

Indian Pharmacopoeia Commission



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Preface

Standards for drugs are of paramount importance for regulating the Quality, Safety and Efficacy of Drugs used in any country. The Indian Pharmacopoeia (IP) is the official book of standards prescribing 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. **IP is the book of standard of the country to be relied upon for quality control of the drugs in India by the regulatory bodies of the Central and States Drugs Control Organizations.** The Pharmacopoeia contributes to the overall control of the quality of medicinal products by providing authentic norms of quality that a product, material or notified medical device is required to meet at any time during its period of use. The Pharmacopoeial Standards, which are publicly available and legally enforceable, are designed to be adopted for the licensing and quality control processes of drugs and are part of the system for safeguarding the health of consumers of medicinal products. The preparation and publication of pharmacopoeia is an exacting task and the rigors involved in preparing the Pharmacopoeia is extremely demanding as the efforts to work out the contents of the monographs of drugs prescribing parameters of quality, efficacy and efficiency are to be prescribed precisely. The field of drugs and pharmaceuticals change at enormous pace not only in the matter of new molecules and dosage forms being introduced but also in the matter of quality control and assurances as newer methods and techniques of identification and determination of purity and impurities are invented and adopted. The I P monographs are therefore to be reviewed and revised periodically to incorporate the changed needs and the I P itself is to be republished periodically incorporating all updates. Addenda are also to be published in between editions to notify and rectify errors if any, in the preceding edition and to incorporate additional monographs on priority basis. The Pharmacopoeial Standards are required to be upgraded regularly as the safety requirements tend to get more and more stringent also. In our country we had not given sufficient attention to streamline the preparation and publication of the Indian Pharmacopoeia, which has often led to criticism about our book of drug standards, its production and distribution and also had resulted in lack of updated national standards. Realizing the facts and also the administrative and scientific matters involved. After independence, the Indian Pharmacopoeia Committee was constituted in 1948, for publication of IP as its main function, which published the IP in 1955, followed by a Supplement in 1960. This Pharmacopoeia contained both western and traditional system 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 early 1970 both in the range of Active Pharmaceutical Ingredients (APIs) and the dosage forms produced. This had totally transformed the profile of the Indian Pharmaceuticals market. Indian Pharma industry had emerged as one of the important global supplier of pharmaceutical products, both to the developed and developing countries. These developments posed major challenges for the IP to reflect the quality standards of the marketed drugs, which the subsequent editions of IP tried to address.

In view of these rapid advances, it was decided to publish a new edition of the Pharmacopoeia and its Addenda at regular and shorter intervals for which the Indian Pharmacopoeia Committee was reconstituted in 1978. In the Pharmacopoeia of India 1985, its Addenda 1989 and 1991, inclusion of traditional system of drugs were limited. However, most of the new drugs manufactured and/or marketed were included, while only those herbal drugs which had definitive quality control standards had got place in it. In view of the continuing rapid increase in the range of drugs produced in India, the IP 1996, its Addendum 2000, Supplement 2000 for Veterinary Products and Addenda 2002 were published. The Addendum 2005 was published by the IPC which included a large number of antiretroviral drugs, and raw plants commonly used in making medicinal products not covered by any other pharmacopoeias and attracted much global attention. The IP Committee decided to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medical need and extent of use of such articles in the country.

The Indian Pharmacopoeia Commission has been established in year 2005. It provided systematic approach and practices for publication of IP 2007 with 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 was published which had taken care of the Amendments to IP 2007 and also incorporated 72 new monographs.

The sixth edition of the Indian Pharmacopoeia (IP 2010) has been published in accordance with the principles and designed 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 informations have been publicized on the website of the IPC, besides following conventional approach of obtaining comments. The feedback and inputs were 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 during compiling and editing the contents of this edition. The IP 2010 incorporates 1918 monographs of drugs out of which 287 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc. 51 monographs were added in Addendum 2012 to IP 2010.

The work on edition of IP 2014 is under active progress. The manuscript has been prepared extensively examined and found worth to be complying with requirements. It is expected that the ensuring edition of IP 2014 will shortly roll out of the press for the usage and reference of stakeholders. The issue of preparation, certification and distribution of IP Reference Substances has been taken on war footing basis and Commission is ready to release 192 IPRS. The Commission is briskly analysing and validating the Certificate of Analysis (COA) of new drugs assigned to it by CDSCO. The Commission has been accredited by various accreditation bodies.

The Central Government established a full-fledged **Indian Pharmacopoeia Commission (IPC)**, an autonomous society registered under the Society Registration Act, 1860, to carry out the important, complicated and arduous job of preparing and publishing the Indian Pharmacopoeia (IP) periodically. While Indian Pharmacopoeia is a book of standards, the National Formulary of India is a book of reference to be used by medicinal practitioners, pharmacists and nurses. The task of publication of National Formulary of India was also assigned to the IP Commission. The work on the next edition of NFI has been commenced and it has optimized that the ensuring edition will come out shortly.

Introduction

The Drugs & Cosmetics Act, 1940 and Rules, 1945 there under prescribe Standards to be complied with imported drugs and by drugs manufactured for sale, stocked or exhibited for sale or distributed. The Second Schedule of the Act states about standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed.

Further, the Drugs and Cosmetics Rules, 1945 under its [A] Part - XII which deals with Standards of drugs states.

A. “Standards of drugs” –

For drugs included in the Indian Pharmacopoeia:

- (a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.
- (b) In case the standards for identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia.

