Ivermectin
n) Ivermectin injection
o) Ranikhet disease vaccine, live
p) Tylosin injection
q) Sterile diluent for live vacccines

REFERENCE STANDARD DIVISION (RSD)

Reference Standard Division is one of the most important Departments of IPC that focuses on various dimensions of Pharmaceutical Chemistry ans this provide reference substances, and conduct testing of CDSCO samples and training. This division is taking the lead in search of today's and tomorrow's requirement in the field of pharmaceutical activity.

Indian Pharmacopoeia Reference Substances are efficiently characterised chemical substances that are used in the official method prescribed in the Indian Pharmacopoeia to ensure the identity, strength and quality of the drug substances and drug products. It is used by the stakeholders to qualify the working standards that are used for routine analysis in the laboratories such as quantitative (e.g. assay and impurity) and qualitative (e.g., identification) analysis. IP Reference substance characterization involves collaboration processes and additional procedures other than those used in routine testing to produce Reference Substances of the highest quality and make them readily available to the public.

A modern analytical laboratory well equipped with modern and sophisticated instruments **(list of instrument attached as annexure - I)** with highly qualified, experienced and trained staff IPL is accredited to NABL ISO 17025:2005 capable of doing chemical and microbiological analysis, qualification testing of candidate reference substance and containerization of such reference substance that becomes Indian Pharmacopoeia Official Reference Substance to be used in conjuction with the official documentary standards published in the Indian Pharmacopoeia. IPL complies with the requirements of ISO 34. IPL is under review of the accreditation of "WHO pre-qualification programme"

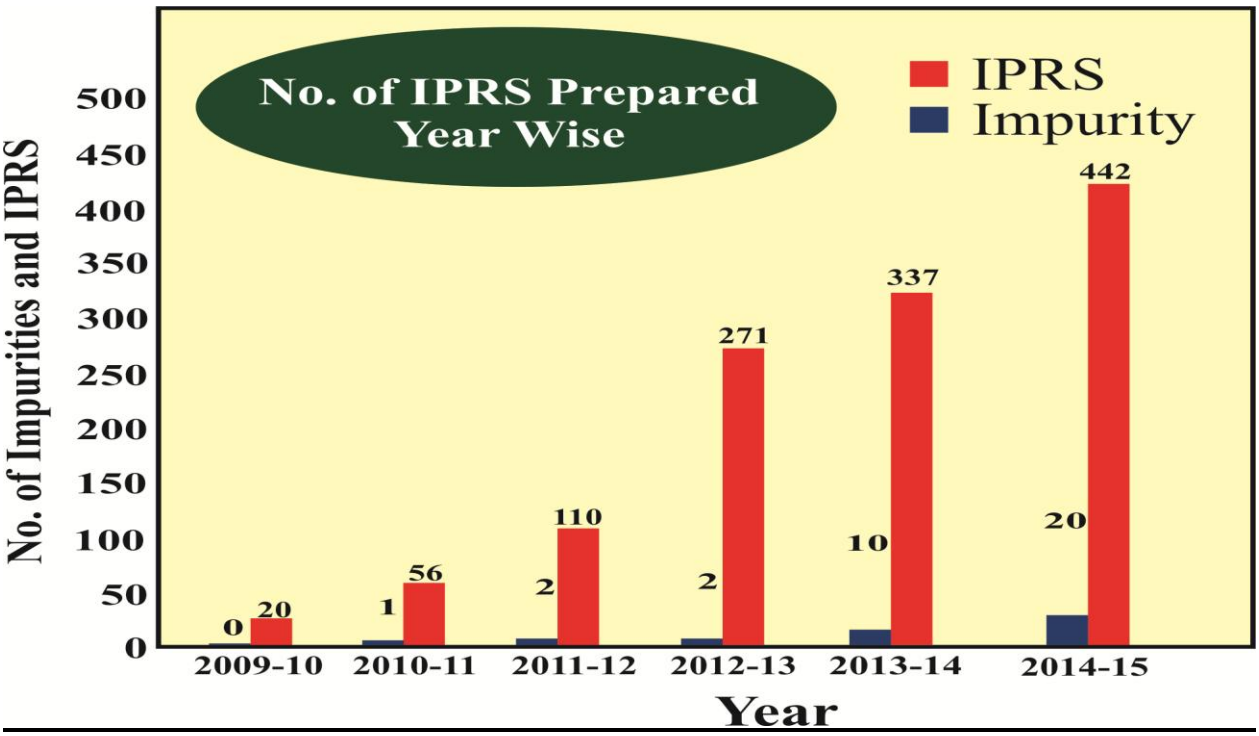
Key Activities of Reference Standard Division (RSD)

- Development of Indian Pharmacopoeia Reference Substances (IPRS)
- Distribution / Sale of IPRS
- New Drug Substance (NDS) analysis
- Port sample analysis
- Inter laboratory sample comparison analysis
- Skill Development of Government Drug Analysts and Regulators

Development of IPRS:-

In the Financial Year 2014-15, total no. of 85 new IPRS and 10 Impurities were developed and updated on our website. Till 31st March 2015, reference standard division has developed a total of 442 IPRS including 10 Impurities. The list of available IPRS at IPC is available on our website www.ipc.gov.in and is also attached in **ANNEXURE – II**

The list of updated IPRS (85) and Impurities (10) are attached in **ANNEXURE – III.**



Total number of 35 New Candidate Materials and 15 Impurities are under validation to develop the IP Reference Substances. The detailed list is attached as **Annexure IV.**

Total no. of 81 IPRS issued for changing of their lot numbers due to old stock had out of stock or less quantity of vials remains.

To prove the stability of already developed IP Reference Substances, retesting is performed on IPRS initially after 2 year followed by the annual retesting. Total 186 IPRS were retested for their integrity of potency in the financial year 2014-15.

The scientist have identified 48 new candidate materials to develop the IPRS required as per IP addendum 2015 & 16.

During the financial year 2014-15 a total of 33 IPRS that went out of stock have been replaced with a New Lot No.

During the financial year 2014-15 a total of 145 new candidate materials have been received from Stakeholders and CDSCO**.**

Distribution / Sale of Indian Pharmacopoeia Reference Substances:

The RSD of Indian Pharmacopoeia Laboratory has distributed/Sold a total number of 4461 IPRS Vials to the private and government authorities. The details are as follow:

- No. of IPRS / Impurity vials dispatched to Private companies / laboratories

= 3540 * 3000/-

= ₹1, 06, 20,000/-

(One Crore, Six Lacs and Twenty Thousand Rs. Only)

- No. of IPRS/Impurity vials dispatched to Govt. drugs testing laboratories

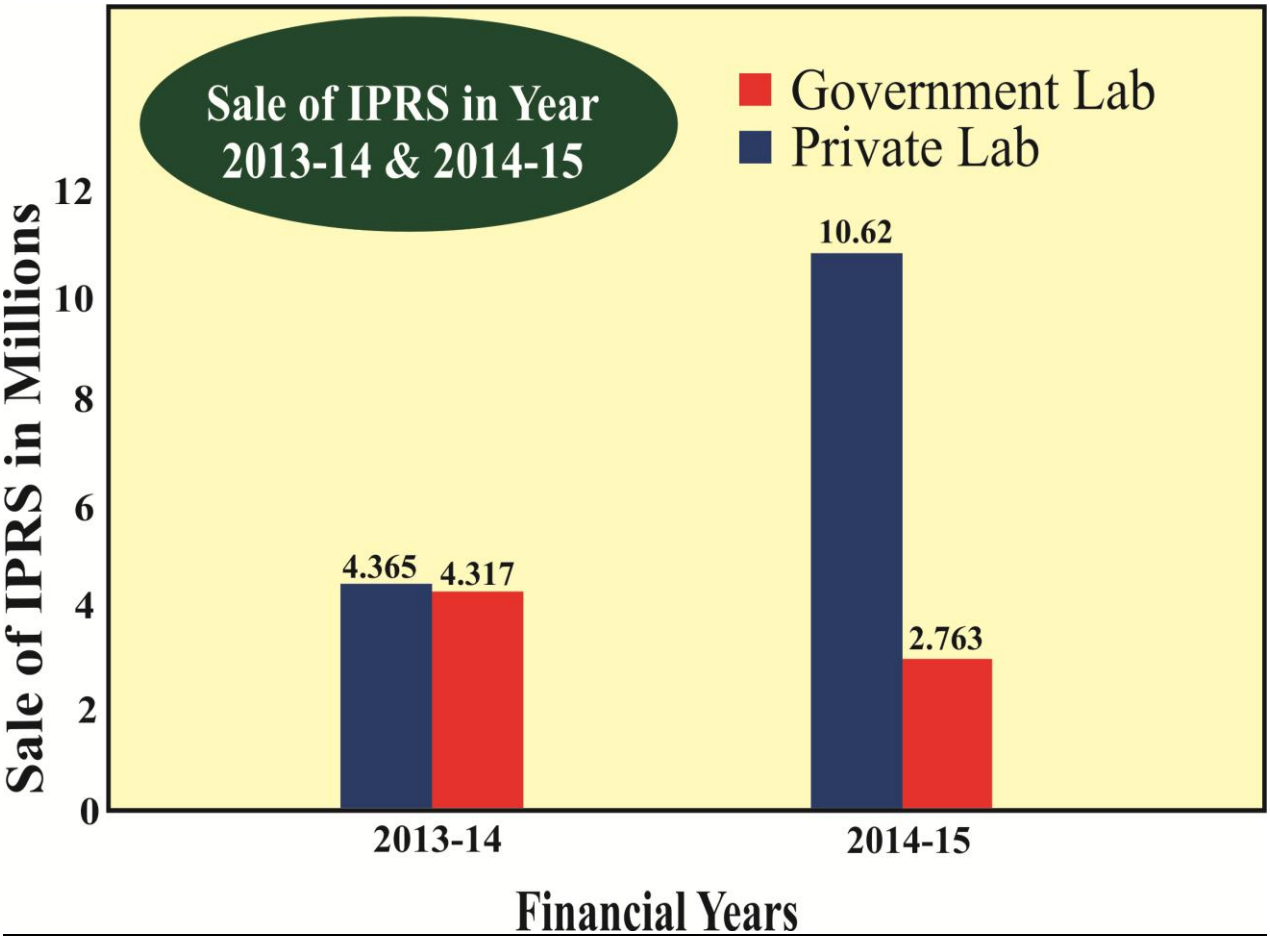
= 921*3000/-

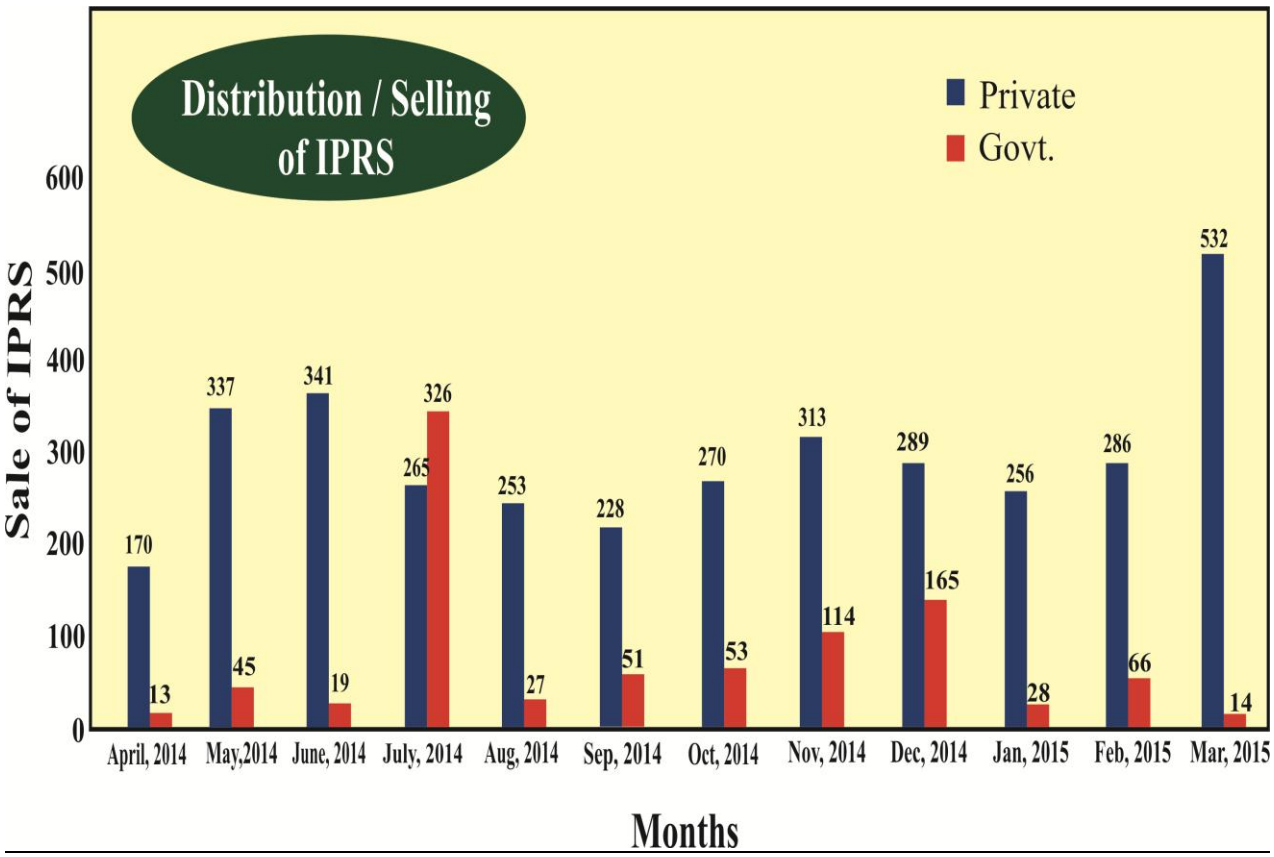
= ₹27, 63000/- (IPRS Supplied free of cost)

(Twenty Seven lacs and Sixty Three Thousand Rs. Only)

Comparison for Sales in financial year 2013-14 and 2014-15

Comparission	***2013-14***	***2014-2015***
Pvt Labs	1455 * 3000/- = ₹43,65000/-	3540 * 3000/- = ₹1,06,20,000/-
Government Labs (free of cost)	1439 * 3000/- = ₹43,17000/-	921 * 3000/- = ₹27,63000/-





New Drug Analysis

IPC has started verifying testing protocols for certain drugs that have recently been introduced in the Indian market on the approval of DCGI office. In the 41st DCC meeting, the members have decided that such test protocols are to be made available for drug testing laboratories/ regulators of the respective states on demand. Indian pharmacopoeia laboratory conducted the testing of new drug molecules received from DCG(I) office and prepared the protocol bank. Protocols, later in form of monographs will be included in the next Indian Pharmacopoeia.

In the financial year 2014-2015, Total no. of 112 New Drugs samples were received from the office of Drugs Controller General (India) for verification.

Port Sample Analysis

In the financial year 2014-15 total no. of 108 port samples were received from CDSCO, IGI cargo complex, New Delhi at IPC, Ghaziabad for the analysis and reports of the same were successfully submitted to the respective CDSCO Office.

Inter Laboratory Comparison Sample Analysis

As Indian Pharmacopoeia Commission, Ghaziabad, is a NABL approved testing laboratory, It is one of the mandatory part of NABL that laboratory should participate in Inter Laboratory comparison programme. In continuation, IPC has analysed 19 ILC Samples (**refer Annexure - V**) for different Laboratories.

Key Achievements of Reference Standard Division for year 2014-15

WHO Pre – qualified Laboratory:

One of the greatest achievement of Indian Pharmacopoeia Commission is that it has successfully qualified WHO-Prequalification audit. IPC is the first WHO prequalified government analytical laboratory in India

Synthesis of Impurities:

Impurities are required for the quality control of the APIs and other formulations. With the increasing facilities in Indian Pharmacopoeia Commission, the activities related to the generation of New Impurities has also been started in Aug. 2014 and so far nine impurities have been developed. The research scientists working in the department of synthesis are following the existing literature as well as devising the new ideas for the synthesis of drug impurities.

Reference Standard Division of Indian Pharmacopoeia Laboratory has introduced Nine Impurity Reference Substances after synthesizing candidate material by In-House Method. During this financial year, a total of nine impurities were synthesized and their characterizations were carried out by IR, ^{1}H-NMR, HPLC and LC-MS.

List of developed Impurities is attached in A**nnexure - VI**

Analysis of Pilot Study of Drug Survey:

For the first time in India, National Institute of Biologicals, CDSCO and IPC have conducted survey of various drug samples to identify Spurious and low Quality Drugs. National Institute of Biologicals, Noida had submitted 220 samples to IPC for the analysis as on trial basis.

Reference Standard Division has carried out the analysis of these 220 drug samples and submitted the report of the same through online software withing a week.

Newly Developed facility in RSD Division

New IPRS Distribution Section:

A separate department for the distribution of IP reference substances has been created in RSD divison. This department maintains all the records and information regarding the distribution of IPRS and impurities to the private and government authorities. For maintaining the quality of IPRS in this divison, RSD has purchased new pharmarefrigerators for storage.

Wet Lab Renovation:

The wet lab of Reference Standard Division has been renovated to meet standard requirement of GLP and WHO norms. The separate almirahs and drawers have been setup for systematic storage of the glassware and chemicals. It helps in the smooth functioning.

SMS Alert facility:

Reference Standard Division has brought a new SMS alert facility for the stakeholders that would inform about the development of Indian Pharmacopoeia and Indian Pharmacopoeia Reference Substance through SMS service.

Automatic IPRS filling machine:

A new facility for the filling of IP Reference Substances has been developed and is functioning in Dr. Nityanand Block. This automatic IPRS filling machine will inhance the tracibility, reduce the human error and would be effective in saving time.

Human Resource Development:

In the current scenario the activities of Reference Standard Divison is increasing in the financial year 2014-15. IPC has recruited numbers of Scientists, Pharma Associates and other office staff for RSD to increase the efficacy of the laboratory. The list of the Reference Standard Division Staff is attached in **Annexure – VII.** Reference Standard Division has also provided Internal and External training to the eminent scientific staff.

1. **Accreditation:**

- Internal audit was conducted from 09/06/2014 to 10/06/2014 in Chemical, Microbiological & Quality Assurance Department as per ISO/IEC 17025:2005. Internal audit of Quality Management System was found satisfactorily.

- Internal audit was conducted from 29/12/2014 to 31/12/2014 in Chemical, Microbiological & Quality Assurance Department as per ISO/IEC 17025:2005. Internal audit of Store and Quality Management System was found satisfactorily by auditor team i.e. Dr. P.L.Sahu, Dr. Robin Kumar, Dr. Anil Kr. Teotia & Mr. Anuj Prakash

- Desktop assessment to verify the continued compliance of ISO/IEC 17025:2005 was completed in the month of July, 2014. The outcome of Desk-top Surveillance audit was received by IPC, Ghaziabad on 18th September, 2014. And it was found satisfactorily during review of Desk-top surveillance audit by Mr. Vikas Kumar Jaiswal (Accreditation Officer, NABL) for the continuation of accreditation of IPC, Ghaziabad for chemical & Biological testing as per the existing scope and authorised signatures in accordance with ISO/IEC 17025:2005.

- WHO team audited IPC from 9th to 11th October 2014 for WHO's prequalification Programme and reported several Observations (Critical-1, Major-4, Other-9) for the complies to observe response for the provided CAPA.

- Started work related to ISO 34, 35 for Reference Material Producer.

Skill Development to Government Drugs Analyst, Regulators and Stakeholder:

As a mandate of IP commission the Reference Standard Division has to provide training to Government Drugs Analysts, Drugs Regulators and Stakeholders. RSD division has already

conducted three training programmes for the Drug Analysts and Drugs Regulator and one "One Day Workshop on Awareness Prgramme on IP and IPRS to Stakeholders at PGIMER. IPC also helps the research scholars and project trainees to complete their projects. In the financial year IPC has provided training to the following participants:-

S.No.	Training Period	Titled	Participants	No. of Participants
1.	30th June 2014 to 11th July 2014	Training Programme on Various Analytical Instruments & Techniques for Government Drugs Analysts	Drugs Analyst	55
2.	27th August 2014 to 29th August 2014	Training programme for Drugs Inspectors on Regulatory Aspects	Drugs Inspectors	41
3.	19th January 2015 to 23rd January 2015	Training Programme on Various Analytical Instruments & Techniques for Government Drugs Analysts	Drugs Analyst	49
4.	17th March 2015	One day workshop on awareness programme of Indian Pharmacopoeia and Indian Pharmacopoeia Reference Substance	Stackholder and Scientific Staff and Student of PGIMER	250

- Two weeks training programme titled "TRAINING PROGRAMME ON VARIOUS ANALYTICAL INSTRUMENTS & TECHNIQUES FOR GOVERNMENT DRUG ANALYSTS" from **30th June 2014 to 11th July, 2014** was conducted at Indian Pharmacopoeia Commission. The training programme was inaugurated by Dr. G. N. Singh, Drugs Controller General (I) and Secretary-cum-Scientific Director, IPC and Dr. V. G. Somani, Joint Drug Controller (I). Total No. of 55 participants from **25** different laboratories of **18** states have participated in the training programme. This training programme covered various lectures on different useful topics from the Experts all over India along with Hands on Training on various analytical instruments i.e. HPLC, GC, GC-HS, FT-IR, AAS, ICP-MS and NMR etc. The vital topics were covered in this training programme such as Role of Government Analysts in public life, Analytical Method validation on HPLC & GC, Laboratory Accreditation as per ISO/IEC 17025:2005 by experts all over the India and IPC Scientific Staff.

- Three Days training programme titled "TRAINING PROGRAMME FOR DRUG INSPECTORS ON REGULATORY ASPECTS" was conducted from **27th August, 2014 to 29th August, 2014** at Indian Pharmacopoeia Commission. The training programme was inaugurated by Dr. G. N. Singh, Drugs Controller General (I) and Secretary-cum-Scientific Director, IPC. Total No. of **41** participants from **13** states (State and Central Govt.) participated in the training programme. The training programme covered various vital lectures on different useful topics from the Experts from all over India. The paramount

topics were covered in this training programme such as 'Impact of recent regulatory changes for clinical trials in India', 'Stability Studies' and 'Commonly Observed deficiencies during Inspection, Investigation & Prosecution under D & C Act, 1940' and Rules thereunder off. Overview of GMPs by experts and eminent scientist all over the India.

- A One week training programme titled "3rd TRAINING PROGRAMME ON VARIOUS ANLAYTICAL INSTRUMENTS AND TECHNIQUES FOR THE GOVERNMENT DRUG ANALYSTS " from **19th Jan, 2015 to 23rd Jan, 2015** was conducted at Indian Pharmacopoeia Commission. The training programme was inaugurated by Dr. G. N. Singh, Drugs Controller General (I) and Secretary-cum-Scientific Director, IPC and Dr.R.K.Khandal, Vice Chancellor, UPTU, Lucknow. Total No. of **49** participants from **20** different laboratories of **18** states have participated in the training programme. During this one week training, theoretical and practical aspects of training courses were covered by individual presentations given by experts from the different region of India. Hands on training on various instruments was provided to the participants and many other activities were covered during the training. The vital topics were covered in this training programme such as Drug testing laboratories in India, Indian Pharmacopoeia Reference Substance & effective use of Impurity standard, Application of LC-MS for drug testing by experts and eminent scientist from all over India.

  Dr. Shailendra Kumar, Director (Drugs) distributed certificates to all the participants and appreciated the overall conduction of the training programme.

- Indian Pharmacopoeia Commission has conducted the One day workshop on "Awareness programme of Indian Pharmacopoeia and IP Reference Substances" at PGIMER, Chandigarh on 17th March 2015 in collaboration with CDSCO, Sub-Zone, Chandigarh.
  The opening ceremony was inaugurated by Shri Navneet Marwah, State Drug Controller, Himachal Pradesh & Prof. A. K. Gupta, Medical Superintendent, PGIMER, Chandigarh. Total No. of 180 Participants from Pharma Industries and about 70 Government Official and Students of PGIMER from all over India attended this workshop. Topics that were covered during this workshop were Role of Indian Pharmacopeia, Maintenance of Primary Standard and Effective use of Working Standards etc from the experts. The programme also included panel discussion among IPC Scientists and participants. The panel discussion provided a good plateform to introduce the Industry with IPC.

  Certificate of Participation was distributed to all the participants and vote of thanks was given by Dr. Naresh Sharma, ADC, CDSCO, Chandigarh at the end of the programme.

- During the financial year 2014-15 Indian Pharmacopoeia Commission has conducted four training programme as mentioned above. In these training programmes, Total no. of 145 Government Analysts, Drug Inspectors and 180 stakeholders from different Laboratories

from the different part of India got useful knowledge. The list of upcoming training programmes is available on our website www.ipc.gov.in .

- In house training programme for the new required Pharmacopoeial Associate were also conducted.
- About 9 research scholar (M.Pharm, M.Sc. and Ph.D. Students) completed their research project from IPC.

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

The Annual Report covers the major activities under the PvPI during the index period. The NCC, established to steer and supervise the programme, and align it with the broader perspective of safer use of medicines in India, has been obliged to publish this report.

During the index period a total of 41,879 reports were received from different AMCs. These reports were reviewed for validity and causality and then, shared with the WHO global safety database, VigiBase. The most commonly reported drugs having ADRs were cisplatin, cyclophosphamide, paclitaxel, fluorouracil, doxorubicin, carboplatin, docetaxel, nevirapine, and ceftriaxone. The common system-organ involvement of ADRs were gastrointestinal, cutaneous, neurological, psychiatric and hematological in that order.

The reports of serious and unexpected were segregated for evaluation by the SRP. The SRP, through application of appropriate medical and scientific judgement, has been engaged in identifying potential signals from the ICSRs, and also in recommending for regulatory actions, if any. During this period, the SRP made three regulatory recommendations that might materially influence the benefit-risk assessment of a medicinal product or that would be sufficient to consider changes in medicinal product administration.

The pharmaceutical industry is recognized globally as a vital stakeholder in any pharmacovigilance programme. Therefore, under the PvPI, industries were welcomed to participate and start reporting ADRs. The response has been promising-a total 2222ICSRs received so far.

One major step by the NCC-PvPI has been introduction of the helpline (1800-180-3024) for facilitating direct reporting of suspected ADRs. Since its inception in October 2013, 3826 calls have been received through the helpline, mostly from Uttar Pradesh (19.31%), Madhya Pradesh (13.54%) and Maharashtra (10.47%). Interestingly, the queries received from the helpline are not limited to ADR reporting, but the facility sometimes has also been used for seeking and providing general drug information.

Until recently ADR reporting under the PvPI was limited to HCPs. One achievement during the index period has been the recognition of the role of consumers in reporting suspected ADRs. A milestone step in this respect was releasing the “Medicine Side Effect Reporting Form for Consumers/Patients” (available in seven vernaculars); thus consumers/patients can now directly report suspected ADRs. Consumers are also encouraged to use the helpline for ADR reporting.

As per recommendations of WHO, countries national pharmacovigilance system should collaborate with NHPs to monitor the safety of medicines used in their respective programmes.

Continuous awareness generation and capacity building of stakeholders in ADR monitoring are the key to success of any pharmacovigilance programme. To sensitize the HCPs in India in the area of pharmacovigilance, the NCC-PvPI organized many CMEs, workshops, conferences and training programme at the NCC, the regional centres and the AMCs. More than 3000 HCPs participated in 19 such programmes held during this period. Besides, a number thoughtfully designed poster for public awareness were published and distributed. Guidance documents for facilitating ADR reporting were published. The NCC regularly published periodic newsletters that contained reports on the progress of the PvPI, current issue related to drug safety and relevant contemporary news items.

