



# Annual Report 2013-14

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INDIAN PHARMACOPOEIA COMMISSION

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## **Foreword**

I feel delighted and privileged to present the 5<sup>th</sup> Annual Report of the Indian Pharmacopoeia Commission (IPC) for 2013-14. The financial year under Report was very challenging as far as the launching of Indian Pharmacopoeia Reference Substances (IPRS) and their acceptability to the stakeholders was concerned. The Commission supplied IPRS worth Rs.45,83,000/- free of cost to the Government Laboratories in the country and their response was overwhelming. The IPRS worth Rs.45,70,849/- was also supplied to the stakeholders and pharma industry and the IPRS received tremendous appreciation.

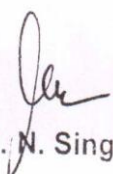
In order to maintain the stringent quality of the drugs and pharmaceuticals by applying modern analytical methods, the Commission has installed high end instruments, viz; NMR, ICP-MS, LC-MS, GC-MS, GC-HS, IC, AAS, FTIR and Cold Room. The Commission has also procured LC-MS Toff and HPTLC which will be commissioned soon on the completion of infrastructure facilities. The Commission also provided training to its stakeholders for the compliance of Pharmacopoeial standards. The Commission has so far certified prepared and labelled 347 chemical IPRS and proposes to prepare another 100 chemical IPRS in the coming fiscal year.

IPC also functions as National Coordination Centre for Pharmacovigilance Programme of India (PvPI). During the index period various steps have been taken such as recognizing 60 more ADRs monitoring centres (total 150), launching of 'PvPI – Helpline' for the healthcare professionals and consumers to provide assistance in ADRs reporting, integration of Revised National Tuberculosis Control Program to monitor the safety of anti TB drugs, development of PvPI toolkit and provided training to more than 8000 healthcare professionals on the concept of PvPI.

IPC is committed to promote the rational use of generic medicines by publishing National Formulary of India (NFI). The process has been started for bringing out 5<sup>th</sup> edition of NFI. The Commission also poised to make the monographs available for the molecules listed in the National List of Essential Medicines (NLEM) on year to year basis.

The task of the Commission would be more challenging in future as the country has high expectations from the institution for execution of the responsibilities vested in it and to cope up with the global standards in this competitive era.

The guidance and the road map given by the Ministry and the assistance provided by the members of Scientific Body and other scientific fraternity along with the incessant efforts of the staff of the Commission have been crucial in achieving the goals. I, on my own and on behalf of my colleagues would like to express my deep sense of gratitude to all those who continuously guided us during the period and to the Government for all the support provided to the IPC for achieving its goals.



(Dr. G. N. Singh)

The Government of India has set up the Indian Pharmacopoeia Commission (IPC) as an autonomous institution to deal with the matters relating to timely publication of the Indian Pharmacopoeia which is the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940 so as to specify the standards of identify, purity and strength of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. The mandate of the Commission includes functions, *inter-alia*, revision and publication of the Indian Pharmacopoeia and the National Formulary of India on a regular basis besides providing Reference Substances for deciding the identity, purity and detecting impurities of drugs and also imparting training to the stakeholders on Pharmacopoeial issues..

The fourth mandate is to ensure the safety of medicines by functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). Since more new drugs are being introduced in the Country which include new chemical entities, high techno pharma products, vaccines as well as new dosage forms, new routes of drug administration and new therapeutic claims of existing drugs. They may cause (pharmaceutical and vaccines) adverse effects which may not be captured in clinical trials. It is therefore, important to monitor both the known and hitherto unknown side effects of medicines. Accordingly, any new information available relating to the safety profile of medicines needs to be analysed. Therefore, it is important to have a standardized and robust Pharmacovigilance and drug safety monitoring programme at national and international level. Collecting all the relevant information in a systematic manner and analyzing the data to arrive at a meaningful conclusion about the safety aspect of the medicines is the rationale behind launching this programme in India. Initially, when the programme launched in the year 2010, AIIMS New Delhi was identified as NCC of PvPI. Later on in the year 2011, MoHFW government of India, identified IPC as NCC for PvPI. The Commission is fully financed by the Central Government with specific budgetary provisions under the administrative control of Ministry of Health and Family Welfare.

The Commission has a three-tier structure comprising the General Body, the Governing Body and the Scientific Body, supported by IPC Secretariat and Indian Pharmacopoeial Laboratory. The IPC also provides training and education to the healthcare professionals, research scholars, and medical and paramedical students on Pharmacopoeial and pharmacovigilance at regular intervals. Till date IPC organized several training/education/awareness programs and more than 10,000 healthcare professionals were trained on the concept of compliance of IP standards and Pharmacovigilance.

The IPC is closely working with similarly placed organizations both at national and international levels such as USP convention, British Pharmacopoeia Commission, European Directorate for the Quality of Medicines and Healthcare (EDQM), Chinese Pharmacopoeia Commission, World Health Organization, National Health Programs for promoting the quality and safety of medicines.

IPC is a unique organization in the country, committed to promoting the quality of drugs and pharmaceuticals, rational use of generic medicines and to ensure safety of medicines.

The standards for drugs are of paramount importance for regulating the quality, safety and efficacy of drugs used in a country. The Indian Pharmacopoeia (IP) is the official book of standards published by the Indian Pharmacopoeia Commission (IPC). It prescribes the standards of identity, purity and strength of drugs to be complied with by drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. In order to support the drug regulatory system, the Indian Pharmacopoeia Committee was constituted in the year 1948 for publication of the IP as its main function. The committee published the IP in 1955, followed by a Supplement in 1960. This Pharmacopoeia contained both western and traditional drugs commonly used in India, and the same policy continued while preparing the Pharmacopoeia of India 1966 and its Supplement 1975. There had been a phenomenal growth and development of the Indian Pharma industry since independence, especially from the early 1970's both in the areas of Active Pharmaceutical Ingredients (APIs) and the dosage forms. This led to the complete transformation of the profile of the Indian Pharmaceuticals market. The Indian Pharma industry emerged as one of the important global suppliers of pharmaceutical products, both to the developed and developing countries. These developments posed major challenges to the IP to reflect the quality standards of the marketed drugs, which the subsequent editions of IP tried to address.

The Indian Pharmacopoeia Commission was established in 2005. It provides systematic approach and practices for publication of IP 2007 with a focus on those drugs and formulations that cover the National Health Care Programmes and the National Essential Medicines. It contained monographs on antiretroviral, anticancer, antituberculosis and herbal drugs. It further emphasized on biological monographs such as Vaccines, Immunoserum for Human use, Blood products, Biotechnological and Veterinary (Biological and non-biological) preparations. Addendum 2008 to the IP 2007 had taken care of the Amendments to IP 2007 and also incorporated 72 new monographs.

The seventh edition of the IP 2014 has recently been published by the Indian Pharmacopoeia Commission in fulfillment of the requirements of the Drugs

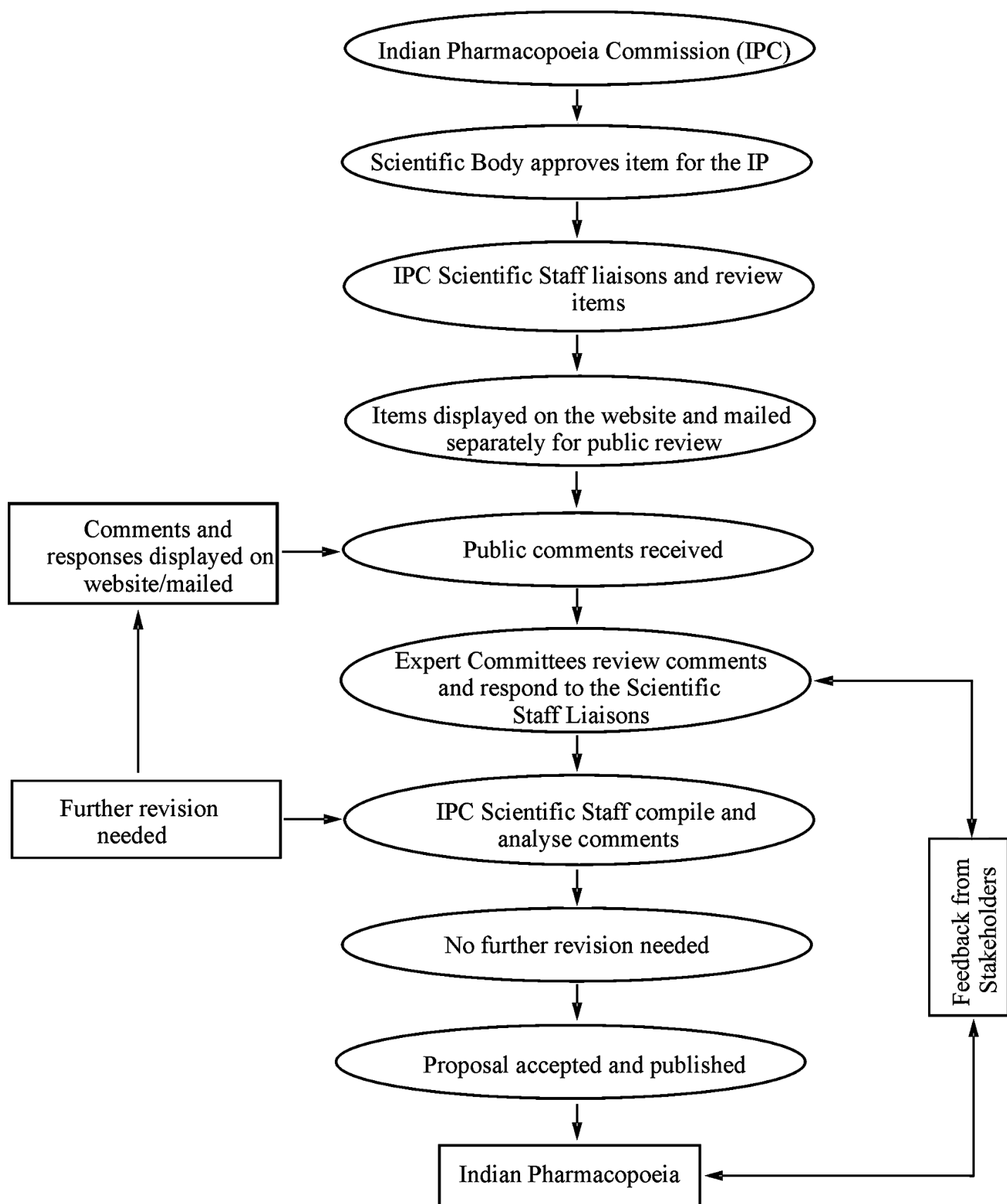
and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and / or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of this pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines. The IP is published in continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines. The Commission has been receiving significant inputs from regulatory, industrial houses, academic institutions, national laboratories, individual scientists and others. The Publication of IP at a regular interval is one of the main mandates of the Commission.

Indian Pharmacopoeia contains procedures for analysis and specifications for the determination of quality of pharmaceutical substances, excipients and dosage forms, etc. IP monograph for an official substance or preparation includes the article's definition, description, identification, packaging, storage, specifications, impurities, assay and specific tests, one or more analytical procedures for each test, acceptance criteria and other requirements etc.

The seventh edition of Indian Pharmacopoeia (IP 2014) is in accordance with the principles and the design plan decided by the Scientific Body of the IPC. To establish transparency in setting standards for this edition, the contents of new monographs, revised appendices and other information have been put on the website of the IPC, besides following conventional approach of obtaining comments from stakeholders. The feedback and inputs have been reviewed by the relevant Expert Committee to ensure the feasibility and practicability of the standards and methods revised. The principle of "openness, justice and fairness" is kept in mind while compiling and editing the contents of this edition.

Special attention has been paid to the Public Review and Comment Process for standards development related to this edition of the Indian Pharmacopoeia for incorporating comments from the stakeholders.





***Methodology adopted for IP Monograph***

The IPC Secretariat and Indian Pharmacopoeia Laboratory (IPL) staff, with the support of different advisory Expert Committee and Expert Members of the Scientific Body have examined the suitability of the standards. In order to make IP 2014 user friendly, the existing format has been suitably revised. The standards prescribed in IP 2014 are encouraged to adhere to the concept of harmonization, keeping in view the technological status to manufacture and analysis of the drugs and pharmaceuticals in the country without compromising with the quality of the products. It strives to update the existing monographs as well as incorporating the new monographs of drug substances based on clinical use of medicines in India and improving their test protocols. The IP 2014 has been considerably revised and improved in respect of the requirements of monographs, appendices and testing protocols by introducing advanced technology. The contents of Appendices are by and large revised in consonance with those adopted internationally. The monographs of special relevance diseases of this region have been given special attention.

In addition, emphasis has been given to bring out harmonisation in the Appendices to establish a sound connection between individual monographs and the relevant appendices, so as to make this edition precise and well structured. Number of monographs and appendices are expanded further to incorporate the latest technological advancement and regulatory compliance. Constant efforts have been made to unify the National Drug Standards and to bring them in conformity with the International Standards progressively by addition of monographs of new drugs and adopting current methodology.

The Indian Pharmacopoeia Reference Substances (IPRS) provide primary reference standards to the stakeholders. The list of available IPRS is updated from time to time on the official website of IPC ([www.ipc.gov.in](http://www.ipc.gov.in)).

The seventh edition of the Indian Pharmacopoeia comprises of four volumes each with different features:

Volume I: Notices; Preface; About Indian Pharmacopoeia Commission; Acknowledgements; Introduction; General Notices; General Chapters and Reference Data.

Volume II: General Notices; Dosage Forms (General Monographs); Drug Substances, Dosage Forms and Pharmaceutical Aids (A to M).

Volume III: General Notices; Drug Substances, Dosage Forms and Pharmaceutical Aids (N to Z); Vaccines and Immunoserum for Human Use; Herbs and Herbal Products; Blood and Blood-related Products; Biotechnology Products and Radiopharmaceutical Preparations.

Volume IV: General Notices; Notices; Veterinary Products and Index.