Drugs & Cosmetics Rule, 1945, Rule 96 further specified as;

B. “Manner of Labelling.”

Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:-

The name of the drug:

For this purpose, the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be –

- (a) for drugs included in Schedule F or Schedule F(1), the name given therein;
- (b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters ‘I.P.’ or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;
- (c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters ‘N.F.I.’;

- (d) for other drugs, the international non-proprietary name, if any, published by the World Health Organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

Drugs & Cosmetics Rules, 1945, Rule 104 also clarify about the Use of letters I.P. as;

C. “Use of letters I.P., etc.”

The letters ‘I.P.’ and recognized abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognized under the Rules.

The Govt. of India have created a separate, dedicated, autonomous institution in the form of the Indian Pharmacopoeia Commission (IPC) to deal with matters relating to timely publication of the Indian Pharmacopoeia which is the official book of standards for drug 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 is to perform, *inter-alia*, functions such as revision and publication of the Indian Pharmacopoeia and National formulary of India on a regular basis besides providing Reference Substances for deciding the identity, purity and also detect impurities of drugs and for imparting training to the stakeholders on Pharmacopoeial issues. The Commission has become fully operational from 1st January, 2009 as an Autonomous Body, fully financed by the Central Government with specific budgetary allocations under the administrative control of the Ministry of Health and Family Welfare.

The Indian Pharmacopoeia Commission (IPC) is an unique organisation of the country situated in the National Capital Region just 20 K.M. away from New Delhi. As already stated, it is an autonomous institution under the administrative control of Ministry of Health & Family Welfare, Government of India and dedicated for setting of standards for Drugs, Pharmaceuticals and health care devices/ technologies, publishing the Indian Pharmacopoeia which is the authentic book of standards under the drugs and Cosmetics Act 1940, besides providing references substances and training. The IPC has been registered as a society under the provisions of the Literary, Scientific and Charitable Societies Registration ACT, 1860 (Act No. 21 to 1860) on 9th December 2004. The functioning of the Commission is governed by the provisions of bye-laws of the IPC. The Commission has its Headquarter in its own campus at Sector-23, Raj Nagar, Ghaziabad (U.P.).

The structure of the Commission is as under:

The Commission has a three-tier structure comprising of the General Body, the Governing Body and the Scientific Body, supported by IPC Secretariat and Indian Pharmacopoeial Laboratory. The IPC also provides research and training facilities to students and scientific staff of various pharmacy and biotechnology colleges from different Universities and from other stakeholders. The structure and composition of the bodies are detailed in the report.

The IPC has collaborations with some international institutions and organizations like USP convention, British Pharmacopoeia Commission, European Directorate for the Quality of Medicines and Healthcare (EDQM), Chinese Pharmacopoeia Commission and the World Health Organization. These were partly inherited from the erstwhile CIPL and partly accomplished afresh. The IPC is to regularly update and prepare monographs of drugs of Active Pharmaceutical Ingredients and their formulations.

The IPC intends to publish the Indian Pharmacopoeia once in two years and addendum in between to incorporate corrections, modifications, additions etc. The IPC has a well established and digitalised library and information centre to cater the needs of its staff and other scientific institutions nearby. The Commission subscribes to national and international online journals, which are made accessible for higher studies and research work. The time ahead will be a challenging period for the Commission for completing the works undertaken on time and to embark on new projects. The IPC is making all efforts within its available resources to meet its aims and objectives and to attain its Mission.

To meet expectation of stakeholders, the Commission is working vigorously and the work is steering satisfactorily to achieve the targets for new edition of IP 2014 where exercises for the 577 new monographs and up-gradation of 1952 monographs have been completed. In this edition, for the first time, 19 new Radiopharmaceutical monographs and one General Chapter is to be included. Emphasis has been laid upon phytopharmaceutical components. Veterinary products have also found space in this ensuring edition. Classical chemical tests have been eliminated with that of internationally acclaimed UV spectrophotometric tests.

Work on NFI's 5th edition is also accelerating in top slot and it is hoped that the 5th edition of NFI will be serving the cause of physicians, nurses and pharmacists in particular and common masses in general. The principle of 'openness, justice and fairness' is kept into consideration while editing /compiling the ensuring edition of NFI and IP. These editions are the outcome of valuable contribution of the members of the expert committees of Scientific Body, professionals of the industry, the public and private testing laboratories and employees of the IPC.

The day is not far when the state-of-the art laboratory will start functioning in the very campus of the Commission under the able guidance, blessings and support of Ministry's officers.

From the Secretary-cum-Scientific Director's Desk

I am immensely delighted to present the fifth annual progress report before yourselves. The financial year under annual report was very challenging for the Commission as far as the question of publication of Indian Pharmacopoeia 2014 edition was concerned and the Commission has come out successfully through hard waters on account of less number of working hands and limited number of high end instruments when the credibility at international level is questioned in terms of quality, efficacy and standardization of drugs. It is pertinent to note that not only Commission prepared manuscript in time but also added 577 new monographs. It gives me satisfying note that our scientists are working day and night and are on verge of adding 19 new monographs on Radiopharmaceuticals along with one General Chapter. The Commission not satiated itself to the timely publication of Pharmacopoeia, the book of standards but also working vigorously on the book of reference called National Formulary of India 5th edition. The onus of this performance goes to the principles of transparency, accountability and punctuality adopted by the Commission willingly. The Commission is working towards rational use of medicines through generic approach. In this direction, the Commission is in the process of certifying, preparing and manufacturing Indian Pharmacopoeia Reference substances and till now most essentially required (300) IP Chemical Reference substances have been certified. The National Coordination Centre of Pharmacovigilance Programme of India (PvPI) has recommended ban on 5 drugs to CDSCO on the basis of ADR received from monitoring centres based in 90 Medical Colleges/Hospitals of the nation.