Since the inception of the PvPI, the TAs has played an indispensible role. In order to appreciate their contribution in ADRs reporting and to motivate them, the NCC organized an award ceremony for TAs.

Through its diverse activities, the NCC-PvPI succeeded in drawing global attention, and international experts from Sweden, Netherlands, Russia and Switzerland visited the NCC during this period. The mutual sharing of knowledge and experiences with these experts, and coordination with different national and international organizations, immensely helped the NCC in further improving the activities under PvPI.

PUBLICATION DIVISION

The Publication Division of Indian Pharmacopoeia Commission (IPC) is performing the entire gamut of publication, documentation, sales & distributions of the Indian Pharmacopoeia (IP), National Formulary of India (NFI), Guidance Manual for Compliance of IP and other official publications in a dedicated and professional manner. The Publication Division in involved for publication of official documents of Indian Pharmacopoeia Commission (IPC) for improving quality of medicines by way of adding new and updating existing monograph in the form of Indian Pharmacopoeia (IP) and National Formulary of India (NFI) to promote rational use of generic medicines.

The official publications of Indian Pharmacopoeia Commission (IPC) are fairly available for sales & distributions through IPC Distribution Networks for the public with the objective of ensuring safety and efficacy through Quality Control Assurance of Pharmaceutical products marketed in India. The revenue generated by sales & distributions of IPC priced publications has been deposited to the consolidated fund of Government of India.

The Publication Division also functions regularly for publication of Pharmacovigilance Programme of India (PvPI) Newsletter on Quarterly basis relating to the direction, assessment, understanding and prevention of adverse effects or any other drug related problem. The Division has also published Guidance Document for Spontaneous Adverse Drug Reaction Reporting, PvPI Posters and Indian Pharmacopoeia Reference Substances (IPRS) – Booklets during the year.

IPC PUBLICATIONS DURING THE FINANCIAL YEAR 2014-15

The Publication Division involved in the official publications of Indian Pharmacopoeia Commission (IPC) during the Financial Year 2014-15 w.e.f. 01/04/2014 to 31/03/2015 are as given below:-

S/N	TITLE OF THE PUBLICATIONS (PUBLISHED DURING FY 2014-15)	QUANTITY
1.	Indian Pharmacopoeia 2014 Addendum 2015 (along with DVD)	3000
2.	Guidance Document for Spontaneous Adverse Drug Reaction Reporting	2000
3.	Indian Pharmacopoeia Reference Substances (IPRS) – Booklets	500
4.	PvPI Laminated Posters	10,000

5.	PvPI Newsletter Vol. 4, Issue 8, Year 2014	5000
6.	PvPI Newsletter Vol. 4, Issue 9, Year 2014	4000
7.	PvPI Newsletter Vol. 4, Issue 10, Year 2014	3000

Table 1: Official Publications of IPC published during Financial Year 2014-15

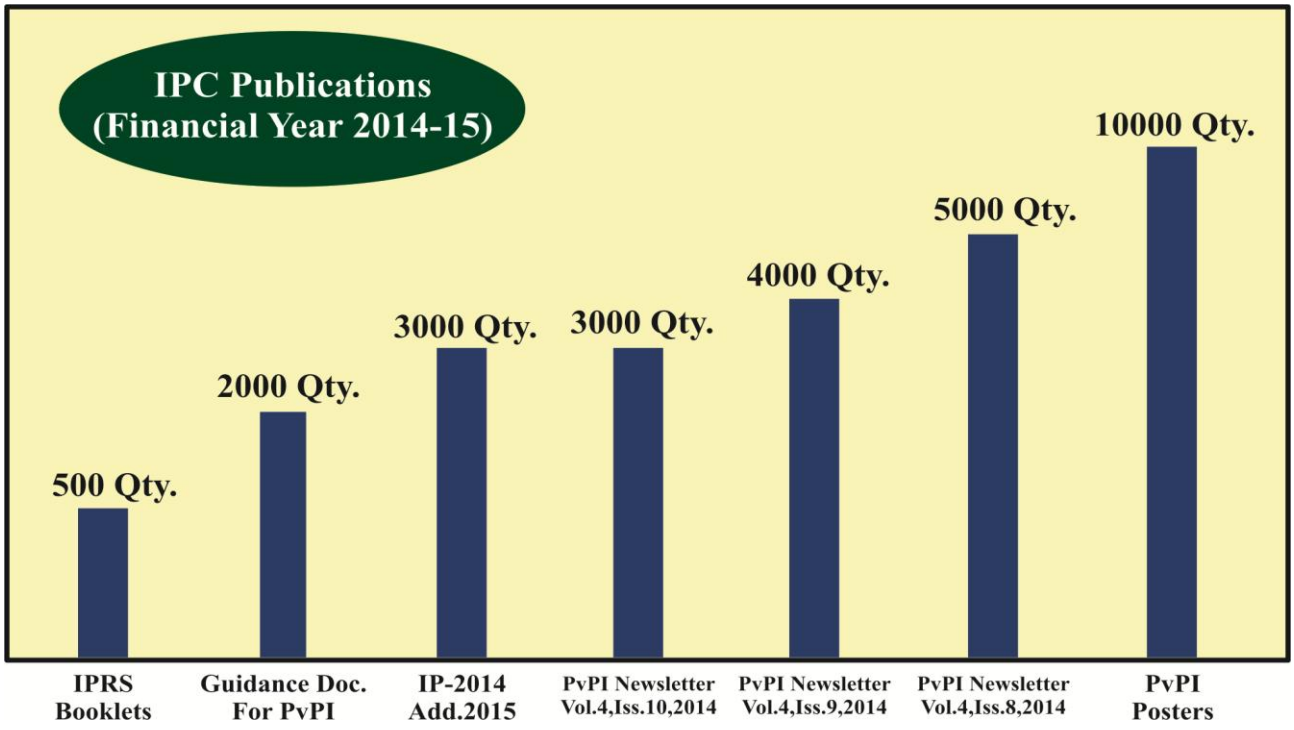


Fig. 1: Official Publications of IPC published during FY 2014-15

STATUS OF SALE & DISTRIBUTIONS OF IPC PUBLICATIONS

The sale & distributions of IPC Publications during the Financial Year 2014-15 w.e.f. 01/04/2014 to 31/03/2015 are as given below:-

S/N	Title of the Publications	Total Number of Copies/Set Printed	Opening Balance as on 01/04/2014	Current Status (As on 01/04/2014- to 31/03/2015)		Stock Balance on 31/03/2015	Revenue Generated (₹)
1.	Indian Pharmacopoeia -2010	3,000	15	Sold	1	04	**₹58,006/-** (£590)
				Complementary	2		
				Defective	08		
2.	DVD of IP- 2010	3,000	2634	Sold	0	2396	**NIL**
				Complementary	238		
3.	National Formulary of	30,000	16243	Sold	75	15212	**₹30,456/-**

	India (NFI)-2011			Complementary	956		
4.	Guidance Manual for Compliance of IP	1,000	602	Sold	01	277	**₹300/-**
				Complementary	324		
5.	Indian Pharmacopoeia-2014 (Along with DVD)	4,000	2580	Sold	862	1650	**₹1,77,09,253/-** (£700=INR 68821/-)
				Complementary	69		
6.	DVD of Indian Pharmacopoeia -14 (Alone)	500	464	Complementary	32	432	**NIL**
7.	Indian Pharmacopoeia -2014 Addendum 2015 (Along with DVD)	3,000	3000	Sold	886	2038	**₹35,80,000/-**
				Complementary	76		
Total Revenue Generated = ₹2,13,78,015/-							
In Words: Rupees Two Crore Thirteen Lacs Seventy Eight Thousand and Fifteen Only							

Table 2: Sale & Distributions of IPC Publications during Financial Year 2014-15

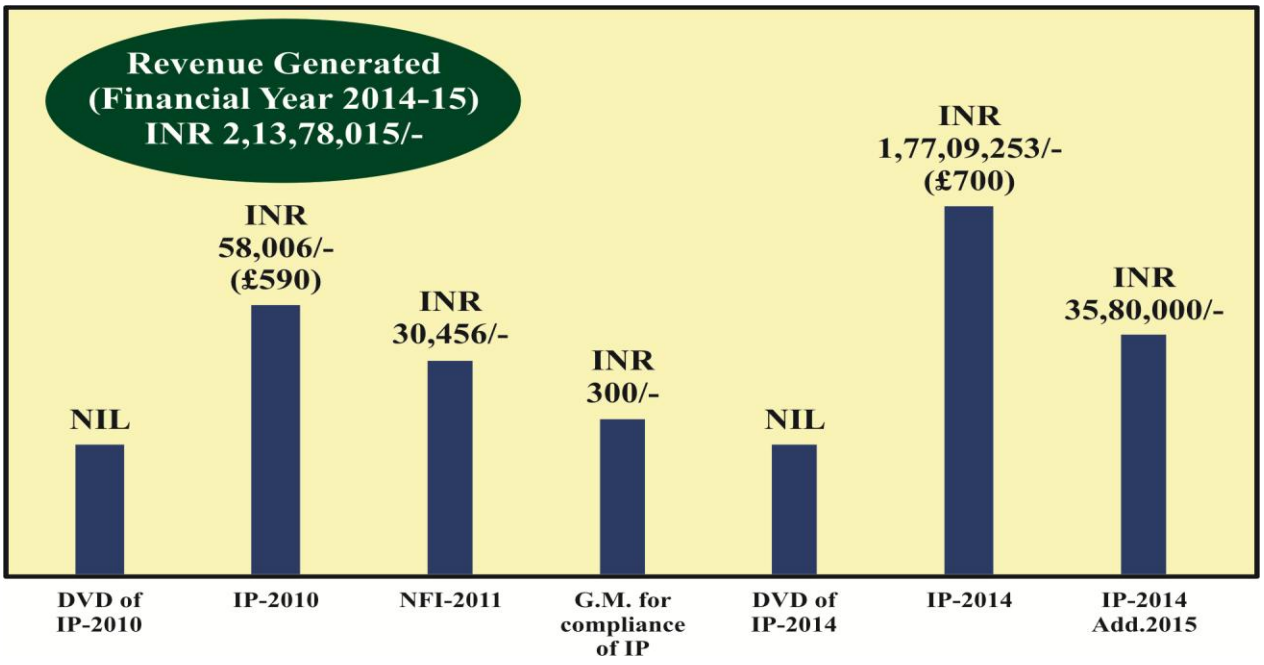


Fig.2: Sale & Distributions of IPC Publications during Financial Year 2014-15

EXPENDITURE

Publication Division had incurred an expenditure of **₹74,89,585/-** (Rupees Seventy Four Lacs Eighty Nine Thousand Five Hundred Eighty Five Only) during the Financial Year 2014-15 w.e.f. 01/04/2014 to 31/03/2015 towards IPC Publications.

LIBRARY AND INFORMATION CENTRE

The IPC Library and Information Centre is the leading Pharmacopoeial Library and Information Centre of the South-East Asia region. The Library & Information Centre aims to collect, preserve, disseminate democratization of information and knowledge to acquire new products and services. Its provides the information in all the fields of Drugs & Pharmaceuticals, Pharmacopoeial research and other related areas for support IPC to update regularly the standards of drugs commonly required for the treatment of diseases prevailing in this country. The IPC Library & Information Centre continuously increases its resources and activities for providing valuable Library & Information Services to support Scientific and Pharmacopoeial work and useful to the Scientists, Health care Professionals and researchers and so on preserve latest collection of documents and creativity for future generations.

Mission

The mission of Library & Information Centre is to provide comprehensive resources and services in support of the testing of Drugs & Pharmaceuticals, research & development and learning needs of the IPC Community. To fulfil this mission, the Library commits to:

- Build collections and create tools.
- Promote intellectual growth and creativity by developing collections, facilitating access to technical information resources and critical evaluation skills and offering research assistance;
- Provide access and promote the novelty and use of internal and external information resources;
- Ensure the preservation and long-lasting availability of Library collections and resources; and
- Create hospitable physical and virtual environment for study, training and research.

Collection Development

The entire Library & Information Centre has collection of more than 11,233 documents including books in all disciplines viz. pharmaceutical chemistry, drugs, pharmacology, pharmacognosy, microbiology, biotechnology, pharmacopoeias of different countries and administration along with its wide range of non-book materials including e-collection, e-journals, e-books, online database (MEDLAR), CD-ROM/DVD, photographs, etc. The library has also an excellent collection of Standards, Bound volume journals, Theses/Dissertations /Training and Project Reports, Periodicals, etc. to support Scientific, Pharmacopoeial and Administrative work.

The Library & Information Centre has subscribed 40 nos. of national and international scientific journals on different subjects to keep up-to-date knowledge. The Library & Information Centre has also installed Fine Docs Document Management Software to preserve Indian Pharmacopoeia with addendum since 1957, National Formulary of India (NFI) and Bound Volume of Journals.

Library & Information Centre

The Library & Information Centre provides following services in support of Scientific, Pharmacopoeial and Administrative work. Some of the major technical services are as follows:-

- Circulation Service
- Reference and Information Services
- CAS and SDI Service
- Indexing and Abstracting
- News Paper Clipping
- Electronic Information Resource Access
- CD-ROM Database search
- OPAC (Online Public Access Catalogue
- Reprographic Services
- Library Publication.

Library Publication

The IPC Library & Information Centre regularly publishes "Library Digitization (Yearly)", "Library Holdings (Quarterly)", "Library Catalogue (Quarterly)" and "Journal's Article Alert (Quarterly)". These publications help the scientific community to keep up to date knowledge of emerging issues in our core subject areas. The library publications are as under: -

- Library Digitization: A Cumulative Index to IP, NFI & Journals
- Library Holdings
- Library Catalogue: A Quarterly Publication
- Journal Article Alert: A Quarterly Publication
- Current Contents: A monthly Publication

Press Communiques

Library & Information Center also provides the press communiqués message via a print media channel between an organization and the Public domain for creating awareness among health professionals, patients and consumers by dissemination of IPC related various activities i.e. IPC Work profile, Compliance of Indian Pharmacopoeia by Stakeholders, PvPI awareness through newspapers across the Nation.

Training Programme

The Library & Information Centre provides the training programme to students, research scholars and officials from Institutes, Universities and Government Departments, taking into account their professional background and needs for meeting the challenges of current times. Students/research scholars have endure training from different departments/ institution namely Adhunik Institute of Education & Research, Meerut, Jamia Hamdard University, NKBR College of Pharmacy, KIET School of Pharmacy etc.

In addition during the year, 1748 nos. of visitors, officials from Government of India, Central Drugs Testing Laboratories (CDTL), State Drugs Testing Laboratories, NISCAIR, CSIR, DIPSAR etc. had visited the IPC Library.

Management of Official Website of IPC

The Library & Information Centre also manages the website content and working on up-gradation of IPC website with e-commerce facility and technology. It comprises of all the activities related to the IPC which ensure the operational integrity, high degree of consistency, uniformity, presentation and further promote excellence, pioneering application oriented research and development in Government of India Cyber Space.

Library Expenditure

The total expenditure of the IPC library was ₹1,00,87,698/- (Rupees One Crore Eighty Seven Thousand Six Hundred Ninety Eight Only) during the year.

STORE DIVISION

Introduction:

Store Division of IPC, is not meagre a store in itself rather may be defined as backbone of this commission. Growing year by year putting its all efforts towards achieving IPC Goals & Mission. At the same time assisting various divisions towards uprising the name of IPC not only at National but also at International platform.

This division is engaged in procuring a number of equipments, Instruments, materials and hiring services falling into different categories for facilitating various divisions at IPC. These activities are performed regularly by stores with the objective of fulfilling organisational needs.

The steps that constitutes the **procurement cycle** are as follows:

- Need Assessment
- Selection of Source as per requisite specification and GFR
- Processing Note sheet for approval
- Placing supply order& work order
- Follow up with the source
- Shipment tracking
- Receipt and inspection of material
- Stock inventory
- Issuance to the requisite division(s) against indent
- Bill Passing & Process for payment.

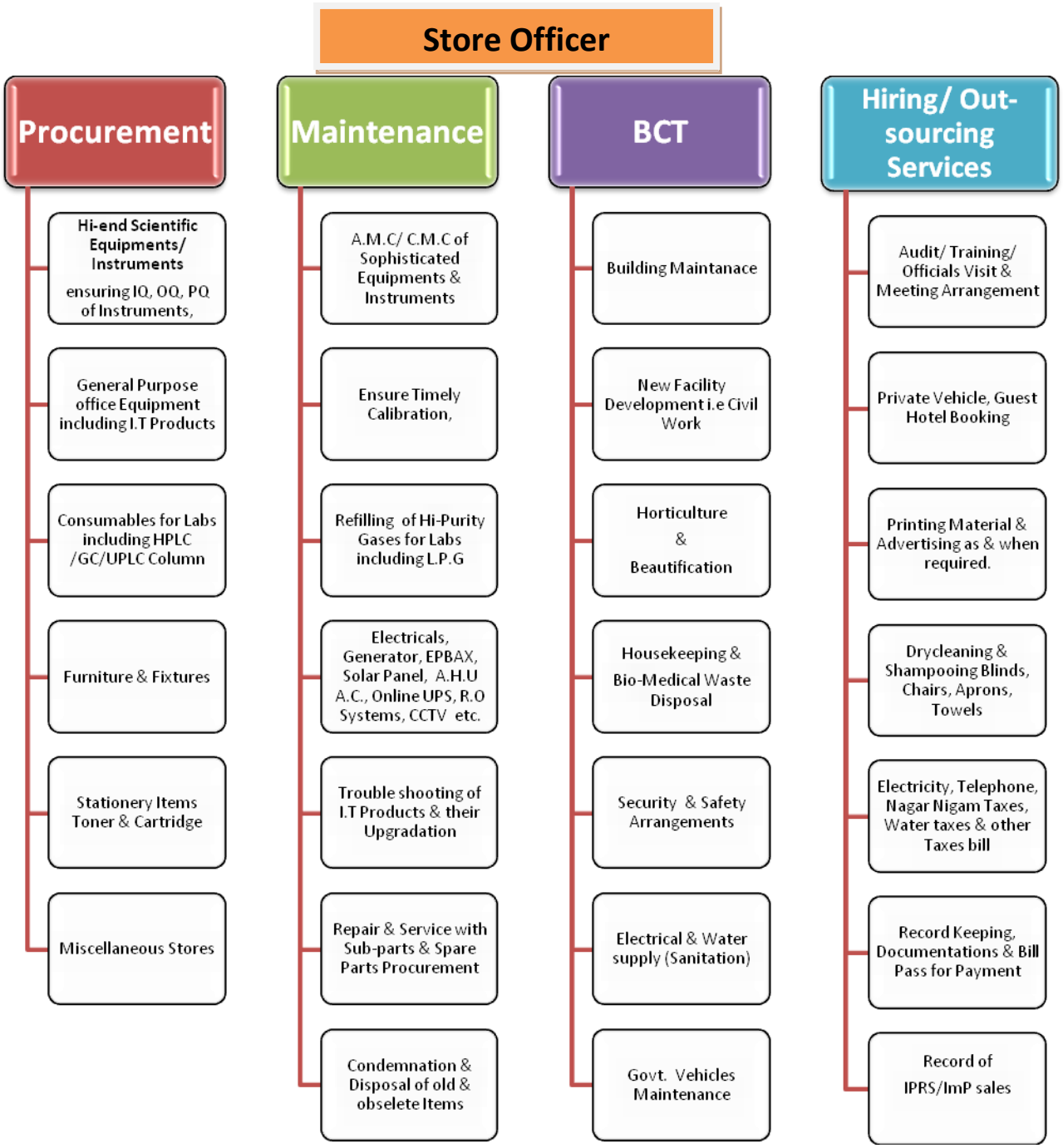
Mission Statement:

To strategically and ethically acquire quality goods and services at the best value for the requisite division at IPC through education, procurement expertise, in addition providing outstanding maintenance & general services.

Vision Statement:

To be recognized for our innovative approach to sourcing, development of strategic alliances and a progressive model of best practices.

Store Division Chart:



Classification of Stores:

All stores to be procured are broadly classified into three categories viz, Non- Consumable Stores (NCS), Limited Time Asset Stores (LTAS) and Consumable Stores (CS).

(I) Non-Consumable Stores (NCS): Stores satisfying any one of the following criteria classified as non-consumable stores:

a) Stores which are intended to be used over prolonged periods before becoming unusable, or obsolete.
b) Stores having a significant disposal value.
c) Stores which are sub-systems, or parts of equipment, which can be potentially repaired and reused, and sensitive.
d) Stores which are either fabricated, or assembled equipment, and which if bought as a single item would have been classified Non-Consumable Stores.

All non-consumable stores have been entered in the Non-consumable stock register.

(II) <u>Consumable Store (CS):</u> Stores satisfying any one of the following criteria classified as CS:

a) Stores which exhaust with lapse of time.
b) Stores which are rendered unusable due to normal wear and tear.
c) Stores which do not have significant disposal value, and
d) Spares of equipment which do not fall either in the NCS or LTAS category.
e) The CS shall be entered in the Consumable Stock register of the appropriate department.

If the spares are purchased for fabricating or manufacturing any equipment, such spares are generally treated as Non Consumable items. However, if a spare has been purchased to replace any spare of equipment, such spare is treated as Consumable Stores, provided such spare do not have any replacement value.

(III) <u>Miscellaneous Stores:</u> Stores satisfying any one of the following criteria classified as LTAS.

a) Stores which have significant value when purchased but rapidly lose their value/relevance with the lapse of time and have very little or negligible disposal value, and/or
b) Stores which can be upgraded either by replacing components/parts or which can be rendered obsolete by the release of new versions or editions.

All miscellaneous stores have been entered in the Miscellaneous stock register

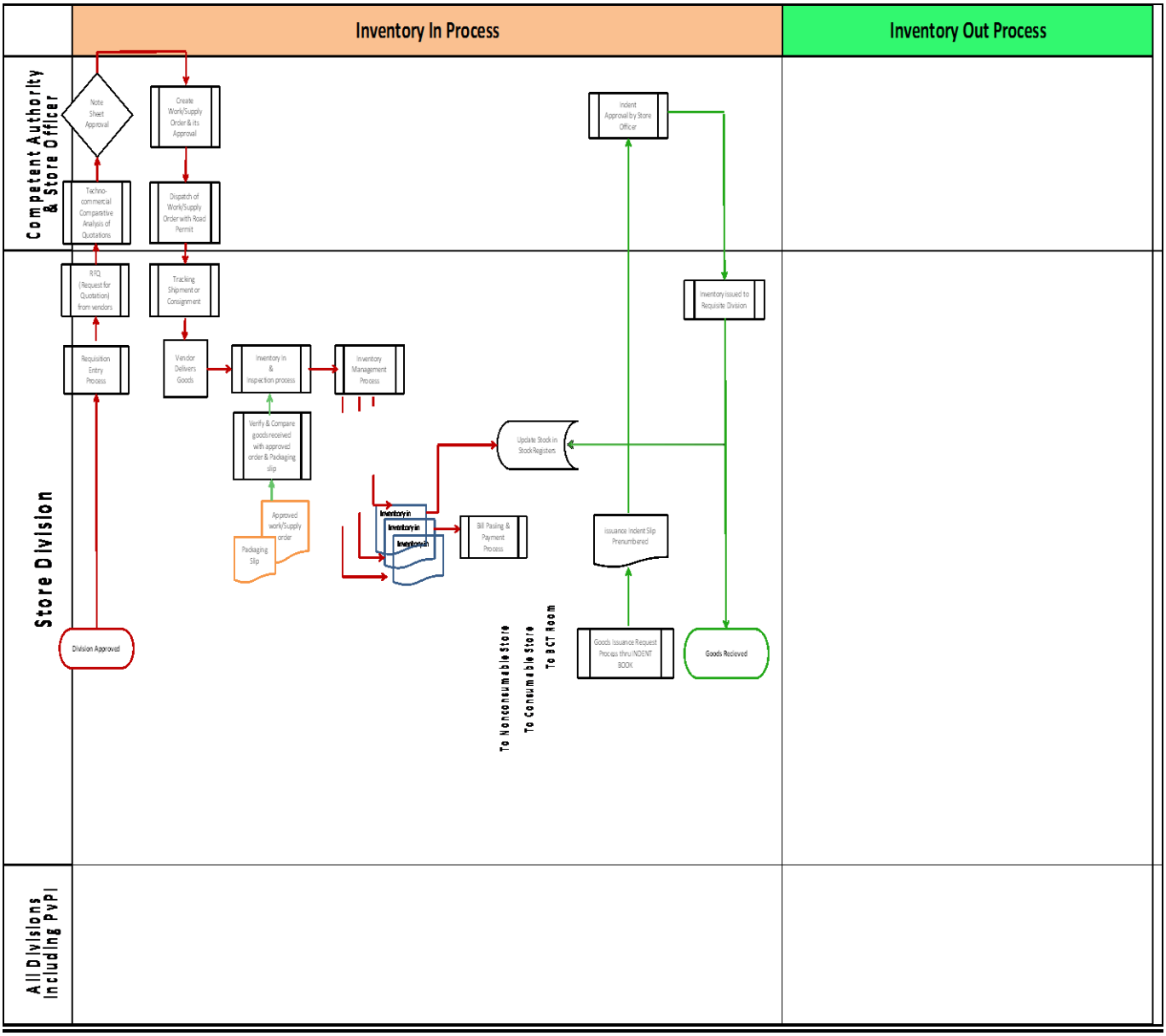
In case of a dispute regarding the classification of an item, the decision of Secretary-cum-Scientific Director of IPC considered to be final.

<u>Financial and Sanctioned Powers during F.Y. 2014-15:</u>

The following table gives the financial limits up to which the concerned person had approval authority for purchases within the allocated budget of the department/project. Such a person has been referred as the Competent Authority to ensure that sufficient funds are available for the purchase.

S.No	Competent Authority	Non-Consumable	Limited Time Asset Store (LTAS)	Consumable Store (CS)
1	**Pr. Scientific officer**	Below Rs. 20,000/-		
2	**Sec- Cum- Scientific Director**	Above Rs. 20,000/- or for all cases		

Inventory Flow Chart:



Procurement of High End Scientific Lab Instruments/ Equipments with:

- Ensuring IQ, OQ, PQ of Instruments.
- Ensure Timely Calibration.

- Their Sub-parts & Spare Parts Procurement.
- Upgradation of Equipments software's.

Procurement of General Purpose Office Equipments with:

Some key items are listed below-

- **BCT**- Generator, AMF Panel, Voltage Corrector, Solar System, E.T.P, A.H.U, UPS, Battery bank, Stabilizer, Automatic sliding door, EPBAX, CCTV, Fire Extinguisher, Gas Cylinder, Camera etc.
- **I.T Products-** Computer and its peripheral, Digital copier Multipurpose office machine, printer, UPS, Scanner, Fax machine etc. & their spare parts, Antivirus Software's
- **Amenities-** Air conditioner, Enclosed Type A/c, Lights, Fan, Dessert Cooler, R.O Systems, Refrigerator, Water- cooler, Vacuum Cleaner etc.