The Standards prescribed in the Indian Pharmacopoeia are to establish the compliance with regulatory requirements on an article. The criteria to be adhered to is as under:

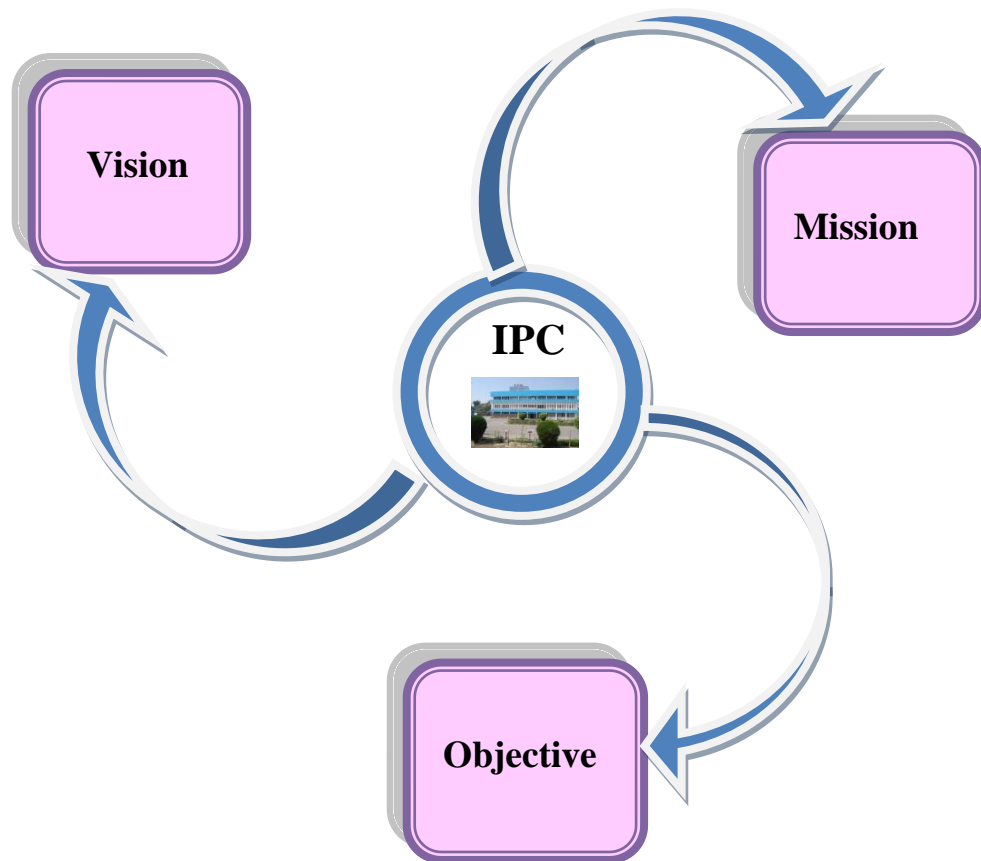
(i) The interpretation of a monograph must be in accordance with all the general requirements, testing methods, texts and notices pertaining to it, indicated in the IP.

(ii) A product is not of standard quality unless it complies with all the requirements of the monograph.

IP 2014 is effective from 1st January 2014. It contains 2548 monographs out of which 577 are new monographs. 19 New Radiopharmaceutical monographs and one General Chapter is included in this edition for the first time. It has been prepared in a user friendly format. Efforts have been made to avoid cross references. Monographs on Veterinary products are an integral part of this edition. Emphasis has been given to the extensive use of Chromatographic methods. Classical chemical tests for identification of an article have been avoided and replaced by more specific IP and UV Spectrophotometer techniques. Phytopharmaceutical monographs have been included. The IP 2014 contains several new monographs which are not available in other leading pharmacopoeia of the globe.

## MISSION, VISION AND OBJECTIVES

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*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 health 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.

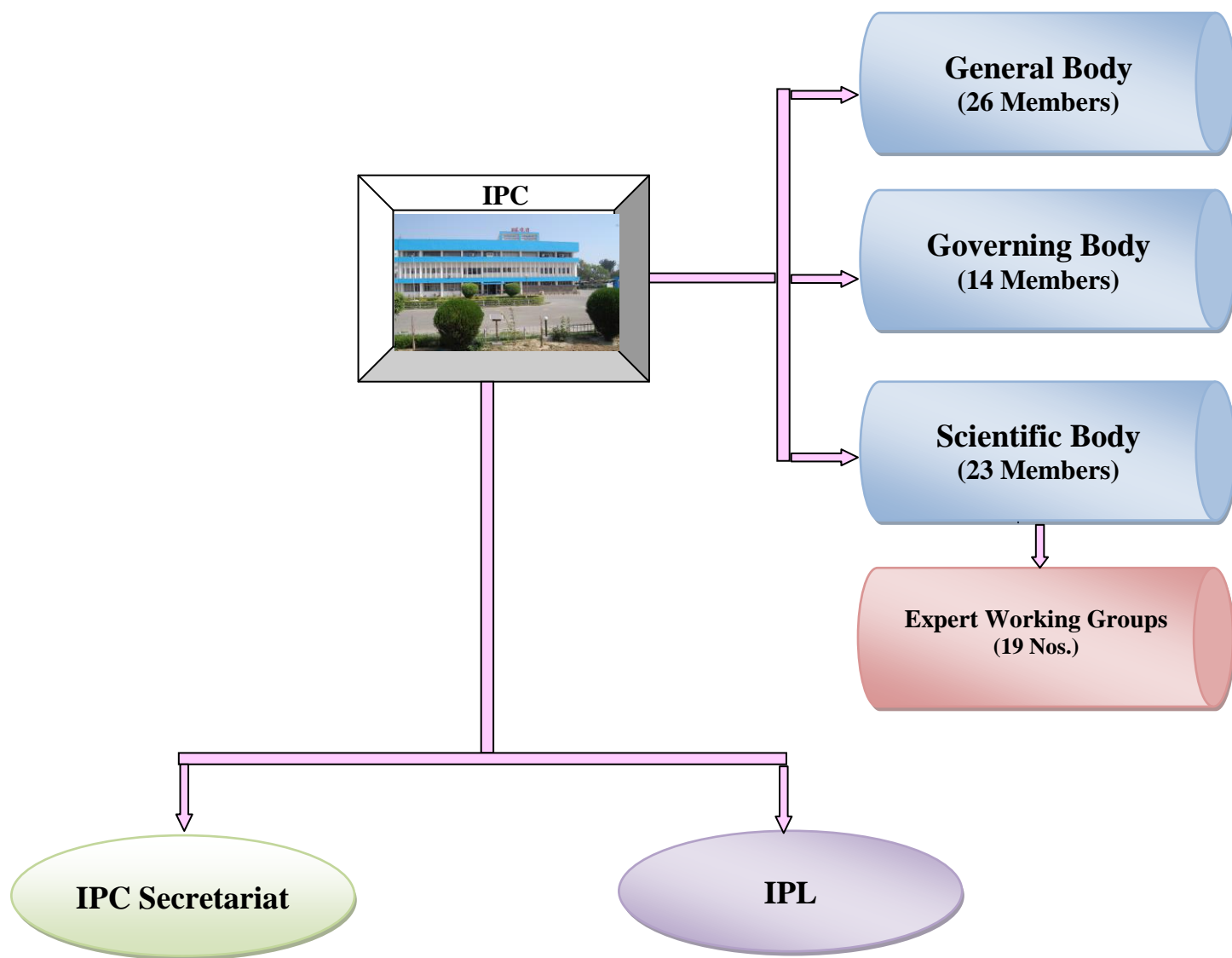
**Objectives:** To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, excipients and dosage forms as well as medical devices, and to keep them updated by reviews and revisions on a regular basis.

- 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

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*Figure: Structure of IPC*

**Bodies of the IPC:**

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

<b>S. No.</b>	<b><i>Designation in Committee</i></b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Shri Lov Verma Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
2.	<i>Co-Chairman</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
3.	<i>Member</i>	Dr. Jagdish Prasad Director General (DGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
4.	<i>Member</i>	Shri R. K. Jain, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
5.	<i>Member</i>	Shri Gautam Guha Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
6.	<i>Member</i>	Dr. Arun Kumar Panda Joint Secretary (R) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
7.	<i>Member</i>	Shri Shambhu Kallollikar Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
8.	<i>Member</i>	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011

9.	<i>Member</i>	Dr. G. N. Singh Drugs Controller General (I), Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road, New Delhi.
10.	<i>Member</i>	Dr. Surinder Singh Director National Institute of Biologicals B-62, Institutional Area Noida-201 307
11.	<i>Member</i>	President, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Aiwan-E-Ghalib Marg, Post Box No. 7020 New Delhi-110 002
12.	<i>Member</i>	Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P).
13.	<i>Member</i>	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
14.	<i>Member-Secretary</i>	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002



The composition of the **General Body** is as follows:

<b>S. No.</b>	<b><i>Designation in Committee</i></b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Shri Lov Verma Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
2.	<i>Co-Chairman</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
3.	<i>Member</i>	Dr. Jagdish Prasad Director General (DGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
4.	<i>Member</i>	Shri R. K. Jain, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
5.	<i>Member</i>	Shri Gautam Guha Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
6.	<i>Member</i>	Dr. Arun Kumar Panda Joint Secretary (R) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
7.	<i>Member</i>	Shri Shambhu Kallollikar Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
8.	<i>Member</i>	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011

9.	<i>Member</i>	Dr. G. N. Singh Drugs Controller General (I), Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road, New Delhi.
10.	<i>Member</i>	Dr. Surinder Singh Director National Institute of Biologicals B-62, Institutional Area Noida-201 307
11.	<i>Member</i>	President, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Aiwan-E-Ghalib Marg, Post Box No. 7020 New Delhi-110 002
12.	<i>Member</i>	Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P).
13.	<i>Member</i>	The Director Central Drugs Laboratory 3, Kyd Street Kolkata
14.	<i>Member</i>	From Regulatory Bodies Central Drugs Standard Control Organisation Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
15.	<i>Member</i>	Dr. C. Adithan Director-Professor Department of Pharmacology Jawaharlal Institute of Postgraduate Medical Education and Research Pondicherry-605 006.
16.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Andhra Pradesh
17.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Sikkim

18.	<i>Member</i>	Commissioners in-charge of Drug Control Administration, Gujarat
19.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Uttar Pradesh
20.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Himachal Pradesh
21.	<i>Member</i>	The Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062.
22.	<i>Member</i>	The President, Indian Drug Manufacturers Association (IDMA) 102-B, Poonam Chambers, 'A' Wing' Dr. Annie Besant Road, Worli Mumbai – 400018
23.	<i>Member</i>	The President, Organization of Pharmaceutical Producers of India (OPPI), Peninsula Corporate Park, Peninsula Chambers, Gr. Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013
24.	<i>Member</i>	Shri. D. G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), Mumbai
25.	<i>Member</i>	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
26.	<i>Member-Secretary</i>	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

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

<b>S. No.</b>	<b>Designation in Committee</b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
2.	<i>Member</i>	Drugs Controller General (I) Dte. General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
3.	<i>Member</i>	Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P).
4.	<i>Member- Secretary</i>	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

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

<b>S. No.</b>	<b>Designation in Committee</b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
2.	<i>Member</i>	Dr. G. N. Qazi Vice Chancellor, Jamia Hamdard Hamdard University, 'A' Category – NAAC, Hamdard Nagar, New Delhi-110 062.
3.	<i>Member</i>	Dr. N. Udupa Principal, Manipal College of Pharmaceutical Sciences, Madhav Nagar, Manipal-576 104. Karnataka
4.	<i>Member</i>	Professor M. R. Yadav Pharmacy Department, Faculty of Technology and Engineering, The M. S. University of Baroda, Vadodara– 390 001 (Gujarat)
5.	<i>Member</i>	Dr. Venugopal WHO Temporary Advisor, A 11, Sarvodaya Enclave, New Delhi-110 017.
6.	<i>Member</i>	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
7.	<i>Member</i>	Professor Praveen Aggarwal, Professor in-charge, Department of Emergency Medicine, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi-110 029.
8.	<i>Member</i>	Professor Y. K. Gupta Head, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi.

9.	<i>Member</i>	Professor (Dr.) Lalji Singh Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P) India
10.	<i>Member</i>	Dr. S. M. Mudda Executive Director – Technical & Operations, Micro Labs Limited, 27, Race Course Road, Bangalore-560 001.
11.	<i>Member</i>	Dr. Manish Gangrade Head-Analytical Development Lab, CIPLA Limited, L.B.S. Marg, Vikhroli (W), Mumbai-400 083.
12.	<i>Member</i>	Dr. J. P. Mehta Plant Manager, Franco-Indian Pharmaceuticals Pvt. Ltd., 20, Dr.E. Moses Road, Worli, Mumbai-400 011.
13.	<i>Member</i>	Dr. Vinay G. Nayak President Technical Operations International Business Division Alembic Ltd, Alembic Road, Vadodara – 390003
14.	<i>Member</i>	Mr. Vinod Arora Vice President (Pharma Research), Ranbaxy Research Laboratories, Plot No. 20, Sector 18, Udyog Vihar Industrial Area, Gurgaon-122 001.
15.	<i>Member</i>	Dr. S. S. Jadhav Executive Director, Quality Assurance & Regulatory Affairs, Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028.
16.	<i>Member</i>	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 INDIA
17.	<i>Member</i>	The Joint Commissioner (Testing), Food & Drugs Laboratory, Nr. Polytechnic, Baroda – 390 002 (Gujarat)

18.	<i>Member</i>	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.
19.	<i>Member</i>	Dr. H. G. Koshia Commissioner, Food & Drugs Control Administration Government of Gujarat, Block No. 8, 1 <sup>st</sup> Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar-382 010.
20	<i>Member</i>	Dr. Prasad V. Kanitkar Director, Plant Operations, Pfizer Global Manufacturing, Pfizer Limited, Thane Belapur Road, K.U. Bazar Post, Turbhe, Navi Mumbai-400 705.
21.	<i>Member</i>	Dr. Anurag Rathore, Associate Professor, Department of Chemical Engineering, Indian Institute of Technology, Hauz Khas, New Delhi-110 016.
22.	<i>Member</i>	Mr. R. Sridharan 603, Sarangi, Lokpuram, Thane (W) – 400 610
23.	<i>Member-Secretary (ex-officio)</i>	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002

1.	<i>Special Invitee</i>	Dr. B. R. Jagashetty Former Drugs Controller of Karnataka Flat No. 702/402, Ram Sridhar Apts, BTM 2nd Stage, 16th Main, Aicoboanagar, Bangalore-560 076
2.	<i>Special Invitee</i>	Mr. S. S. Venkatakrishnan Former Drugs Controller of Kerala 12/548, (GNRA 47), Dhanyasree, Vrindavanam Gardens, Old P O Lane, Kodunganoor, Thiruvananthapuram-695 013

The composition of the **National Consultative Committee (NCC)** of the **Indian Pharmacopoeia Commission** is as follows:

<b>S. No.</b>	<b>Designation in Committee</b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Dr. Vishwa Mohan Katoch, Secretary to the Govt. of India (DHR), and Director General, Indian Council of Medical Research, Ramalingaswamy Bhawan, Ansari Nagar, New Delhi-110 029.
2.	<i>Co-Chairman</i>	<i>Mr. R. K. Jain</i> <i>Additional Secretary &amp; Director General (CGHS)</i> <i>Ministry of Health &amp; Family Welfare</i> <i>Nirman Bhawan</i> <i>New Delhi-110 011.</i>
3.	<i>Member</i>	Dr. Surinder Singh Director (I/C), National Institute of Biologicals B-62, Institutional Area Noida-201 307
4.	<i>Member</i>	Professor (Dr.) Lalji Singh Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P) India
5.	<i>Member</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
6.	<i>Member</i>	Professor C. K. Kokate Vice-Chancellor KLE University Belgaum
7.	<i>Member</i>	Dr. G. N. Qazi Vice-Chancellor, Jamia Hamdard Hamdard University, 'A' Category – NAAC, Hamdard Nagar, New Delhi-110 062.