The journey of the IPC seems to be more challenging in the times ahead as it has to provide highly updated and upgraded infrastructure facilities needed for executing the responsibilities vested with it and to meet the international and national standards expected out of such an institution. State of the art infrastructural facilities, human resources and creating congenial environment for delivering the services as done by other Standards Setting institutions globally are priority needs. The IPC intends to become role model in times to come for its quality services and humility of approach by way of cooperation, coordination and involvement of it's stakeholders.

The guidance and approach extended by the Ministry and cooperation provided by the members of Scientific Body and other expert members alongwith the staff of the IP Commission are highly praiseworthy. I would like to extend my deep sense of gratitude to all those who guided during the period and to the Government for the unfettered support provided to the IP Commission to achieve its targets.

With best wishes.

Dr.G.N.Singh

MISSION, VISION AND OBJECTIVES

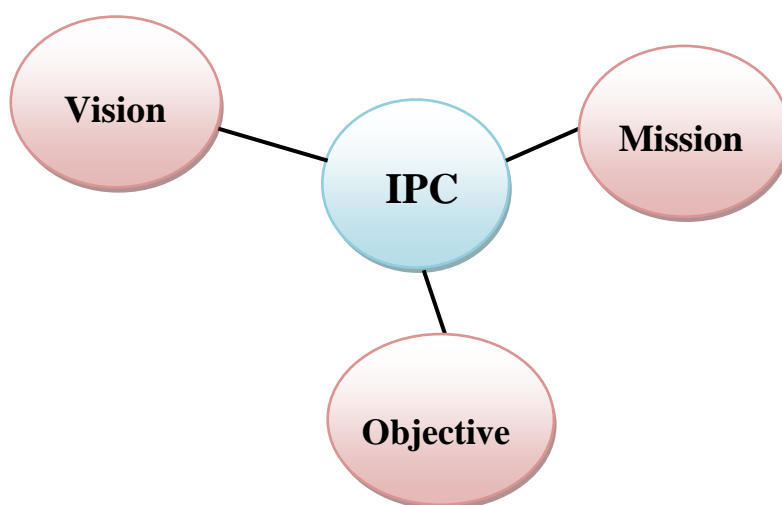


Fig: 2-Functions of IPC

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

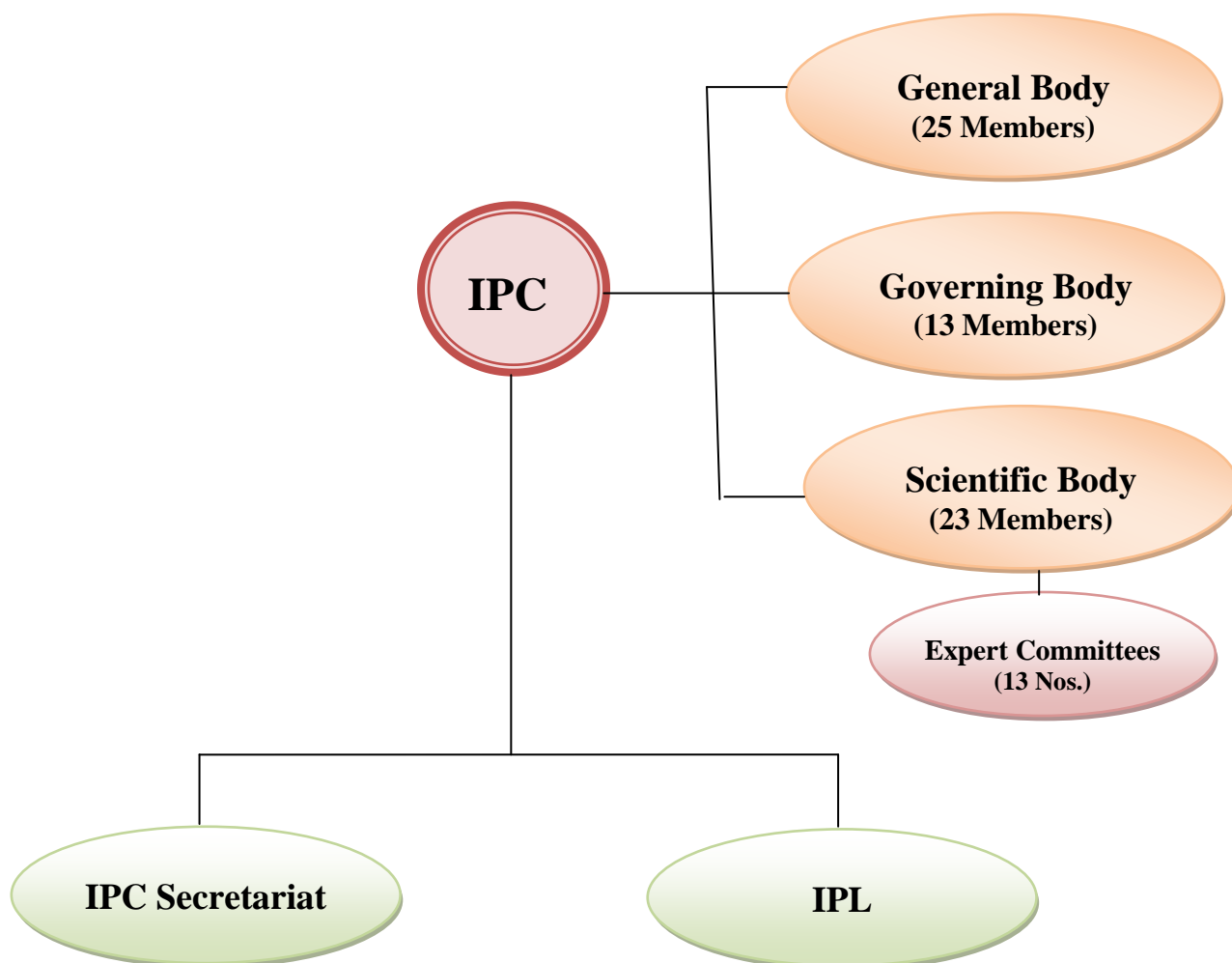


Fig.-1 Structure of IPC

Bodies of the IPC:

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

S. No.	<i>Designation in Committee</i>	Name & Address
1.	<i>Chairman</i>	Shri Keshav Desiraju 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>	Shri R. K. Jain, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	<i>Member</i>	Shri S. K. Srivastava Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
5.	<i>Member</i>	Dr. Arun Kumar Panda Joint Secretary (R) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	<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.
7.	<i>Member</i>	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	<i>Member</i>	Dr. Surinder Singh Director National Institute of Biologicals B-62, Institutional Area Noida-201 307

9.	<i>Member</i>	Shri Shambhu Kallollikar Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
10.	<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
11.	<i>Member</i>	Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P).
12.	<i>Member</i>	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
13.	<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:

S. No.	<i>Designation in Committee</i>	Name & Address
1.	<i>Chairman</i>	Shri Keshav Desiraju 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>	Shri R. K. Jain, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	<i>Member</i>	Shri S. K. Srivastava Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
5.	<i>Member</i>	Dr. Arun Kumar Panda Joint Secretary (R) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	<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.
7.	<i>Member</i>	Shri Shailendra Kumar Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	<i>Member</i>	Dr. Surinder Singh Director National Institute of Biologicals B-62, Institutional Area Noida-201 307

9.	<i>Member</i>	Shri Shambhu Kallollikar Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
10.	<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
11.	<i>Member</i>	Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P).
12.	<i>Member</i>	The Director Central Drugs Laboratory 3, Kyd Street Kolkata
13.	<i>Member</i>	From Regulatory Bodies Central Drugs Standard Control Organisation Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
14.	<i>Member</i>	Dr. C. Adithan Director-Professor Department of Pharmacology Jawaharlal Institute of Postgraduate Medical Education and Research Pondicherry-605 006.
15.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Andhra Pradesh
16.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Sikkim
17.	<i>Member</i>	Commissioners in-charge of Drug Control Administration, Gujarat
18.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Uttar Pradesh

19.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Himachal Pradesh
20.	<i>Member</i>	The Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062.
21.	<i>Member</i>	The President, Indian Drug Manufacturers Association (IDMA) 102-B, Poonam Chambers, 'A' Wing' Dr. Annie Besant Road, Worli Mumbai – 400018
22.	<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
23.	<i>Member</i>	Shri. D. G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), Mumbai
24.	<i>Member</i>	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
25.	<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:

S. No.	Designation in Committee	Name & Address
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:

S. No.	Designation in Committee	Name & Address
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. B. Sesikera Director, National Institute of Nutrition, Jamai-Osmania Post Office, Tarnaka Road, Hyderabad, Andhra Pradesh 500 007.
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>	Dr. Patel Bharatkumar Natubhai 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 st 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
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The composition of the **National Consultative Committee (NCC)** of the **Indian Pharmacopoeia Commission** is as follows:

S. No.	Designation in Committee	Name & Address
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 & Director General (CGHS)</i> <i>Ministry of Health & 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
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Scientific Activities & Achievements

1. New Monographs Drafted for next VIIth edition of IP

Following 315 new chemical monographs were drafted during this period for next edition and put up on the website for stakeholders comments.

- 1 Acamprosate Calcium
- 2 Acesulfame Potassium
- 3 Acetretin Capsules
- 4 Aciclovir Cream
- 5 Aciclovir Dispersible Tablets
- 6 Aciclovir Eye ointment
- 7 Aciclovir Oral suspension
- 8 Acitretin
- 9 Adefovir dipivoxil
- 10 Adefovir Tablets
- 11 Adenosine
- 12 Adenosine Injection
- 13 Adipic Acid
- 14 Albendazole Oral Suspension
- 15 Alfacalcidol
- 16 Alfacyclodextrin
- 17 Alfuzosin Hydrochloride
- 18 Alfuzosin Prolonged-release Tablets
- 19 Alfuzosin Tablets
- 20 Alprazolam Prolonged-release Tablets
- 21 Alprostadil
- 22 Alprostadil Injection
- 23 Aminophylline Prolonged-release Tablets
- 24 Amiodarone Intravenous Infusion
- 25 Amisulpride
- 26 Amisulpride Tablets
- 27 Amorolfine Hydrochloride
- 28 Aprotinin
- 29 Aripiprazole
- 30 Ascorbyl Palmitate
- 31 Aspirin Gastro-resistant Tablets
- 32 Atomoxetine Hydrochloride
- 33 Atracurium Besylate Injection
- 34 Atracurium Besylate
- 35 Azelaic acid
- 36 Azelastine Eye Drop
- 37 Azelastine Hydrochloride
- 38 Bambuterol Hydrochloride
- 39 Bambuterol Tablets
- 40 Benazepril Hydrochloride
- 41 Benazepril Hydrochloride Tablets
- 42 Benzoyl Peroxide Cream
- 43 Benzoyl Peroxide Gel