List of some Items procured during Financial Year 2014-15 are mentioned below:

Sr. No	Description		Issued to Division	Qty
1	Air Conditioner Enclosed Type		Biologics Section- 01 Nos. IPRS - 02 Nos.	3
2	Air Conditioner Enclosed Type		Wet Lab Chemistry	3
3	Access Control System	Access intelligent Control	BCT	4
		Smart Card Reader for door		16
		Access Control Integrated Software		1
4	Spiral Binding Machine		PA to Director	1
5	Laptop	Pavilion I5, Window 8, 4 GB RAM, 1 TB HDD, 2 GB Graphics, 15.6" Screen	Cash Section	1
6	Camera-(Bosch Digital)	Video Recorder MPEG	BCT	2
		Outdoor Camera-Optical & Digital Zoom		2
		1/3" CCD high Sensiti--vity Color Camera		6
		Autodome Controller with Yostic		1
		LG fixed Dome Camera with 3/6mm		20
7	Centrifugal Blower	Capacity 3.0 H.P	Phyto-pharmaceutical	1
		Capacity 1.0 H.P	Phyto-pharmaceutical	1
8	Conductivity Meter		Chemistry Division	1
9	All in one Desktop Computer- Lenovo Desktop **Intel Core I3,** Window 8 With TFT screen		Library Division - 03 Nos. AR&D Division - 05 Nos. Pharmacology - 03 Nos. Admin Division- 02 Nos. PvPI- 01 Nos. Store division- 01 Nos. Stock of Store- 01 Nos.	16
10	All in one Desktop Computer- Lenovo Desktop **Intel Core I5,** Window 8 With TFT Screen		Cash Section- 01 Nos. Library/Publication- 01 Nos. Store Division- 01 Nos.	3

11	Temperature Indicator		Microbiology Division	10
12	Digital Thermo Indicator		AR&D	8
13	Digital Temperature Indicator			12
14	Electrical Panel With Automation with Mcc for 5.5 Ton Condensing Unit with Installation		BCT	3
15	Wall/ Pedestal Fan, Make- Orient		Store division	10
16	Fume Hood System -5' Progressive Bypass		Phytopharmaceutical	1
17	Hi Air Flow Economical		Microbiology Division	1
18	Laser Printer- Samsung		AR&D Division - 02 Nos.	9
			Pharmacology - 02 Nos.	
			Admin Division- 02 Nos.	
			Stock of Store - 03 Nos.	
19	Automatic Phase Corrector Panel (3 Phase)		BCT	4
			BCT	1
20	Pass Box	Dynamic	IPRS Section	1
		Static	IPRS Section	1
21	Air Shower with Pre-filter & HEPA Filter Suitable for entry of 2 Person		Cold Room- IPRS Section	1
22	SMS Module		Chemistry Division	1
23	TDS Meter & Timer with Calibration		P.A Director- 1 Nos.	2
			Microbiology- 1 Nos.	
24	**UPS System**	10 KVA online	PvPI Conference & PvPI Section	2
		0.8 KVA Line interactive	Library Division - 03 Nos.	15
			AR&D Division - 05 Nos.	
			Pharmacology - 03 Nos.	
			Cash Section- 01 Nos.	
			Admin Division- 02 Nos.	
			Store division- 01 Nos.	
25	Voltage Corrector- Servomotor Operated Capacity. 3 x 350 KVA Rating 120 to 280 Volts		BCT	1

Procurement of Computer & its Peripheral for AMC Centre's across India thru DGS&D Rate Contracts:

During Financial year 2014-15, these were the logistic supports to enhance ADR Reporting from AMCs across India to PvPI as well as strengthen PvPI section at IPC.

	Sr. No.	Description	Qty. in Nos.	Issued to
Phase 1	**1**	Lenovo Desktop Computer Intel Core I3 with 18.5" TFT Monitor	15	PvPI Division
	2	Laser Printer Samsung Model - ML-2161	15	
	3	UPS Paradyne- 800	15	

Phase 2	**1**	Lenovo Desktop Computer Intel Core I3 with 18.5" TFT Monitor	17	PvPI Division
	2	Laser Printer Samsung Model- ML-2161	7	
	3	UPS Paradyne- 800 0.8 KVA	7	

In 1st Phase- Twelve Sets of mentioned items were dispatched to different PvPI centers across India whereas three sets were installed at Indian Pharmacopoeia Commission, Ghaziabad.

In 2nd Phase- Seven Sets of mentioned items were dispatched to different PvPI centres across India whereas ten Desktop Computer were installed at Indian Pharmacopoeia Commission, Ghaziabad.

Procurement of Furniture includes:

- A.H.U Shed, Compactors, Compact Workspace with Pedestal & Keyboard unit
- Diff. Types of Tables & Chairs: for Officer's, Computers, Assistants, Conference, Anti-vibration Tables etc.
- Almirah/Cabinet of different sizes, selves, materials etc.
- Wall Panelling, Showcase Panelling, False Ceiling, Display Boards etc.

List as follows for F.Y 2014-15:

S.No	Description		Issued to/ Fitted into Division	Qty
1	Lab Furniture H900 mm "C" frame (Wall Table with CPU Trolley & under Cabinet) with trunkings		Wet Lab, Chemistry & Biologics	N/A
2	Chemical Storage Cabinet	Without Ventilation	Wet Lab in Chemistry	5
		With Ventilation	Pharmaceuticals & Lab	9
	Apparatus Storage base Cabinet		For Wet Lab & Pharmaceuticals	10
3	Dynamic Garment Cubical		AR&D	5
4	S.S.Working Table Plain		Chemistry	5
5	S.S.Working Stool plain		Chemistry	5

6	S.S. Shoe Rack Both Side Customised		Chemistry	1.25 RMI
7	**Modular Furniture**	**Modular Partition System** of Min. 50-70 mm MS frame Powder Coated both Side Prelaminated Particle Boards on Minimum 10 mm thickness	Administration	242 Sq. Ft
		Modular Workstation/ Work surface of at least 22 mm Prefabricated & Prelaminated Particle Board with sliding Keyboard tray, CPU Trolley etc. Complete with Lock , handles, Drawer unit, Vertical Support	Administration	162.50 Sq. Ft.
		Modular Storage System of Prelaminated board with Shelves, Lock & Handles Depth- 12"	Administration	66.80 Sq. Ft
8	**Modular Furniture**	**Modular Storage System** made of 18mm Pre-laminated Particle	(P.A.Director)	37 Sq. Ft.
		Modular Working Table	(P.A.Director)	30 Sq. Ft.
		Modular Partition System of Min. 70 mm MS frame Powder Coated both Side Prelaminated Particle Boards on Minimum 10 mm thickness	(P.A.Director)	61 Sq. Ft.
		Modular Storage System of Prelaminated board with Shelves, Lock & Handles Depth- 12"	(P.A.Director)	31 Sq. Ft.
9	**Compactor**	Compactor Storage System (SFFD)	(Administration)	1
		Compactor Storage System (SFMD)	(Administration)	1
		Shelf & Accessories	(Administration)	06 Sq. Ft.
10	**Chairs**	**Officer** Revolving Chair	Requisite division	1
		Visitor Chair Revolving		25

Procurement of Consumables for Labs:

- **Chemicals & Reagents**
- **Glassware's** – Burettes, Beakers, Reagents bottles, Filtration Assembly, Volumetric flask, Funnels, Pipettes, Test Tubes, Adapters, Crucibles, Desiccators, Dishes & Cylinders
- **Plasticwares**– Glass fiber filters, Syringe filter, Membrane Filter, Filter holder, Centrifuge tubes
  PTFE ware etc
- **Various Gases, Columns for HPLC & GC**,
- Reference Standard for drugs testing purpose.
- **Miscellaneous Items**- Labs Coats, disposable(Gloves, face mask, head cap, Shoe cover), Filter papers, Syringes, Packaging items

Consumption Report of Chemicals & Reagent for financial Year 2014-15:

Sr. No.	Particulars	Pack Size	Total Pack	Chemistry	RSD	Biologics	AR&D	Micro	Phtyo	P. Cology
1	**Acetonitrile HPLC**	2.5 Ltr	**302**	266	8	4	20			4
2	**Acetic Acid Glacial**	500 ML	**8**	8						
3	**Acetone AR 2.5. Ltr.**		**1**				1			
4	**Ammonia Solution 25% GR**	500 ML	**5**	4			1			
5	**Buffer Solution PH 4.00**	100 ML	**5**				5			
6	**Buffer Solution PH 9.18**	100 ML	**5**				5			
7	**Dichloromethene AR**	2.5 Ltr	**1**				1			
8	**ESI-L-Low coneentration**	100 ML	**3**	3						
9	**Ethanol HPLC**	500 ML	**58**	32				2		24
10	**Formamide LR**	500 ML	**2**				2			
11	**Hydrochloric Acid**	500 ML	**7**	4	2		1			
12	**Hydrogen Peroxide 30 %**		**1**	1						
13	**Methanol HPLC**	2.5 Ltr	**350**	308	6	4	20			12
14	**Acetonitrile AR**	2.5 Ltr	**25**	25						
15	**Dichloromethene AR**	500 ML	**10**	10						
16	**Methy Red Indicator**	25 Gm	**8**	8						
17	**Formic Acid**	250 ML	**6**	6						
18	**N Hexane HPLC**	1 Ltr	**5**	5						
19	**Iso Propyl Alcohol HPLC**	1 Ltr	**5**	5						
20	**Sodium hydroxide pellets**	500 GM	**11**	11						
21	**Water for HPLC**	1 Ltr	**10**	10						

List of Glassware procured in F.Y 2014-15:

Sr. No.	Particulars	Pack Size	Total Pack	Chemistry	Biologics	Phtyo	P. Cology

1	**Beaker**	250 ML	**15**		5	10	
2	**Beaker**	500 ML	**5**		5		
3	**Vials 20 MM**	5 ML	**20210**	20210			
4	**Vials 13 MM**	2ML	**6936**	6936			
5	**Reagent Bottle**	25 ML	**10**				10
6	**Reagent Bottle**	50 ML	**10**				10
7	**Reagent Bottle**	100 ML	**10**				10
8	**Reagent Bottle**	250 ML	**10**				10
9	**Reagent Bottle**	500 ML	**10**				10
10	**Reagent Bottle**	1000 ML	**10**				10
11	**Reagent Bottle**	2000 ML	**10**				10
12	**Test Tube**	20 ML	**30**	30			
13	**Tubes Centrifuge**	15 ML	**30**	30			
14	**Tubes Centrifuge**	50 ML	**20**	20			
15	**Beaker**	5 ML	**20**	20			
16	**Beaker**	10 ML	**20**	20			
17	**Cylinder**	20 ML	**10**	10			

List of Plasticware procured in F.Y 2014-15:

S. No.	Particulars	Pack Size	Total	Chemistry	Micro	Phtyo	Biologics
1	**Bluescrew Caps with septa**	100	**35**	20		10	5
2	**Screw Cap Vialsclear**	100	**15**	10			5
3	**Vials with Cap and Septa**		**300**	300			
4	**Vials with Cap and Septa**		**700**	700			
5	**Screw Top Amber Vials**	100	**10**	10			
6	**Disposable Syringe**	2 ML	**500**	500			
7	**Disposable Syringe**	5 ML	**500**	500			
8	**Disposable Syringe**	10 ML	**500**	500			
9	**Plastic Dropper**	3 ML	**500**	500			
10	**Catoted Magnet ,Cyl Shape 9 X20 MM**		**12**	12			
11	**Catoted Magnet ,Egg Shape 6 X15MM**		**12**	12			
12	**Memberance Filter 0.22 um X 47 mm**		**5**	5			
13	**Memberance Filter 0.45 um X 47 mm**		**5**	5			
14	**Membrane Filter 0.45 um X47 mm**		**10**	10			
15	**Membrane Filter Funnel**	300 ML	**5**		5		
16	**Membrane Filter Funnel PC/PP**	300 ML	**5**		5		
17	**Micro Tips 1000- 5000**	100	**5**		5		

18	**Ultra Clean 18 mm Screw Cap W/Scpta**	100	**5**	5			
19	**Rubber Stopper 13 mm**		**5000**	5000			
20	**Rubber Stopper 20 mm**		**20000**	20000			

List of Column's procured during F.Y 2014-15:

HPLC and GC are separation techniques which have gained a strong foothold in chemical laboratories uses column of various shapes, size & specifications. The basic purpose of both techniques is to separate and quantify the components of organic mixtures. List for columns procured is as follows:

Sr. No.	Particulars	Specification	Make	Cat. No.	Requisite Division	Qty.
1	HP-1 GC Column	methyl siloxane Length 30 m, Dia- 320 µm, Film thickness- 1 µm	Agilent	19091Z-213	AR&D	1
2	HP-50 50% Phenyl methylsiloxane	Length- 30 m, Dia- 530 µm, Film thickness- 1 µm	Agilent	19095L-023	AR&D	1
3	HP- 5 GC Column	30 m x 0.32 mm x 0.25 µm	Agilent	19091J-413	AR&D	1
4	DB-1701, GC Column	Length- 30 m, Dia- 320 µm, Film thickness- 1 µm	Agilent (J&W)	123-0733	AR&D	1
5	DB- FFAP GC Column	Length- 30 m, Dia- 320 µm, Film thickness- 1 µm	Agilent (J&W)	123-3234	AR&D	1
6	DB- Waxeta, GC Column	Length- 30 m, Dia- 320 µm, Film thickness- 1 µm	Agilent (J&W)	123-7334	AR&D	1
7	DB-5 MS UI GC Column	60 m x 0.32 mm x 1.0 µm	Agilent (J&W)	123-5563UI	AR&D	1
8	DB- 1301 GC Column	30 m x 0.53 mm x 1.0 µm	Agilent (J&W)	125-1332	AR&D	1
9	DB-624 GC Column	30 m x 0.32 mm x 1.40 µm	Agilent (J&W)	124-1334	AR&D	1
10	Agilent Eclipse Plus C-18	150 x 4.6 mm x 5 µm	Agilent Technologies	959993-902	Chemistry	2
11	Agilent Eclipse Plus C-18	250 x 4.6 mm x 5µm	Agilent Technologies	959990-902	Chemistry	2
12	Chiral Pack IA	150 x 4.6 mm x 5 µm	Daicel	80324	Chemistry (PLS)	1
13	Chiral Pack ADH	250 x 4.6 mm x 5 µm	Daicel	19325	Chemistry (PLS)	1
14	Chiral Pack ODH	250 x 4.6 mm x 5 µm	Daicel	14325	Chemistry (PLS)	1
15	Chiral Pack AGP	150 x 4.0 mm x 4 µm	Daicel	30714	Chemistry (PLS)	1
16	Inersil ODS 3V	250 x 4.6 mm x 5µm	GL Sciences Inc.	5020-01802	Chemistry	8
17	Purospher ® Star-RP- 18e	250 x 4.6 mm x 5µm	Merck Millipore	1.51456.0008	Chemistry	4

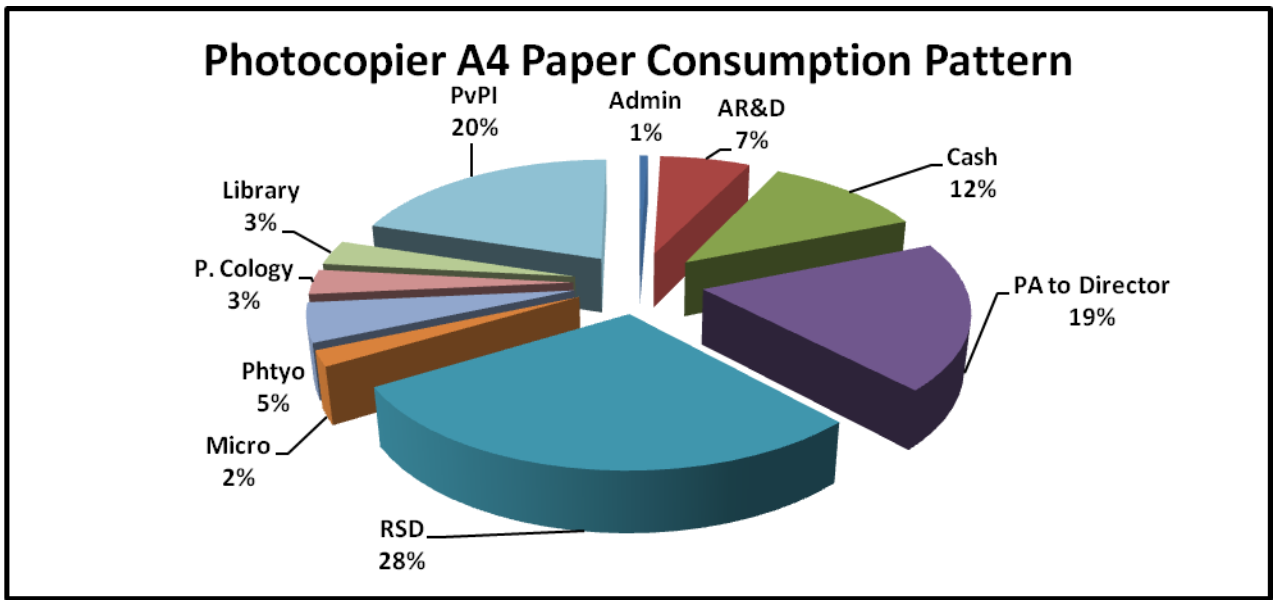
18	Oyester ODS- 3	150 x 4.6 mm x 3.0 µm	Merck Millipore	5.06244.0001	Chemistry	2
19	HPLC Column C-08	50 x 4.6 mm x 3.5 µm	Necleodur (Orbit)	MZ0912-50046	Chemistry	1
20	HPLC Column C-18	125 x 4.6 mm x 5 µm	Nucleodur	760001.46	Pharmacognosy - 02	2
21	HPLC Column C-18	125 x 4.0 mm x 5 µm	Nucleodur	760001.40	AR&D - 01	1
22	HPLC Column C-18	250 x 4.6 mm x 5 µm	Nucleodur	760002.46	Pharmacognosy - 02 AR&D - 01	3
23	HPLC Column C-18	150 x 4.6 mm x 5 µm	Nucleodur	760008.46	AR&D - 01	1
24	HPLC Column C-18	150 x 4.0 mm x 5 µm	Nucleodur	760008.40	AR&D - 01	1
25	HPLC Column C-08	250 x 4.6 mm x 5 µm	Nucleodur	760703.46	Pharmacognosy - 03	3
26	HPLC Column C-08	150 x 4.6 mm x 5 µm	Nucleodur	760702.46	Pharmacognosy - 02 AR&D - 01	3
27	HPLC Column C-18	50 x 4.6 mm x 5 µm	Nucleodur	760004.46	Chemistry	1
28	HPLC Column C-08	250 x 4.6 mm x 5 µm	Nucleodur	760703.46	Chemistry	10
29	HPLC Column C-08	150 x 4.6 mm x 5 µm	Nucleodur	760702.46	Chemistry	10
30	HPLC Column C-18	250 x 4.6 mm x 5 µm	Nucleodur	760002.46	Chemistry	20
31	HPLC Column C-18	150 x 4.6 mm x 5 µm	Nucleodur	760008.46	Chemistry	20
32	GC Column OPTIMA-1	30 x 0.32 mm x 0.25 µm	Nucleodur	726302.30	Chemistry	2
33	GC Column OPTIMA WAX	30 x 0.25 mm x 0.25 µm	Nucleodur	726600.30	Chemistry	2
34	GC Column OPTIMA-624	30 x 0.32 mm x 1.8 µm	Nucleodur	726787.30	Chemistry	2
35	GC Column OPTIMA-624	30 x 0.53 mm x 3 µm	Nucleodur	726789.30	Chemistry	2
36	HPLC Column C-18	150 x 4.6 mm x 3.5 µm	Nucleodur (Orbit)	MZ0902-150046	Pharmacognosy - 06	6
37	HPLC Column C-18	50 x 4.6 mm x 3.5 µm	Nucleodur (Orbit)	MZ0902-50046	Chemistry	1
38	HPLC Column C-18	150 x 3.0 mm x 3.5 µm	Nucleodur (Orbit)	MZ0902-150030	Chemistry	5
39	HPLC Column C-18	150 x 4.6 mm x 3 µm (Phenyl)	Nucleodur (Perfectsil)	MZ1447-150046	AR&D - 01	1
40	HPLC Column C-18	125 x 4.0 mm x 5 µm	Waters		AR&D - 01	1
41	HPLC Column C-18	250 x 4.6 mm x 5 µm	Waters	186002560	AR&D - 01	1
42	HPLC Column C-18	150 x 4.6 mm x 5 µm	Waters	186002559	AR&D - 01	1

43	HPLC Column C-18	150 x 3.9 mm x 5 µm	Waters		AR&D - 01	2
44	HPLC Column C-18	150 x 4.0 mm x 5 µm	Waters		AR&D - 01	1
45	HPLC Column C-18	150 x 4.6 mm x 3 µm (Phenyl)	Waters		AR&D - 01	1
46	HPLC Column C-18	50 x 2.1 mm x 1.7 µm	Waters		AR&D - 01	1
47	HPLC Column C-08	150 x 4.6 mm x 5 µm	Waters	186002737	AR&D - 01	1
48	X Terra Ms Waters C-18	100 x 4.6 mm x 3.5 µm	Waters	186000436	Chemistry	1
49	X Terra Ms Waters C-18	150 x 4.6 mm x 3.5 µm	Waters	186000440	Chemistry	2
50	Symmetry C-18	150 x 4.6 mm x 3.5 µm	Waters	WAT200632	Chemistry	1
51	HPLC Column C-4	150 x 4.6 mm x 3 µm	YMC	BS12S03-1546WT	Chemistry	1

Procurement of Stationery Items:

List of some stationery Items procured for financial Year 2014-15:

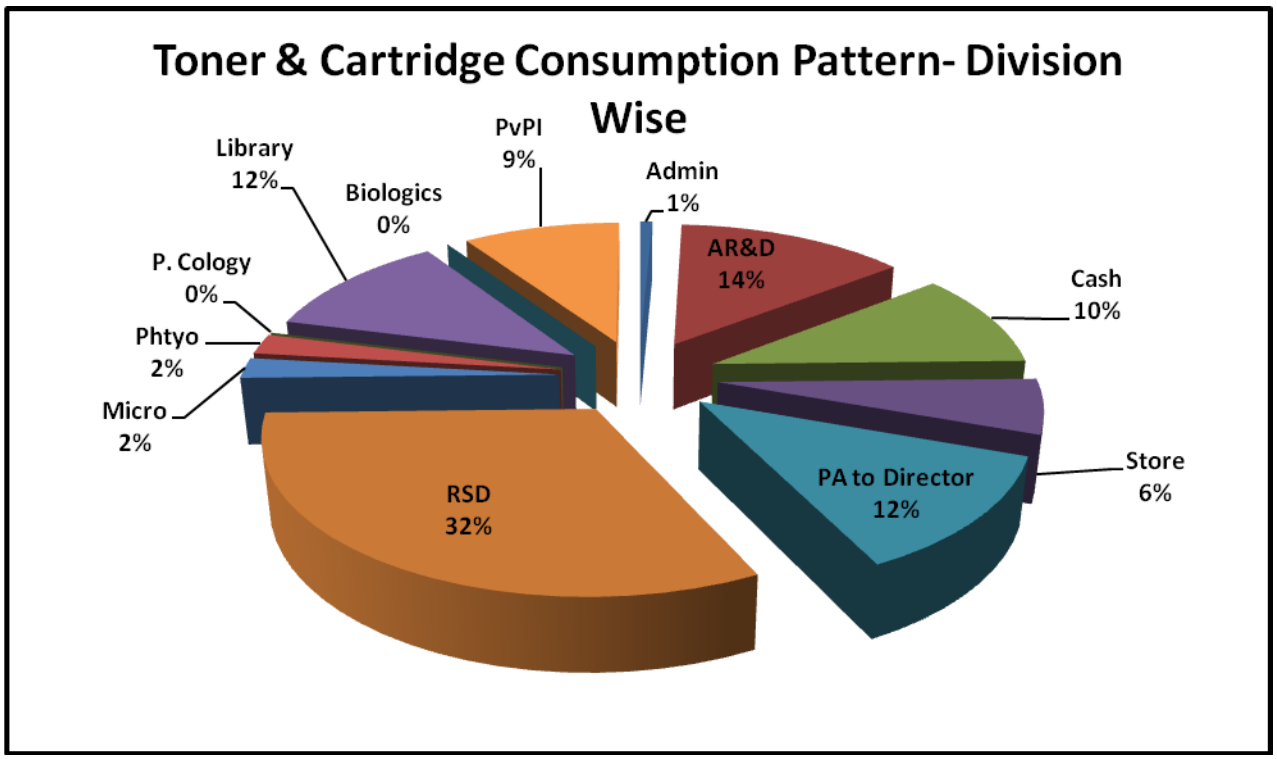
S. No.	Particulars	Total	Admin	AR&D	Cash Section	Stores	PA to Director	RSD	Micro	Phtyo	P. Cology	Library	Biologics	PvPI
1	Photocopier Paper A4 75 GSM	**530**	3	33	58	32	95	142	10	25	16	16		100
2	Ring Binder RB 402	**408**			16			300	20	50	22			
3	Box File	**250**			20		12	120	10	30	10			48
4	Conference pad	**792**				12	250	30			90			410
5	Plastic Folder Button Type	**480**					120			40	30			290
6	Ball Pen Use & Thru	**1256**		30	8	18	155	110		60	175	10	30	660
7	L-Shape Folder	**330**	50		20	20		50	40	10	85			55



Procurement of Toner & Cartridges during F.Y 2014-15:

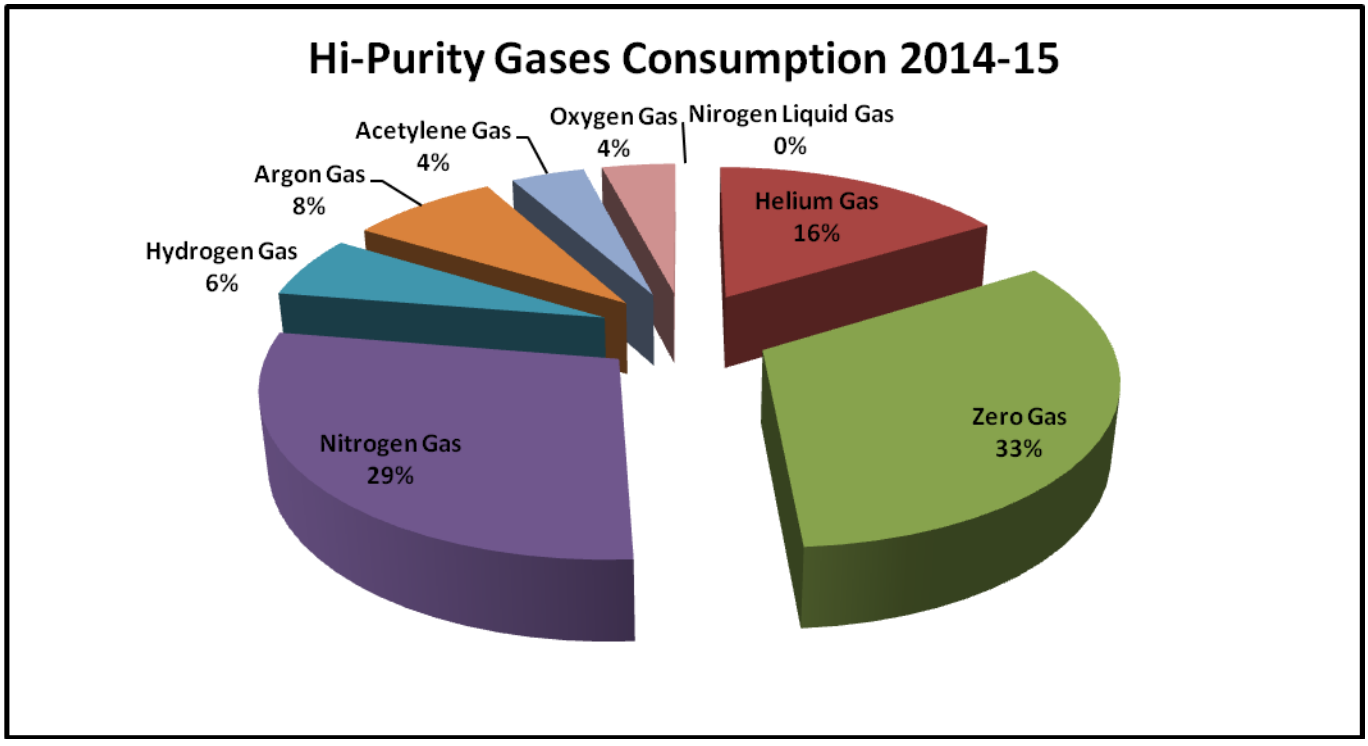
S. No.	Particulars	Toner/ Cartridge No.	Total	Admin	AR&D	Cash	Store	PA to Director	RSD	Microbiology	Phyto	P. Cology	Library	Biologics	PvPI
1	**HP Toners & Cartridges**	Q2612A	**19**		7			8					4		
2		CB436A	**3**	1					1	1					
3		CC388A	**10**			8			2						
4		Q6511A	**4**		4										
5		CC530A BK	**2**										2		
6		CC531A Cy	**2**										2		
7		CC532A Mg	**2**										2		
8		CC533A Yl	**2**										2		
9		704 Bl	**13**		1				12						
10		704 Col	**3**		1				2						
11		862 Bl	**2**				2								
12		CE250A	**1**						1						
13	**Canon Toner**	LBP 2900	**1**								1				
14	**Samsung Toner**	SCX-4521	**4**				2	2							
15		K409S Bl	**1**										1		
16		K409S Mg	**1**										1		
17		K409S Yl	**1**										1		
18		K409S Cy	**1**										1		
19		ML-D3470A	**6**						4		2				

20		MLT-D1043S	**30**			6		7	11	1					5
21		MLT-D101S	**5**												5
22		K508S Bl	**2**						2						
23		K508S Mg	**2**						2						
24		K508S Yl	**2**						2						
25		K508S Cy	**2**						2						
26	**Konica Minolta**	1690MF Black	**1**		1										
27		1690 MF Yellow	**1**		1										
28		1690MF Cyan	**1**		1										
29		1690 MF Magenta	**1**		1										
30	**Toshiba Toners**	2820C Bl	**1**				1								
31		2820 Cy	**1**				1								
32		2820 Mg	**1**				1								
33		2820Yl	**1**				1								
34		200 Bl	**1**		1										
35		T-4530D	**3**						3						
36		18	**1**							1					
37		256 SE	**4**		1										3
Grand Total			**138**	**1**	**19**	**14**	**8**	**17**	**44**	**3**	**3**	**0**	**16**	**0**	**13**

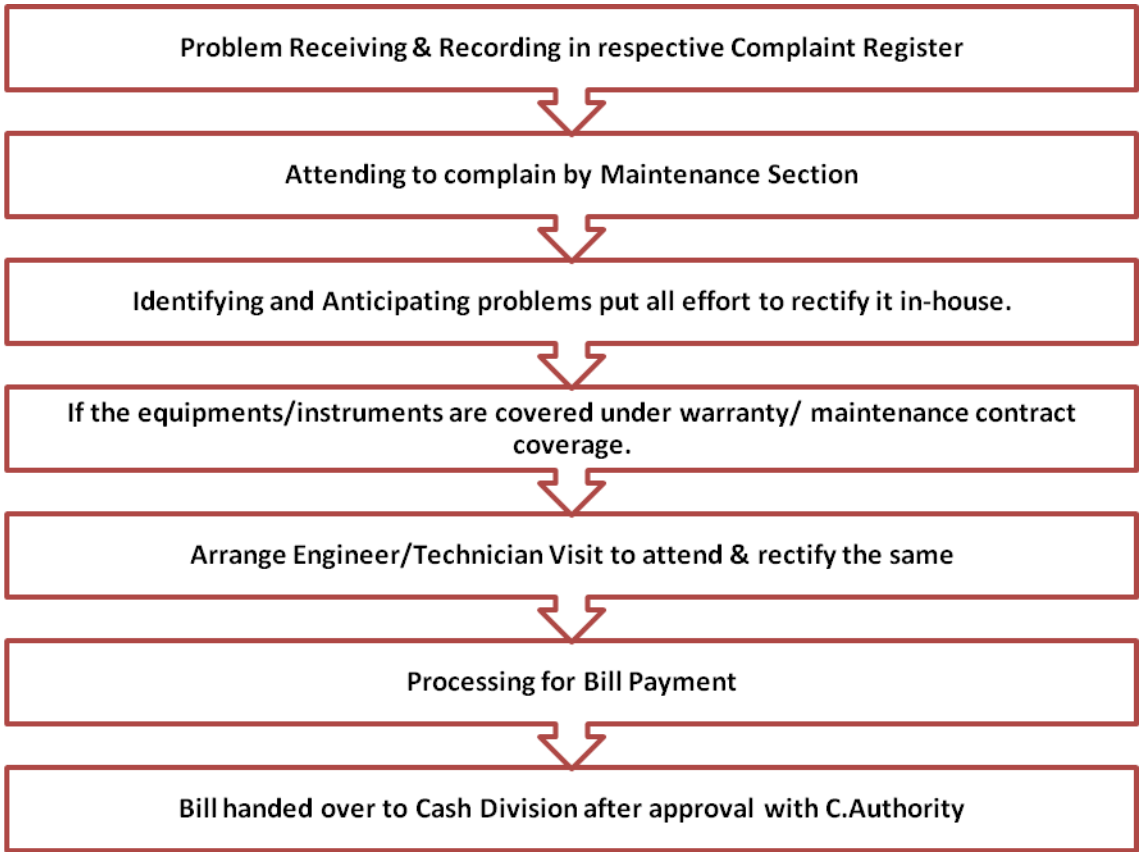


Consumption of some Hi-purity Gases during F.Y 2014-15:

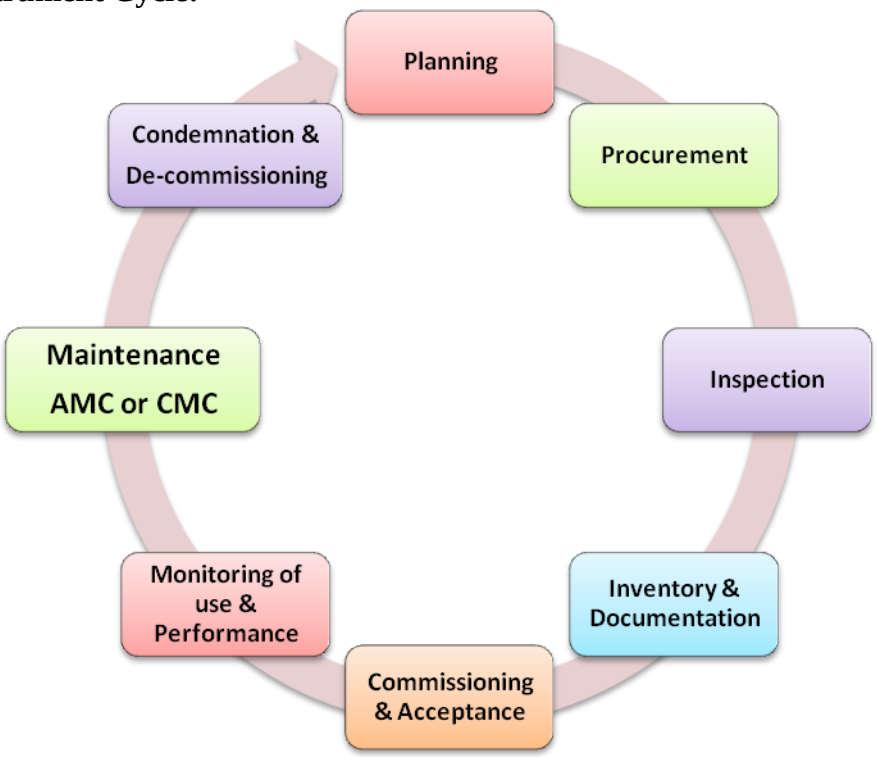
S. No.	Particulars of Gas	No. of Refilling Cylinder	April-14	May-14	June-14	July-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jen-15	Feb-15	Mar-15
1	Helium Gas	8	-	-	-	3	3	-	-	-	-	-	2	-
2	Zero Gas	16	-	-	-	2	2	2		2	5	-	3	-
3	Nitrogen Gas	14	-	-	-	3	2	1		4	3	-	1	-
4	Hydrogen Gas	3	-	-	-	1	-	-	-	1	-	-	1	-
5	Argon Gas	4	-	-	-	1	3	-	-	-	-	-		-
6	Acetylene Gas	2	-	-	-	-	1	-	-	-	-	-	1	-
7	Oxygen Gas	2	-	-	-	-	-	-	-	-	-	-		2



Maintenance Cycle:



Equipment/Instrument Cycle:



AMC/CMC of Lab Equipments & Instruments:

Purpose of AMC/CMC is to maintain the equipments/ Instruments to the appropriate standards as prescribed by equipment manufacturer by prompt service & refurbish them with genuine spares, so as to ensure that IPC equipments/ Instruments to be used with maximum output i.e.

a) Maximum availability and reliability of equipments
b) Minimum downtime and Maximum Uptime
c) Reduce frequency of breakdown
d) Prevention of wastage of consumables and spares
e) Life Expectancy increases
f) Readiness of the equipment for emergency use whenever required

S.No.	Name of Equipment/ Instruments	Qty.	Division
01.	EPABX System	01	BCT
02.	Telephone Cabling & Digital Handset	-	
03.	Bio- Metric Attendance Machine	01	Administration
04.	RO Systems	06	BCT
05.	Toshiba E-Studio 2820C	01	Store
06	Toshiba E- Studio 207	01	F&A.O.
07.	Toshiba E- Studio 200	01	AR&D
08.	Toshiba E- Studio 256	01	AR&D
09.	Toshiba E- Studio 256	01	PvPI
10.	Toshiba E- Studio 18	01	Microbiology
11.	Toshiba E- Studio 167	01	Pharmacology
12.	Toshiba E- Studio 305	01	Chemistry
13.	FTIR Spectrum One	01	Chemistry
14.	U.V. Spectrophotometer, Lambda- 25	01	Microbiology
15.	Spectrophoto Florimeter- LS 50B	01	R&D
16.	Walk-in-Cooling Cabinet (36600 Ltr.)	01	RSD
17.	Library Software	01	Library
18.	HPLC- 1100 Series	01	Pharmacognosy
19.	Gas Chromatography, GC-6890	01	AR&D
20.	HPLC 1260 (All Detector)	02	Chemistry
21.	Dionex Fast HPLC	02	Chemistry
22.	Dionex Fast HPLC	01	AR&D

23.	GC Head Space with FID (GC-MS)	01	Chemistry
24.	GCMS-MS (GC-QQQ)	01	Chemistry
25.	LCMS-MS	01	Chemistry
26.	Dionex HPLC (UV Detector)	02	Chemistry
27.	KF Titrator	02	Chemistry
28.	Analytical Micro Balance 7 Digit	01	Chemistry
29.	Analytical Balance 5 Digit	03	Chemistry
30.	Thermo Gravimetric Analyser (TGA)	01	Chemistry
31.	Water Purification System (Milli-Q)	02	Chemistry
32.	KF with Coulometer	01	Chemistry
33.	Water HPLC	01	Chemistry

List of Sophisticated Instruments Calibrated:

Purpose: Calibration refers to the act of evaluating and adjusting the precision and accuracy of measurement. Calibration is intended to eliminate or reduce bias in an instrument's readings over a range for all continuous values.

Under mentioned Equipments were calibrated during F.Y 2014-15.

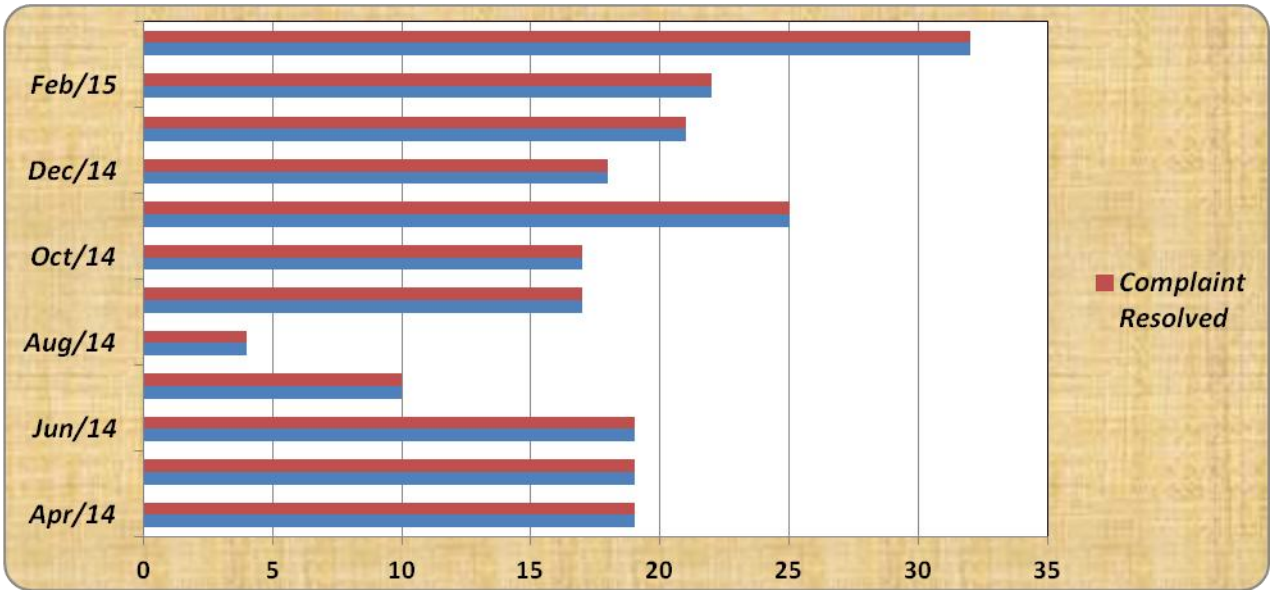
S.No.	Particulars	Qty.	Requisite Div.
1	G.C. Flow Meter	1	Chemistry
2	G.C. Oven	2	
3	Digital Thermometer	4	Chemistry
4	Validation of Horizontal Autoclave	3 Cycle	Microbiology
5	Laminar Air Flow	2	
6	Digital Thermo Hygrometer	2	
7	Ultra Centrifuge	1	
8	Glass Thermometer (-10 to 250°C)	1	
9	Glass Thermometer (-10 to 110°C)	1	
10	Digital Temperature Indicator	1	
11	Muffle Furnace	1	Chemistry
12	Data Logger	1	
13	Stop Watch	1	
14	Glass Thermometer (0 to 360°C)	1	
15	Glass Thermometer (-10 to 110°C)	1	
16	Vacuum Oven (DTI + VG)	1	
17	U.V. Spectrophotometer, Model No. Lambda- 25	1	Microbiology
18	PTS Reader, Model No.- PTS 500 & TS 502	1	

19	Micro plate Absorbance Reader, Model No.- TS 500	1	
20	Validation of Fume Hood	1	Chemistry
21	E-2 Grade Weighing Box	1	Chemistry
22	Vernier Calliper	1	Microbiology
23	Temp. Indicator in Bacteriological Incubator	1	
24	BOD Incubator	1	
25	CO2 Incubator	2	
26	Data Logger	1	
27	Glass Thermometer	1	
28	Balance (Mettler)	1	
29	Balance (Precisa)	1	
30	Hot Air Oven	3	
31	Dial Pressure Gauge in Autoclave (Nat Steel)	2	
32	Compound Gauge in Autoclave	2	
33	Temp. Gauge in Autoclave (Nat Steel)	1	
34	Dial Pressure Gauge in Vertical Autoclave	1	
35	Temp. Gauge in Vertical Autoclave	1	
36	Thermo Hygrometer	9	Chemistry

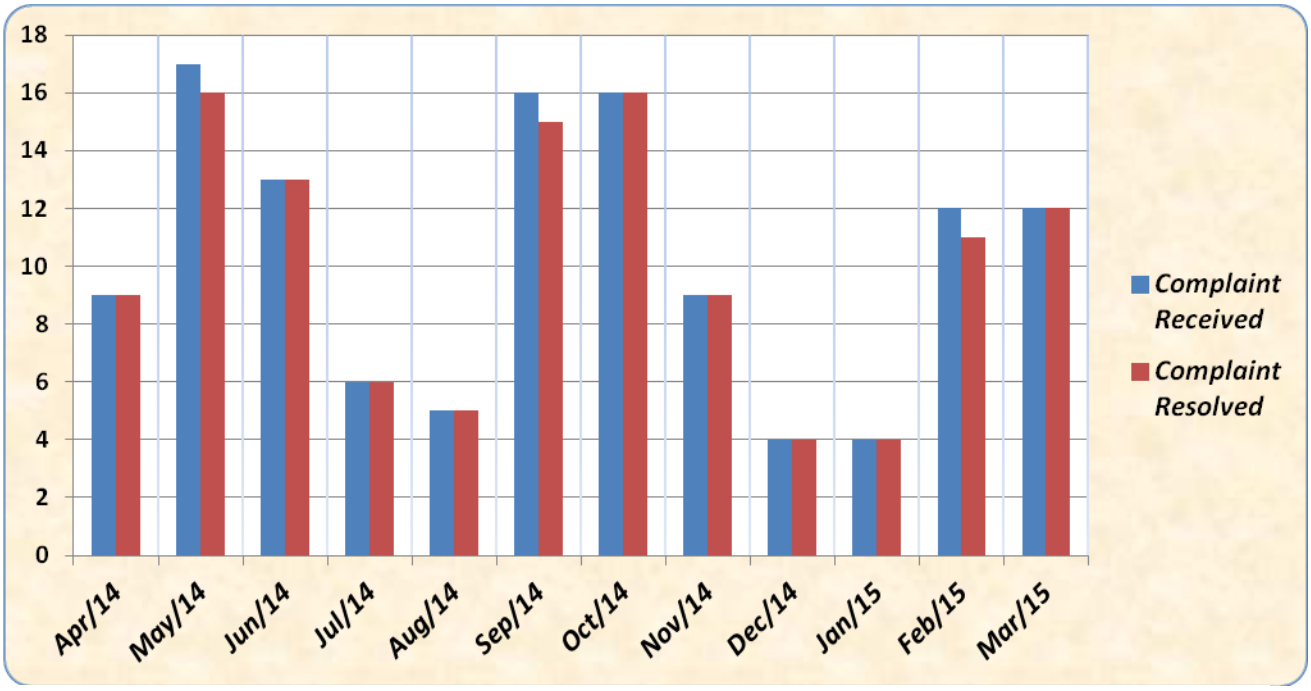
Complaint Received & Resolved Successfully for F.Y 2014-15: The data is represented month-wise in tabular & chart form. The Details are as follow:

	Computer Complaint		**Miscellaneous Complaint**		**A.C. Complaint**	
Month	**Received**	**Resolved**	**Received**	**Resolved**	**Received**	**Resolved**
Apr-14	19	19	9	9		
May-14	19	19	17	16		
Jun-14	19	19	13	13		
Jul-14	10	10	6	6		
Aug-14	4	4	5	5		
Sep-14	17	17	16	15	3	3
Oct-14	17	17	16	16	5	5
Nov-14	25	25	9	9	1	1
Dec-14	18	18	4	4	0	0
Jan-15	21	21	4	4	0	0
Feb-15	22	22	12	11	2	1
Mar-15	32	32	12	12	7	7
Grand Total	**223**	**223**	**123**	**120**	**18**	**17**

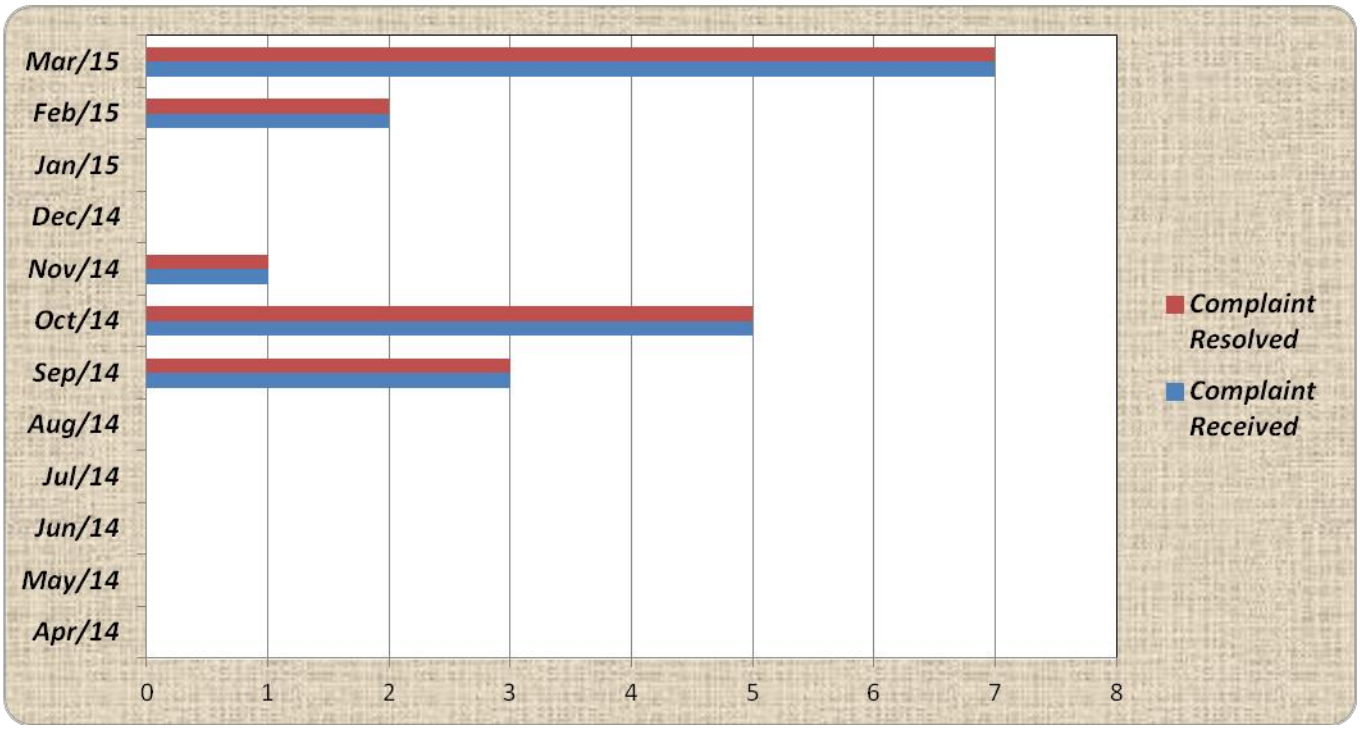
Computer Complaint Received & Resolved:



Miscellaneous Complaint Received & Resolved:



Air-Conditioner's Complaint Received & Resolved:



BCT (Building Care Taker):

- New facility development includes demolish, construction, furnishing as required ergonomically by smartly utilization of existing space.
- Upgradation of labs as per National & International Standards
- A.H.U Shade, Fencing, Flooring, Tiling, Whitewash, enamelling, False Ceiling
- Face-lifting of Building.

New IPRS Distribution Section:

A separate department for the distribution of IP reference substances has been created in RSD division. This department maintains all the records and information regarding the distribution of IPRS and impurities to the private and government authorities. For maintaining the quality of IPRS in this division, Store has purchased new pharma refrigerators for storage.

Wet Lab Renovation:

The wet lab of Reference Standard Division has been renovated to meet standard requirement of GLP and WHO norms. The separate almirahs and drawers have been setup for systematic storage of the glassware's and chemicals. It helps in the smooth functioning.

Automatic IPRS filling machine:

A new facility for the filling of IP Reference Substances has been developed. This automatic IPRS filling machine enhances the traceability, reduces the human error and is effective in saving time.

Upgradation of Microbiology Division:

Under the upgradation plan of this division as per GLP & ISO 17025 Norms renovation works has been carried out such as AHU Installation, View Panel, Clean Room Partitions, Doors, Pass Box, Epoxy Flooring, Lights & Electrical Works, etc.

Upgradation of Phyto Pharmaceutical Division:

Under the upgradation plan of this division as per GLP & ISO 17025 Norms renovation works has been carried out such as View Panel, Doors, Vitrified Flooring, Furniture (i.e., Lab Furniture, Chemical Storage Cabinet, Apparatus Storage Cabinet, Fume Hood & Electrical Works, etc.

Rehabilitation of Administration Division:

Due to expansion of PvPI division it was required to shift the Administration Division from PvPI Block to Main Administrative Wing along with necessary Civil Work, View Panel, False Ceiling Furniture (i.e., Modular Furniture, Compactors, Chairs), Lights & Electrical Works, etc.

Commissioning of Porta cabin:

A Numbers of Porta Cabins have been raised during 2014-15 includes Store, UPS Room, Gym, Main Entrance and Exiting Gate of IPC. This structure is easy to install and dismantle.

Condemnation/Buyback of Old, Unserviceable, Unrepairable, Outdated & Idle Equipments, Furniture's & Miscellaneous Items.

Various Items from different divisions were placed in scrap yard due to following reasons**:**

A. **Beyond economical repair** Instruments/Equipments: The cost of repairing them were considerably high after looking at the current value (taking depreciation into account) & the age of the equipment.
B. **Technically obsolete** - Parts and service support are no longer available.
C. Equipment/ Instrument life get completed & may be breakdown any time.
D. Damage or broken furniture
E. Rusted & other Non-conforming Misc. Items etc.

Therefore all such items amassed by store Division and a Screening Committee/Condemnation committee constituted for Inspection, recommendation & Condemnation of these items thru open tendering. The List of items got approved for condemnation is given below. Open Tender vide tender No. IPC/5531/13-14, dt. 16.09.2014 & 29.09.2014 has been floated twice but could not succeed as:

- ✓ 1st time Highest bid value for these items were Rs. 12,50,000/- but successful bidder had not submitted an EMD amount of Rs. 1,25,000/- (10% of Quoted Amount) which was not accordance of terms & Condition mentioned in NIT.
- ✓ In Re-Tender Highest Quoted price was 8,21,000/- which was almost 40% lesser than earlier H1 value.

Hiring/ Outsourcing Services & facilities for smooth functioning like**:**

- ➢ Bio-Medical Waste Collection & Disposal, Sanitation & Housekeeping

- Processing & submitting monthly Electricity, Telephone & Broadband Bills for payment.
- Private Vehicle, Hotel Accommodation
- Printing material & Advertising as & when required.
- Dry-cleaning & Shampooing Blinds, Chairs, Aprons, Towels etc.

Biomedical Waste Disposal:

Since Biomedical Waste is infectious & hazardous in nature, so it has been safely collected at a regular interval from laboratories to a predefined secluded storage area in IPC premises & handed over to M/s Synergy Waste, Delhi on monthly basis for its appropriate treatment & disposal.