8.	<i>Member</i>	Professor Y. K. Gupta Head, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi.
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**Website**

Dr. D.B.A. Narayana (*Chair*), Dr. Venugopal, Mr. G..S. Bedi.

### 1. Preparation of Manuscript of IP 2014

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 IP 2014 was checked by the subject experts and officials of IPC and send for printing.

#### (i) 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 Immunoserum Monographs, Veterinary Surgical Monographs were admitted.

#### General Chapters

- 2.2.17. DNA based Authentication techniques
- 2.2.18. Transfusion and Infusion Assemblies and similar Medical Devices
- 2.2.19. Amino Acid Analysis
- 2.3.51. 2-Ethylhexanoic Acid
- 2.3.52. Assay of Folic Acid
- 2.3.53. Ammonium
- 2.3.54. Assay of Alpha tocopherol
- 2.3.55. Fluorides
- 2.4.35. Bulk Density and Tapped Density of Powders
- 2.4.36. Completeness of Solution
- 2.4.37. Crystallinity
- 2.4.38. Specific Surface Area
- 2.4.39. Mass Spectroscopy
- 2.4.40. Ethylene Oxide and Dioxan
- 2.4.41. Acetic Acid in Peptides
- 2.4.42. Inductively Coupled Plasma - Mass Spectroscopy
- 2.4.43. Characterisation of Crystalline and Partially Crystalline solids by X-ray Power Diffraction
- 2.4.44. Flash Point
- 2.5.11. Polymorphism

## Monographs on drug substances, dosage forms and pharmaceutical aids

Acamprosate Calcium	Bicalutamide Tablets
Acesulfame Potassium	Bortezomib
Acetretin Capsules	Cabergoline
Aciclovir Cream	Cabergoline Tablets
Aciclovir Dispersible Tablets	Caffeine Citrate Oral Solution
Aciclovir Eye Ointment	Calcipotriol Anhydrous
Aciclovir Oral Suspension	Calcipotriol Ointment
Acitretin	Calcitonin (Salmon)
Adefovir Dipivoxil	Calcitonin (Salmon) Injection
Adefovir Tablets	Calcium Dobesilate Monohydrate
Adenosine	Carboplatin
Adenosine Injection	Carboplatin Injection
Adipic Acid	Carboxymethylcellulose Calcium
Albendazole Oral Suspension	Carboxymethylcellulose Eye Drops
Alfacalcidol	Carisoprodol
Alfuzosin Hydrochloride	Carisoprodol Tablets
Alfuzosin Prolonged-release Tablets	Cefpirome Injection
Alfuzosin Tablets	Cefpirome Sulphate
Alprazolam Prolonged-release Tablets	Ceftiofur Sodium
Alprostadil	Celiprolol Hydrochloride
Alprostadil Injection	Celiprolol Tablets
Aminophylline Prolonged-release Tablets	Chloramphenicol Ear Drops
Amiodarone Intravenous Infusion	Chlorohexidine Mouthwash
Amisulpride	Cilostazol
Amisulpride Tablets	Cilostazol Tablets
Amorolfine Hydrochloride	Citicoline Sodium
Aprotinin	Clemastine Fumarate
Aripiprazole	Clemastine Tablets
Ascorbyl Palmitate	Clindamycin Injection
Aspirin Gastro-resistant Tablets	Clindamycin Phosphate
Atomoxetine Hydrochloride	Clobetasol Cream
Atracurium Besylate Injection	Clobetasol Ointment
Atracurium Besylate	Clobetasol Propionate
Azelaic acid	Clobetasone Butyrate
Azelastine Eye Drop	Clobetasone Cream
Azelastine Hydrochloride	Corn Oil
Bambuterol Hydrochloride	Cottonseed Oil
Bambuterol Tablets	Crotamiton
Benazepril Hydrochloride	Crotamiton Cream
Benazepril Hydrochloride Tablets	Alfacyclodextrin
Benzoyl Peroxide Cream	Betacyclodextrin
Benzoyl Peroxide Gel	Cyclopentolate Eye Drops
Betahistine Mesilate	Cyclopentolate Hydrochloride
Betamethasone Valerate Cream	Cyclosporine
Betaxolol Eye Drops	Cyclosporine Capsules
Betaxolol Hydrochloride	Dalteparin Sodium
Bezafibrate	Dalteparin Sodium Injection
Bezafibrate Tablets	Desmopressin
Bicalutamide	Desmopressin Intranasal Solution

Diclofenac Prolonged-release Tablets	Flumazenil Injection
Diltiazem Injection	Fluorometholone
Dipivefrine Eye drops	Fluorometholone Eye Drops
Dipivefrine Hydrochloride	Flupentixol Decanoate
Dipyridamole	Flupentixol Injection
Dipyridamole Tablets	Flurazepam Capsules
Divalproex Prolonged-release Tablets	Flurazepam Hydrochloride
Dobutamine Hydrochloride	Flurbiprofen Eye Drops
Dobutamine Injection	Flurbiprofen Sodium
Docetaxel Anhydrous	Flutamide Tablets
Domperidone Suspension	Fluticasone Cream
Dopamine Hydrochloride	Fluticasone Nasal Spray
Dopamine Injection	Fluticasone Ointment
Doxapram Hydrochloride	Fluvastatin Capsules
Doxapram Injection	Fluvastatin Sodium
Drotaverine Tablets	Fluvoxamine Maleate
Dutasteride	Fluvoxamine Tablets
Ebastine	Fosinopril Sodium
Eberconazole Nitrate	Fosinopril Sodium Tablets
Entacapone	Gemcitabine Hydrochloride
Ephedrine Nasal Drops	Gemcitabine Injection
Epinastine Eye Drops	Gemfibrozil
Epinastine Hydrochloride	Gemfibrozil Capsules
Eplerenone	Glutaraldehyde Solution
Eptifibatide	Strong Glutaraldehyde Solution
Eptifibatide Injection	Glycerin Oral Solution
Erlotinib Hydrochloride	Diluted Glyceryl Trinitrate
Erlotinib Tablets	Hydrocortisone Ointment
Esmolol Hydrochloride	Hydrocortisone Acetate Cream
Ethambutol Injection	Hydrogenated Vegetable Oil
Ethanolamine	Hydroxychloroquine Sulphate
Ethophylline and Theophylline Tablets	Hydroxychloroquine Tablets
Ethyl Vanillin	Hydroxyethylcellulose
Ethylparaben	Hydroxypropyl Methylcellulose Phthalate
Etidronate Disodium	Hydroxyzine Hydrochloride
Etidronate Tablets	Hydroxyzine Oral Solution
Etoricoxib	Hydroxyzine Tablets
Etoricoxib Tablets	Imatinib Tablets
Ezetimibe	Imidurea
Ezetimibe Tablets	Invert Syrup
Famciclovir	Iopanoic Acid
Famciclovir Tablets	Iopanoic Acid Tablets
Flavoxate Hydrochloride	Irbesartan
Flavoxate Tablets	Irbesartan and Hydrochlorothiazide Tablets
Flucloxacillin Capsules	Irbesartan Tablets
Flucloxacillin Oral solution	Iron and Folic Acid Syrup
Flucloxacillin Sodium	Iron and Folic Acid Tablets
Fludarabine Phosphate	Isopropyl Palmitate
Fludarabine Phosphate Injection	Isopropyl Rubbing Alcohol
Flumazenil	Isotretinoin

Ivermectin	Phenylramidol Hydrochloride
Ivermectin Injection	Phenylramidol Tablets
Labetalol Injection	Pitavastatin Calcium
Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets	Polacrillin Potassium
Lapatinib Ditosylate	Polyvinyl Acetate Phthalate
Lapatinib Tablets	Polyvinyl Alcohol
Leflunomide	Potassium Chloride for Injection
Leflunomide Tablets	Prednisolone Sodium Phosphate Eye Drops
Levodropropizine	Pemetrexed Disodium
Levofloxacin Injection	Procarbazine Hydrochloride
Levosinbutamol Hydrochloride	Progesterone
Levosinbutamol Inhalation Solution	Progesterone Injection
Lithium Carbonate Prolonged-release Tablets	Propylidone
Lorazepam	Propylidone Injectable Oil Suspension
Lorazepam Injection	Pyridostigmine Bromide
Lorazepam Tablets	Pyridostigmine Injection
Meloxicam	Pyridostigmine Tablets
Mesalazine	Racecadotril
Mesalazine Prolonged-release Tablets	Racecadotril Capsules
Metoprolol Injection	Racecadotril Sachet
Midazolam	Raloxifene Hydrochloride
Midazolam Injection	Rebamipide
Midazolam Oral Solution	Reboxetine Methanesulphonate
Mifepristone	Repaglinide
Mifepristone Tablets	Repaglinide Tablets
Misoprostol Tablets	Risendronate Sodium
Mitomycin	Ritodrine Hydrochloride
Mitomycin Injection	Ritodrine Injection
Morphine Tablets	Ritodrine Tablets
Moxifloxacin Eye Drops	Rupatidine Fumarate
Moxifloxacin Hydrochloride	Saquinavir Capsules
Mupirocin	Selegiline Hydrochloride
Mupirocin Ointment	Selegiline Tablets
Nicorandil	Sertraline Hydrochloride
Nicorandil Prolonged-release Tablets	Sertraline Tablets
Nicorandil Tablets	Silver Sulphadiazine
Octyl Dodecanol	Silver Sulphadiazine Cream
Ofloxacin Oral Suspension	Sodium Nitopruside
Ornidazole Injection	Sodium Nitopruside Injection
Oxacillin Capsules	Monobasic Sodium Phosphate
Oxacillin Sodium	Sodium Valproate Gastro-resistant Tablets
Ozagrel Hydrochloride	Sorafenib Tablets
Paracetamol Infusion	Sorafenib Tosylate
Paracetamol Paediatric Oral Suspension	Soyabean Oil
Parecoxib Sodium	Sulpiride
Paroxetine Hydrochloride	Sulpiride Tablets
Paroxetine Tablets	Surgical Spirit
Petrolatum	Tenofovir Fumarate, Lamivudine and Efavirenz Tablets
Phenylethyl Alcohol	Theophylline Prolonged-release Tablets
	Tranexamic Acid



Tranexamic Acid Injection  
 Tranexamic Acid Tablets  
 Triclofos Oral Solution  
 Triclofos Sodium  
 Ursodeoxycholic Acid  
 Ursodeoxycholic Acid Tablets  
 Vecuronium Bromide  
 Vecuronium Bromide Injection  
 Voglibose  
 Voglibose Dispersible Tablets  
 Voglibose Tablets  
 Zonisamide  
 Zopiclone  
 Zopiclone Tablets  
 Zuclopenthixol Acetate  
 Zuclopenthixol Acetate Injection

#### **New Drugs Substances Monographs**

Agomelatine  
 Arbidol Hydrochloride  
 Arterolane Maleate  
 Asenapine Maleate  
 Atosiban Acetate  
 Azelnidipine  
 Azacitidine  
 Biapenam  
 Brinzolamide  
 Choline Fenofibrate  
 Dapoxetine Hydrochloride  
 Dexlansoprazole  
 Dienogest  
 Eletriptan Hydrobromide  
 Eslicarbazepine  
 Fasoterodine Fumarate  
 Fasudil Hydrochloride  
 Fenspiride Hydrochloride  
 Fingolimod Hydrochloride  
 Fomepizole  
 Frovatriptan Succinate  
 Galanthamine Hydrobromide  
 Ibudilast  
 Ilaprazole  
 Iloperidone  
 Levo Bupivacaine Hydrochloride  
 Lubiprostone  
 Moexipril Hydrochloride  
 Naproxinod  
 Ramelteon  
 Rilpivirine  
 Roflumilast  
 Rufinamide

Safinamide Methane Sulphonate  
 Seratrodast  
 Tapentadol Hydrochloride  
 Tauroursodeoxycholic Acid  
 Tofluprost  
 Tolvaptan  
 Tranilast  
 Trimethobenzamide Hydrochloride  
 Udenafil  
 Ulipristal Acetate

#### **Antibiotic Monographs**

Colistimethate Injection  
 Colistimethate Sodium  
 Colistin Sulphate  
 Colistin Tablets  
 Gramicidin  
 Natamycin  
 Natamycin Ophthalmic Suspension  
 Netilmicin Sulphate  
 Sisomicin Sulphate  
 Sisomicin Sulphate Injection  
 Teicoplanin  
 Tyrothricin