44	Betacyclodextrin
45	Betahistine Mesilate
46	Betamethasone Valerate cream
47	Betaxolol Eye Drops
48	Betaxolol Hydrochloride
49	Bezafibrate
50	Bezafibrate Tablets
51	Bicalutamide
52	Bicalutamide Tablets
53	Bortezomib
54	Cabergoline
55	Cabergoline Tablets
56	Caffeine Citrate Oral Solution
57	Calcipotriol Anhydrous
58	Calcipotriol Ointment
59	Calcitonin (Salmon)
60	Calcitonin (Salmon) Injection
61	Calcium Dobesilate Monohydrate
62	Carboplatin
63	Carboplatin Injection
64	Carboxymethylcellulose Calcium
65	Carboxymethylcellulose Eye Drops
66	Carisoprodol
67	Carisoprodol Tablets
68	Cefpirome Injection
69	Cefpirome Sulphate
70	Ceftiofur sodium
71	Celiprolol Hydrochloride
72	Celiprolol Tablets
73	Chloramphenicol Ear Drops
74	Chlorohexidine Mouthwash
75	Cilostazol
76	Cilostazol Tablets
77	Citicoline Sodium
78	Clemastine Fumarate
79	Clemastine Tablets
80	Clindamycin Injection
81	Clindamycin Phosphate
82	Clobetasol Cream
83	Clobetasol Ointment
84	Clobetasol Propionate
85	Clobetasone Butyrate
86	Clobetasone Cream
87	Colistimethate Injection
88	Colistimethate Sodium
89	Corn Oil
90	Cottonseed oil
91	Crotamiton
92	Crotamiton Cream
93	Cyclopentolate Eye Drops
94	Cyclopentolate Hydrochloride
95	Cyclosporine

96	Cyclosporine Capsules
97	Dalteparin Sodium
98	Dalteparin Sodium Injection
99	Desmopressin
100	Desmopressin Intranasal Solution
101	Diclofenac Prolonged-release Tablets
102	Diltiazem Injection
103	Dipivefrine Eye drops
104	Dipivefrine Hydrochloride
105	Dipyridamole
106	Dipyridamole Tablets
107	Divalproex Prolonged-release Tablets
108	Dobutamine Hydrochloride
109	Dobutamine Injection
110	Docetaxel Anhydrous
111	Domperidone Suspension
112	Dopamine Hydrochloride
113	Dopamine Injection
114	Doxapram Hydrochloride
115	Doxapram Injection
116	Drotaverine Tablets
117	Dutasteride
118	Ebastine
119	Eberconazole nitrate
120	Entacapone
121	Ephedrine Nasal Drops
122	Epinastine Eye Drops
123	Epinastine Hydrochloride
124	Eplerenone
125	Eptifibatide
126	Eptifibatide Injection
127	Erlotinib Hydrochloride
128	Erlotinib Tablets
129	Esmolol Hydrochloride
130	Ethambutol Injection
131	Ethanolamine
132	Ethophylline and Theophylline Tablets
133	Ethyl Vanillin
134	Ethylparaben
135	Etidronate Disodium
136	Etidronate Tablets
137	Etoricoxib
138	Etoricoxib Tablets
139	Ezetimibe
140	Ezetimibe Tablets
141	Famciclovir
142	Famciclovir Tablets
143	Flavoxate Hydrochloride
144	Flavoxate Tablets
145	Flucloxacillin Capsules
146	Flucloxacillin Oral solution
147	Flucloxacillin Sodium

148	Fludarabine Phosphate
149	Fludarabine Phosphate Injection
150	Flumazenil
151	Flumazenil Injection
152	Fluorometholone
153	Fluorometholone Eye Drops
154	Flupentixol Decanoate
155	Flupentixol Injection
156	Flurazepam Capsules
157	Flurazepam Hydrochloride
158	Flurbiprofen Eye Drops
159	Flurbiprofen Sodium
160	Flutamide Tablets
161	Fluticasone Cream
162	Fluticasone Nasal Spray
163	Fluticasone Ointment
164	Fluvastatin Capsules
165	Fluvastatin Sodium
166	Fluvoxamine Maleate
167	Fluvoxamine Tablets
168	Fosinopril Sodium
169	Fosinopril Sodium Tablets
170	Gemcitabine Hydrochloride
171	Gemcitabine Injection
172	Gemfibrozil
173	Gemfibrozil Capsules
174	Glutaraldehyde Solution
175	Glycerin Oral Solution
176	Hydrocortisone Ointment
177	Hydrocortisone Acetate Cream
178	Hydrogenated Vegetable Oil
179	Hydroxychloroquine Sulphate
180	Hydroxychloroquine Tablets
181	Hydroxyethylcellulose
182	Hydroxypropyl Methylcellulose Phthalate
183	Hydroxyzine Hydrochloride
184	Hydroxyzine Oral Solution
185	Hydroxyzine Tablets
186	Imatinib Tablets
187	Imidurea
188	Invert Syrup
189	Iopanoic Acid
190	Iopanoic Acid Tablets
191	Irbesartan
192	Irbesartan and Hydrochlorothiazide Tablets
193	Irbesartan Tablets
194	Iron and Folic Acid Syrup
195	Iron and Folic Acid Tablets
196	Isopropyl Palmitate
197	Isopropyl Rubbing Alcohol
198	Isotretinoin
199	Ivermectin

200	Ivermectin Injection
201	Labetalol Injection
202	Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
203	Lapatinib Ditosylate
204	Lapatinib Tablets
205	Leflunomide
206	Leflunomide Tablets
207	Levodropropizine
208	Levofloxacin Injection
209	Levosaltbutamol Hydrochloride
210	Levosaltbutamol Inhalation Solution
211	Lithium Carbonate Prolonged-release Tablets
212	Lorazepam
213	Lorazepam Injection
214	Lorazepam Tablets
215	Meloxicam
216	Mesalazine
217	Mesalazine Prolonged-release Tablets
218	Metoprolol Injection
219	Midazolam
220	Midazolam Injection
221	Midazolam Oral Solution
222	Mifepristone
223	Mifepristone Tablets
224	Misoprostol Tablets
225	Mitomycin
226	Mitomycin Injection
227	Monobasic Sodium Phosphate
228	Morphine Tablets
229	Moxifloxacin Eye Drops
230	Moxifloxacin Hydrochloride
231	Mupirocin
232	Mupirocin Ointment
233	Nicorandil
234	Nicorandil Prolonged-release Tablets
235	Nicorandil Tablets
236	Octyl dodecanol
237	Ofloxacin Oral Suspension
238	Ornidazole Injection
239	Oxacillin Capsules
240	Oxacillin Sodium
241	Ozagrel Hydrochloride
242	Paracetamol Infusion
243	Paracetamol Paediatric Oral Suspension
244	Parecoxib Sodium
245	Paroxetine hydrochloride
246	Paroxetine Tablets
247	Petrolatum
248	Phenylethyl Alcohol
249	Phenylramidol Hydrochloride
250	Phenylramidol Tablets
251	Pitavastatin Calcium