During financial year 2014-15 approx 600 Kg to 700 Kg of biomedical waste disposed.

Meeting Arrangement: to Government Drugs Analyst, Regulators and Stakeholder by Store Division:

- As a mandate of IP Commission various divisions has to provide training to Government Drugs Analysts, Drugs Regulators and their Stakeholders.
- IPC also helps the research scholars and project trainees to complete their projects.

In order to make all events i.e. Meeting/Training/Official Visit/ Audit successful, it is ensured that all the resources needed for the same are available well in time i.e. stationery along with conference Room facilities equipped with a whiteboard, Projector, Projection screen, Remote, P.A Systems, Alternative Power supply etc.

List of meetings by various divisions facilitated successfully at IPC by this division are:

Training facilitated for Reference Standard Division:

RSD division has been facilitated in conducting its three training programmes for the Drug Analysts and Drugs Regulator and one "One Day Workshop on Awareness Programme on IP and IPRS to Stakeholders at PGIMER.

S.No	Subject	Training Period	Participant
1	Training Programme on Various Analytical Instruments & Techniques for Government Drugs Analysts	30th June 2014 to 11th July 2014	Drugs Analyst
2	Training programme for Drugs Inspectors on Regulatory Aspects	27th August 2014 to 29th August 2014	Drugs Inspectors
3	Training Programme on Various Analytical Instruments & Techniques for Government Drugs Analysts	19th January 2015 to 23rd January 2015	Drugs Analyst
4	One day workshop on awareness programme of Indian Pharmacopoeia and Indian Pharmacopoeia Reference Substance	17th March 2015	Stakeholder and Scientific Staff and Student of PGIMER
5	Project Trainees	01st April 2014 to 31st March 2015	

Training facilitated for PvPI Division:

S.No.	Agenda	Training Period	Participant
1	Induction cum Training Programme of Newly recruited Technical Associates	8th September to 12th September, 2014	New Technical Associates
2	Induction cum Training Programme of Newly recruited Technical Associates	24th November to 28th November, 2014	New Technical Associates
3	Workshop on Causality Assessment, Signal Detection and Data Mining	9th December, 2014	SRP Members
4	National & International Scenario on Pharmacovigilance	16th December, 2014	Staff members of IPC
5	QMS Training of AEFI Personnel	17th December, 2014	Staff Members of NCC and AEFI
6	Hands on Training on VigiFlow	31st December, 2014 to 1st January, 2015	AMC Members of SGRRITS, Dehradun
7	Induction cum Training Programme of Newly recruited Technical Associates	16th February to 20th February, 2015	New Technical Associates

Training facilitated for other Division too such as Microbiology & PA to Director as & when required.

ORGANIZED/PARTICIPATED SCIENTIFIC MEETINGS /CONFERENCES / WORKSHOP AND OTHERS

AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT

Scientific Meetings attended during April, 2014 to March 2015

1. Attended Meeting on 23.04.14 to 25.04.14 with Experts at Mumbai.
2. Attended a Meeting with Veterinary Experts and Stakeholders on dated 02.05.14 at IPC, Ghaziabad.
3. Attended Meeting on dated 21.05.14 to 23.05.14 with Experts at IPC, Ghaziabad.
4. Attended Meeting on dated 16.06.14 to 18.06.14 with Experts at Mumbai.
5. Attended Analyst Training Programme from 30.06.14 to 11.07.14 at IPC, Ghaziabad.
6. Attended Estate Committee meeting on dated 11.07.14 at IPC, Ghaziabad.
7. Attended meeting on a Issue of Pholcodine at FDA Bhawan, New Delhi on dated 16.07.14.
8. Attended meeting of Rate Contract on dated 18.07.14 at IPC, Ghaziabad.
9. Attended Seminar on Participation of Consumers/Patients in Pharmacovigilance programme of India on dated 01.08.14 at IPC, Ghaziabad.
10. Attended Director's meeting on dated 11.08.14 at IPC, Ghaziabad.
11. Attended Seminar on Column Chemistry by Meck on dated 21.08.14 at IPC, Ghaziabad.
12. Attended Training Programme for Drug Inspector from 27.08.14 to 29.08.14 at IPC, Ghaziabad
13. Attended 4th IPA-EDQM Technical Conference from dated 09.09.14 to 10.09.14 at Mumbai.
14. Attended True Scale Meeting at FDA Bhawan, New Delhi on 11.09.14.
15. Attended Meeting with Experts of Parenterals Group on dated 16.09.14 at IPC, Ghaziabad.
16. Attended Condemnation Meeting on dated 16.09.14 at IPC, Ghaziabad.
17. Attended Meeting on dated 22.09.14 to 24.09.14 with Experts at IPC, Ghaziabad.
18. Attended BIS Meeting on Food Additives Sectional Committee at Manak Bhawan, New Delhi on dated 20.10.14.
19. Attended Visit of Swedish Delegation on dated 25.11.14 at IPC, Ghaziabad.
20. Attended release of IP Addendum 2015 to IP-2014 at Nirman Bhawan, New Delhi on dated 28.11.14.
21. Attended 29th SB Meeting at IPC, Ghaziabad on dated 02.12.14.
22. Attended Meeting on dated 15.12.14 to 17.12.14 with Experts at IPC, Ghaziabad.

23. Attended BIS Meeting on Inorganic Chemicals Sectional Committee at Manak Bhawan, New Delhi on dated 30.12.14.
24. Attended Ist SB Meeting of CCRH at Janak Puri, New Delhi on dated 02.01.15.
25. Attended 3rd Training Programme on Various Analytical Instruments Technique for Government Drug Analyst on dated 19.01.15 to 23.01.15 at IPC, Ghaziabad.
26. Attended Meeting on dated 25.02.15 to 27.02.15 with Experts at IPC, Ghaziabad.
27. Attended One Day Workshop on Awareness of IP and IPRS at PGIMER, Chandigarh on dated 17.03.15.

PHOTOGRAPHS OF IPC AT A GLANCE

RSD Division

Group Photo of IPC Scientist with Government Drug's Analyst from various States

Training programme titled "Training Programme for Drug Inspectors on Regulatory Aspects" from 27th August, 2014 to 29th August, 2014, was conducted at Indian Pharmacopoeia Commission

Group Photo of IPC Scientist with Drug Inspector from State & Central Government

Group Photo of IPC Scientist with Government Drug's Analyst from various States

IPC Scientist and CDSCO at PGIMER Chandigarh

Botanical Reference substances (BRS)/ Phytochemical Reference substances (PRS) Development

Padmashree Dr. Jagdish Prasad, DG, DGHS MoHFW, GoI, addressing Scientists of IPC on the Foundation Day of IPC on 2nd January, 2015

Shri K L Sharma, JS(R) reviewing PvPI activities along with Dr. G.N. Singh, DCG(I), & Dr. Surinder Singh, Director, NIB and IPC officials

Participants of Expert Committee Meeting of NFI 2016 at AIIMS, New Delhi

STRENGTH OF STAFF AT IPC

Name	Designation
Dr. Gyanendra Nath Singh	Secretary-cum-Scientific Director
Analytical Research & Development Division	
Dr. Anil Kumar Teotia	Principal Scientific Officer
Dr. S. C. Mathur	Senior Scientific Officer
Mr. Dinesh Kumar Sharma	Scientific Officer
Biologics Division	
Dr. Jai Prakash	Senior Principal Scientific Officer
Mrs. M. Kalaivani	Scientific Assistant
Microbiology Division	
Dr. Jai Prakash	Senior Principal Scientific Officer
Mr. Alok Sharma	Scientific Officer
Smt. Ritu Tiwari	Scientific Assistant
Phytopharmaceuticals Division	
Dr. Jai Prakash	Senior Principal Scientific Officer
Dr. Manoj Kumar Pandey	Scientific Officer
Pharmaceutical Chemistry & Reference Substances Division	
Dr. P. L. Sahu	Principal Scientific Officer
Dr. Robin Kumar	Principal Scientific Officer
Mr. Anuj Prakash	Senior Scientific Officer
Mrs. Meenakashi Dahiya	Senior Scientific Officer
Mr. Satya Prakash Tyagi	Scientific Officer
Mr. Utpal Nandi	Scientific Assistant
Mr. Ravindra Verma	Scientific Assistant
Mr. Ramji Rathore	Scientific Assistant
Ms. Manisha Trivedi	Scientific Assistant

Pharmacovigilance Programme of India (PvPI) Cell

Dr. V. Kalaiselvan	Principal Scientific Officer
Mr. Pawan Kumar Saini	Scientific Officer
Mrs. Akanksha Bisht	Scientific Assistant
Mr. Prasad Thota	Scientific Assistant

Publication Division

Mr. K. K. Singh	Library & Information Officer
Mr. Dinesh Kumar Sharma	Scientific Officer

Library Division

Mr. K. K. Singh	Library & Information Officer
Mr. B. D. Sharma	Senior Laboratory Attendant

Store Division

Mr. Manish Jain	Store Officer
Mr. Bijender Kumar	Laboratory Attendant/Store Incharge

Finance & Accounts Division

Mr. Chandan Kumar	Finance & Accounts Officer

Administration

Mr. I. J. S. Oberoi	Administrative Officer (I/C)
Ms. Renu Kapoor	Upper Divisional Clerk
Mr. Rajendra Kumar Sharma	Peon/BCT

ANNEXURE

Annexure – I

(AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT)

Additions:

Aripiprazole Tablets
Barium Sulphate Oral Suspension
Brimonidine Tartrate
Brimonidine Tartrate Eye Drops
Brinzolamide Ophthalmic Suspension
Budesonide Inhalation
Budesonide Powder for Inhalation
Calcium Pantothenate Tablets
Citicoline Injection
Citicoline Prolonged-release Tablets
Citicoline Tablets
Clemastine Oral Solution
Dorzolamide Hydrochloride
Dorzolamide Eye Drops
Dorzolamide and Timolol Eye Drops
Dutasteride Capsules
Ebastine Tablets
Entacapone Tablets
Eslicarbazepine Tablets
Ifosfamide
Ifosfamide Injection
Iloperidone Tablets
Isotretinoin Capsules
KetotifenFumarate Tablets
Lacidipine
Lacidipine Tablets
Lactulose Oral Powder
Metformin Oral Solution
Methadone Oral Solution
Methylphenidate Hydrochloride
Methylphenidate Hydrochloride Prolonged-release Tablets
Metolazone
Metolazone Tablets

Mirtazapine
Mirtazapine Tablets
Nabumetone
Nabumetone Tablets
Netilmicin Injection
Rabeprazole Injection
Raloxifene Hydrochloride Tablets
Ranitidine Oral Solution Ranitidine Tablets
Sitagliptin Phosphate
Sitagliptin Tablets
Sodium Nitrite
Sodium Nitrite Injection
Tadalafil
Tadalafil Tablets
Tamsulosin Prolonged-release Capsules
Terazosin Tablets
Tibolone
Tibolone Tablets
Tolterodine Tartrate Tablets
Torsemide
Torsemide Tablets
Voriconazole
Voriconazole Tablets
Sterile Water for Inhalation

Vaccines and Immunosera for Human Use

1) BCG for Immunotherapy Bacillus Calmette-Guerin (BCG) for Immunotherapy
2) Influenza Vaccine (Human, Live Attenuated)Influenza Vaccine (Human, Live Attenuated)

Herbs and Herbal Products

1) Asthisamhrta
2) Bassant
3) Bassant Dry Extract
4) Birmi
5) Draksha
6) Ginseng
7) Ginseng Dry Extract
8) Hingu
9) Lodhra
10) Mirch
11) Sahajana Leaf

12) Sahajana Stick
13) Shankhpushpi

Radiopharmaceutical Preprarations

1) Gallium Citrate [^{67}Ga] Injection
2) Strontium (^{89}Sr) Chloride Injection
3) Technetium (^{99m}Tc) Colloidal Rhenium Sulphide Injection
4) Technetium (^{99m}Tc) Exametazime Injection
5) Technetium (^{99m}Tc) HYNIC-TOC Injection
6) Technetium (^{99m}Tc) Macrosalb Injection
7) Technetium (^{99m}Tc) Mertiatide Injection
8) Technetium (^{99m}Tc) Tetrofosmin Complex Injection
9) Technetium (^{99m}Tc) TRODAT-1 Injection
10) Urea (^{14}C) Capsules

Annexure – II

(AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT)

Omissions

1. Azelaic acid
2. Ceftazidine Injection
3. Clobazam Capsules.
4. Sodium Dihydrogen Phosphate Dihydrate

Annexure – III

(AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT)

ERRATA- 003 TO IP-2014

2.4.26. Solubility

Page 202. Insert before **Undecenoic Acid**.

Ulipristal Acetate. Freely soluble in *dichloromethane*, soluble in *methanol*, *acetone*, *ethanol* and insoluble in *water*.

4.2 General Reagents

Page 785 Insert before **Ferrous Ammonium Sulphate.**

Ferric Sulphate Pentahydrate. Iron (III) Sulphate Pentahydrate; $Fe_2(SO_4)_3,5H_2O$ = 489.9

Analytical reagent grade of commerce.

White to yellowish powder.

Store in well-closed, light-resistant containers.

Tablets. Page 959

Effervescent Tablets.

Disintegration. Line 2

Change **from**: containing water

to: containing 200 ml of water

Acesulphame Potassium. Page 984, 3798

Identification B. line 2

Change **from**: *cellulose*.

to: *cellulose* F254.

Impurity A. line 2

Change **from**: *silica gel.*

to: *silica gel G.*

Acitretin Page 993

Heavy Metals. Line 2.

Change **from** : Method C

T o : Method B

Adenosine. Page 997

Appearance of solution. Line 1,

Change **from**: solution (Solution A)

to : solution in hot *water* (Solution A)

Related substances. After chromatographic system.

Adenosine impurity G, Correction factor,

Change **from** : 0.4

to: 1.4

Allopurinol. Page 1012

Related substances. Insert after chromatographic system.
The elution order of the peaks is allopurinol impurity A, allopurinol impurity B, allopurinol impurity C and allopurinol. The retention time for allopurinol is about 10 minutes.

Allopurinol Tablets. Page 1013

Related substances. Insert after chromatographic system.
The elution order of the peaks is allopurinol impurity A, allopurinol impurity B, allopurinol impurity C and allopurinol. The retention time for allopurinol is about 10 minutes.

Alprazolam Prolonged-release Tablets. Page 1016

Uniformity of content.
Test solution.
Change **from**: ultrasound for 2 minutes.
to: ultrasound.

Aminocarproic Acid. Page 1031

Assay. lines 2 and 3,
Delete. and add 15 ml of *mercuric acetate* solution.

Aminocarproic Acid Injection. Page 1032

Assay. lines 4 and 5,
Delete. and add 15 ml of *mercuric acetate* solution.

Aminocarproic Acid Tablets. Page 1032

Assay. line 4 .
Delete. and add 15 ml of *mercuric acetate* solution.

Amioradone Hydrochloride. Page 1037

Heavy metals.
Change **from**: Method C
to: Method B

Amlodipine Tablets. Page 1046

Dissolution. Medium, line 2,
Change **from**: 900 ml
to: 500 ml
Line 3
Change **from**: 45 minutes
to: 30 minutes
Line 10
Change **from**: 70 per cent
to: 75 per cent

Amoxycillin Trihydrate. Page 1054

Labelling. Delete.

Amoxycillin Dispersible Tablets. Page 1056

Insert at the end
Labelling.

The label states (1) the strength in terms of the equivalent amount of amoxycillin; (2) that the tablets should be dispersed in water immediately before use.

Anticogulant Citrate Phosphate Dextrose Adenine Solution. Page 1075

Assay. *For dextrose.* last line

Change **from**: $C_6H_{12}O_6$.

to: $C_6H_{12}O_6.H_2O$.

Atorvastatin Calcium. Page 1099

Description. Insert at the end.

It shows polymorphism.

Water.

Change **to**: **Water** (2.3.43). Not more than 6.0 per cent.

Betahistine Tablets. Page 1166

Uniformity of content. *Test solution.*

Change **to**: Disperse one tablet to a 25 ml volumetric flask and add about 15 ml of mobile phase, mix with the aid of ultrasound and dilute to 25.0 ml with the mobile phase, filter.

Bezafibrate. Page 1185

Chlorides. Change **to**:

Chlorides (2.3.12). Boil 0.83 g with 30 ml of *water* for 5 minutes, cool and filter. The filtrate complies with the limit test for chlorides (300 ppm).

Bisacodyl. Page 1194

Related substance. *Test solution,* Line 1.

Change **from**: 50 g

to: 50 mg

Carbamazepine. Page 1266

Chlorides(2.3.12).

Change **to**: Boil 1.5 g in 30 ml of *water* for 5 minutes, cool and filter. The filtrate complies with the limit test for chlorides (165 ppm).

Cefadroxil Tablets. Page 1295

Related substances. Para2, lines 2 and 3

Change **from**: Run the chromatogram 6 times the retention times of the principal peak.

to: For test solution, run the chromatogram 6 times the retention times of the principal peak.

Clotrimazole Pessaries. Page 1444, 3836

Assay.

Reference solution.

Change **to:** Dissolve 20 mg of *clotrimazole RS* in 70 ml of *methanol*, add sufficient *0.02 M phosphoric acid* to produce 100.0 ml and dilute 1.0 ml of the resulting solution to 5.0 ml with methanol.

Disodium Edetate. Page 1594

Impurity A.

Reference solution. Line 1

Change **from**: *nitrilotriacetic acid*

to: *nitrilotriacetic acid* (disodium edetate impurity A)

Para 2, line 6.
Change **from**: principal peak
to: corresponding peak

Docusate Sodium. Page 1610

Heavy metals.
Change **to**: Dissolve 4.0 g in 20 ml of *ethanol (80 per cent v/v)*. 12 ml of the solution complies with the limit test for heavy metals, Method D (10 ppm), using 10 ml of *lead standard solution (2 ppm Pb*).

Entacapone. Page 1662

Related substances. After chromatographic system, para 3, line 5
Change **from** : more than twice
to : more than

para 3, line 11
Change **from** : not more than the area
to : not more than twice the area

Loss on drying. line 3
Change **from** : 49 mm of mm Hg
to : 49 mm of Hg

Assay. para 2
Change **to:** Inject reference solution (a). The test is not valid unless the resolution between the peaks corresponding to entacapone impurity A and entacapone is not less than 2.0.

Inject reference solution (b). The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 1.0 per cent for entacapone peak.

Flumazenil. Page 1779

N,N – dimethylformamide diethyl acetate.
Reference solution (a). Line 2
Change **from**: 0.00006 per cent w/v
to: 0.6 µl per ml

Diluted Glyceryl Trinitrate. Page 1872

Related substances. *Test solution (a).*
Change **to**: Dissolve a quantity of the substance under examination in *methanol* to obtain a solution containing 1.0 per cent w/v of nitroglycerin and centrifuge, if necessary, to obtain a clear liquid solution or apply directly 1.0 per cent w/v nitroglycerin.

Para 1, line 1,
Change **from**: 20 µl
to: 40 µl

Griseofulvin. Page 1876

Related substances. last para. line 1.
Change **from**: ratio (r)
to: ratio (R).

last para. line 6.
Change **from**: is less than 0.6

to: is less than 0.6 R.

last para. line 10.
Change **from**: is less than 0.15
to: is less than 0.15 R.

Griseofulvin Tablets. Page 1877

Related substances. last para. line 1.
Change **from**: ratio (r)
to: ratio (R).

last para. line 6.
Change **from**: is less than 0.6
to: is less than 0.6 R.

last para. line 10.
Change **from**: is less than 0.15
to: is less than 0.15 R.

Hydroxyzine Oral Solution. Page 1923

Identification B
Test Solution. line 3
Change **from**: dilute to 10.0 ml with solvent mixture,
to: dilute to 50.0 ml with solvent mixture,

Irbesartan and Hydrochlorothiazide Tablets. Page 1995, 3878

Assay. Chromatographic system, mobile phase.
Change **from**: 1.36 g of *monobasic potassium phosphate*
to: 1.36 g of *monobasic potassium phosphate* in 900 ml of *water*

Meclofenamic Acid. Page 3542

Related substance. After chromatographic system, para 1. line 2
Change **from**: 4500 theoretical plates.
to: 900 theoretical plates.

Heavy metals.
Change **from**: Method D
to: Method B

Metformin Hydrochloride. Page 2186

Related Substances. Chromatographic system. Line 2.
Change **from** : 10 mm.
to : 10 µm.

Mifepristone. Page 2234

Optical rotation (2.4.22).

Change **to**: **Specific optical rotation** (2.4.22). 124° to 135°, determined in a 0.5 per cent w/v solution in *dichloromethane,* when determined at 20°.

Mupirocin. Page 2265

Related substances. After chromatographic system, para1

Change **to**: Inject reference solution (b). This test is not valid unless resolution between the second of the 2 peaks due to hydrolysis products and the peak due to mupirocin is not less than 7.0 in the chromatogram obtained with reference solution (b).

Assay. After chromatographic system, para 1,

Change **to**: Inject reference solutions (a) and (b). This test is not valid unless resolution between the second of the 2 peaks due to hydrolysis products and the peak due to mupirocin is not less than 7.0 in the chromatogram obtained with reference solution (b). The relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Nalidixic Acid Tablets. Page 2293

Assay. Lines 3 and 4

Change **from**: *0.1 M sodium hydroxide*

to: *1.0 M sodium hydroxide*

Line 7

Change **from**: *0.1 M sodium hydroxide*

to: *0.01M sodium hydroxide*

Naltrexone Hydrochloride. Page 2298

Ethanol. line 1

Change **from**: 3.0 per cent v/v

to: 3.0 per cent

Nandrolone Decanoate Injection. Page 2301

Identification. *Test solution*. Line 2

Change **from**: *carbon tetrachloride*

to: *chloroform*

Reference solution. Line 2

Change **from**: *carbon tetrachloride*

to: *chloroform*

Naphazoline Nitrate. Page 2303

Identification C. Line 1

Change **from**: Dissolve about 0.5 mg in 1 ml of *methanol*

to: To 1 ml of 0.05 per cent w/v in *methanol*

Naphthylacetylethylenediamine. Delete the test.

Naproxen. Page 2305

Identification B. line 1

Change **from**: 0.04 per cent w/v.

to: 0.004 per cent w/v.

line 3

Change **from**: absorbance

to: specific absorbance

Nevirapine. Page 2324

Line 1

Change **to** : $C_{15}H_{14}N_4O$ Mol. Wt. 266.3

(anhydrous)
$C_{15}H_{14}N_4O.1/2H_2O$ Mol. Wt. 275.3
(hemihydrate)

Nicotinic Acid. Page 2334.

Heavy metals. Line 4
Change **from**: Method B
to: Method A

Nortriptyline Tablets. Page 2356

Uniformity of content. *Test solution*.
Change **to**:
Test solution. Transfer one tablet to 100.0 ml volumetric flask, add about 5 ml of *water* and disperse with the aid of ultrasound. Add about 50.0 ml of *methanol*, mix with the aid of ultrasound for 30 minutes and dilute to 100.0 ml with *water*. Centrifuge and use the supernatant liquid, dilute if necessary.

Octyldodecanol. Page 2365

Assay.
Chromatographic system, temperature:
Change **to**:

column time (min)	temperature (º)
0 - 2	180
2 - 22	180 – 280
22 - 52	280

Ondansetron Hydrochloride. Page 2376

Assay. After chromatographic system, para 1, line 2
Delete. for ondansetron is about 1.0

Ondansetron Injection. Page 2377

Assay. After chromatographic system, para 1, line 2
Delete. for ondansetron is about 1.0

Ondansetron Orally Disintegrating Tablets. Page 2377

Related substances. Last para, line 4
Change **form**: 0.5
to: 1.89
Line 6
Change **form**: 1.2
to: 0.77

Uniformity of content.
Test solution. Lines 2 and 3
Change **from**: and filter.
to: filter, dilute if necessary.

Ondansetron Tablets. Page 2380

Dissolution. Para 1, line 9

Change **from**: *ondansetron hydrochloride dihydrate RS*
to: *ondansetron hydrochloride RS*

Ornidazole. Page 2385

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Ornidazole Injection. Page 2385

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Ornidazole Tablet. Page 2386

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Oseltamivir Capsules. Page 2391

Related substances. *Reference solution (a).*
Change **from**: A 0.1 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.
to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.1per cent w/v of oseltamivir.

Assay. *Reference solution.*
Change **from**: A 0.02 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.
to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.02 per cent w/v of oseltamivir.

Oseltamivir Oral Suspension. Page 2392

Related substances. *Reference solution (a).*
Change **from**: A 0.1 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.

to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.1per cent w/v of oseltamivir.

Oxazepam. Page 2395

Identification A. line 2
Change **from**: *oxazepam RS*.
to: *oxazepam RS* or with the reference spectrum of oxazepam.

Identification B. First para, line 3
Change **from**: Dilute 10.0 ml of solution A to 100.0 ml with *ethanol (95 per cent)* (solution B).
to: Dilute 5.0 ml of solution A to 20.0 ml with *ethanol (95 per cent)* (solution B).

Paracetamol. Page 2429

Related substances. Chromatographic system, line 1
Change **from**: 4.0 mm,
to: 4.6 mm,

Paracetamol Tablets. Page 2434

Related substances. chromatographic system. line 1

Change **from** : 4.0 mm,

to: 4.6 mm,

Penicillamine. Page 2443

Heavy metals. line 1

Change **from**: 10.0 ml

to: 12.0 ml

Phenylmercuric Nitrate. Page 2481

Inorganic mercuric compounds. Lines 7 and 8

Change **from**: Method A (2.3.13). Use *lead standard solution (1 ppm Pb)*

to: Method D (2.3.13). Use 10 ml of *lead standard solution (1 ppm Pb)*

Phenytoin. Page 2483

Heavy metals. line 2

Change **from** : Method D

to : Method B

Polysorbate 20. Page 2516

Identification A. lines 2 and 3.

Change **from**: *polysorbate RS* or with the reference spectrum of polysorbate.

to: *polysorbate 20 RS* or with the reference spectrum of polysorbate 20.

Polysorbate 80. Page 2517

Identification A. lines 2 and 3.

Change **from**: *polysorbate RS* or with the reference spectrum of polysorbate.

to: *polysorbate 80 RS* or with the reference spectrum of polysorbate 80.

Potassium Clavulanate Diluted. Page 2525

Assay. Chromatographic system, injection volume

Change **from** : 20 µl

to : 10 µl

Progesterone Injectable Suspension. Page 2567

Assay.

Reference solution. Line 2

Change **from** : 4.0

to : 10.0 ml

Line 4,

Change **from** : 10 ml

to : 25 ml

Propionic acid. Page 2576

Heavy metals. line 4

Change **from**: 10.0 ml
to: 12.0 ml

Rizatriptan Tablets. Page 2681

Related substances. *Reference solution (a).*
Change **from**: A 0.0001 per cent w/v solution of *rizatriptan benzoate RS* in the solvent mixture.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.0001 per cent w/v of rizatriptan in the solvent mixture.

Uniformity of content.
Test solution. Line 3
Change **from**: Rizatriptan Benzoate.
to: Rizatriptan Benzoate equivalent to Rizatriptan.

Reference solution.
Change **from**: A 0.005 per cent w/v solution of *rizatriptan benzoate RS* in the mobile phase.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.005 per cent w/v of rizatriptan in the mobile phase.

Assay. *Reference solution.*
Change **from**: A 0.005 per cent w/v solution of *rizatriptan benzoate RS* in the mobile phase.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.005 per cent w/v of rizatriptan in the mobile phase.