#### **Radiopharmaceutical Monographs**

Radiopharmaceuticals  
 (<sup>131</sup>I) Meta-Iodobenzyl Guanidine Injection for Diagnostic Use  
 (<sup>131</sup>I) Meta-Iodobenzyl Guanidine Injection for Therapeutic Use  
 Fluorodeoxyglucose (<sup>18</sup>F) Injection  
 Samarium (<sup>153</sup>Sm) Ethylene Diamine Tetramethylene Phosphonate (EDTMP) Injection  
 Sodium Fluoride (<sup>18</sup>F) Injection  
 Sodium Iodide (<sup>131</sup>I) Capsules for Diagnostic Use  
 Sodium Iodide (<sup>131</sup>I) Capsules for Therapeutic Use  
 Sodium Iodide (<sup>131</sup>I) Solution  
 Sodium Pertechnetate (<sup>99m</sup>Tc) Injection (Fission)  
 Sodium Pertechnetate (<sup>99m</sup>Tc) Injection (Non-fission)  
 Sodium Phosphate (<sup>32</sup>P) Injection  
 Technetium (<sup>99m</sup>Tc) DMSA Injection  
 Technetium (<sup>99m</sup>Tc) DTPA Injection  
 Technetium (<sup>99m</sup>Tc) EC Injection  
 Technetium (<sup>99m</sup>Tc) ECD Injection  
 Technetium (<sup>99m</sup>Tc) Glucoheptonate Injection  
 Technetium (<sup>99m</sup>Tc) Mebrofenin Injection  
 Technetium (<sup>99m</sup>Tc) Medronate Complex Injection  
 Technetium (<sup>99m</sup>Tc) MIBI Injection

**Herbal Monographs**

Amaltas  
Bala  
Basil Oil  
Bakuci  
Belladonna Soft Extract  
Black Pepper Oil  
Caraway Oil  
Cardamom Oil  
Clove Bud Oil  
Clove Leaf Oil  
Clove Stem Oil  
Cumin Oil  
Dill Seed Oil  
Ergot  
Ivy Leaf  
Ivy Leaf Dry Extract  
Kaunch  
Lavender Oil  
Lemon Grass Oil  
Lemon Oil  
Lime Oil  
Mentha Arvensis Oil  
Nagakesar  
Nutmeg Oil  
Prepared Ergot  
Rosemarry Oil  
Thyme Oil  
Valerian Dry Extract  
Valerian Root  
Vidanga  
Vijaysara

**Human Vaccines**

Cholera Vaccine (Inactivated, Oral)  
Diphtheria Vaccine (Adsorbed) for Adults and Adolescents  
Group A Meningococcal Conjugate Vaccine  
Meningococcal Polysaccharide A and C Vaccine  
  
Rotavirus Vaccine (Live Attenuated, Oral)

**Insulin Products**

Biphasic Insulin Aspart Injection  
Biphasic Insulin Lispro Injection  
Insulin Aspart  
Insulin Aspart Injection  
Insulin Lispro  
Insulin Lispro Injection

**Biotechnology Products**

Erythropoietin for Injection

Erythropoietin Injection  
Filgrastim Injection  
Interferon Alfa-2a Injection  
Interferon Alfa-2b Injection  
Interferon Beta-1a Concentrated Solution  
Recombinat Streptokinase Injection

**Veterinary Non-biological Monographs**

Activated Charcoal  
Adrenaline Tartrate  
Albendazole Oral Suspension  
Amitraz Pour-on  
Amoxycillin Oral Powder  
Amoxycillin Injection  
Ampicillin Injection  
Ampicillin Sodium  
Ampicillin Trihydrate  
Benzocaine  
Benzyl Benzoate Application  
Benzylpenicillin Injection  
Benzylpenicillin Potassium  
Benzylpenicillin Sodium  
Betamethasone Injection  
Betamethasone Sodium Phosphate  
Buserelin  
Buserelin Injection  
Calcium Levulinate Injection  
Carprofen  
Cefoperazone Injection  
Cefoperazone Sodium Intramammary Suspension  
Cefpodoxime Oral Suspension  
Cefpodoxime Tablets  
Ceftizoxime for Injection  
Ceftizoxime Sodium  
Ceftriaxone Injection  
Chloramphenicol  
Chloramphenicol Sodium Succinate  
Chlorpheniramine Injection  
Chlorpromazine Hydrochloride  
Chlorpromazine Injection  
Cholecalciferol  
Chorionic Gonadotropin  
Ciprofloxacin Injection  
Ciprofloxacin Tablets  
Cloprostenol Injection  
Cloprostenol Sodium  
Closantel Sodium Dihydrate  
Cloxacillin Injection  
Cloxacillin Sodium  
Cynocobalamin  
Cynocobalamin Injection

Decoquate  
 Decoquate Premix  
 Deltamethrin  
 Deltamethrin Pour-on  
 Dexamethasone Injection  
 Dexamethasone Sodium Phosphate  
 Diazepam  
 Diazepam Injection  
 Diclazuril  
 Dicloxacillin Sodium  
 Diethylcabamazine Citrate  
 Diethylcabamazine Tablets  
 Docetaxel Injection  
 Enrofloxacin  
 Febantel  
 Febendazole Granules  
 Fenbendazole Oral Paste  
 Fenbendazole Oral Powder  
 Fenbendazole Oral Suspension  
 Ferrous Fumerate Tablets  
 Flunixin Megglumine  
 Frusemide Injection  
 Furazolidone  
 Gentamicin Injection  
 Iron Dextran Injection  
 Isoflupredone Acetate  
 Isoflupredone Acetate Injectable Suspension  
 Ivermectin Oral Paste  
 Ivermectin Pour-on  
 Levamisole Hydrochloride  
 Levofloxacin Hemihydrate  
 Light Kaolin  
 Light Magnesium Carbonate  
 Lignocaine Hydrochloride  
 Lignocaine Injection  
 Lincomycin Hydrochloride  
 Magnesium Sulphate  
 Marbofloxacin  
 Meloxicam Injection  
 Mepyramine Injection  
 Mepyramine Maleate  
 Methyl Ergometrine Injection  
 Methylprednisolone Acetate  
 Methylprednisolone Acetate Injection  
 Monosulfiram  
 Morphine Injection  
 Morphine Sulphate  
 Moxidectin  
 Moxidectin Injection  
 Neomycin Sulphate

Nicolsamide  
 Oestradiol Benzoate  
 Oestradiol Injection  
 Ornidazole  
 Oxytetracycline Hydrochloride  
 Oxytetracycline Hydrochloride Injection  
 Oxytetracycline Injection  
 Paclitaxel Injection  
 Pentobarbitone Sodium  
 Promethazine Hydrochloride  
 Promethazine Injection  
 Pyridoxine Hydrochloride  
 Sodium Dihydrogen Phosphate Dihydrate  
 Sodium Thiosulphate  
 Streptomycin Sulphate  
 Sulphadiazine and Trimethoprim Tablets (Co-trimazine Tablets)  
 Sulphadimidine  
 Sulphadimidine Injection  
 Sulphadimidine Sodium  
 Sulphadimidine Tablets  
 Sulphadiazine  
 Testosterone Propionate  
 Testosterone Propionate Injection  
 Thiabendazole  
 Tinidazole Tablets  
 Tocopheryl Acetate  
 Trimethoprim  
 Xylazine Hydrochloride  
 Zinc Oxide Cream

### **Veterinary Biological Monographs**

Bluetongue Vaccine Inactivated  
 Brucella Abortus (Strain 19 Vaccine) Live  
 Brucella Melitensis (Strain Rev.1) Vaccine, Live,

Canine Adenovirus Vaccine, Inactivated  
 Canine Adenovirus Vaccine, Live  
 Haemorrhagic Septicaemia Vaccine- Alum Treated  
 Laryngotracheitis Vaccine, Live (Avian Infectious Laryngotracheitis Vaccine, Live)  
 Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats

### **Veterinary Diagnostic Monograph**

Avian Tuberculin Purified Protein Derivative (PPD)

### **Veterinary Immunosera Monographs**

Clostridium Novyi Alpha Antitoxin  
 Clostridium Perfringens Antitoxins  
 Clostridium Perfringens Beta Antitoxin

Clostridium Perfringens Epsilon Antitoxin  
Clostridium Tetani Antitoxin

Sterile Linen Thread in Distributor  
Sterile Non-absorbable Strands in Distributor

**Veterinary Surgical Monographs**

Sterile Braided Silk Suture in Distributor  
Sterile Catgut in Distributor

Sterile Poly (ethylene terephthalate) Suture in Distributor

Sterile Polyamide 6 Suture in Distributor

Sterile Polyamide 6/6 Suture in Distributor

**ii) Amendment List 1 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 was finalized and put up on website for appropriate time and released on 31.03.2014 by the Secretary-cum-Scientific Director of IPC. Total more than 100 amendments taken place in the monographs/tests.

**iii) New Monographs Drafted for next Addendum 2015 to IP 2014**

Following 57 new chemical monographs were drafted during this period for next addendum 2015 to IP 2014 and put up on the website for stakeholders comments.

**iv) Verification of Analytical methods for IP**

The IPC team was vigorously involved in analytical verification of various tests in the existing monographs of IP-2014 and the monographs drafted for addendum 2015 to IP 2014. Carried out verification of analytical method for drugs samples received from various stakeholders for verification of different tests of IP monographs. During this period following samples were verified.

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 Donepezil HCl.
44. Verified full monograph of Ranitidine Oral Solution.
45. Verified full monograph of Tadalafil Tablets.

**v) Development of Veterinary Monographs (IV<sup>th</sup> Vol. of IP-2014)**

Organized and coordinated the work related to the development of veterinary monographs for the 4<sup>th</sup> volume of VIIth edition with the expert group of veterinary manufacturers under the chairmanship of Dr. Rishendra Verma, IVRI, Izatnagar. The second workshop/meeting was arranged on 08<sup>th</sup> April, 2013 at IPC, GZB.

## **BIOLOGICALS AND PHYTOPHARMACEUTICAL DIVISION**

### **1) Monographs on Herbal Drugs**

Herbal medicines have been used by the humanity since time immemorial for various healthcare needs. Their complex nature poses the challenge for analysis and quality control. Multiple factors affect the quality of herbal medicines. Pharmacopoeial herbal monographs in IP contain information including the definition of the herbal ingredient relative to the monograph title followed by specifications. The specifications cover the various tests for critical quality attributes of the herbal ingredients, procedures and acceptance criteria. The monographs employ various verified / validated analytical procedures that are feasible to be performed. Based on the queries of stakeholders and meeting of the expert committee members of Herbal Products the monographs were amended

New monographs included in IP 2014 are:

<b>New Monographs for IP 2014</b>		<b>Revised Monographs</b>	<b>General chapters</b>
<b>Herbal Monographs and</b>	<b>Essential Oils Monograph</b>		
<b>Amaltas (<i>Cassia fistula</i>)</b>	Basil Oil	Belladonna Dry Extract	DNA-Based Authentication
Vidanga ( <i>Embelia ribes</i> )	Black Pepper Oil	Shatavari( <i>Asparagus racemosus</i> )	Techniques
Nagakesar ( <i>Measa ferra</i> )	Caraway Oil	Clove Oil	Flash point
Kaunch ( <i>Mucuna pruriens</i> )	Cardamom Oil	Coriander Oil	
Vijayasara ( <i>Pterocarpus marsupium</i> )	Clove Bud Oil	Eucalyptus Oil	
Bala ( <i>Sida acuta</i> )	Clove Leaf Oil	Peppermint Oil	
Bakuci ( <i>Psoralea corylifolia</i> )	Clove Stem Oil		
Belladonna Soft Extract	Cumin Oil		
Ergot	Dill Seed Oil		
Ivy Leaf Dry Extract	Lavender Oil		
Ivy Leaf	Lemon Grass Oil		
Prepared Ergot	Lemon Oil		
Valerian Dry Extract	Lime Oil		
Valerian Root	Mentha arvensis Oil		
	Nutmeg Oil		
	Rosemarry Oil		
	Thyme Oil		

New and revised monographs in Addendum 2015 to IP 2014:

<b>New Monographs</b>	<b>Revised Monographs</b>
Birmi ( <i>Taxus wallichiana</i> )	Amaltas ( <i>Cassia fistula</i> )
Asthsamhrta ( <i>Cissus qudrangularis</i> )	Vidanga ( <i>Embellia ribes</i> )
Shankhpushpi ( <i>Convolvulus pluricaulis</i> )	

Besides the above mentioned monographs, several other amendments are also incorporated in IP 2014.

### **2) Monographs on Biologicals**

#### **a. Biotechnology derived Products**

Biotechnology derived therapeutic products are drugs derived from living cells. Biologic medicines include recombinant molecules such as monoclonal antibodies, fusion proteins and other protein therapeutics. Compared to small molecule drugs, these biologic 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.

New monographs included in IP 2014 are:

New Monographs		Revised Monographs	
Insulin Monographs	Biotech Monographs	Monographs	General Chapter
Insulin Aspart	Erythropoietin for Injection	Erythropoietin Concentration Solution	Biotechnology Derived Therapeutic Products
Insulin Aspart Injection	Erythropoietin Injection	Filgrastim Concentrated Solution	
Insulin Lispro	Filgrastim Injection	Interferon alpha 2 Concentration Solution	
Insulin Lispro Injection	Interferon Alpha 2a Injection	Recombinant Streptokinase Bulk Solution	
Biphasic Insulin Aspart Injection	Interferon Alpha 2b Injection		
Biphasic Insulin Lispro Injection	Interferon Beta 1a Concentration Solution		
	Recombinant Streptokinase for Injection		

Besides the above mentioned monographs, several other amendments are also incorporated in IP 2014.

## b. Blood and blood products

New monographs included in IP 2014 are:

Monographs	General Chapter
Anti-A Blood grouping Serum	Determination of ABO Blood Group of Blood Donors.
Anti-B Blood grouping Serum	
Human Plasma Protein Fraction	
Human Coagulation Factor IX	
Fibrin Sealant Kit	
Human Albumin	
Human Normal Immunoglobulin	
Human Normal Immunoglobulin for Intravenous Use	
Dried Human Antihaemophilic Fraction (Freeze dried Human Coagulation factor VIII)	

Besides the above mentioned monographs, several other amendments are also incorporated in IP 2014.

## c. Human Vaccines

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 monographs included in IP 2014 are:

#### New Monographs

Diphtheria Vaccine (Adsorbed) for Adults and Adolescents  
Group A Meningococcal Conjugate Vaccine

Cholera Vaccine (Inactivated, Oral)  
Meningococcal Polysaccharide A & C Vaccine

Rotavirus Vaccine (Live Attenuated, Oral)

#### Revised Monographs

Diphtheria and Tetanus Vaccine (Adsorbed)  
Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)  
Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and  
*Haemophilus influenza* type b Conjugate Vaccine (Adsorbed)  
Hepatitis B Vaccine (rDNA)

Measles, Mumps and Rubella Vaccine (Live)  
Pneumococcal Polysaccharide Vaccine (Liquid / Adsorbed)  
Poliomyelitis Vaccine (Inactivated)  
Tetanus Vaccine (Adsorbed)

Besides the above mentioned monographs, several other amendments are also incorporated in IP 2014.