252	Polacrilin Potassium
253	Polyvinyl Acetate Phthalate
254	Polyvinyl Alcohol
255	Potassium Chloride for Injection
256	Prednisolone Sodium Phosphate Eye Drops
257	Premetrexed Disodium
258	Procarbazine Hydrochloride
259	Progesterone
260	Progesterone Injection
261	Propylidone
262	Propylidone Injectable Oil Suspension
263	Pyridostigmine Bromide
264	Pyridostigmine Injection
265	Pyridostigmine Tablets
266	Racecadotril
267	Racecadotril Capsules
268	Racecadotril Sachet
269	Raloxifene Hydrochloride
270	Rebamipide
271	Reboxetine Methanesulphonate
272	Repaglinide
273	Repaglinide Tablets
274	Risendronate Sodium
275	Ritodrine Hydrochloride
276	Ritodrine Injection
277	Ritodrine Tablets
278	Rupatidine Fumarate
279	Saquinavir Capsules
280	Selegiline Hydrochloride
281	Selegiline Tablets
282	Sertraline Hydrochloride
283	Sertraline Tablets
284	Silver Sulphadiazine
285	Silver Sulphadiazine Cream
286	Sodium Nitoprusside
287	Sodium Nitroprusside injection
288	Sodium Valproate Gastro-resistant Tablets
289	Sorafenib Tablets
290	Sorafenib Tosylate
291	Soyabean Oil
292	Strong Glutaraldehyde Solution
293	Sulpride
294	Sulpride Tablets
295	Surgical Spirit
296	Tenofovir fumarate, lamivudine and efavirenz tablets
297	Theophylline Prolonged-release Tablets
298	Tranexamic Acid
299	Tranexamic Acid Injection
300	Tranexamic Acid Tablets
301	Triclofos Oral Solution
302	Triclofos Sodium
303	Ursodeoxycholic Acid

304	Ursodeoxycholic Acid Tablets
305	Vecuronium Bromide
306	Vecuronium Bromide Injection
307	Voglibose
308	Voglibose Dispersible Tablets
309	Zonisamide
310	Zopiclone
311	Zopiclone Tablets
312	Zuclopenthixol Acetate
313	Zuclopenthixol Acetate Injection
314	Terfenadine Oral Suspension
315	Terfenadine Tablets

2. Revision/Upgradation of existing monographs for VIIth edition of IP.

The following monographs were revised/ upgraded for next VIIth edition of IP in respect of different tests like Assay, Related substances etc.

1	Amikacin
2	Amikacin Injection
3	Amikacin Sulphate
4	Amiodarone Hydrochloride
5	Amiodarone Tablets
6	Ampicillin Trihydrate
7	Aspirin
8	Azithromycin
9	Azithromycin Tablets
10	Bupivacaine Hydrochloride
11	Bupivacaine Injection
12	Butylparaben
13	Caffeine
14	Cefuroxime Axetil
15	Chloroquine Phosphate
16	Chloroquine Phosphate tablets
17	Cholecalciferol Tablets
18	Clarithromycin
19	Clofazimine
20	Clofazimine Capsules
21	Clonidine Hydrochloride
22	Clotrimazole
23	Cloxacillin Sodium
24	Codeine Phosphate
25	Colchicine Tablets
26	Cyclizine Hydrochloride
27	Cyclophosphamide Injection
28	Diazepam

29	Digoxin
30	Diphenhydramine Hydrochloride
31	Dithranol
32	Docetaxel Injection
33	Donepezil Tablets
34	Doxepin Hydrochloride
35	Econazole Nitrate
36	Etoposide
37	Finasteride Tablets
38	Fluphenazine Decanoate
39	Fluphenazine Decanoate Injection
40	Fluphenazine Hydrochloride
41	Fumaric Acid
42	Haloperidol
43	Homatropine Hydrobromide
44	Hydrochlorothiazide
45	Hydrochlorothiazide Tablets
46	Hyoscine Butylbromide
47	Hyoscine Hydrobromide
48	Hyoscine Hydrobromide Injection
49	Hyoscine Hydrobromide Tablets
50	Ipratropium Bromide
51	Isoprenaline Hydrochloride
52	Isoprenaline Injection
53	Lamivudine
54	Lamivudine , Nevirapine and Stavudine Dispersible Tablets
55	Lamivudine and Zidovudine Tablets
56	Lamotrigine Prolonged-release Tablets
57	Levamisole Hydrochloride
58	Levodopa
59	Levofloxacin Hemihydrate
60	Levonorgestrel Tablets
61	Lignocaine and Adrenaline Injection
62	Mepyramine Maleate
63	Methadone Hydrochloride
64	Methotrexate
65	Methotrexate Injection
66	Methotrexate Tablets
67	Methylergometrine Maleate
68	Methylparaben
69	Mexiletine Hydrochloride
70	Mianserin Hydrochloride
71	Montelukast Sodium
72	Nicotinic Acid