Saquinavir Mesylate Tablets. Page 2712.

Dissolution. Line 2,
Change **from** : 5.82 mg,
to : 5.82 g.

Line 2,
Change **from** : 16.7 mg,
to : 16.7 g.

Related substances. *Reference solution (a).*Line 2,
Change **from** : *saquinavir mesylate RS*
to : *saquinavir mesylate RS* equivalent to *saquinavir*

Assay.*Reference solution*. Lines 1 and 2,
Change **from** : *saquinavir mesylate RS*
to : *saquinavir mesylate RS* equivalent to *saquinavir*

Sildenafil Tablets. Page 2726

Assay. After chromatographic system, para 1, line 4
Change **from**: 5.0 per cent.
to: 2.0 per cent

Sisomicin Sulphate Injection. Page 2733

Identification. *Test Solution.*
Change **to** : Dilute a suitable volume of injection (if required) to contain 1.0 percent w/v solution of sisomicin sulphate.

Sorafenib Tosylate. Page 2774

Paratoluenesulphonic acid. Line 1

Change **from**: 26.4 per cent to 27.6 per cent.
to: 25.6 per cent to 28.3 per cent.

Heavy metals.
Change **from**: 2.0 g complies with the limit test for heavy metals, Method B (10 ppm).
to: 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Loss on drying. Line 1
Change **from**: Not more than 0.5 per cent,
to: Not more than 1.0 per cent,

Tadalafil Tablets. Page 3934

Dissolution. Speed and time.
Change **from**: 50 rpm and 30 minutes.
to: 50 rpm ,10 minutes and 30 minutes.

D. Lines 1 and 2
Change **to**: Not less than 40 per cent of the stated amount of $C_{22}H_{19}N_3O_4$ at 10 minutes and not less than 80 per cent of the stated amount of $C_{22}H_{19}N_3O_4$ at 30 minutes.

Veterinary Monographs.

Flunixin Meglumine. Page 3527

Identification. line 2
Change **from**: *flunixin RS*
to: *flunixin meglumineRS*

Related Substance.
Reference Solution (a). line 1
Change **from**: *flunixin RS*
to: *flunixin impurity B RS*

Reference Solution (c). line 1
Change **from**: *flunixin RS*
to: *flunixin impurity C RS*

last para, lines 1 to 4
Change **from**: The area of the peak is not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.2 per cent).
to: In the chromatogram obtained with the test solution, the area of any peak corresponding to flunixin impurity A and flunixin impurity B is not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.2 per cent).

ERRATA- 004 TO IP-2014

2.4.26 Solubility

Page 176
Change **from**: Atosibane Acetate
Change **to**: Atosiban Acetate

Page 180
Insert before **Chorionic Gonadotropin**
Chlorthalidone. Soluble in *methanol;* slightly soluble in *ethanol (95 per cent);* practically insoluble in *water,* in *ether,* and in *chloroform.*

3.1 Infrared Reference Spectra

Page 362
Change **from**: Atosibane Acetate
Change **to**: Atosiban Acetate

Acesulphame Potassium. Page 984, 3798

Related substances. Change **to**:

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.1 g of the substance under examination in *water* and dilute to 10.0 ml with *water*.

Reference solution (a). A 0.004 per cent w/v solution of *acesulphame potassium impurity B RS (5-chloro-6-methyl-1,2,3-oxathiazin-4(3H)-one 2,2-dioxide RS)* in *water*. Dilute 1.0 ml of this solution to 200.0 ml with *water*.

Reference solution (b). Dilute 1.0 ml of the test solution to 100.0 ml with *water*. Further dilute 1.0 ml of this solution to 10.0 ml with *water*.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (3 µm),
- mobile phase: a mixture of 40 volumes of *acetonitrile*, 60 volumes of 0.33 per cent w/v solution of *tetrabutylammonium hydrogen sulphate*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 234 nm,
- injection volume: 20 µl.

The relative retention time with reference to acesulphame for acesulphame impurity B is about 1.6.

Inject reference solution (b). The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0 for the principal peak.

Inject reference solutions (a), (b) and the test solution. Run the chromatogram 3 times the retention time of the principal peak. In the chromatogram obtained with the test solution, the area of any peak corresponding to acesulphame impurity B is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (20 ppm). The area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent). The sum of areas of all the secondary peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) except for the peak due to acesulphame impurity B (0.05 per cent).

Acetazolamide Tablets. Page 986

Identification A. Line 2.
Change **from**: add 2 ml of *1 M sodium hydroxide*

to: add 10 ml of *1 M sodium hydroxide*

Alprazolam. Page 1015

Loss on drying.

Change **to**: Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105^0.

Ambroxol Hydrochloride. Page 1025, 3802

Related substances. Chromatographic system, mobile phase, line 3

Change **from**: *ammonium phosphate*

to: *ammonium phosphate, dibasic*

Assay. Chromatographic system, mobile phase, lines 2 and 3

Change **from**: *ammonium dihydrogen phosphate*

to: *ammonium phosphate, dibasic*

Amitriptyline Hydrochloride. Page 1044

Assay. Chromatographic system, mobile phase, line 3

Change **from**: adjusted to pH with

to: adjusted to pH 7.7 with

Atorvastatin Tablets. Page 1100

Uniformity of content. *Test solution.*

Change to: Disperse one tablet in 3 ml of *water*, add 25 ml of *methanol* and mix with the aid of ultrasound, make up to 50 ml with the *solvent mixture*, filter. Dilute sufficient amount of the the filtrate with solvent mixture to produce a solution containing 0.008 per cent w/v of atorvastatin.

Atosibane Acetate. Page 1102

Change Title **to:** **Atosiban Acetate**

Para 1, line 1.

Change **from**: Atosibane Acetate

to: Atosiban Acetate

Category.

Change **to**: Oxytocin antagonist.

Identification. Line 2.

Change **from**: *atosibane acetate RS*

to: *atosiban acetate RS*

Related substance. *Reference solution.*

Line 1.

Change **from**: *atosibane acetate*

to: *atosiban acetate RS*

Ciprofloxacin. Page 1399

Identification B. Line 2.

Change **from**: *silica gel G*
to: *silica gel GF254*

Ciprofloxacin Injection. Page 1400

Identification. Line 2.
Change **from**: *silica gel G*
to: *silica gel GF254*

Ciprofloxacin Hydrochloride. Page 1401

Identification B. Line 2.
Change **from**: *silica gel G*
to: *silica gel GF254*

Ciprofloxacin Tablets. Page 1403

Identification B. Line 2.
Change **from**: *silica gel G*
to: *silica gel GF254*

Clemastine Tablets. Page 1415

Identification A. Line 1.
Change **from**: peak
to: spot

Clotrimazole Cream. Page 1443

2-Chlorotritanol. After chromatographic system, para 1, line 2
Change **from**: 6000 theoretical plates.
to: 1800 theoretical plates .

Clotrimazole Pessaries. Page 1444

Related substances. After chromatographic system, para 1, line 3
Change **from**: 6000 theoretical plates.
to: 1800 theoretical plates.

Assay. After chromatographic system, para 1, line 3
Change **from**: 6000 theoretical plates.
to: 1800 theoretical plates.

Dalteparin Sodium Injection. Page 1505

Anti-factor Xa activity. *Reference solution*. Lines 1 and 2
Change **from**: *dalteparin sodium solution for bioassays RS*
to: low molecular mass heparins

Anti-factor IIa activity. *Reference solution*. Lines 1 and 2
Change **from**: *dalteparin sodium solution for bioassays RS*
to: low molecular mass heparins

Dexamethasone Injection. Page 1526

Identification.

Change **to**: In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak due to dexamethasone sodium phosphate in the chromatogram obtained with the reference solution (a).

Free dexamethasone. *Reference solution (b)*. line 2

Change **from**: *dexamethasone phosphate RS*

to: *dexamethasone sodium phosphate RS*

Assay. *Reference solution (a)*. line 2

Change **from**: *dexamethasone phosphate RS*

to: *dexamethasone sodium phosphate RS*

Reference solution (b). line 2

Change **from**: *dexamethasone phosphate RS*

to: *dexamethasone sodium phosphate RS*

Dobutamine Hydrochloride. Page 1604

Related substances. After chromatographic system, para2, line 6.

Change **from**: not more than 0.2 times the area

to: not more than the area

Para 2, line 8

Change **from**: reference solution (b) (0.1 per cent)

to: reference solution (b) (0.5 per cent)

Flavoxate Tablets. Page 1764

Related substances. Insert after *Reference solution (c)*.

Reference solution (d). A 0.03 per cent w/v solution of *3- methylflavone-8-carboxylic acid RS* in *chloroform*.

Last para, lines 1 and 2

Change **from**: Apply 50 µl of test solution (a), 10 µl of reference solution (a) and 25 µl of reference solution (b).

to: Apply 10 µl of reference solution (a), (c), (d), test solution (b), 25 µl of reference solution (b) and 50 µl of test solution (a).

Flucytosine. Page 1770

Heavy metals (2.3.13). Line 2.

Change **from**: Method D (20 ppm)

to: Method B (20 ppm).

Fludrocortisone Acetate. Page 1777

Identification C. *Reference solution (a)*

Change **from**: *Fludrocortisone RS.*

to**:** *Fludrocortisone acetate RS*

Fludrocortisone Tablets. Page 1778

Identification . *Reference solution (a)*

Change **from**: *Fludrocortisone RS.*

to**:** *Fludrocortisone acetate RS*

Fluoxetine Capsules. Page 1792

Related substance. After chromatographic system. para 2, line 8,
Change **from**: 0.05 time
to: 0.1 times

Fluoxetine Tablets. Page 1795

Related substance. After chromatographic system. para 2, line 8,
Change **from**: 0.05 time
to: 0.1 times

Flupentixol Decanoate. Page 1796

Dose.
Change **to**: Intramuscular injection, 20 to 40 mg.

Related substance. After chromatographic system. Para 3, lat line.
Change **from**: reference solution (d)
to: reference solution (c)

Assay. Para 2, line 1.
Change **from**: 0.0294 g
to: 0.02944 g

Flutamide Capsule. Page 1809

Dissolution. Para 1, last line.
Change **to**: Calculate the content of $C_{11}H_{11}F_3N_2O_3$ in the medium form a known concentration of *flutamide RS* prepared by initially dissolving in *methanol* and further diluting with the dissolution medium.

Uniformity of content. Delete the test.

Gentamicin Sulphate. Page 1856

Sulphate. Line 2.
Change **from**: anhydrous basis
to: dried basis

Hydroxychloroquine Sulphate. Page 1915, 3868

Related substances. Chromatographic system, gradient programme,

Change **to**:

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
2	100	0
10	85	15
18	0	100
25	0	100

Human Insulin. Page 1963.

Para 1, lines 2 to 5.
Change **from** : It is produced either by enzymatic modification and suitable purification of insulin obtained from the pancreas of the pig or by a method based on recombinant DNA (rDNA).
to: It is produced by a method based on recombinant DNA (rDNA) technology.

Biphasic Isophane Insulin Injection. Page 1977.

Tests
pH (2.4.24).
Change **from**: 6.9 to 7.5
to: 6.9 to 7.8

Irbesartan and Hydrochlorthaizide Tablets. Page 1995, 3878

Dissolution (2.5.2). Chromatographic system. mobile phase. line 2
Change **from**: 1.36 g of *monobasic potassium phosphate,*
to: 1.36 g of *monobasic potassium phosphate* in 1000 ml of *water,*

Diluted Isosorbide Dinitrate. Page 2012.

Identification A.
Change **to**: In the assay, the principal peak in the chromatogram obtained with the test solution (b) corresponds to the peak in the chromatogram obtained with the reference solution (b)

Heavy metals. Delete the test.
Loss on drying. Delete the test.

Assay. *Reference solution (a).*
Change **from**: *isosorbide dinitrate RS*
to: *diluted isosorbide dinitrate RS*

Reference solution (d), Line 1.
Change **from**: 20 mg
to: 10 mg

Isosorbide Dinitrate Tablets. Page 2013

Identification A. *Reference solution.* Line 1
Change **to**: *diluted isosorbide dinitrate RS*

Uniformity of content. *Reference solution.*
Change **to**: A solution *diluted isosorbide dinitrate RS* equivalent to 0.005 per cent w/v of isosorbide dinitrate in the mobile phase

Dissolution. *Reference solution.* Line 1
Change **from**: *isosorbide dinitrate RS*
to: *diluted isosorbide dinitrate RS*
Assay. *Reference solution (a).* Line 2.
Change **from**: *isosorbide dinitrate RS*
to: *diluted isosorbide dinitrate RS*

Labetalol. Page 2048

Insert before **Assay.**
Other tests. Comply with the tests stated under Parenteral preparations.

Metoclopramide Tablets. Page 2212, 3899

Uniformity of content. Change **to**:

Uniformity of content. Complies with the test stated under Tablets.

Determine by liquid chromatography (2.4.14), as described in the Assay with the following modifications.

Test solution. Disperse one tablet in 30 ml of *water*, with the aid of ultrasound for 20 minutes and dilute to 100.0 ml with *water*. Centrifuge and use the supernatant liquid.

Calculate the content of $C_{14}H_{22}ClN_3O_2$, HCl in the tablet.

Nitrazepam Tablets. Page 2343

Dissolution. Insert in the beginning

NOTE - Carry out the following procedure in subdued light.

Pemetrexed Disodium Heptahydrate. Page 2442, 3916

Enantiomeric purity. Chromatographic system, mobile phase
Change **from**: α-cyclodextrin
to: β-cyclodextrin

Related Substance. Chromatographic System,
Change **from**:

Name	Relative retention time
Pemetrexed impurity A[1]	0.82
Pemetrexed impurity B[2]	0.87
Pemetrexed impurity C[3]	0.88
Pemetrexed (Retention time: about 26 minute	1.0

[1](2*S*)-2-[[4-[2-(2-amino-1-methyl-4-oxo-4,7-dihydro-1H-pyrrolo[2,3-*d*]pyrmidin-5-yl)ethyl]benzoyl]amino]- pentanedioic acid,

[2] (2*S*, 2'*S*) – 2,2'- [[(5*R*)- 2,2'- diamino- 4,4'6-trioxo-1,4,4',6,7,7'-hexahydro-1'*H*, 5*H*-5,6'-bipyrollol[2,3-*d*]pyrimidine-5,5'-diyl]bis(ethylenebenzene-4,1diylcarbonylimin)]dipentanedioic acid,

[3](2*S*, 2'*S*) – 2,2'- [[(5*S*)- 2,2'- diamino- 4,4'6-trioxo-1,4,4',6,7,7'-hexahydro-1'*H*, 5*H*-5,6'-bipyrollol[2,3-*d*]pyrimidine-5,5'-diyl]bis(ethylenebenzene-4,1diylcarbonylimin)]dipentanedioic acid,

to:

Name	Relative retention time
Pemetrexed impurity A[1]	0.82
Pemetrexed impurity B[2]	0.87
Pemetrexed impurity C[3]	0.88
Pemetrexed impurity D[4]	0.90
Pemetrexed impurity E[5]	0.94
Pemetrexed (Retention time: about 26 minute)	1.0

[1](2*S*)-2-[[4-[2-(2-amino-1-methyl-4-oxo-4,7-dihydro-1H-pyrrolo[2,3-*d*]pyrmidin-5 yl)ethyl]benzoyl]amino]- pentanedioic acid,

[2] (2*S*, 2'*S*) – 2,2'- [[(5*R*)- 2,2'- diamino- 4,4'6-trioxo-1,4,4',6,7,7'-hexahydro-1'*H*, 5*H*-5,6'-bipyrollol[2,3-*d*]pyrimidine-5,5'-diyl]bis(ethylenebenzene-4,1diylcarbonylimin)]dipentanedioic acid,

[3](2*S*, 2'*S*) – 2,2'- [[(5*S*)- 2,2'- diamino- 4,4'6-trioxo-1,4,4',6,7,7'-hexahydro-1'*H*, 5*H*-5,6'-bipyrollol[2,3-*d*]pyrimidine-5,5'-diyl]bis(ethylenebenzene-4,1diylcarbonylimin)]dipentanedioic acid,

4(2S)-2-[[(4S)-4-[[4-[2-(2-amino-4-oxo-4,7-dihydro-1H-pyrrolo[2,3-d]pyrimidin-5- yl)ethyl]benzoyl]amino]-4-carboxybutanoyl]amino]pentanedioic acid

[5](2*R*)-2-[[4-[2-(2-amino-4-oxo-4,7-dihydro-1H-pyrrolo[2,3-*d*]pyrmidin-5 yl)ethyl]benzoyl]amino]- pentanedioic acid,

Assay. Chromatographic System. Line 10
Delete. "- a gradient programme using the condition below",

Quetiapine Tablets. Page 2608

Dissolution. Para 3, line 3,4 and 5
Change **to**: Calculate the content of $C_{21}H_{25}N_3O_2S$ in the medium.

Quinidine Sulphate. Page 2610

Dihydroquinidine sulphate. Delete this test.

Quinine Dihydrochloride. Page 2616

Dihydroquinine dihydrochloride. Delete this test.

Quiniodochlor. Page 2621

Loss on drying (2.4.19). Line 3
Change **from**: 24 hours
to: 5 hours

Ramipril and Hydrochlorthiazide. Page 2641

Labelling.
Delete the labeling.

Ritodrine Injection. Page 2675

Related substances. After chromatographic system, para 2, line 7

Add after "reference solution (a) (1.0 per cent)."

" not more than one such peak has an area greater than 0.25 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent)"

Rosuvastatin Tablets. Page 2684

Uniformity of content. *Test solution.*
Change **to**: Disperse one tablet in 50 ml of mobile phase, mix with the aid of ultrasound and dilute to 100 ml with the mobile phase, filter. Dilute further, if necessary, with the mobile phase to produce a solution containing 0 .005 per cent w/v solution of rosuvastatin.
Related substances. *Reference solution (a).*
Change **to**: Dissolve a suitable quantity of *rosuvastatin calcium RS* in the mobile phase to obtain a solution containing 0.05 per cent w/v rosuvstatin

Stearyl Alcohol. Page 2791

Assay. After chromatographic system,
Para 1, Delete the following sentence.
and the relative standard deviation for replicate injections calculated with the area ratio of stearyl alcohol to cetyl alcohol is not more than 1.5 per cent.

Sucralose. Page 2801, 3932

Assay. After chromatographic system, para 1, line 2
Change **from**: 2.0 per cent
to: 2.0.

Travoprost. Page 2904

Assay. Chromatographic system. last line,
Change **from**: 920 100 0
to: 90 100 0

Travoprost Eye Drops. Page 2905

Related substances. *Test solution.*
Change **to**: Dilute the eye drops, if necessary with the solvent mixture, to produce a solution containing 0.004 per cent w/v of travoprost.

Related substance. Para 2, line 2. ,
Change **from**: 5-trans travoprost is 1.05
to**:** 5,6- trans travoprost is 1.1[Note—*Travaprost RS* contains a small percentage of the 5,6- trans isomer]

Related substance. Para 3, line 2.
Change **from**: 5-trans travoprost
to**:** 5,6- trans travoprost

Tropicamide Eye Drops. Page 2929

Related substances. *Test solution.*
Change **to**: Extract a volume containing 50 mg of tropicamide with 10 ml of *chloroform,* filter through *sodium sulphate anhydrous* and dilute to 10.0 ml with *chloroform.*

Para 1, line 1.
Change **from**: 20 µl
to: 40 µl

Voglibose. Page 2979

Specific optical rotation.
Add in the end. **"**at 20° ".

Zidovudine. Page 3003, 3953

Related substances. Para 1, lines 4 to 10
Change **from**: Any secondary spots observed in the chromatogram obtained with the test solution correspond to those of the principal spots in the chromatogram obtained with the reference solution. No secondary spot in the chromatogram obtained with the test solution is more intense than the principal spot in the chromatogram obtained with the reference solution (0.5 per cent).

to: Any secondary spot observed in the chromatogram obtained with the test solution corresponding to triphenylmethanol is not more intense than the corresponding spot in the chromatogram obtained with the reference solution (0.5 per cent). No other secondary spot in the chromatogram obtained with the test solution is more intense than the principal spot in the chromatogram obtained with the reference solution (0.5 per cent).

Vaccines and Immunosera for Human Use

BCG for Immunotherapy. Page 3957.

Production

General Provisions

Para 1, Lines 5 to 7,

Change **from:** Staff involved in production and testing of BCG Vaccine shall be examined periodically for tuberculosis.

to: Staff involved in production and testing of BCG for Immunotherapy shall be examined periodically for tuberculosis.

Para 2, Lines 4 and 5.

Change **from:** The vaccine is prepared from cultures which are derived from the master seed lot

to: The product is prepared from cultures which are derived from the master seed lot

SEED LOT

Bacteria and Fungi.

Change Title **to: Bacterial and Fungal contamination.**

FINAL BULK

Bacteria and Fungi.

Change Title **to: Bacterial and Fungal contamination.**

Virulent mycobacteria.

Change **to:** Examine the final bulk as prescribed under Test using 6 guinea pigs.

FINAL LOT

Tests

Change **to: Bacterial and Fungal contamination.** Carry out the test for sterility (2.2.11). The reconstituted product complies with the test for sterility, except for the presence of mycobacteria.

Temperature stability. Delete the test**.**

Labelling.

Change **to:** The label states (1) the minimum and the maximum number of viable units per vial in the reconstituted product; (2) that the product must be protected from direct sunlight at a temperature between 2 and 8º; (3) for intravescical instillation only; not intended for immunization; (4) to be used immediately after reconstitution.

Biotechnology Products

Erythropoeitin for Injection. Page 3352.

Usual strengths. Read “per vial” as “per container”.

Erythropoeitin Injection. Page 3355.

Usual strengths. Read “per vial” as “per container”.

Filgrastim Concentrated Solution. Page 3359

Identification
C. Determine by size-exclusion chromatography (2.4.16).
Change **to**: In the test for dimers and related substances of higher molecular mass, the retention time of the principal peak obtained with the test solution is similar to that of the principal peak obtained with the reference solution.

Filgrastim Injection. Page 3363

B. Determine by size-exclusion chromatography (2.4.16).
Change **to**: In the test for dimers and related substances of higher molecular mass, the retention time of the principal peak obtained with the test solution is similar to that of the principal peak obtained with the reference solution.

Interferon Alpha 2a Injection. Page 3369.

Tests
pH (2.4.24).
Change **to**: **pH** (2.4.24). Comply with the limits as approved by National Regulatory Authority.

Annexure – IV

(AR&D DIVISION & MONOGRAPHS DEVELOPMENT DIVISION & IP TECHNICAL SECRETARIAT)

List of New monographs to be included in Addendum-2016	
Sl No	**Monographs**
1.	Abiraterone Acetate
2.	Acebutolol Capsules
3.	Analgin
4.	Atomoxetine Capsules
5.	Bendamustine Hydrochloride
6.	Bendamustine Hydrochloride Injection
7.	Benzoyl Peroxide
8.	Bortezomib Injection
9.	Carbidopa and Levodopa Orally Disintegrating Tablets
10.	Celecoxib
11.	Chlorinated Lime
12.	Clobazam Tablets
13.	Colistine Sulphate Oral Suspension
14.	Doxycycline Dispersible Tablets
15.	Drospirenone
16.	Drospirenone and Ethinyl Estradiol Tablets
17.	Drotaverine Hydrochloride
18.	Duloxetine Hydrochloride
19.	Duloxetine Hydrochloride Tablets
20.	Entecavir
21.	Entecavir Tablets
22.	Esomeprazole Magnesium Gastro-resistant Capsules
23.	Exemestane
24.	Exemestane Tablets
25.	Fenofibrate Tablets
26.	Fluconazole Oral Suspension
27.	Fulvestrant
28.	Gabapentin
29.	Gabapentin Capsules
30.	Gabapentin Tablets
31.	Glucosamine Sulphate Sodium Chloride
32.	Indapamide Prolonged-release Tablets
33.	Latanoprost
34.	Levetiracetam

35.	Levetiracetam Oral Solution
36.	Levetiracetam Prolonged-release Tablets
37.	Methocarbamol
38.	Methocarbamol Tablets
39.	Metoprolol Succinate
40.	Metoprolol Succinate Prolonged-Release Tablets
41.	Metronidazole Gel
42.	Nicardipine Hydrochloride
43.	Nifedipine Prolonged-release Capsules
44.	Olmesartan Medoxomil
45.	Pemetrexed disodium for injection
46.	Pioglitazone and Metformin Hydrochloride Tablets
47.	Pirfenidone
48.	Pirfenidone Tablets
49.	S-Dapoxetine
50.	Tacrolimus
51.	Tacrolimus Capsules
52.	Teicoplanin Injection
53.	Tramadol Prolonged-release Tablets
54.	Trifluridine
55.	Trifluridine Eye Drops
56.	Trimebutine Maleate
57.	Trospium Chloride
58.	Venlafexine Hydrochloride
59.	Venlafexine Tablets
60.	Ziprasidone Hydrochloride Monohydrate
61.	Zolmitriptan Nasal Spray
62.	Paroxetine Prolonged Release Tablets
63.	Olmesarten Medoxomil Tabletes

REFERENCE STANDARD DIVISION

Annexure – I (List of Instruments)

S. No.	Name of Equipment	Model/Type/Year of make	Instrument ID	Range & Accuracy
1.	HPLC	Dionex Ultimet 3000	IPC/CHEM/INST/036	U.V. –Vis
2.	HPLC	Dionex Ultimet 3000	IPC/CHEM/INST/037	U.V. –Vis
3.	HPLC	Agilent 1200	IPC/CHEM/INST/043	U.V. –Vis
4.	HPLC	Agilent 1200	IPC/CHEM/INST/042	U.V. –Vis
5.	HPLC	Agilent 1200	IPC/CHEM/INST/018	U.V. –Vis
6.	HPLC	Agilent 1200	IPC/CHEM/INST/019	U.V. –Vis
7.	HPLC	Dionex Ultimet 3000	IPC/CHEM/INST/020	U.V. –Vis
8.	HPLC	Dionex Ultimet 3000	IPC/CHEM/INST/021	U.V. –Vis
9.	TGA/DSC	Star ĕ System Mettler Toledo	IPC/CHEM/INST/032	25-1100^{0}C
10.	FT-IR	Spectrum one Perkin Elmer	IPC/CHEM/INST/007	400-4000cm^{-1}
11.	LC-MS-MS	Agilent 6520	IPC/CHEM/INST/025	20-3000amu
12.	GC-MS Triple Qaud	Agilent 7890A	IPC/CHEM/INST/026	20-1050amu
13.	GC-HS	Agilent 7890A	IPC/CHEM/INST/027	-
14.	HPLC	Waters 2695	IPC/CHEM/INST/002	U.V. –Vis
15.	Analytical Balance	Metter Toledo AT200	IPC/CHEM/INST/006	0.01mg. to 220gm
16.	Analytical Balance	Metter Toledo XP205	IPC/CHEM/INST/028	0.01mg. to 220gm
17.	Analytical Balance	Metter Toledo XP205	IPC/CHEM/INST/029	0.01mg. to 220gm
18.	Volumetric KF Titrator	V30/ Metter Toledo	IPC/CHEM/INST/031	1-5 %
19.	Analytical Balance	Metter Toledo XP205	IPC/CHEM/INST/053	0.01mg. to 220gm
20.	FT-IR Microscope	Perkin Elmer	IPC/CHEM/INST/033	400-4000cm^{-1}
21.	Hot Air Oven	NSW-143	IPC/CHEM/INST/012	ambient to 300^{0}C
22.	Vacuum Oven	NSW (Narang)	IPC/CHEM/INST/009	0-760mm. Hg ambient to 300^{0}C
23.	Serogical Water Bath	Sonar	IPC/CHEM/INST/013	-
24.	Coulometric KF Titrator	Metter Toledo V30	IPC/CHEM/INST/031	-
25.	UV Visible Spectrometer	Perkin Elmer	IPC/CHEM/INST/060	200-800nm
26.	Sonicator	Branson 1510	IPC/CHEM/INST/032	-
27.	Muffle Furnace	Toshiba	IPC/CHEM/INST/010	Ambient to 800^{0}C
28.	Potentiometer	Metter Toledo T50	IPC/CHEM/INST/054	-
29.	NMR	Agilent 500/54/AR	IPC/CHEM/INST/051	500 MHz
30.	Euro Vector – Elemental Analyser	Euro EA 3000	IPC/CHEM/INST/046	-
31.	ICP-MS 6000	Perkin Elmer – Nex ION – 300X	IPC/CHEM/INST/048	-
32.	Ion Chromatography	Dionex-ICS 5000 DC	IPC/CHEM/INST/044	-
33.	Microbalance	Sartorius CPA2P	IPC/CHEM/INST/047	1mg -500mg
34.	Microbalance	Metter Toledo XPTU	IPC/CHEM/INST/030	1mg -500mg