### 3) Veterinary Monographs

A separate volume (Vol. 4) is dedicated specially for veterinary monograph in IP 2014, it contains following list monographs and general chapters.

#### New Non Biological Monographs: 37

Amitraz Pour-on  
Amoxicillin Oral Powder  
Buserelin  
Buserelin Injection  
Carprofen  
Cefoperazone Sodium Intramammary Suspension  
Ceftizoxime Sodium  
Ceftizoxime for Injection  
Cloprostenol Sodium  
Cloprostenol Injection  
Closantel Sodium Dihydrate  
Decoquinat  
Decoquinat Premix  
Deltamethrin  
Deltamethrin Pour-on  
Diclazuril  
Enrofloxacin  
Febantel  
Febendazole Granules  
Febendazole Oral Paste  
Febendazole Oral powder  
Febendazole Oral Suspension  
Flunixin Meglumine  
Isoflupredone Acetate  
Isoflupredone Acetate Injectable Suspension  
Ivermectin Oral Paste  
Ivermectin Pour-on  
Marbofloxacin  
Meloxicam Injection  
Moxidectin  
Moxidectin Injection  
Sulphadiazine and Trimethoprim Tablets (Co-trimazine Tablets)  
Sulphadimidine  
Sulphadimidine Sodium  
Sulphadimidine Injection  
Sulphadimidine Tablets  
Xylazine Hydrochloride

#### Revised Monograph :14

#### New Biological Monographs: 13

Bluetongue Vaccine Inactivated  
BrucellaAbortus (Strain19 Vaccine) Live  
BrucellaMelitensis (Strain Rev. 1) Vaccine, Live  
Canine Adenovirus Vaccine, Inactivated  
Canine Adenovirus Vaccine, Live  
HaemorrhagicSepticaemiaVaccine-Alum Treated  
Laryngotracheitis Vaccine, Live (Avian Infectious Laryngotracheitis Vaccine, Live)  
Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats  
Bordetella pertussis Alpha Antitoxin  
Bordetella pertussis Antitoxins  
Bordetella pertussis Beta Antitoxin  
Bordetella pertussis Epsilon Antitoxin  
Clostridium Antitoxin (Clostridium Tetani Antitoxin)

#### New Diagnostics Monograph :01

Avian Tuberculin Purified Protein Derivative (PPD)

#### New Surgicals Monographs :07

Catgut in Distributor  
Non-absorbable Strands in Distributor  
Linen Thread in Distributor  
Poly (ethylene terephthalate) Suture in Distributor  
Polyamide 6 Suture in Distributor  
Polyamide 6/6 Suture in Distributor

#### New General Chapter :01

Cultures for the Production of Veterinary Vaccines

#### General Monograph :05

Veterinary liquid preparations for cutaneous application  
Intrauterine Preparations  
Veterinary Oral Pastes  
Veterinary Immunosera  
Terminology Used in Monographs on Veterinary Vaccines



Infectious Bursal Disease Vaccine, Inactivated	Salmonella pullorum Antigen to Salmonella pullorum Coloured Antigen
Infectious Chicken Anaemia Vaccine , Inactivated	Anthrax Spore Vaccine
Infectious Coryza Vaccine , Inactivated	Avian Infectious Bronchitis Vaccine, Inactivated
Marek's Disease Vaccine, Live	Avian Spirochaetosis Vaccine, Inactivated
Ranikhet Disease Vaccine, Inactivated	Blackquarter Vaccine
Reo Virus Vaccine, Inactivated	Fowl Cholera Vaccine, Inactivated
Salmonella Vaccine, Inactivated	Inclusion Body Hepatitis (IBH) Vaccine, Inactivated

#### 4) **National Formulary of India (2011)**

The monographs, chapters and appendices in the 4<sup>th</sup> Edition of NFI is thoroughly revised for 5<sup>th</sup> Edition of NFI.

#### 5) **New Drug Analysis : 02**

Actively participated in analysis of new drug samples related to herbal drugs and veterinary drugs received in the department

#### 6) **Microbiological testing of drugs**

Microbial Bioassay of candidate reference material of IPRS: 08

- New Drugs Samples: 35 for microbiological testing
- Port Samples: 09 for microbiological testing
- Miscellaneous Drug Samples: 06 for microbiological testing

#### **Participation in Inter Laboratories Comparison Programme**

- Inter Laboratories Comparison Samples: 05 for microbial tests/parameters

#### 7) **National and International audits for accreditation of testing labs**

- **Pre-qualification audit** of microbiological laboratory was conducted by a team of assessors of **WHO**, as a initial process of WHO accreditation procedure for laboratories.
- Successfully completed **NABL Surveillance Audit 2013**

#### 8) **Monographs and related work from microbiological division**

- Addition of new Antibiotics monographs in IP 2014: 13
- New General chapters: 03

##### **New Antibiotics Monographs:13**

timethate Sodium  
timethate Injection  
tin Sulphate  
tin Tablet  
icidin  
mycin  
mycin Ophthalmic Suspension

##### **New General Chapters:03**

Transfusion and Infusion Assemblies and Similar Medical Devices  
Amino Acid Analysis  
Maintenance, Identification, Preservation and Disposal of Microorganisms  
**Revised General Chapters:03**  
Sterility  
Bacterial Endotoxin Test  
Microbial contamination in non sterile products

micin Sulphate  
 nicin Sulphate  
 nicin Sulphate Injection  
 thricin  
 oplanin  
 timethate Sodium

**Revised Monographs:02**  
 Water for Injections in Bulk  
 Purified Water

- Bacterial Endotoxin Test: Included in 47 Parenteral Preparations Monographs in IP 2014,
- 08 Blood and Blood Related Products Monographs,
- 03 Veterinary Monographs
- Test for *Shigella* included in Microbial Contamination Test: 16 Monograph.

#### 9) **Technical coordination with WHO**

- Provided expert advice to WHO, Geneva for preparation of Technical Report Series 986 on ‘Specifications of Pharmaceutical Preparations’
- Prepared working document on Good Pharmacopoeial Practices on
  - a) Monograph on Herbals
  - b) Analytical test procedures and methodologies

## **Reference Standard Division**

### ➤ **Indian Pharmacopoeia Laboratory**

A modern analytical laboratory capable of doing chemical and microbiological analysis, qualification testing of candidate reference materials and containerization of such reference materials which becomes Indian Pharmacopoeia official Reference Materials to be used in conjunction with the official documentary standards published in the Indian pharmacopoeia.

Indian Pharmacopoeia Laboratory is well equipped with Highly Modern Sophisticated Instruments. The list of Instruments is as under :-

1. LC-MS/MS Q-TOF Agilent 6520
2. NMR, Agilent 500/54/AR, Cryostat,
3. GC-MS Triple Quad Agilent 7890A
4. GC-HS Agilent 7890A
5. ICP –MS 6000, Perkin Elmer , Model: NexION 300X,
6. HPLC, Agilent 1200 Series
7. HPLC, Dionex Ultimet 3000
8. HPLC, Water 2695
9. UV-VIS, Lambda 35
10. Atomic Absorption Spectrometer, Model- Agilent, AA240 series,
11. FT-IR Spectrum one Perkin Elmer
12. FTIR, Perkin Elmer, FT microscope spotlight 200 & frontier
13. Polarimeter, Perkin Elmer-241
14. Mettler Toledo Autotitrator T-50
15. Mettler Toledo DL55 Titrator
16. Mettler Toledo KF Titrator
17. TGA/DSC Mettler Toledo Model Star è System
18. Coulometric KF Titrator (C-30) Mettler Toledo
19. Digital Tablet Dissolution Test Apparatus, LABINDIA, DISO TEST
20. Tablet Dissolution Tester (USP24), Electrolab
21. Dionex ICS-5000 DC, Ion Chromatograph with VWD, ECD & Conductivity Detectors
22. Euro Vector Elemental Analyser Model : EURO EA3000
23. Particle Size Analyzer, Model: Microtrac S3000/S3500,
24. Microwave reaction system, Model: Multiwave 3000, Perkin Elmer,
25. pH Meter, Mettler Toledo, Seven Compact 5220
26. pH Meter, Mettler Toledo, Seven Easy
27. Sartorius Microbalance CPA2P Part I & II
28. Analytical Balance- Mettler Toledo XP205
29. Analytical Balance-Mettler Toledo, XP2U
30. DSC – 6000, Perkin Elmer
31. Vacuum Oven, NSW-251
32. Muffle Furnace, Toshiba
33. NSW-143 Oven
34. Sonar Serlogical Water bath
35. Rei-Services Ultrasonic
36. Prolabo-Ultrasonic
37. Water Purifier, Millipore

➤ **IP Reference Substances (IPRS)**

Reference Substances certain monographs required the use of a chemical reference substance or a biological reference preparation or a reference spectrum. These are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the Pharmacopoeia and are not necessarily suitable in other circumstances. IP Reference Substances, abbreviated to IPRS (and referred to as RS in the individual Monographs) are issued by the Indian pharmacopoeia Commission (IPC). They are the official standards to be used in cases of arbitration. Secondary Standards (Working Standards) may be used for routine analysis, provided they are standardized at regular intervals against the Reference Substances.

Reference Substances are also abbreviated to IPRS and Standard Preparations of antibiotics are issued by agencies authorised by the IPC. They are standardized against the International Standards and Reference Preparations established by the World Health Organization (WHO). The potency of these preparations is expressed in International Units.

➤ **Activity of Indian Pharmacopoeia Laboratory**

- 1- IPRS Development
- 2- New Drugs Analysis
- 3- Port Sample Analysis
- 4- Inter Laboratory Comparison and Misc. Sample Analysis
- 5- Monograph Verification and Development for IP

**1- IPRS Development**

Reference Standard Division has developed total **347** IPRS including **8** Impurities up to March of 2014 which is available on our website [www.ipc.gov.in](http://www.ipc.gov.in) for Stakeholders. The list of available 347 IPRS is given below:

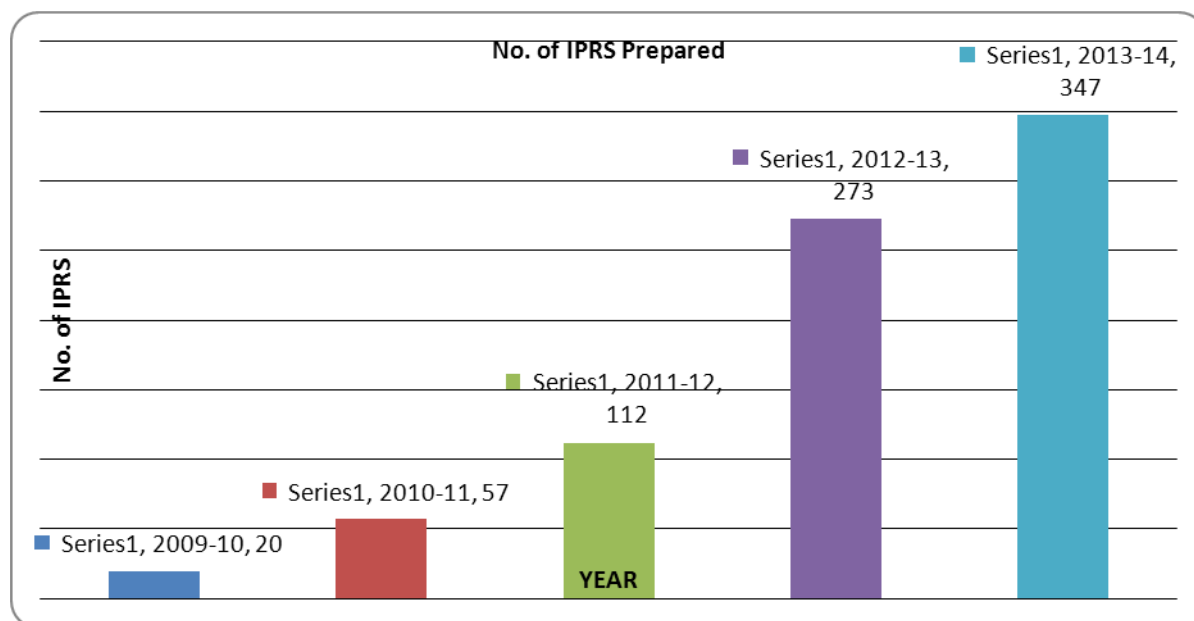
- |                                 |                                 |
|---------------------------------|---------------------------------|
| 1. Abacavir Sulphate            | 18. Ampicillin                  |
| 2. Acebutolol Hydrochloride     | 19. Ampicillin Sodium           |
| 3. Aceclofenac                  | 20. Ampicillin Trihydrate       |
| 4. Acetazolamide                | 21. Anastrozole                 |
| 5. Aciclovir                    | 22. Artemether (Artemetherum)   |
| 6. Allopurinol                  | 23. Artesunate                  |
| 7. Alprazolam                   | 24. Ascorbic Acid (Vit. C)      |
| 8. Amantadine Hydrochloride     | 25. Aspirin                     |
| 9. Ambroxol Hydrochloride       | 26. Atazanavir Sulphate         |
| 10. Amiloride Hydrochloride     | 27. Atenolol                    |
| 11. Aminophylline               | 28. Atorvastatin Calcium        |
| 12. Amiodarone Hydrochloride    | 29. Atropine Sulphate           |
| 13. Amitriptyline Hydrochloride | 30. Azathioprine                |
| 14. Amlodipine Besylate         | 31. Baclofen                    |
| 15. Amodiaquine Hydrochloride   | 32. Beclomethasone Dipropionate |
| 16. Amoxycillin Sodium          | 33. Benzhexol Hydrochloride     |
| 17. Amoxycillin Trihydrate      | 34. Benzocaine                  |