73	Nitrazepam
74	Nortriptyline Hydrochloride
75	Ondansetron Oral Solution
76	Ondansteron Tablets
77	Orphenadrine Citrate
78	Orphenadrine Hydrochloride
79	Perphenazine
80	Phenobarbitone
81	Phentolamine Injection
82	Phentolamine Mesylate
83	Phenylephrine Hydrochloride
84	Phenytoin
85	Phenytoin Sodium
86	Pholcodine
87	Pilocarpine Nitrate
88	Pregabalin
89	Primaquine Tablets
90	Propylparaben
91	Pyridoxine Hydrochloride
92	Ramipril and Hydrochlorothiazide Tablets
93	Ranitidine Hydrochloride
94	Ribavirin
95	Salbutamol Syrup
96	Salicylic Acid
97	Salmeterol Xinafoate
98	S-amlodipine Besylate
99	Sodium Methylparaben
100	Sodium Propylparaben
101	Sodium Stibogluconate
102	Terbutaline Tablets
103	Thiotepa Injection
104	Thyroxine Tablets
105	Timolol Maleate
106	Tolbutamide
107	Tolnaftate
108	Travoprost Eye Drops
109	Triamterene
110	Trimethoprim
111	Tropicamide
112	Verapamil Injection
113	Vinorelbine Injection

3. Revision/upgradation of General chapters for the next VIIIth edition of IP.

The following 15 General Chapters were revised/ upgraded for the next VIIth edition of IP in view of the latest technology developments and to harmonise with other international pharmacopoeias.

- 2.3.51. 2-Ethylhexanoic Acid
- 2.3.53. Ammonium
- 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
- 2.5.11. Polymorphism
- 2.4.17. Thin-Layer Chromatography
- 2.4.27. Refractive Index
- 2.4.29. Weight Per Milliliter and Relative Density (Specific Gravity)
- 2.4.34. Nuclear Magnetic Resonance Spectrometry
- 2.5.7. Particle Size Distribution Estimation
- 2.5.8. Optical Microscopy: Particle Size by Microscopy

4. Amendment list 3 to IP 2010

Worked on the queries/suggestions received from different stakeholders including pharma industries and after discussing and taking views of the subject expert group for IP, the same is finalized and put up on website for appropriate time and released on 11.04.2012 by the Secretary-cum-Scientific Director of IPC. Total more than 32 amendments taken place in the following monographs/tests.

AMENDMENTS

- 2.2.10. Microbiological Assay of Antibiotics
- 2.3.21. *N,N*-Dimethylaniline. Page 83
- 2.3.27. Hydroxyl Value. Page 85
- Inhalation Preparations. Page 726
- Microbial contamination. Page 740
- Adrenaline Injection. Page 779
- Ampicillin. Page 2879
- Ampicillin Sodium. Page 2880
- Ampicillin Injection. Page 2880
- Ampicillin Trihydrate. Page 2881
- Bupivacaine Hydrochloride. Page 933
- Carvedilol Tablets. Page 992
- Cinnarizine. Page 1088
- Dextrose. Page 1190
- Docetaxel Trihydrate. Page 1242
- Doxycycline Hydrochloride. Page 1257

Specific optical rotation. Line 1
 Imipenem. Page 1486
 Miconazole Nitrate. Page 2933
 Neotame. Page 1769
 Ondansetron Oral Solution. Page 1818
 Paracetamol Oral Suspension. Page 2940
 Phenoxyethanol. Page 2942
 Simvastatin Tablets. Page 2104
 Streptomycin Sulphate. Page 2161
 Sulphadiazine. Page 2169
 Sulphadiazine Tablets. Page 2170
 Telmisartan Tablets. Page 2960
 Thiopentone Sodium. Page 2216
 Thiopentone Injection. Page 2217
 Travoprost Eye Drops. Page 2251
 Zoledronic Acid. Page 2339

5. Amendment list 4 to IP 2010

Worked on the queries/suggestions received from different stakeholders including pharma industries and after discussing and taking views of the subject expert group for IP, the same is finalized and put up on website for appropriate time and released on 12.09.2012 by the Secretary-cum-Scientific Director of IPC. Total more than 77 amendments taken place in the following monographs/tests.

AMENDMENTS

General Notices. Page 11, 713, 1731
 2.2.9. Microbial Contamination in Non Sterile Products. Page 37
 4.3. Indicators and Indicator Test Papers. Page 623
 4.5. Volumetric Reagents and Solutions.
 Amlodipine Tablets. Page 807
 S-Amlodipine Besylate. Page 808
 Amphotericin B. Page 820
 Ampicillin Trihydrate. Page 2881
 Aspirin. Page 2882
 Azithromycin. Page 857
 Barium Sulphate. Page 872
 Compound Benzoic Acid Ointment. Page 887
 Bupivacaine Injection. Page 934
 Butylparaben. Page 942
 Cefaclor Oral Suspension. Page 995
 Cefuroxime Axetil. Page 1026
 Cephalexin. Page 1031
 Cholecalciferol Tablets. Page 2896
 Ciclesonide Inhalation. Page 1083
 Clarithromycin. Page 1101
 Clomipramine Capsules. Page 1111
 Clopidogrel Tablets. Page 1119
 Absorbent Cotton. Page 1137
 Crospovidone. Page 1141
 Diclofenac Tablets. Page 2900