35.	pH Meter	Metter Toledo S No. 1232025343	IPC/CHEM/INST/023	0-14
36.	pH Meter	Metter Toledo S No. 1232085215	IPC/CHEM/INST/024	0-14
37.	pH Meter	Metter Toledo Seven Compact 5220 S No. B236292285	IPC/CHEM/INST/056	0-14
38.	Microbalance	Metter Toledo XPTU	IPC/CHEM/INST/052	1mg -500mg
39.	Water Purifier	Merck Millipore S No BM1NA5237B	IPC/CHEM/INST/038	-
40.	Water Purifier	Merck Millipore S No BM1NA5237E	IPC/CHEM/INST/039	-
41.	Test Dissolution Apparatus	Lab India S.No 6L628	IPC/CHEM/INST/040	-
42.	Particle Size Analyser	Microtrac S3500	IPC/CHEM/INST/049	
43.	Atomic Absorption Spectrometer	Agilent AA250	IPC/CHEM/INST/059	-
44.	Microwave Reaction System	Perkin Elmer Multiwave 3000	IPC/CHEM/INST/062	-
45.	Viscometer	Antonparr Rheolab QC	IPC/CHEM/INST/078	-
46.	Polarimeter	Antonparr MCP200	IPC/CHEM/INST/079	-
47.	Digital Conductivity Meter	Multitech Instrument Co. (P) Ltd.	IPC/CHEM/INST/077	-
48.	DSC 6000	Perkin Elmer	IPC/CHEM/INST/045	Upto 450^{o}C
49.	UV Visible Spectrophotometer	Perkin Elmer	IPC/CHEM/INST/061	200-800nm
50.	Disintegration Test Apparatus	Electrolab	IPC/CHEM/INST/068	-
51.	Centrifuge	REMI, R-4C	IPC/CHEM/INST/057	-

REFERENCE STANDARD DIVISION

Annexure – II (List of IPRS available at IPC Website)

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
1.	Abacavir Sulphate	IPRS/28/13	200mg
2.	Acebutolol Hydrochloride	IPRS/149/12	200 mg
3.	Aceclofenac	IPRS/137/14	200 mg
4.	Acetazolamide	IPRS/135/12	200 mg
5.	Aciclovir	IPRS/15/11	200 mg
6.	Acitretin	IPRS/128/13	200 mg
7.	Agomelatine	IPRS/80/13	200 mg
8.	Albendazole	IPRS/26/14	200 mg
9.	Alfuzosin Hydrochloride	IPRS/121/13	200 mg
10.	Allopurinol	IPRS/01/10	200 mg
11.	Alprazolam	IPRS/14/11	200 mg
12.	Amantadine Hydrochloride	IPRS/243/12	200mg
13.	Ambroxol Hydrochloride	IPRS/121/14	200 mg
14.	Amikacin Sulphate	IPRS/208/12	200 mg
15.	Amiloride Hydrochloride	IPRS/228/12	200 mg
16.	Aminophylline	IPRS/43/11	200 mg
17.	Amiodarone Hydrochloride	IPRS/45/11	200 mg
18.	Amisulpride	IPRS/69/13	200 mg
19.	Amitriptyline Hydrochloride	IPRS/20/11	200 mg
20.	Amlodipine Besylate	IPRS/66/14	200 mg
21.	Amodiaquine Hydrochloride	IPRS/65/10	200 mg
22.	Amoxycillin Sodium	IPRS/218/12	200 mg
23.	Amoxycillin Trihydrate	IPRS/47/14	200 mg
24.	Ampicillin	IPRS/25/13	200mg
25.	Ampicillin Sodium	IPRS/182/12	200 mg
26.	Ampicillin Trihydrate	IPRS/113 /12	200 mg
27.	Anastrozole	IPRS/119/12	50 mg
28.	Aripiprazole	IPRS/68/13	200 mg
29.	Artemether (Artemeteherum)	IPRS/46/12	200 mg
30.	Arterolane Maleate	IPRS/91/13	200 mg
31.	Artesunate	IPRS/88/10	200 mg
32.	Ascorbic Acid (Vit. C)	IPRS/23/12	200 mg
33.	Asenapine Maleate	IPRS/18/14	200 mg
34.	Aspirin	IPRS/136/12	200 mg
35.	Atazanavir Sulphate	IPRS/12/11	200 mg
36.	Atenolol	IPRS/02/10	200 mg
37.	Atomoxetine Hydrochloride	IPRS/114/13	200 mg
38.	Atorvastatin Calcium	IPRS/65/14	200 mg
39.	Atropine Sulphate	IPRS/215/12	50 mg
40.	Azathioprine	IPRS/45/13	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
41.	Azelnidipine	IPRS/90/13	200 mg
42.	Azithromycin	IPRS/62/14	200 mg
43.	Baclofen	IPRS/141/12	200 mg
44.	Bambuterol Hydrochloride	IPRS/10/14	200 mg
45.	Beclomethasone Dipropionate	IPRS/23/14	200 mg
46.	Benzhexol Hydrochloride	IPRS/37/13	200mg
47.	Benzocaine	IPRS/211/12	200 mg
48.	Betacyclodextrin	IPRS/12/14	200 mg
49.	Betahistine Hydrochloride	IPRS/122/12	200 mg
50.	Betamethasone Dipropionate	IPRS/49/13	200 mg
51.	Betamethasone Valerate	IPRS/83/10	25 mg
52.	Bisacodyl	IPRS/98/12	200 mg
53.	Bromhexine Hydrochloride	IPRS/134/13	200 mg
54.	Bronopol	IPRS/107 /12	200 mg
55.	Buclizine Hydrochloride	IPRS/07/13	200 mg
56.	Budesonide	IPRS/244/12	200mg
57.	Buspirone Hydrochloride	IPRS/160/12	200 mg
58.	Caffeine	IPRS/122/14	200 mg
59.	Calcium Gluconate	IPRS/106/12	200 mg
60.	Calcium Levulinate	IPRS/173/12	200 mg
61.	Calcium Pantothenate	IPRS/264/12	200 mg
62.	Capecitabine	IPRS/75/10	200 mg
63.	Captopril	IPRS/125/12	200 mg
64.	Carbamazepine	IPRS/47/11	200 mg
65.	Carbidopa	IPRS/127/12	200 mg
66.	Carboxymethylcellulose Sodium	IPRS/103/13	200 mg
67.	Carvedilol	IPRS/61/10	200 mg
68.	Cefaclor	IPRS/250/12	200mg
69.	Cefadroxil	IPRS/58/13	200 mg
70.	Cefazolin Sodium	IPRS/19/13	200mg
71.	Cefepime Hydrochloride	IPRS/57/10	200 mg
72.	Cefixime	IPRS/36/14	200 mg
73.	Cefoperazone Sodium	IPRS/180/12	200 mg
74.	Cefotaxime Sodium	IPRS/185/12	200 mg
75.	Cefpirome Sulphate	IPRS/05/14	200 mg
76.	Cefpodoxime Proxetil	IPRS/68/14	200 mg
77.	Ceftriaxone Sodium	IPRS/60/13	200 mg
78.	Cefuroxime Axetil	IPRS/32/12	200 mg
79.	Cefuroxime Sodium	IPRS/21/13	200mg
80.	Cephalexin	IPRS/193/12	200 mg
81.	Cetrimide	IPRS/10/12	200 mg
82.	Cetrizine Hydrochloride	IPRS/69/14	200 mg
83.	Chloramphenicol	IPRS/16/12	200 mg
84.	Chloramphenicol Palmitate	IPRS/02/13	200mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
85.	Chlordiazepoxide	IPRS/22/11	200 mg
86.	Chlorhexidine Gluconate Solution	IPRS/122/13	200 mg
87.	Chlorhexidine Hydrochloride	IPRS/24/13	200mg
88.	Chloroquine Phosphate	IPRS/58/12	200 mg
89.	Chloroquine Sulphate	IPRS/59/12	200 mg
90.	Chlorpheniramine Maleate	IPRS/37/14	200 mg
91.	Chlorthalidone	IPRS/09/10	200 mg
92.	Cilastatin Sodium	IPRS/83/12	200 mg
93.	Cilostazol	IPRS/73/13	200 mg
94.	Cimetidine	IPRS/24/11	200 mg
95.	Cinnarizine	IPRS/123/12	200 mg
96.	Ciprofloxacin	IPRS/41/14	200 mg
97.	Ciprofloxacin Hydrochloride	IPRS/67/14	200 mg
98.	Citalopram Hydrobromide	IPRS/69/12	200 mg
99.	Clarithromycin	IPRS/30/14	200 mg
100.	Clindamycin Hydrochloride	IPRS/184/12	200 mg
101.	Clindamycin Phosphate	IPRS/100/13	200 mg
102.	Clobazam	IPRS/161/12	200 mg
103.	Clofazimine	IPRS/257/12	200mg
104.	Clomipramine Hydrochloride	IPRS/137/12	200 mg
105.	Clonazepam	IPRS/124/12	200 mg
106.	Clonidine Hydrochloride	IPRS/63/14	200 mg
107.	Clopidogrel Bisulphate	IPRS/70/14	200 mg
108.	Clotrimazole	IPRS/121/12	200 mg
109.	Cloxacillin Sodium	IPRS/189/12	200 mg
110.	Clozapine	IPRS/111/13	200 mg
111.	Cyanocobalamin (Vit. B12)	IPRS/124/14	200 mg
112.	Cyclizine Hydrochloride	IPRS/224/12	200 mg
113.	Cycloserine	IPRS/16/13	200mg
114.	Cyproheptadine Hydrochloride	IPRS/135/13	200 mg
115.	Cyproterone Acetate	IPRS/65/12	200 mg
116.	Cytarabine	IPRS/134/12	50 mg
117.	Dapoxetine Hydrochloride	IPRS/60/14	200 mg
118.	Dexamethasone Sodium Phosphate	IPRS/203/12	50 mg
119.	Dexlansoprazole	IPRS/96/13	200 mg
120.	Dextromethorphan Hydrobromide	IPRS/141/14	200 mg
121.	Diacerein	IPRS/14/12	200 mg
122.	Diazepam	IPRS/128/12	200 mg
123.	Diclofenac Sodium	IPRS/38/14	200 mg
124.	Dicloxacillin Sodium	IPRS/198/12	200 mg
125.	Dicyclomine Hydrochloride	IPRS/103/12	200 mg
126.	Didanosine	IPRS/241/12	200mg
127.	Dienogest	IPRS/92/13	200 mg
128.	Diethylcarbamazine Citrate	IPRS/251/12	200mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
129.	Diloxanide Furoate	IPRS/99/12	200 mg
130.	Diltiazem Hydrochloride	IPRS/01/13	200mg
131.	Diphenhydramine Hydrochloride	IPRS/26/11	200 mg
132.	Dipyridamole	IPRS/132/13	200 mg
133.	Disodium Edetate	IPRS/108/12	200 mg
134.	Disulfiram	IPRS/162/12	200 mg
135.	Divalproex Sodium	IPRS/93/12	200 mg
136.	Domperidone	IPRS/27/11	200 mg
137.	Domperidone Maleate	IPRS/50/11	200 mg
138.	Donepezil Hydrochloride	IPRS/08/10	200 mg
139.	Dothiepin Hydrochloride	IPRS/06/13	200 mg
140.	Doxepin Hydrochloride	IPRS/05/13	200 mg
141.	Doxofylline	IPRS/77/12	200 mg
142.	Doxycycline Hydrochloride	IPRS/52/13	200 mg
143.	D-Panthenol	IPRS/223/12	200 mg
144.	Dutasteride	IPRS/107/13	200 mg
145.	Ebastine	IPRS/64/13	200 mg
146.	Efavirenz	IPRS/236/12	200mg
147.	Eletriptan Hydrobromide	IPRS/97/13	200 mg
148.	Emtricitabine	IPRS/34/13	200mg
149.	Enalapril Maleate	IPRS/127/14	200 mg
150.	Enrofloxacin	IPRS/42/13	200 mg
151.	Entacapone	IPRS/71/13	200 mg
152.	Ephedrine Hydrochloride	IPRS/177/12	200 mg
153.	Eplerenone	IPRS/06/14	200 mg
154.	Ergotamine Tartrate	IPRS/261/12	50mg
155.	Erythromycin	IPRS/51/13	200 mg
156.	Erythromycin Estolate	IPRS/05/10	200 mg
157.	Erythromycin Stearate	IPRS/114 /12	200 mg
158.	Escitalopram Oxalate	IPRS/76/10	200 mg
159.	Eslicarbazepine Acetate	IPRS/17/14	200 mg
160.	Esomeprazole Magnesium Trihydrate	IPRS/52/11	200 mg
161.	Ethambutol Hydrochloride	IPRS/262/12	200 mg
162.	Ethinylestradiol	IPRS/86/10	25 mg
163.	Ethionamide	IPRS/235/12	200mg
164.	Ethyl Vanillin	IPRS/07/14	200 mg
165.	Etidronate Disodium	IPRS/46/13	200 mg
166.	Etodolac	IPRS/49/12	200 mg
167.	Etophylline	IPRS/13/14	200 mg
168.	Etoposide	IPRS/232/12	200mg
169.	Etoricoxib	IPRS/65/13	200 mg
170.	Ezetimibe	IPRS/77/13	200 mg
171.	Famciclovir	IPRS/72/13	200 mg
172.	Famotidine	IPRS/29/11	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
173.	Felodipine	IPRS/11/13	200 mg
174.	Fenbendazole	IPRS/138/12	200 mg
175.	Fenofibrate	IPRS/67/12	200 mg
176.	Fenspiride Hydrochloride	IPRS/89/13	200 mg
177.	Ferrous Fumarate	IPRS/156/12	200 mg
178.	Ferrous Gluconate	IPRS/190/12	200 mg
179.	Fexofenadine Hydrochloride	IPRS/03/11	200 mg
180.	Finasteride	IPRS/29/12	200 mg
181.	Flucloxacillin Sodium	IPRS/119/13	200 mg
182.	Fluconazole	IPRS/128/14	200 mg
183.	Fluorouracil	IPRS/126/12	200 mg
184.	Fluoxetine Hydrochloride	IPRS/21/11	200 mg
185.	Flurbiprofen Sodium	IPRS/221/12	50 mg
186.	Flutamide	IPRS/12/13	200 mg
187.	Fluticasone Propionate	IPRS/120/12	200 mg
188.	Fluvastatin Sodium	IPRS/116/13	200 mg
189.	Folic Acid	IPRS/18/12	200 mg
190.	Fosinopril Sodium	IPRS/120/13	200 mg
191.	Frusemide/Furosemide	IPRS/29/14	200 mg
192.	Fumaric Acid	IPRS/04/14	200 mg
193.	Furazolidone	IPRS/191/12	200 mg
194.	Fusidic Acid	IPRS/246/12	200mg
195.	Galanthamine Hydrobromide	IPRS/84/13	200 mg
196.	Gatifloxacin	IPRS/188/12	200 mg
197.	Gefitinib	IPRS/240/12	200mg
198.	Gemcitabine Hydrochloride	IPRS/131/13	200 mg
199.	Gemfibrozil	IPRS/115/13	200 mg
200.	Gemifloxacin Mesylate	IPRS/247/12	200mg
201.	Gentamicin Sulphate	IPRS/133/12	200mg
202.	Glibenclamide	IPRS/12/12	200 mg
203.	Gliclazide	IPRS/54/11	200 mg
204.	Glimepiride	IPRS/49/14	200 mg
205.	Glipizide	IPRS/30/11	200 mg
206.	Glycine	IPRS/30/13	200mg
207.	Griseofulvin	IPRS/254/12	200mg
208.	Guaiphenesin	IPRS/130/14	200 mg
209.	Haloperidol	IPRS/163/12	200 mg
210.	Homatropine Hydrobromide	IPRS/61/13	200 mg
211.	Homatropine Methylbromide	IPRS/04/13	200 mg
212.	Hydralazine Hydrochloride	IPRS/263/12	200 mg
213.	Hydrochlorothiazide	IPRS/07/10	200 mg
214.	Hydrocortisone Acetate	IPRS/15/13	200mg
215.	Hydrocortisone Sodium Succinate	IPRS/14/14	200 mg
216.	Hydroxyzine Hydrochloride	IPRS/74/13	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
217.	Hyoscine Butyl Bromide	IPRS/132/12	50 mg
218.	Ibuprofen	IPRS/144/14	200 mg
219.	Ilaprazole	IPRS/86/13	200 mg
220.	Iloperidone	IPRS/106/13	50 mg
221.	Imatinib Mesylate	IPRS/118/12	200 mg
222.	Imidurea	IPRS/102/13	200 mg
223.	Imipramine Hydrochloride	IPRS/15/12	200 mg
224.	Indapamide	IPRS/51/12	200 mg
225.	Indomethacin	IPRS/233/12	200mg
226.	Irbesartan	IPRS/78/13	200 mg
227.	Isoniazid	IPRS/25/10	200 mg
228.	Isosorbide Dinitrate Diluted (40 %)	IPRS/92/12	200 mg
229.	Isoxsuprine Hydrochloride	IPRS/159/12	200 mg
230.	Ivermectin	IPRS/70/12	200 mg
231.	Ketamine Hydrochloride	IPRS/26/10	200 mg
232.	Ketoconazole	IPRS/34/12	200 mg
233.	Ketoprofen	IPRS/22/13	200mg
234.	Ketorolac Tromethamine	IPRS/05/12	200 mg
235.	Labetalol Hydrochloride	IPRS/195/12	200 mg
236.	Lamivudine	IPRS/237/12	200mg
237.	Lamotrigine	IPRS/66/10	200 mg
238.	Lansoprazole	IPRS/84/12	200 mg
239.	Leflunomide	IPRS/67/13	200 mg
240.	Levamisole Hydrochloride	IPRS/178/12	200 mg
241.	Levocetirizine Hydrochloride	IPRS/72/14	200 mg
242.	Levodopa	IPRS/131/12	200 mg
243.	Levofloxacin Hemihydrate	IPRS/04/11	200 mg
244.	Levonorgestrel	IPRS/20/14	200 mg
245.	Levosalbutamol Sulphate	IPRS/248/12	200mg
246.	Lignocaine Hydrochloride	IPRS/204/12	200 mg
247.	Lindane (Gamma Benzene Hexachloride)	IPRS/19/12	200 mg
248.	Linezolid	IPRS/209/12	200 mg
249.	Lisinopril	IPRS/85/12	200 mg
250.	Lithium Carbonate	IPRS/164/12	200 mg
251.	Loperamide Hydrochloride	IPRS/152/12	200 mg
252.	Lopinavir	IPRS/77/10	200 mg
253.	Lorazepam	IPRS/11/14	200 mg
254.	Losartan Potassium	IPRS/35/10	200 mg
255.	Magaldrate	IPRS/105/12	200 mg
256.	Mannitol	IPRS/110 /12	200 mg
257.	Mebendazole	IPRS/102/12	200 mg
258.	Mebeverine Hydrochloride	IPRS/153/12	200 mg
259.	Meclizine Hydrochloride	IPRS/42/10	200 mg
260.	Mefenamic Acid	IPRS/181/12	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
261.	Mefloquine Hydrochloride	IPRS/13/11	200 mg
262.	Meloxicam	IPRS/104/13	200 mg
263.	Meropenem	IPRS/91/12	200 mg
264.	Mesalazine	IPRS/76/13	200 mg
265.	Metformin Hydrochloride	IPRS/131/14	200 mg
266.	Methotrexate	IPRS/231/12	200mg
267.	Methyl Prednisolone	IPRS/133/13	200 mg
268.	Methyl Salicylate	IPRS/234/12	200 mg
269.	Methyldopa	IPRS/20/13	200mg
270.	Methylprednisolone Acetate	IPRS/214/12	50 mg
271.	Metoclopramide Hydrochloride	IPRS/11/10	200 mg
272.	Metoprolol Tartrate	IPRS/04/10	200 mg
273.	Metronidazole	IPRS/42/14	200 mg
274.	Metronidazole Benzoate	IPRS/37/12	200 mg
275.	Miconazole Nitrate	IPRS/256/12	200mg
276.	Mifepristone	IPRS/22/14	200 mg
277.	Minoxidil	IPRS/226/12	200 mg
278.	Mometasone Furoate	IPRS/02/14	200 mg
279.	Montelukast Sodium	IPRS/31/12	200 mg
280.	Mosapride Citrate Dihydrate	IPRS/144/12	200 mg
281.	Moxifloxacin Hydrochloride	IPRS/110/13	200 mg
282.	Mycophenolate Mofetil	IPRS/45/10	200 mg
283.	Nandrolone Phenyl Propionate	IPRS/19/10	200 mg
284.	Naproxen	IPRS/04/12	200 mg
285.	Nebivolol Hydrochloride	IPRS/56/11	200 mg
286.	Neomycin Sulphate	IPRS/154/12	200 mg
287.	Nevirapine	IPRS/49/10	200 mg
288.	Nicotinamide (Niacinamide)	IPRS/38/12	200 mg
289.	Nicotinic Acid (Niacin)	IPRS/39/12	200 mg
290.	Nicoumalone	IPRS/41/12	200 mg
291.	Nifedipine	IPRS/57/11	200 mg
292.	Nitrazepam	IPRS/227/12	200 mg
293.	Nitrofurantoin	IPRS/196/12	200 mg
294.	Norethisterone	IPRS/24/14	200 mg
295.	Norfloxacin	IPRS/117/12	200 mg
296.	Nortriptyline Hydrochloride	IPRS/09/13	200 mg
297.	Nystatin	IPRS/253/12	200 mg
298.	Ofloxacin	IPRS/40/14	200 mg
299.	Olanzapine	IPRS/09/11	200 mg
300.	Omeprazole	IPRS/146/14	200 mg
301.	Ondansetron	IPRS/26/13	200mg
302.	Ondansetron Hydrochloride	IPRS/71/10	200 mg
303.	Ormeloxifene Hydrochloride	IPRS/21/14	200 mg
304.	Ornidazole	IPRS/75/14	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
305.	Orphenadrine Citrate	IPRS/229/12	200 mg
306.	Oseltamivir Phosphate	IPRS/78/10	200 mg
307.	Oxacillin Sodium	IPRS/118/13	200 mg
308.	Oxcarbazepine	IPRS/145/12	200 mg
309.	Pantoprazole Sodium Sesquihydrate	IPRS/79/10	200 mg
310.	Paracetamol	IPRS/54/14	200 mg
311.	Penicillamine	IPRS/17/13	200mg
312.	Pentazocine	IPRS/35/13	200mg
313.	Pheniramine Maleate	IPRS/199/12	200 mg
314.	Phenobarbitone	IPRS/17/12	200 mg
315.	Phenoxyethanol	IPRS/249/12	200 mg
316.	Phenoxymethylpenicillin Potassium	IPRS/252/12	200mg
317.	Phenylephrine Hydrochloride	IPRS/133/14	200 mg
318.	Phenylpropanolamine Hydrochloride	IPRS/197/12	200 mg
319.	Phenytoin Sodium	IPRS/31/11	200 mg
320.	Pioglitazone Hydrochloride	IPRS/56/14	200 mg
321.	Piperacillin	IPRS/43/13	200 mg
322.	Piracetam	IPRS/32/11	200 mg
323.	Piroxicam	IPRS/170/12	200 mg
324.	Potassium Citrate	IPRS/157/12	200 mg
325.	Potassium Sorbate	IPRS/112 /12	200 mg
326.	Povidone-Iodine	IPRS/212/12	200 mg
327.	Praziquantel	IPRS/63/12	50 mg
328.	Prednisolone Acetate	IPRS/219/12	200 mg
329.	Prednisolone Sodium Phosphate	IPRS/169/12	200 mg
330.	Pregabalin	IPRS/55/14	200 mg
331.	Primaquine Phosphate	IPRS/259/12	200 mg
332.	Probenecid	IPRS/32/10	200 mg
333.	Prochlorperazine Maleate	IPRS/166/12	200 mg
334.	Proguanil Hydrochloride	IPRS/12/10	200 mg
335.	Promethazine Hydrochloride	IPRS/89/12	200 mg
336.	Promethazine Theoclate	IPRS/167/12	200 mg
337.	Propranolol Hydrochloride	IPRS/32/14	200 mg
338.	Propyphenazone	IPRS/60/12	200 mg
339.	Pseudoephedrine Hydrochloride	IPRS/158/12	200 mg
340.	Pyrantel Pamoate	IPRS/73/10	200 mg
341.	Pyrazinamide	IPRS/27/10	200 mg
342.	Pyridoxine Hydrochloride (Vit. B6)	IPRS/76/14	200 mg
343.	Pyrimethamine	IPRS/13/10	200 mg
344.	Quetiapine Fumarate	IPRS/60/11	200 mg
345.	Quinine Dihydrochloride	IPRS/129/12	200 mg
346.	Quinine Sulphate	IPRS/28/14	200 mg
347.	Quiniodochlor	IPRS/174/12	200 mg
348.	Rabeprazole Sodium	IPRS/134/14	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
349.	Racecadotril	IPRS/124/13	200 mg
350.	Raloxifene Hydrochloride	IPRS/108/13	200 mg
351.	Ramipril	IPRS/08/11	200 mg
352.	Ranitidine Hydrochloride	IPRS/08/12	200 mg
353.	Repaglinide	IPRS/109/13	200 mg
354.	Ribavirin	IPRS/151/12	200 mg
355.	Riboflavin	IPRS/258/12	200mg
356.	Rilpivirine	IPRS/88/13	200 mg
357.	Risedronate Sodium	IPRS/66/13	200 mg
358.	Ritodrine Hydrochloride	IPRS/130/13	200 mg
359.	Ritonavir	IPRS/10/13	200 mg
360.	Roflumilast	IPRS/81/13	200 mg
361.	Rosuvastatin Calcium	IPRS/135/14	200 mg
362.	Roxithromycin	IPRS/80/10	200 mg
363.	Rufinamide	IPRS/82/13	200 mg
364.	Rupatadine Fumarate	IPRS/123/13	50 mg
365.	S(-)Amlodipine Besylate	IPRS/01/11	200 mg
366.	Salbutamol	IPRS/01/14	200 mg
367.	Salbutamol Sulphate	IPRS/54/13	200 mg
368.	Salicylic Acid	IPRS/80/14	200 mg
369.	Salmeterol Xinafoate	IPRS/62/12	50 mg
370.	Saquinavir Mesylate	IPRS/242/12	200mg
371.	Secnidazole	IPRS/01/12	200 mg
372.	Sildenafil Citrate	IPRS/77/14	200 mg
373.	Simvastatin	IPRS/50/13	200 mg
374.	Sodium Valproate	IPRS/94/12	200 mg
375.	Spiramycin	IPRS/22/12	200mg
376.	Stavudine	IPRS/239/12	200mg
377.	Sulphadimidine	IPRS/41/13	200 mg
378.	Sulphadoxine	IPRS/81/12	200 mg
379.	Sulphamethoxazole	IPRS/115 /12	200 mg
380.	Sumatriptan Succinate	IPRS/27/13	200mg
381.	Tamoxifen Citrate	IPRS/230/12	200 mg
382.	Tamsulosin Hydrochloride	IPRS/86/12	200 mg
383.	Tapentadol Hydrochloride	IPRS/94/13	200 mg
384.	Telmisartan	IPRS/78/14	200 mg
385.	Tenofovir Disproxil Fumarate	IPRS/58/10	200 mg
386.	Terazosin Hydrochloride	IPRS/130/12	200 mg
387.	Terbutaline Sulphate	IPRS/136/13	200 mg
388.	Testosterone Propionate	IPRS/64/14	200 mg
389.	Theophylline	IPRS/155/12	200 mg
390.	Thiamine Hydrochloride (Vit. B1)	IPRS/40/11	200 mg
391.	Thiamine Mononitrate	IPRS/255/12	200mg
392.	Thiocolchicoside	IPRS/171/12	200 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
393.	Thyroxine Sodium (Levothyroxine Sodium)	IPRS/105/13	200 mg
394.	Timolol Maleate	IPRS/207/12	50 mg
395.	Tinidazole	IPRS/36/12	200 mg
396.	Tizanidine Hydrochloride	IPRS/03/12	200 mg
397.	Tocopheryl Acetate	IPRS/14/13	200mg
398.	Tolnaftate	IPRS/33/12	200 mg
399.	Tolterodine Tartrate	IPRS/87/12	200 mg
400.	Tolvaptan	IPRS/93/13	200 mg
401.	Topiramate	IPRS/11/11	200 mg
402.	Topotecan Hydrochloride	IPRS/19/11	100 mg
403.	Tramadol Hydrochloride	IPRS/42/12	200 mg
404.	Tranexamic Acid	IPRS/03/14	200 mg
405.	Triamcinolone	IPRS/17/10	200 mg
406.	Triamcinolone Acetonide	IPRS/21/10	200 mg
407.	Triamterene	IPRS/90/12	200 mg
408.	Trimetazidine Hydrochloride	IPRS/172/12	200 mg
409.	Trimethoprim	IPRS/34/14	200 mg
410.	Triprolidine Hydrochloride	IPRS/225/12	200 mg
411.	Tropicamide	IPRS/216/12	50 mg
412.	Udenafil	IPRS/79/13	200 mg
413.	Ursodeoxycholic Acid	IPRS/101/13	200 mg
414.	Valproic Acid	IPRS/140/12	200 mg
415.	Valsartan	IPRS/07/11	200 mg
416.	Verapamil Hydrochloride	IPRS/25/12	200 mg
417.	Warfarine Sodium	IPRS/54/12	200 mg
418.	Warfarine Sodium Clathrate	IPRS/55/12	200 mg
419.	Xylometazoline Hydrochloride	IPRS/205/12	50 mg
420.	Zidovudine	IPRS/238/12	200mg
421.	Zoledronic Acid	IPRS/53/12	200 mg
422.	Zolpidem Tartrate	IPRS/10/11	200 mg
423.	2-Methyl-5-nitro imidazole (impurity)	IMP/01/12	20 mg
424.	Potassium Monoethyl Sulphate (impurity)	IMP/01/11	25 mg
425.	7-aminodesacetoxycephalosporanic acid	IMP/001/13	20 mg
426.	E-isomers (Cefuroxime Axetil Impurity)	IMP/002/13	20 mg
427.	D3-isomers (Cefuroxime Axetil Impurity)	IMP/003/13	20 mg
428.	Dicyandiamide	IMP/004/13	20 mg
429.	6,7-dimethoxy-2-(piperazin-1-yl) quinazolin-4-	IMP/005/13	20 mg
430.	2-chloro-6,7-dimethoxyquinazolin-4-amine	IMP/006/13	20 mg
431.	Triphenylmethanol	IMP/007/13	20 mg
432.	zidovudine–related compound B	IMP/008/13	20 mg
433.	Azithromycin impurity A	IMP/01/14	20 mg
434.	Guanine	IMP/02/14	20 mg
435.	Meso ethambutol (RS isomer)	IMP/03/14	20 mg
436.	Lamivudine impurity C	IMP/04/14	20 mg