- |     |                              |      |                                   |
|-----|------------------------------|------|-----------------------------------|
| 35. | Betahistine Hydrochloride    | 91.  | Cyproterone Acetate               |
| 36. | Betamethasone Dipropionate   | 92.  | Cytarabine                        |
| 37. | Betamethasone Valerate       | 93.  | Dexamethasone Sodium Phosphate    |
| 38. | Bisacodyl                    | 94.  | Dextromethorphan Hydrobromide     |
| 39. | Bromhexine Hydrochloride     | 95.  | Diacerein                         |
| 40. | Bronopol                     | 96.  | Diazepam                          |
| 41. | Buclicine Hydrochloride      | 97.  | Diclofenac Sodium                 |
| 42. | Budesonide                   | 98.  | Dicloxacillin Sodium              |
| 43. | Buspirone Hydrochloride      | 99.  | Dicyclomine Hydrochloride         |
| 44. | Caffeine                     | 100. | Didanosine                        |
| 45. | Calcium Gluconate            | 101. | Diethylcarbamazine Citrate        |
| 46. | Calcium Levulinate           | 102. | Diloxanide Furoate                |
| 47. | Capecitabine                 | 103. | Diltiazem Hydrochloride           |
| 48. | Captopril                    | 104. | Diphenhydramine Hydrochloride     |
| 49. | Carbamazepine                | 105. | Disodium Edetate                  |
| 50. | Carbidopa                    | 106. | Disulfiram                        |
| 51. | Carvedilol                   | 107. | Divalproex Sodium                 |
| 52. | Cefaclor                     | 108. | Domperidone                       |
| 53. | Cefazolin Sodium             | 109. | Domperidone Maleate               |
| 54. | Cefepime Hydrochloride       | 110. | Donepezil Hydrochloride           |
| 55. | Cefixime                     | 111. | Dothiepin Hydrochloride           |
| 56. | Cefoperazone Sodium          | 112. | Doxepin Hydrochloride             |
| 57. | Cefotaxime Sodium            | 113. | Doxofylline                       |
| 58. | Cefpodoxime Proxetil         | 114. | D-Panthenol                       |
| 59. | Cefuroxime Axetil            | 115. | Efavirenz                         |
| 60. | Cefuroxime Sodium            | 116. | Emtricitabine                     |
| 61. | Cephalexin                   | 117. | Enalapril Maleate                 |
| 62. | Cetrimide                    | 118. | Enrofloxacin                      |
| 63. | Cetirizine Dihydrochloride   | 119. | Ephedrine Hydrochloride           |
| 64. | Chloramphenicol              | 120. | Ergotamine Tartrate               |
| 65. | Chloramphenicol Palmitate    | 121. | Erythromycin Estolate             |
| 66. | Chlordiazepoxide             | 122. | Erythromycin Stearate             |
| 67. | Chlorhexidine Hydrochloride  | 123. | Escitalopram Oxalate              |
| 68. | Chloroquine Phosphate        | 124. | Esomeprazole Magnesium Trihydrate |
| 69. | Chloroquine Sulphate         | 125. | Ethambutol Hydrochloride          |
| 70. | Chlorpheniramine Maleate     | 126. | Ethinylestradiol                  |
| 71. | Chlorthalidone               | 127. | Ethionamide                       |
| 72. | Cilastatin Sodium            | 128. | Etidronate Disodium               |
| 73. | Cimetidine                   | 129. | Etodolac                          |
| 74. | Cinnarizine                  | 130. | Etoposide                         |
| 75. | Ciprofloxacin                | 131. | Famotidine                        |
| 76. | Ciprofloxacin Hydrochloride  | 132. | Felodipine                        |
| 77. | Citalopram Hydrobromide      | 133. | Fenbendazole                      |
| 78. | Clarithromycin               | 134. | Fenofibrate                       |
| 79. | Clindamycin Hydrochloride    | 135. | Ferrous Fumarate                  |
| 80. | Clobazam                     | 136. | Ferrous Gluconate                 |
| 81. | Clofazimine                  | 137. | Fexofenadine Hydrochloride        |
| 82. | Clomipramine Hydrochloride   | 138. | Finasteride                       |
| 83. | Clonazepam                   | 139. | Fluconazole                       |
| 84. | Clopidogrel Bisulphate       | 140. | Fluorouracil                      |
| 85. | Clotrimazole                 | 141. | Fluoxetine Hydrochloride          |
| 86. | Cloxacillin Sodium           | 142. | Flurbiprofen Sodium               |
| 87. | Cyanocobalamin (Vit. B12)    | 143. | Flutamide                         |
| 88. | Cyclizine Hydrochloride      | 144. | Fluticasone Propionate            |
| 89. | Cycloserine                  | 145. | Folic Acid                        |
| 90. | Cyproheptadine Hydrochloride | 146. | Frusemide/Furosemide              |

147.	Furazolidone	202.	Mefloquine Hydrochloride
148.	Fusidic Acid	203.	Meropenem
149.	Gatifloxacin	204.	Metformin Hydrochloride
150.	Gefitinib	205.	Methotrexate
151.	Gemifloxacin Mesylate	206.	Methyl Prednisolone
152.	Gentamicin Sulphate	207.	Methyl Salicylate
153.	Glibenclamide	208.	Methyldopa
154.	Gliclazide	209.	Methylprednisolone Acetate
155.	Glimepiride	210.	Metoclopramide Hydrochloride
156.	Glipizide	211.	Metoprolol Tartrate
157.	Glycine	212.	Metronidazole
158.	Griseofulvin	213.	Metronidazole Benzoate
159.	Guaiphenesin	214.	Miconazole Nitrate
160.	Haloperidol	215.	Minoxidil
161.	Homatropine Methylbromide	216.	Mometasone Furoate
162.	Hydralazine Hydrochloride	217.	Montelukast Sodium
163.	Hydrochlorothiazide	218.	Mosapride Citrate Dihydrate
164.	Hydrocortisone Acetate	219.	Mycophenolate Mofetil
165.	Hyoscine Butyl Bromide	220.	Nandrolone Phenyl Propionate
166.	Ibuprofen	221.	Naproxen
167.	Imatinib Mesylate	222.	Nebivolol Hydrochloride
168.	Imipramine Hydrochloride	223.	Neomycin Sulphate
169.	Indapamide	224.	Nevirapine
170.	Indomethacin	225.	Nicotinamide (Niacinamide)
171.	Isoniazid	226.	Nicotinic Acid (Niacin)
172.	Isosorbide Dinitrate Diluted (40 %)	227.	Nicoumalone
173.	Isoxsuprine Hydrochloride	228.	Nifedipine
174.	Ivermectin	229.	Nitrazepam
175.	Ketamine Hydrochloride	230.	Nitrofurantoin
176.	Ketoconazole	231.	Norethisterone
177.	Ketoprofen	232.	Norfloxacin
178.	Ketorolac Tromethamine	233.	Nystatin
179.	Labetalol Hydrochloride	234.	Ofloxacin
180.	Lamivudine	235.	Olanzapine
181.	Lamotrigine	236.	Omeprazole
182.	Lansoprazole	237.	Ondansetron
183.	Levamisole Hydrochloride	238.	Ondansetron Hydrochloride
184.	Levocetirizine Hydrochloride	239.	Ornidazole
185.	Levodopa	240.	Orphenadrine Citrate
186.	Levofloxacin Hemihydrate	241.	Oseltamivir Phosphate
187.	Levosaltbutamol Sulphate	242.	Oxcarbazepine
188.	Lignocaine Hydrochloride	243.	Pantoprazole Sodium Sesquihydrate
189.	Lindane (Gamma Benzene Hexachloride)	244.	Paracetamol
190.	Linezolid	245.	Penicillamine
191.	Lisinopril	246.	Pentazocine
192.	Lithium Carbonate	247.	Pheniramine Maleate
193.	Loperamide Hydrochloride	248.	Phenobarbitone
194.	Lopinavir	249.	Phenoxyethanol
195.	Losartan Potassium	250.	Phenoxymethylpenicillin Potassium
196.	Magaldrate	251.	Phenylephrine Hydrochloride
197.	Mannitol	252.	Phenylpropanolamine Hydrochloride
198.	Mebendazole	253.	Phenytoin Sodium
199.	Mebeverine Hydrochloride	254.	Pioglitazone Hydrochloride
200.	Meclizine Hydrochloride	255.	Piperacillin
201.	Mefenamic Acid	256.	Piracetam
		257.	Piroxicam

258.	Potassium Citrate	307.	Terbutaline Sulphate
259.	Potassium Sorbate	308.	Testosterone Propionate
260.	Povidone-Iodine	309.	Theophylline
261.	Praziquantel	310.	Thiamine Hydrochloride (Vit. B1)
262.	Prednisolone Acetate	311.	Thiamine Mononitrate
263.	Prednisolone Sodium Phosphate	312.	Thiocolchicoside
264.	Pregabalin	313.	Timolol Maleate
265.	Primaquine Phosphate	314.	Tinidazole
266.	Probenecid	315.	Tizanidine Hydrochloride
267.	Prochlorperazine Maleate	316.	Tocopheryl Acetate
268.	Proguanil Hydrochloride	317.	Tolnaftate
269.	Promethazine Hydrochloride	318.	Tolterodine Tartrate
270.	Promethazine Theoclate	319.	Topiramate
271.	Propranolol Hydrochloride	320.	Topotecan Hydrochloride
272.	Propyphenazone	321.	Tramadol Hydrochloride
273.	Pseudoephedrine Hydrochloride	322.	Triamcinolone
274.	Pyrantel Pamoate	323.	Triamcinolone Acetonide
275.	Pyrazinamide	324.	Triamterene
276.	Pyridoxine Hydrochloride (Vit. B6)	325.	Trimetazidine Hydrochloride
277.	Pyrimethamine	326.	Trimethoprim
278.	Quetiapine Fumarate	327.	Tripolidine Hydrochloride
279.	Quinine Dihydrochloride	328.	Tropicamide
280.	Quiniodochlor	329.	Valproic Acid
281.	Rabeprazole Sodium	330.	Valsartan
282.	Ramipril	331.	Verapamil Hydrochloride
283.	Ranitidine Hydrochloride	332.	Warfarine Sodium
284.	Ribavirin	333.	Warfarine Sodium Clathrate
285.	Riboflavin	334.	Xylometazoline Hydrochloride
286.	Ritonavir	335.	Zidovudine
287.	Rosuvastatin Calcium	336.	Zoledronic Acid
288.	Roxithromycin	337.	Zolpidem Tartrate
289.	S(-)Amlodipine Besylate	338.	2-Methyl-5-nitro imidazole (impurity)
290.	Salmeterol Xinafoate	339.	Potassium Monoethyl Sulphate (impurity)
291.	Saquinavir Mesylate	340.	7-aminodesacetoxycephalosporanic acid (Cefadroxil Monohydrate Impurity B)
292.	Secnidazole	341.	E-isomers (Cefuroxime Axetil Impurity)
293.	Sildenafil Citrate	342.	D3-isomers (Cefuroxime Axetil Impurity)
294.	Simvastatin	343.	Dicyandiamide
295.	Sodium Valproate	344.	6,7-dimethoxy-2-(piperazin-1-yl)quinazolin-4-amine (Terazosin Impurity C)
296.	Spiramycin	345.	2-chloro-6,7-dimethoxyquinazolin-4-amine (Terazosin Impurity A)
297.	Stavudine	346.	Triphenylmethanol
298.	Sulphadimidine	347.	zidovudine-related compound B
299.	Sulphadoxine		
300.	Sulphamethoxazole		
301.	Sumatriptan Succinate		
302.	Tamoxifen Citrate		
303.	Tamsulosin Hydrochloride		
304.	Telmisartan		
305.	Tenofovir Disproxil Fumarate		
306.	Terazosin Hydrochloride		

During the year 2013, additional 171 new IPRS including 8 Impurities were developed and updated on our website. 78 more candidate materials are under development for IPRS. To prove the stability of already developed IPRS, retesting of the IPRS are being done initially after 2 year than annually. Total 97 IPRS were retested for their integrity of potency.

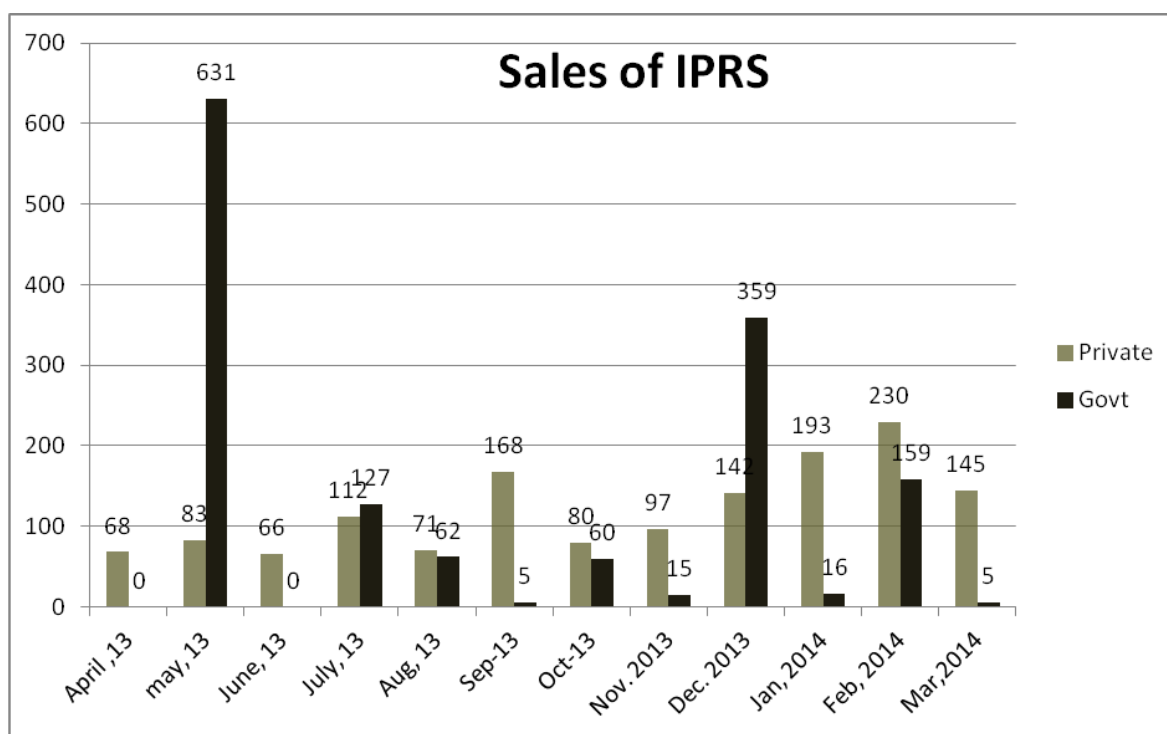


- No. of IPRS/Impurity vials dispatched to Govt. drugs testing laboratories  
 = 3426 and 39  
 = 3465 (Rs. 1, 04, 34000/- IPRS Supplied free of cost)

- No. of IPRS / Impurity vials dispatched to Private companies / laboratories  
 = (1629\*3000) = 48, 87000/-  
 + (31\*4000) = 1, 24,000/-  
 =50, 11,000/-

**Grand Total**





## 2- New Drug analysis

The IPC has started verifying test protocols of certain drugs which introduced recently in the Indian market on approval of DCGI office. In the 41st DCC meeting, the members have desired that such test protocols be made available to drug's testing laboratories/ regulators of the respective states on demands. Indian pharmacopoeia laboratory organised testing of new drugs molecule received from DCG(I) office and prepared the protocol bank. Protocol later in form of monograph will be included in the next Indian Pharmacopoeia. Total **261** New Drugs are received for testing at IPC.

## 3- Port Sample Analysis

In 2013 total 144 port samples were received from CDSCO, IGI cargo complex, New Delhi at IPC, Ghaziabad for the analysis and successfully submitted the report to the CDSCO Office, New Delhi.

## 4- Monograph Verification and Development for IP

In IP-2014, **43** New Monographs has been added which is developed from new drug substances as well **19** Radiopharmaceuticals Monographs with one general chapter on radiopharmaceutical included. 17 new radiopharmaceuticals monographs are under process to be including in upcoming IP edition. List is given below:

- |                          |                      |
|--------------------------|----------------------|
| 1. Agomelatine           | 4. Asenapine Maleate |
| 2. Arbidol Hydrochloride | 5. Atosibane Acetate |
| 3. Arterolane Maleate    | 6. Azacitidine       |

- |                               |                                     |
|-------------------------------|-------------------------------------|
| 7. Azelnidipine               | 26. Lubiprostone                    |
| 8. Biapenem                   | 27. Mitiglinide Calcium Dihydrate   |
| 9. Brinzolamide               | 28. Moexipril Hydrochloride         |
| 10. Choline Fenofibrate       | 29. Naproxcinod                     |
| 11. Dapoxetine Hydrochloride  | 30. Ramelteon                       |
| 12. Dexlansoprazole           | 31. Rilpivirine                     |
| 13. Dienogest                 | 32. Roflumilast                     |
| 14. Eletriptan Hydrobromide   | 33. Rufinamide                      |
| 15. Eslicarbazepine Acetate   | 34. Sildenafil Methane Sulphonate   |
| 16. Fasoterodine Fumarate     | 35. Seratrodast                     |
| 17. Fasudil Hydrochloride     | 36. Tapentadol Hydrochloride        |
| 18. Fenspiride Hydrochloride  | 37. Tauroursodeoxycholic Acid       |
| 19. Fingolimod Hydrochloride  | 38. Tofluprost                      |
| 20. Fomepizole                | 39. Tolvaptan                       |
| 21. Frovatriptan Succinate    | 40. Tranilast                       |
| 22. Galanthamine Hydrobromide | 41. Trimethobenzamide Hydrochloride |
| 23. Ibudilast                 | 42. Udenafil                        |
| 24. Ilaprazole                | 43. Ulipristal Acetate              |
| 25. Iloperidone               |                                     |

## **Radiopharmaceutical Monographs**

1. ( $^{131}\text{I}$ ) Meta-Iodobenzyl Guanidine Injection for Diagnostic Use
2. ( $^{131}\text{I}$ ) Meta-Iodobenzyl Guanidine Injection for Therapeutic Use
3. Fluorodeoxyglucose ( $^{18}\text{F}$ ) Injection
4. Samarium ( $^{153}\text{Sm}$ ) Ethylene Diamine Tetramethylene Phosphonate (EDTMP) Injection
5. Sodium Fluoride ( $^{18}\text{F}$ ) Injection
6. Sodium Iodide ( $^{131}\text{I}$ ) Capsules for Diagnostic Use
7. Sodium Iodide ( $^{131}\text{I}$ ) Capsules for Therapeutic Use
8. Sodium Iodide ( $^{131}\text{I}$ ) Solution
9. Sodium Pertechnetate ( $^{99\text{m}}\text{Tc}$ ) Injection (Fission)
10. Sodium Pertechnetate ( $^{99\text{m}}\text{Tc}$ ) Injection (Non-fission)
11. Sodium Phosphate ( $^{32}\text{P}$ ) Injection
12. Technetium ( $^{99\text{m}}\text{Tc}$ ) DMSA Injection
13. Technetium ( $^{99\text{m}}\text{Tc}$ ) DTPA Injection
14. Technetium ( $^{99\text{m}}\text{Tc}$ ) EC Injection
15. Technetium ( $^{99\text{m}}\text{Tc}$ ) ECD Injection
16. Technetium ( $^{99\text{m}}\text{Tc}$ ) Glucoheptonate Injection
17. Technetium ( $^{99\text{m}}\text{Tc}$ ) Mebrofenin Injection
18. Technetium ( $^{99\text{m}}\text{Tc}$ ) Medronate Complex Injection
19. Technetium ( $^{99\text{m}}\text{Tc}$ ) MIBI Injection

### ➤ **TRAINING PROGRAMS:**

- 1- Induction Training Program for newly recruited Drug Inspectors of CDSCO was organised by Indian Pharmacopoeia Commission, Ghaziabad in two phases from 15<sup>th</sup> July, 2013 to 02<sup>nd</sup> August, 2013 and 02<sup>nd</sup> September, 2013 to 20<sup>th</sup> September, 2013.
- 2- IPC Ghaziabad has successfully organised TRAINING PROGRAMME ON VARIOUS ANALYTICAL INSTRUMENTS & TECHNIQUES FOR GOVERNMENT DRUG ANALYSTS” from 25<sup>th</sup> November to 06<sup>th</sup> December 2013. Approx forty government analysts from various State Laboratories pan India had attended the same.

### ➤ **ACCREDITATION :**

#### **1- NABL**

To strengthen the quality system & documentation, globally accepted NABL certification ISO 17025 and NABL certification ISO 17025:2005 were achieved by

IPC in September 2011 for Chemicals and Biological Testing with full devotion of IPC staff within few months after filling the application in very first attempt. Recently NABL has extended their accreditation for two years after auditing RSD by their auditor for the 2 days (**10<sup>th</sup> to 11<sup>th</sup> August, 2013**) at IPC. Now the IPC is adopting uniform approach for determining laboratory competence, encourage laboratories to adopt internationally accepted testing and reliable results.

## 2- WHO

In the context of increasing access to quality control laboratories that meet recommended international standards for testing of medicines, WHO, together with UNICEF, UNAIDS, UNFPA, UNITAID and with the support of the World Bank, invite **quality control laboratories which are committed to providing a service of testing of products used in the treatment of HIV/AIDS, Tuberculosis, Malaria and in Reproductive Health, to UN agencies** to submit an WHO prequalification.

To meet the international parameters of testing, Indian Pharmacopoeia Commission, Ghaziabad has successfully completed the first stage of WHO Prequalification Programme held from 10<sup>th</sup> February, 2014 to 14<sup>th</sup> February, 2014. WHO had suggested observation to comply for the fulfilment of qualification programme, **IPC is the first government laboratory in India to participate in Prequalification Quality Control Laboratories of WHO**. The following experts from WHO had audited the same.

- 1- Dr. Jitika Sabartova, Technical Officer, WHO
- 2- Mr. Andrew John Charvill, Expert WHO
- 3- Mrs. Robyn Susan Isaacson, Expert WHO

## ➤ QUALITY ASSURANCE

- To improve the quality of documentation, QA section established & is functioning since Nov, 2011.
- Newly joined Pharma associate were trained in lab as well as in documentation related to NABL.
- Procedures were developed to keep the data of Reference Standard Division in safe custody and are archived in QA section
- New log book of IPC were implemented in lab and other area where required.
- Evaluation of more than 1000 of reports received from other labs, including IPL. Participating in validation of IPRS done.
- Various SOP of different activity has been upgraded and 10 new SOP are under review to fulfil the requirement of WHO prequalification programme.

### **List of Newly Prepared SOP**

<b><u>S.No.</u></b>	<b><u>Name of SOP</u></b>
1.	SOP for Handling of Out OF Specification Results
2.	SOP for Cleaning And Validation OF HPLC Vials
3.	SOP for Operation and Calibration for Disintegration Test Apparatus
4.	SOP for Validation of SpreadSheet
5.	SOP for Allocation of Operational Rights
6.	SOP for Use of bracketing standard for quantitative analysis by HPLC/GC
7.	STP for Environmental Monitoring of Temperature and Humidity of Laboratory.
8.	SOP for Cleaning of Laboratory Glassware
9.	SOP for Safety for Personnel Working in Chemistry Laboratory
10.	SOP for General Instruction for Use of HPLC

### **List of Updated SOP**

<b><u>S.No.</u></b>	<b><u>Name of SOP</u></b>
1.	SOP for Change Control Procedure
2.	SOP for Internal Audit
3.	SOP for pH Meter
4.	SOP for Internal Proficiency Testing

### **Seminars/ Training Programmes / Symposia / Workshops / Meetings attended:**

Following meetings / programmes were held during April,2013- March,2014.

1. A meeting with Dr. Rishendra Verma, Joint Director, IVRI, Izzat Nagar was held on 08.04.2013 on Veterinary monographs at IPC.
2. IPC technical staff attended the joint IPC-USP Symposium at ITC Maurya, New Delhi on 16.04.2013 and 17.04.2013.
3. IPC team attended the WHO II<sup>nd</sup> World Pharmacopoeia meeting at Oberoi Hotel, New Delhi on 18.04.2013 and 19.04.2013.
4. A meeting with experts Sh. J.L. Sipahimalani & Sh. R. Sridharan and Mr. V.K. Kapoor was held for reviewing IP-2014 manuscript volume-I and IV at IPC, from 13.05.2013 to 15.05.2013.
5. Meeting with Prof. B. Suresh, Chairman, Scientific Body and Dr. Nitya Anand, Ex-chairman, SB of IPC on 16.05.2013 at IPC for reviewing and planning IPC activities.
6. A meeting with experts Sh. J.L. Sipahimalani, Sh. R. Raghunandan and Sh. R. Sridharan was held for reviewing IP-2014 Volume-II and III at IPC, from 29.05.2013 to 31.05.2013.
7. A meeting was held with Dr. K.V. Surindernath, Vice-President and Dr. Ashok Dang, Director from USP (India), Hyderabad at IPC on 27.06.2013.
8. “First Training Programme of Induction of Drug Inspectors of CDSCO from 15.07.2013 to 02.08.2013” held at IPC. Dr. Jagdish Prasad, DGHS was Chief Guest and visited the IPC-IPL Facilities.
9. Sh. Desi Raju, Secretary, Ministry of Health & Family Welfare and Chairman, IPC was Chief Guest for the concluding session of the training Programme of Drug Inspectors of CDSCO and visited the IPC-IPL Facilities.
10. The Reassessment of NABL (ISO/IEC 17025:2005) accreditation of IPL of IPC was held from 10<sup>th</sup> to 11<sup>th</sup> August, 2013.
11. The Second Training Programme ‘Induction of Drug Inspectors of CDSCO from 02.09.2013 to 20.09.2013’ was held at IPC.
12. The 27<sup>th</sup> Scientific Body meeting was held at FDA, Bhawan, New Delhi on 14.09.2013.
13. The Scientific Delegation of Kenya visited IPC facilities on 27.09.2013.

- 14.** A meeting with Chief Architect at Nirman Bhawan, New Delhi regarding clearance of DPR of proposed New Building of IPL at IPC was held on 14.10.2013.
- 15.** 7<sup>th</sup> edition of Indian Pharmacopoeia IP-2014 was released by Hon'ble Health Minister, Mr. Gulab Navi Azad on at 04.11.2013 at Nirman Bhawan, New Delhi.
- 16.** Training Programme of Government Laboratory Analyst of Central and States was held in IPC from 25.11.2013 to 06.12.2013.
- 17.** IPC technical team received Best Research Paper Award for the Year, 2015 in the field for Pharmaceutical Analysis on 04.01.2014.
- 18.** The Second Scientific Body meeting of Pharmacopoeial Commission for Indian Medicine (PCIM) at CCRAS, New Delhi was attended by IPC technical staff on 3.01.2014.
- 19.** WHO-QCL Pre-qualification Programme, Assessment by WHO, Geneva Team of IPC-IPL was held from 10<sup>th</sup> to 14<sup>th</sup>, Feb., 2014.
- 20.** IPC technical team attended 13<sup>th</sup> IPC-USP Science and Standard Symposium held at HICC, Hyderabad on 26<sup>th</sup> -27<sup>th</sup> Feb., 2014.

## PHARMACOVIGILANCE PROGRAM OF INDIA (PvPI)

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The progress/achievements/initiatives of PvPI for the period of April 2013 to March 2014 as follows:

### **1. Establishment of ADRs monitoring Centre**

MCI approved medical institutions and corporate hospitals showed their willingness to participate in PvPI Programme. Several institutions submitted their letter of Intent to participate in PvPI. After assessing the suitability, 4<sup>th</sup> Working Group meeting held on 18<sup>th</sup> October recommended to induct 60 more ADRs monitoring centre (AMC) under PvPI.

In total 150 AMCs are functioning to monitor and report ADRs to NCC.

### **2. Generation of ADRs during the period of April 2013 to March 2014**

Individual Case Safety Reports (ICSRs) submitted to NCC for the mentioned period was 36,651. (Total ICSR in national drug safety database is 99,587).

### **3. Introducing Helpline facility for assistance in ADRs reporting**

IPC has introduced an helpline i.e. 1800 180 3024 (toll free) for providing assistance in ADRs reporting for the healthcare professionals and general public. By using this number citizens can call across the country to seek information about ADRs reporting. This facility further upgraded by sending SMS acknowledgement for the ADRs reporter in order to build their confidence.

### **4. Development of PvPI toolkit and web link**

NCC and WHO-India Country Office jointly developed PvPI web link and PvPI toolkit to make the programme publically available. PvPI toolkit is a package of simple Pharmacovigilance tools and description of supporting processes for the conduct of Pharmacovigilance in India. This was launched on 9<sup>th</sup> December 2013 at Hyderabad.

### **5. Documentation grading and Completeness Score for Indian ICSR**

As per the WHO-UMC assessment, the documentation and completeness score for Indian ICSR for the above period was 0.83 (Annexure 3).



**6. Collaboration with Revised Tuberculosis Control Programme to monitor the safety of anti TB drugs**

NCC and Revised Tuberculosis Control Programme formally agreed on 11<sup>th</sup> October to monitor the safety of anti tubercular drugs used in the programme.