S. No.	Name of Reference Substance	Lot No.	Qnty./Vial
437.	Guaiphenesin impurity A	IMP/05/14	1 ml
438.	Phenoxyacetic acid	IMP/06/14	20 mg
439.	4-aminophenol	IMP/07/14	20 mg
440.	4-nitrophenol	IMP/08/14	20 mg
441.	4- chloroacetanilide	IMP/09/14	20 mg
442.	Mesityl oxide	IMP/10/14	1 ml

REFERENCE STANDARD DIVISION

Annexure – III (List of IPRS Developed and Updated)

S.No.	Name of IPRS	LOT No.	Qty
1.	Nortriptyline Hydrochloride	IPRS/09/13	200 mg
2.	Erythromycin	IPRS/51/13	200 mg
3.	Doxycycline Hydrochloride	IPRS/52/13	200 mg
4.	Salbutamol Sulphate	IPRS/54/13	200 mg
5.	Cefadroxil	IPRS/58/13	200 mg
6.	Ceftriaxone Sodium	IPRS/60/13	200 mg
7.	Homatropine Hydrobromide	IPRS/61/13	200 mg
8.	Ebastine	IPRS/64/13	200 mg
9.	Etoricoxib	IPRS/65/13	200 mg
10.	Risedronate Sodium	IPRS/66/13	200 mg
11.	Leflunomide	IPRS/67/13	200 mg
12.	Aripiprazole	IPRS/68/13	200 mg
13.	Amisulpride	IPRS/69/13	200 mg
14.	Entacapone	IPRS/71/13	200 mg
15.	Famciclovir	IPRS/72/13	200 mg
16.	Cilostazol	IPRS/73/13	200 mg
17.	Hydroxyzine Hydrochloride	IPRS/74/13	200 mg
18.	Mesalazine	IPRS/76/13	200 mg
19.	Ezetimibe	IPRS/77/13	200 mg
20.	Irbesartan	IPRS/78/13	200 mg
21.	Udenafil	IPRS/79/13	200 mg
22.	Agomelatine	IPRS/80/13	200 mg
23.	Roflumilast	IPRS/81/13	200 mg
24.	Rufinamide	IPRS/82/13	200 mg
25.	Galanthamine Hydrobromide	IPRS/84/13	200 mg
26.	Ilaprazole	IPRS/86/13	200 mg
27.	Rilpivirine	IPRS/88/13	200 mg
28.	Fenspiride Hydrochloride	IPRS/89/13	200 mg
29.	Azelnidipine	IPRS/90/13	200 mg
30.	Arterolane Maleate	IPRS/91/13	200 mg
31.	Dienogest	IPRS/92/13	200 mg
32.	Tolvaptan	IPRS/93/13	200 mg
33.	Tapentadol Hydrochloride	IPRS/94/13	200 mg
34.	Dexlansoprazole	IPRS/96/13	200 mg
35.	Eletriptan Hydrobromide	IPRS/97/13	200 mg
36.	Calcium Pantothenate	IPRS/264/12	200 mg
37.	Clindamycin Phosphate	IPRS/100/13	200 mg
38.	Ursodeoxycholic Acid	IPRS/101/13	200 mg
39.	Imidurea	IPRS/102/13	200 mg

40.	Carboxymethylcellulose Sodium	IPRS/103/13	200 mg
41.	Meloxicam	IPRS/104/13	200 mg
42.	Dutasteride	IPRS/107/13	200 mg
43.	Raloxifene Hydrochloride	IPRS/108/13	200 mg
44.	Repaglinide	IPRS/109/13	200 mg
45.	Moxifloxacin Hydrochloride	IPRS/110/13	200 mg
46.	Clozapine	IPRS/111/13	200 mg
47.	Atomoxetine Hydrochloride	IPRS/114/13	200 mg
48.	Gemfibrozil	IPRS/115/13	200 mg
49.	Fluvastatin Sodium	IPRS/116/13	200 mg
50.	Oxacillin Sodium	IPRS/118/13	200 mg
51.	Flucloxacillin Sodium	IPRS/119/13	200 mg
52.	Fosinopril Sodium	IPRS/120/13	200 mg
53.	Alfuzosin Hydrochloride	IPRS/121/13	200 mg
54.	Chlorhexidine Gluconate Solution	IPRS/122/13	200 mg
55.	Racecadotril	IPRS/124/13	200 mg
56.	Acitretin	IPRS/128/13	200 mg
57.	Ritodrine Hydrochloride	IPRS/130/13	200 mg
58.	Gemcitabine Hydrochloride	IPRS/131/13	200 mg
59.	Dipyridamole	IPRS/132/13	200 mg
60.	Amikacin Sulphate	IPRS/208/12	200 mg
61.	Thyroxine Sodium (Levothyroxine Sodium)	IPRS/105/13	200 mg
62.	Iloperidone	IPRS/106/13	50 mg
63.	Rupatadine Fumarate	IPRS/123/13	50 mg
64.	Salbutamol	IPRS/01/14	200 mg
65.	Tranexamic Acid	IPRS/03/14	200 mg
66.	Fumaric Acid	IPRS/04/14	200 mg
67.	Cefpirome Sulphate	IPRS/05/14	200 mg
68.	Eplerenone	IPRS/06/14	200 mg
69.	Ethyl Vanillin	IPRS/07/14	200 mg
70.	Bambuterol Hydrochloride	IPRS/10/14	200 mg
71.	Lorazepam	IPRS/11/14	200 mg
72.	Betacyclodextrin	IPRS/12/14	200 mg
73.	Etophylline	IPRS/13/14	200 mg
74.	Hydrocortisone Sodium Succinate	IPRS/14/14	200 mg
75.	Eslicarbazepine Acetate	IPRS/17/14	200 mg
76.	Asenapine Maleate	IPRS/18/14	200 mg
77.	Levonorgestrel	IPRS/20/14	200 mg
78.	Ormeloxifene Hydrochloride	IPRS/21/14	200 mg
79.	Mifepristone	IPRS/22/14	200 mg
80.	Albendazole	IPRS/26/14	200 mg
81.	Quinine Sulphate	IPRS/28/14	200 mg
82.	Dapoxetine Hydrochloride	IPRS/60/14	200 mg
83.	Azithromycin	IPRS/62/14	200 mg

84.	Clonidine Hydrochloride	IPRS/63/14	200 mg
85.	Salicylic Acid	IPRS/80/14	200 mg
86.	6-demethylazithromycin (Azithromycin impurity A)	IMP/01/14	20 mg
87.	Guanine	IMP/02/14	20 mg
88.	Meso ethambutol (RS isomer)	IMP/03/14	20 mg
89.	2-hydroxybenzenecarboxylic acid (salicylic acid) (Lamivudine impurity C)	IMP/04/14	20 mg
90.	2-methoxyphenol (guaiacol) (guaiphenesin impurity A)	IMP/05/14	1 ml
91.	Phenoxyacetic acid	IMP/06/14	20 mg
92.	4-aminophenol	IMP/07/14	20 mg
93.	4-nitrophenol	IMP/08/14	20 mg
94.	4- chloroacetanilide	IMP/09/14	20 mg
95.	Mesityl oxide	IMP/10/14	1 ml

REFERENCE STANDARD DIVISION

Annexure – IV (List of IPRS Under Validation)

S.No.	Name of IPRS	Lot No.
1.	Docusate Sodium	IPRS/81/14
2.	Isotretinoin	IPRS/82/14
3.	Povidone	IPRS/83/14
4.	Propylparaben	IPRS/84/14
5.	Malic Acid	IPRS/85/14
6.	Cetostearyl Alcohol	IPRS/89/14
7.	Methylparaben	IPRS/91/14
8.	Crospovidone	IPRS/92/14
9.	Cellulose Acetate Phthalate (CAP)	IPRS/93/14
10.	Chlorpromazine Hydrochloride	IPRS/94/14
11.	Miconazole	IPRS/95/14
12.	Butyl Hydroxytoluene	IPRS/97/14
13.	Menthol	IPRS/98/14
14.	Diethyl Phthalate	IPRS/99/14
15.	Citric Acid	IPRS/100/14
16.	Sodium Starch Glycolate	IPRS/101/14
17.	Saccharine Sodium	IPRS/102/14
18.	Fluvoxamine Maleate	IPRS/103/14
19.	Stearic Acid	IPRS/166/14
20.	piperazine (hexahydrate)	IPRS/167/14
21.	Ceftazidime	IPRS/168/14
22.	Betamethasone	IPRS/169/14
23.	Prednisolone	IPRS/170/14
24.	Indinavir Sulphate	IPRS/171/14
25.	Sorbitol	IPRS/172/14
26.	Flurbiprofen	IPRS/173/14
27.	Sodium Lauryl Sulphate	IPRS/174/14
28.	Oxytetracycline	IPRS/175/14
29.	Danazol	IPRS/176/14
30.	Menthone	IPRS/01/15
31.	Eugenol	IPRS/02/15
32.	Quercetin	IPRS/03/15
33.	Linalool	IPRS/04/15
34.	Camphor	IPRS/05/15
35.	Borneol	IPRS/06/15
36.	thymidine (Stavudine)	IMP/11/14
37.	2-Ethylhexanoic acid (Amoxycillin Sodium/ Dicloxacillin Sodium)	IMP/12/14
38.	hydrazine sulphate (Hydralazine Hydrochloride/ Isoniazid)	IMP/13/14
39.	piperazine (hexahydrate) (trimetazidine impurity G)	IMP/14/14
40.	N, N-Dimethylaniline (Ampicillin/ Ampicillin Sodium/ Ampicillin Trihydrate/ Amoxycillin Sodium/ Amoxycillin Trihydrate/ Cloxacillin Sodium/ Dextromethorphan Hydrobromide/ Dicloxacillin Sodium/ Piperacillin)	IMP/16/14

41.	palmitic acid (Stearic Acid, Sorbitan Oleate, Propofol Injection)	IMP/17/14
42.	thymine (zidovudine impurity C/ Stavudine)	IMP/18/14
43.	theobromine (Theophylline)	IMP/19/14
44.	5-Chloro-1-methyl-4-nitroimidazole (Azathioprine)	IMP/20/14
45.	thiourea (Quinine Sulphate/ Quinidine Sulphate/ Quinine Bisulphate/ Quinine Dihydrochloride)	IMP/21/14
46.	imidazole (Ondansetron Hydrochloride/ Clotrimazole impurity D)	IMP/22/14
47.	[(+)-(S)-(o-chlorophenyl)-6,7-dihydrothieno(3,2-c]pyridine-5(4H)-acetic acid] RS (clopidogrel bisulphate) (clopidogrel impurity A RS)	IMP/24/14
48.	montelukast styrene (montelukast sodium)	IMP/25/14
49.	montelukast sulphoxide isomers (montelukast sodium)	IMP/26/14
50.	Irbesartan Impurity A (Irbesartan)	IMP/27/14

REFERENCE STANDARD DIVISION

Annexure – V (List of ILC Samples/PT Samples)

S.No.	Name of NDS received	Registration No.
1	Buprenorphine Tablets IP	MISC/86/14
2	Cefixime Tablets	MISC/98/14
3	Ceftriaxone Injection	MISC/99/14
4	Ciprofloxacin Tablets	MISC/100/14
5	Diclofenac Sodium Tablets	MISC/101/14
6	Tinidazole Tablets	MISC/102/14
7	ILC for Essential Oil	MISC/115/14
8	ILC for Fragrance	MISC/116/14
9	Ebastine (200 mg)	MISC/117/14
10	Caffeine Injection	MISC/124/14
11	Buffer Solution Q1	MISC/125/14
12	Sodium Chloride Solution 0.7%	MISC/126/14
13	Buffer Solution P1	MISC/133/14
14	Unknown PT samples from NDTL, New Delhi	MISC/141/14
15	Sodium chloride Injection	MISC/144/14
16	Sodium chloride & dextrose Injection	MISC/145/14
17	Rifampicin	MISC/149/14
18	Oral Rehyhydration salt	MISC/14-a/15
19	Amoxycillin trihydarte Capsules	MISC/14-b/15

Annexure – VI (List of Impurities Developed)

S.No	Name of the API	Chromatographic Purity	Yield	Name of the Impurity
1.	Montelukast Sodium	81.77%	48.78g	Montelukast Sulphoxide
2.	Montelukast Sodium	89.71%	29.59g	Montelukast Styrene
3.	Clopidogral Bisulphate	95.69%	7.47g	Clopidogral Impurity A ((+)-(S)-(o-chlorophenyl)-6,7-dihydrothieno(3,2-c]pyridine-5(4H0-acetic acid)
4.	Irbesartan	98.12%	22.42g	Irbesartan Impurity A (1-(pentonoylamino)-N-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]cyclopentane-carboxamide)
5.	Baclofen	99.84%	4.63g	Baclofen Impurity A ((4RS)-4-(4-
6.	Diclofenac	77.05%	21.54g	chlorophenyl)pyrrolidin-2-one)
7.	Pregabalin	95.54%	2.12g	Pregabalin Lactum
8.	Chloramophenicol	99.72%	28.16g	2-Amino-1-(4-nitrophenyl)propane-1,3-diol
9.	Bromhexine Hydrochloride	73.12%	0.02g	Impurity D (4-Bromo-2-((cyclohexyl(methyl)amino)methyl)aniline

STORE DIVISION

Annexure (List of All Hi-End Scientific Equipment Procured)

S.No.	Ref. No.	Order Date	Vendor	Items	Qty
1	IPC 01	28.09.2010	Agilent Tech	**LCMS-MS**	1
2	IPC 01	28.09.2010	Agilent Tech	**GCMS-MS**	1
3	IPC 01	28.09.2010	Agilent Tech	**HPLC (PDA/RI/FLORANCE/ECD)**	2
4	IPC 01	28.09.2010	Dionex India	**FAST HPLC**	2
5	IPC 01	28.09.2010	Agilent Tech	**GC HEAD SPACE WITH FID**	1
6	IPC 03	30.03.2011	Mettler Toledo	**ANA. BAL 5 DIG.**	3
7	IPC 03	30.03.2011	Mettler Toledo	**ANA. MICRO BAL 7 DIG.**	1
8	IPC 02	18.02.2011	Shiva Global	**CHNS ANALYZER**	1
9	IPC 02	18.02.2011	Agilent Tech	**HPLC (PDA)**	2
10	IPC 02	18.02.2011	Agilent Tech	**AAS**	1
11	IPC 03	30.03.2011	Mettler Toledo	**K F TITRATOR**	2
12	IPC 03	30.03.2011	Perkin Elmer	**ICP-MS**	1
13	IPC 03	30.03.2011	Perkin Elmer	**DSC**	1
14	IPC 03	30.03.2011	Mettler Toledo	**TGA**	1
15	IPC 03	30.03.2011	Agilent Tech	**NMR**	1
16	IPC 01	30.03.2011	Agilent Tech	**HPLC (PDA/RI/FLORANCE/ECD)**	1
17	IPC 01	30.03.2011	Dionex India	**FAST HPLC**	1
18	IPC 03	21.05.2011	Perkin Elmer	**FTIR with Microscope**	1
19	IPC 03	21.05.2011	Dionex India	**HPLC (UV)**	2
20	IPC 04	27.10.2011	Mettler Toledo	**K F with Coulometer**	1
21	IPC 04	27.10.2011	Metrohm India	**Laser Particle Size Analyzer**	1
22	IPC 04	27.10.2011	Millipore India	**Water Purification System**	2
23	IPC 04	27.10.2011	Dionex India	**Ion Chromatography System**	1
24	IPC 07	05-02-2013	Mettler Toledo	**Analytical balance 5 digit**	1
25	IPC 07	05-02-2013	Mettler Toledo	**Analytical micro balance 7 digit**	1
26	IPC 05	21.03.2013	Agilent Tech	**HPLC system with Accessories**	1
27	IPC 05	21.03.2013	Agilent Tech	**FTIR System with Accessories**	1
28	IPC 05	21.03.2013	Perkin Elmer	**UV Spectrophotometer**	1
29	IPC 06	28-03-2013	Perkin Elmer	**LCMS (TOF) Peptide Mapping**	1
30	IPC 06	28-03-2013	Vitan Medical	**Auto Titrator**	1

31	IPC 06	28-03-2013	Anchrom Ent.	**HPTLC System**	1
32	IPC 08	30-11-2013	Perkin Elmer	**GC with FID Head Space & Liquid Auto Sampler**	1
33	IPC 08	30-11-2013	Anton Paar	**Digital Polarimeter**	1
34	IPC 08	30-11-2013	Anton Paar	**Rotational Viscometer**	1
35	IPC 08	30-11-2013	Electrolab	**Disintegration Test Apparatus**	1
36	IPC 09	31-03-2014	Mettler Toledo	**Automatic Powder Dosing Instrument for IPRS Model- Quantos QB5 consisting 5 Digit Balance**	1
37	IPC 09	31-03-2014	Mettler Toledo	**Automatic Powder Dosing Instrument for IPRS Model- Quantos QB5 consisting 6 Digit Balance**	1
				Total:	**44**

STORE DIVISION

Annexure (List of Items to be Procured-under process)

Sr. No.	Brief Descriptions	Qty Req.	Requisite Division
1	Biosafety Cabinet	02	Microbiology
2	Exhaust Fan	01	RSD
3	Wall/ Pedestal Fan	08	Admin & Store division
4	Hi Air Flow Economical	01	Microbiology
5	S.S Working Stool 12" Dia approx, Fixed Type	06	Microbiology
6	Solar Power System (Lighting)	10 Kw	PvPI
7	Solar Lamp Post Along Railway Track Boundary Wall	05	BCT
8	Computer, UPS & Printer	07	AMC centre across India
9	Computer, UPS & Printer	10 Set	PvPI
10	Ultrasonic Bath	02	RSD & Biologics
11	Hot Air Oven	01	Biologics
12	Vertical Gel Electrophoresis with 300 Volt Power Supply	01	Biologics
13	Double Door Refrigerator	01	Biologics

14	Gel Rocker	01	Biologics
15	Western Blot Apparatus	01	Biologics
16	PC with Printer, scanner & copier	03	Biologics
17	Gel Dryer	01	Biologics
18	Heating Mantle	01	Biologics
19	HPLC	04	AR&D
20	PH Meter	02	AR&D
21	Sonicator	01	AR&D
22	VU.V Spectrophotometer	01	AR&D
23	Dissolution Apparatus	01	AR&D
24	Modular Furniture along with: a) Compactor 5 Rows b) Computer Table c) Meeting Table d) Total Chair	N/A 01 04 01 08	PvPI Division
25	CCTV Surveillance Monitoring System	01	Library

STORE DIVISION

Annexure (List of New Facility Development-under process)

Sr.No.	Brief Description	Action Plan
1.	Replacement of old & low capacity Electrical wiring.	To be carried out by CPWD.
2.	Effluent Treatment Plant may be placed in IPC Campus.	Taken up with HLL.
3.	Major renovation and addition of wash rooms/ toilets the IPC Building Campus.	Taken up with HLL.
4.	Construction of State of the Art Laboratory**.**	Work in Progress. GDA Approval has taken for much-awaited Construction.
5.	Chemical Synthesis Lab.	Finalization of BOQ Consultant to be identified.
6.	Creation of Maintenance Wing & Recruitment of staff there to.	Action Completed. Qualified civil & electrical engineers to be hired to take up day to day requirements of civil and electrical works.
7.	Condemnation/ Buyback of Old, Unserviceable, Unrepairable, Outdated & Idle Equipments & Furnitures/ Items.	Work in Progress. Tender floated & due on dt. 29.09.2015.

Creation of International Cooperation Division in IPC:

As per direction of Sh. Sudanshu Pandey, Joint Secretary, Ministry of Commerce and Industry during his visit to Indian Pharmacopoeia Commission on 7th September, 2015, it was decided to create a new division known as "International Cooperation Division" in IPC so that various countries of SAARC/ASEAN, Latin America, Africa, Commonwealth of independence States and Others will benefits in Countries upgrading their data and the India Pharmacopoeia will get the due recognition in these countries. Accordingly it was decided to renovate the existing Administrative Block by erecting False Ceiling, Glass Doors/Partitions, Civil Works/ Electrical Installations/Ducting & Air Conditioning. Submitted for consideration and approval of the Estate Committee.

Renovation of RS Iyer Hall:

As important meetings are held in the RS Iyer Hall frequently with Indian/Foreign Dignitaries, it is very much essential to renovate RS Iyer Hall at the earliest by erecting Wall Panelling, Repair/Replacement of Desks, Air Conditioners, Sound System, Floor Mat, etc. Here it is mentioned that no renovation work was carried out ever since RS Iyer Hall was established.

These works will be carried out at the prevailing approved rates of Tenders/ Limited Tendering. The services of the carpenter who did the work in CDSCO will be utilized, if his work in CDSCO is found satisfactorily.

Mini Meeting Rooms for Individual Departments:

There has been demand from various departments such as AR&D, PvPI, Phytopharmaceutical, etc. for creating Mini Meeting Rooms. As Conference/ Meeting Rooms are already available at RS Iyer Hall, PvPI Block & Q.A. Section of Chemistry Division, it may not be possible to create Mini Meeting Rooms for Individual Departments due to paucity of space.

Renovation of Canteen:

As many new employees are joining the organization and also several training programme are being conducted frequently, there has been space constraint in the existing canteen. As such it is very much essential to create more space by expending the existing place. In order to maintain proper hygiene, wall tiles are to be placed in kitchen, washing area to avoid the problem of seepage. Also Chimney should be installed in the kitchen for proper ventilation and carry out white washing of the entire canteen premises. These works will be carried out through Rate Contract/Limited Tender, etc. keeping in view the provisions of GFR.

Extension of Solar Power:

Old lightening Systems have been replaced by LED Lightening in the entire PvPI Block. Further it is proposed to action the same in other divisions in a phased manner starting with Reference Standard Division at Padam Shree Nitya Anand Block in ground floor of the main building followed by Instrumentation Lab and WET Lab on the First Floor.

Requirement of Solar Power will be to the tune of 30 KVA (appx) for extension. After completion of this work, total solar power of IPC would be 55 KVA (appx).

The works may be carried out as per DGS&D Rate Contract/MNRE Rate Contract/State Solar Development Authority Rate Contract.

Repair/Reconstruction of Boundary Wall of IPC:

The boundary wall of IPC campus has developed cracks, particularly facing railway line as it was constructed by CPWD long back. The boundary wall facing railway line may be demolished and new wall may be constructed. The other three sides of boundary wall may be plastered and white washed. This works need to be carried out on priority.

The work may be carried out through CPWD.

STATEMENT OF ACCOUNTS