**7. Assisting in Vaccine safety**

NCC is working with AEFI and Immunization Technical Support Unit to ensure the vaccine safety. Vaccine ICSRs reported to NCC were communicated to AEFI/UIP of Ministry of Health & Family Welfare.

**8. Visit of International Experts to NCC**

Dr. Ruth Savage, Medical Assessor and Senior Research Fellow at the Centre for Adverse Reactions Monitoring (CARM), New Zealand Pharmacovigilance centre visited IPC on 26<sup>th</sup> November 2013. She presented a talk on ‘Data Mining and Signal Detection’ and put limelight on “Global Prospective of PvPI’. She reviewed the activities under PvPI and also appreciated the progress of pharmacovigilance activities in India.

**9. Education and Training**

NCC Organized Continuing Medical Education (CME) on Pharmacovigilance to create awareness among healthcare professionals in ADRs reporting and patient’s safety at different places in the country as follows:

- a. 1st CME was organized at the Department of Clinical Pharmacology, Sher-I-Kashmir Institute of Medical Science (SKIMS), at Srinagar (J&K) on 23<sup>rd</sup> October 2013. 150 delegates attended the Programme.
- b. 2nd CME was organized at Dr. Rajendra Prasad Government Medical College Tanda (Kanagra), H.P. on 31<sup>st</sup> October 2013. 280 delegates had participated in the Programme.
- c. 3rd CME was organized at U.P. Rural Institute of Medical Sciences and Research, Safai, Etawah, Uttar Pradesh on 8<sup>th</sup> November 2013. Over 210 delegates participated in the Programme.

- d. 4th CME was organized at the Rajendra Institute of Medical Sciences at Ranchi, Jharkhand, on 30<sup>th</sup> November 2013. Over 260 delegates attended the Programme.
- e. 5th CME was organized at Jawaharlal Nehru Medical College, Aligarh Muslim University, at Aligarh, U.P on 7th Nov. 2013. Over 80 delegates attended the Programme.
- f. 6th CME was Organized by Indian Medical Association in Collaboration with NCC-PvPI at Chennai, Tamil Nadu on 22Feb. 2014. Over 60 delegates were educated in the Programme for Pharmacovigilance.

NCC also organized training programme for technical associates of AMCs as follows:

- a. Induction cum training programme for the newly recruited Technical Associates (TAs) was organized by NCC from 10-13<sup>th</sup> February 2014 at IPC Ghaziabad. During this training programme 30 TAs participated and experienced on Pharmacovigilance practices and hands on training on VigiFlow.
- b. 3<sup>rd</sup> Training cum meeting of coordinators and Technical Associate of North Zone was held on 27<sup>th</sup> July 2013 at Lecture Theatre Complex, PGIMER, Chandigarh. 20 participants participated in the programme.
- c. East Zone Regional centre for Training and Technical Support organized a training programme at Auditorium of College of Nursing, IPGMER, Kolkata on 23 April 2013. Over 115 participants was present in the training programme.
- d. A Training Programme on VigiFlow was organized by Regional Centre KEM on dated 15 April 2013 at KEM, Mumbai. 6 participants were present in the Programme.

## **10 Signal Review Panel Meeting**

The first meeting of PvPI Signal Review Panel was held on 20th February, 2014 at Indian Pharmacopoeia Commission, Ghaziabad and the second meeting on 21st and 22nd March, 2014 at CDSCO Zonal Office, Mumbai, under the chairperson, Prof. Urmila Thatte. During this meeting it was discussed the road map and future course of action required. Also debated whether PvPI need software for signal detection. The panel recommended PvPI may use the facilities/services provided by WHO-UMC.

## LIBRARY AND INFORMATION CENTRE

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### Library & Information Centre (Section):

The Library & Information Centre has open access system for self arrangement for users. Books are processed by using AACR-II code for cataloguing and Dewey Decimal Classification. The Call Number in the OPAC helps in locating the books on the shelves. Books are arranged on the shelves in numerical order from 000-999. The IPC Library & Information Centre divided in to 5 Sections:

- Circulation Section
- Periodical Section
- Reference Section
- Reprographic Section
- Internet Section

### PROCUREMENT OF BOOKS:

The Library & Information Centre houses an excellent collection of more than 11,000 documents including books, Indian & International Standards, and Pharmacopoeias of different Countries. The IPC Library & Information Centre has procured the books to support Scientific, Pharmacopoeial and Administrative work during the year (01/04/2013 – 31/03/2014) as appended below: -

S. No.	ITEMS NAME	QUANTITY
1.	Total Books Procured	322 (appx.)

### PROCUREMENT OF NON-BOOK MATERIALS:

The IPC Library & Information Centre caters to the needs of scientists of the Commission, Health professionals, and researchers from within and outside the Country. The IPC Library & Information Centre has also procured the following non-book materials during the year (01/04/2013 – 31/03/2014): -

S.No.	ITEMS NAME	QUANTITY
1.	CD/DVD-ROM	11
2.	Theses/Dissertations/Training Report	5
3.	Magazines	17
4..	Newspaper	8

## **SUBSCRIPTION OF JOURNALS:**

The Library & Information Centre has subscribed 39 national and international scientific journals on different subjects to keep up-to-date knowledge in the field of Pharmacopoeial, Pharmaceuticals and Drugs Standardization etc.

## **LIBRARY & INFORMATION CENTRE SERVICES DURING THE YEAR 01/04/2013 – 31/03/2014:**

The IPC Library & Information Centre provides the following services during the year 01/04/2013 to 31/03/2014 to support Scientific, Pharmacopoeial and Administrative work: -

### **i) Document Delivery Services:**

The IPC Library & Information Centre has issued/consulted approximately 326 books to its staff during the year 01/04/2013 to 31/03/2014.

### **ii) Reference Service:**

The Library & Information Centre maintains a separate reference collection consisting of rare and costly reference books on various areas of science. The IPC Library & Information Centre provided the reference service to staff members and external users. Approximately 5448 books has been consulted during the year 01/04/2013 to 31/03/2014.

### **iii) CAS and SDI Service:**

The Library & Information Centre provided the facility of Selective Dissemination of Information (SDI) and Current Awareness Services (CAS) to the staff members and outside visitors of library during the year.

### **iv) Indexing and Abstracting:**

The Library & Information Centre provided the Index and Abstracts of subscribed national and international journals on monthly basis to the staff members and outside visitors of library during the year.

### **v) News Paper Clipping:**

The Library & Information Centre provided the news paper clipping and other news items from Government, Pharmaceutical Industry and other areas on weekly basis to the staff members and outside visitors of library during the year.

### **vi) Reprographic Services:**

The Library & Information Centre provided the photocopy service to their users. This section has officially photocopied approximately 1481 pages during the year 01/04/2013 to 31/03/2014.

**vii) Electronic Information Resource Access:**

The Internet Section of Library & Information Centre is equipped with 10 computers with printer and latest configuration. The staff members including PvPI Technical Associates have utilized the service during the year.

**viii) CD/DVD-ROM Database search:**

The Library & Information Centre provides the CD/DVD-ROM database search facility to their staff members. The CD-ROM of British Pharmacopoeia, European Pharmacopoeia, United State Pharmacopoeia, USB Flash Drive of USP 2013, International Pharmacopoeia, DVD of Indian Pharmacopoeia, and Pharmacokinetic Profiling in Drug Research have been searched during the year 01/04/2013 to 31/03/2014.

**TRAINING PROGRAMME:**

The Library & Information Centre provided the training programme to students, research scholars and officials from Institutes, Universities and Government Departments during the year 01/04/2013 to 31/03/2014 taking into account their professional background and needs for meeting the challenges of current times. During the year 8 students/research scholars have undergone training from different departments of Indian Pharmacopoeia Commission.

Moreover, during the year many students, research scholars and Officials from GOI have visited the Indian Pharmacopoeia Commission like from Karnataka State Drugs Control, CSIR-NISCAIR, DIPSAR, KIET School of Pharmacy, Gitarattan International Business School, M.M.H. College, Ghaziabad.

## INTRODUCTION

Indian pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health & Family Welfare, Government of India. Basic function of Indian Pharmacopoeia Commission is to update regularly the Standards of Drugs commonly required for treatment of diseases prevailing in this region. IPC regularly publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of **Indian Pharmacopoeia (IP)** whereas **National Formulary of India (NFI)** promotes rational use of generic medicines. IPC also publishes **Guidance Manual for Compliance of Indian Pharmacopoeia (IP)** in collaboration with Central Drugs Standard Control Organization & WHO-Country Office intended to enable the users of IP to perform the activities related to performance of the tests or associated activities prescribed in the IP and also to understand or interpret the requirements of IP for proper compliance of the requirements thereof. The latest Edition of **Indian Pharmacopoeia 2014** is under printing and it will be published at the earliest.

Indian pharmacopoeia Commission (IPC) also publishes **Pharmacovigilance Programme of India (PvPI)** Newsletter on Quarterly basis. Pharmacovigilance is an integral part of healthcare delivery systems. It promotes health professionals regarding drug safety profile by reviewing case reports of various ADR monitoring centres submitted to National Coordination Centre- Pharmacovigilance Programme of India (PvPI).

## PUBLICATIONS OF IPC

The following Official Publications are published by the Indian Pharmacopoeia Commission during the financial year 01.04.2013 to 31.03.2014. The details are as appended below:-

S. No.	Title of the Publication
1.	Indian Pharmacopoeia (IP) 2014 (along with DVD)
2.	PvPI Pamphlets
3.	Brochure of Indian Pharmacopoeia (IP) 2014
4.	PvPI Newsletter Vol. 3, Issue 5, 2013
5.	PvPI News Letter Vol. 3, Issue 6 2013
6.	PvPI Newsletter Vol. 3, Issue 7, 2013

## SALE & DISTRIBUTION OF IPC PUBLICATIONS

The status of sales & distributions of official publications of IPC upto 31-03-2014 as given below: -

S/N	IPC Publications	Total Copies Printed	Status		Revenue
1.	I.P. -2007	4894	Sold	03	Total revenue generated = <b>Rs. 31,500/-</b>
			Compl.	1133	
2.	I.P.-2007 Addendum 2008	1500	Sold	01	Total revenue generated = <b>Rs. 21,00/-</b>
			Compl.	37	
3.	I.P. -2010	3000	Sold	15	Total revenue generated = <b>Rs. 3,00,000/-</b>
			Compl.	0	
4.	DVD of I.P.- 2010	3000	Sold	17	Total revenue generated = <b>Rs. 3,50,000/-</b>
			Compl.	162	
5.	I.P. -2010 Addendum 2012	1500	Sold	0	Total revenue generated = <b>NIL</b>
			Compl.	2	
6.	NFI-2011	30000	Sold	170	Total revenue generated = <b>Rs. 64,672/-</b>
			Compl.	235	
7.	Guidance Manual for Compliance of IP	1000	Sold	59	Total revenue generated = <b>Rs.15,145/-</b>
			Compl.	85	
8.	I.P. -2014	4000	Sold	1359	Total revenue generated = <b>Rs. 2,74,25,000/-</b>
			Compl.	58	
9.	DVD of IP 2014	500	Compl.	36	Total revenue generated = <b>NIL</b>
<b>Total = Rs. 2,81,88,422/-</b>					
<b>Rupees Two Crore Eighty One Lakhs Eighty Eight Thousand Four Hundred Twenty Two Only</b>					

## PHOTOGRAPHS OF IPC AT A GLANCE



Inauguration of Second Induction Course for Drug Inspectors of CDSCO in collaboration with IPC from 15-07-2013 to 02-08-2013 by Dr. (Prof.) Jagdish Prasad, DG, DGHS, Min. of H&FW



Inauguration of Second Induction Course for Drug Inspectors of CDSCO in collaboration with IPC from 02-09-2013 to 20-09-2013 by Sh. S. K. Srivastava, Additional Secretary & Fin. Advisor, Min. of H&FW





Visit of Mr. Lahouari Belgharbi, WHO on 15-07-2013



New Modern Laboratory, IPC Visit of Dr. (Prof.) Jagdish Prasad, DG, DGHS, Min. of H&FW on 15-07-2013

## IPC STAFF (as on 31<sup>st</sup> March, 2014)

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Name	Designation
Dr. Gyanendra Nath Singh	Secretary-cum-Scientific Director

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### Technical Staff

#### Research & Development Division

Dr. Raman Mohan Singh	Principal Scientific Officer
Dr. S. C. Mathur	Scientific Officer
Mr. Dinesh Kumar Sharma	Scientific Assistant
Mr. Pawan Kumar Saini	Scientific Assistant

#### Pharmacology and Microbiological Division

Dr. Jai Prakash	Principal Scientific Officer
Dr. Nishant Dafale	Senior Scientific Officer
Dr. V. Kalaiselvan	Senior Scientific Officer
Mr. Alok Sharma	Scientific Officer
Mr. Manoj Kumar Pandey	Scientific Assistant
Ms. Akanksha Bisht	Scientific Assistant
Mrs. M. Kalaivani	Scientific Assistant
Mr. Prasad Thota	Scientific Assistant

#### Pharmaceutical Chemistry & Reference Substances Division

Dr. Anil Kr Teotia	Senior Scientific Officer
Dr. Robin Kumar	Senior Scientific Officer
Mr. Anuj Prakash	Senior Scientific Officer
Mrs. Meenakashi Dahiya	Senior Scientific Officer
Mr. Y. K. Kush	Scientific Assistant
Mr. Satya Prakash Tyagi	Scientific Assistant
Smt. Ritu Tiwari	Scientific Assistant
Mr. Utpal Nandi	Scientific Assistant
Mr. Ravindra Verma	Scientific Assistant
Mr. Ramji Rathore	Scientific Assistant
Mr. Gaurav Kumar	Scientific Assistant
Ms. Manisha Trivedi	Scientific Assistant
Mr. C. Saravanan	Scientific Assistant

## **Non-Technical Staff**

### **Library and Publication 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

### **Administration and Cash Division**

Mr. I. J. S. Oberoi	Admn. Officer (I/C)
Mr. Udai Pal	Hindi Translator
Mr. Chandan Kumar	Finance & Accounts Officer
Ms. Renu Kapoor	Upper Divisional Clerk
Mr. Satyaveer Singh	Senior Laboratory Attendant
Mr. Rajendra Kumar Sharma	Peon

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# **Statements of Account 2013-14**



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