Diphenhydramine Hydrochloride. Page 1232
Fenofibrate Capsules. Page 2912
Fluconazole. Page 2913
Fluticasone Propionate Inhalation. Page 1383
Fluticasone Propionate Powder for Inhalation. Page 1383
Fumaric Acid. Page 1394
Glibenclamide Tablets. Page 1415
Glimepiride Tablets. Page 1419
Griseofulvin Tablets. Page 1428
Ipratropium Powder for Inhalation. Page 2921
Isosorbide Dinitrate Tablets. Page 1522
Diluted Isosorbide Mononitrate. Page 1524
Isosorbide Mononitrate Tablets. Page 1525
Ketorolac Tromethamine. Page 1543
Lamotrigine Sustained-release Tablets. Page 1567
Levodopa and Carbidopa Tablets. Page 1576
Losartan Potassium and Amlodipine Tablets. Page 2927
Mefloquine Tablets. Page 2931
Melphalan Injection. Page 1647
Meropenem Injection. Page 1656
Methylparaben. Page 1672
Mometasone Furoate. Page 1700
Naproxen Sustained-release Tablets. Page 1757
Nevirapine Tablets. Page 1772
Nifedipine. Page 2935
Omeprazole. Page 1813
Omeprazole Capsules. Page 1814
Ondansetron Orally Disintegrating Tablets. Page 1816
Ondansetron Oral Solution. Page 1818
Oxcarbazepine. Page 1832
Oxytocin. Page 1842
Potassium Clavulanate. Page 1937
Potassium Clavulanate Diluted. Page 1938
Prednisolone Tablets. Page 1952
Propylparaben. Page 1991
Ranitidine Hydrochloride. Page 2043
Secnidazole. Page 2095
Sodium Metabisulphite. Page 2132
Sodium Methylparaben. Page 2132
Sodium Propylparaben. Page 2134
Sorbitol Solution (70 per cent) (Crystallising). Page 2955
Sorbitol Solution (70 per cent) (Non-Crystallising). Page 2956
Stearic Acid. Page 2958
Stearyl Alcohol. Page 2155
Sumatriptan. Page 2173
Thyroxine Tablets. Page 2222
Travoprost. Page 2250
Triamterene. Page 2256
Triprolidine Hydrochloride. Page 2268
Valsartan. Page 2286
Purified Water. Page 2314
Zinc Sulphate Monohydrate. Page 2970

6. Amendment list 5 to IP 2010

Worked on the queries/suggestions received from different stakeholders including pharma industries and after discussing and taking views of the subject expert group for IP, the same is finalized and put up on website for appropriate time and released on 11.03.2013 by the Secretary-cum-Scientific Director of IPC. Total more than 92 amendments taken place in the following monographs/tests.

AMENDMENTS

2.4.22. Optical Rotation and Specific Optical Rotation. Page 143

2.4.26. Solubility

2.4.2. Atomic Absorption Spectrometry. Page 109

2.4.4. Flame Photometry. Page 110

2.5.2. Dissolution Test. Page 189

4.2. General Reagents.

4.3. Indicators and Indicator Test Papers

4.5. Volumetric Reagents and Solutions.

5.2. Biological Indicators. Page 639

Capsules. Page 721

Alprazolam. Page 786

Alprazolam Tablets. Page 787

Amphotericin B. Page 820

Ampicillin Sodium. Page 824

Ampicillin Injection. Page 825

Atenolol. Page 847

Atenolol Tablets. Page 848

Atorvastatin Tablets. Page 850

Azithromycin Oral Suspension. Page 860

Benzhexol Hydrochloride. Page 884

Calcitriol Capsules. Page 961

Cefadroxil Oral Suspension. Page 2891

Cefotaxime Sodium Injection. Page 1017

Cefpodoxime Tablets. Page 1020

Citric Acid Monohydrate. Page 1100

Colchicine and Probenecid Tablets. Page 1132

Crosscarmellose Sodium. Page 1139

Dapsone. Page 1162

Dicyclomine Tablets. Page 1206

Activated Dimethicone. Page 1230

Disodium Edetate. Page 1234

Donepezil Hydrochloride. Page 1248

Donepezil Tablets. Page 1249

Doxofylline Tablets. Page 1254

Efavirenz, Emtricitabine and Tenofovir Tablets. Page 2904

Enoxaparin Sodium. Page 1276

Enoxaparin Injection. Page 1279

Ephedrine Oral Solution. Page 1281

Erythromycin. Page 1290

Erythromycin Tablets. Page 1291

Ethinylestradiol Tablets. Page 1307

Fentanyl Citrate. Page 1339
Fluoxetine Hydrochloride. Page 1369
Folic Acid. Page 1384
Framycetin Sulphate. Page 1388
Glibenclamide. Page 1414
Hydrochloric Acid. Page 1450
Dilute Hydrochloric Acid. Page 1450
Hyoscine Butylbromide. Page 1466
Lamivudine and Zidovudine Tablets. Page 1561
Lamivudine, Nevirapine and Stavudine Dispersible Tablets. Page 1563
Lansoprazole. Page 1568
Lansoprazole Capsules. Page 1570, 2925
Levocetirizine Hydrochloride. Page 1573
Linezolid Tablets. Page 1591
Lithium Carbonate Tablets. Page 1596
Loperamide Tablets. Page 1601
Lopinavir. Page 1602
Heavy Magnesium Oxide. Page 1623
Medroxyprogesterone Acetate. Page 1640
Menthol. Page 1649
Meropenem Injection. Page 1656
Minoxidil. Page 1697
Multiple Electrolyte and Dextrose Injection Type V. Page 1715
Neotame. Page 1769
Nifedipine Sustained-release Tablets. Page 1781
Olanzapine Tablets. Page 1812
Omeprazole Capsules. Page 1814
Ondansetron Orally Disintegrating Tablets. Page 2938
Oseltamivir Phosphate. Page 1827
Oseltamivir Capsules. Page 1828
D-Panthenol. Page 1856
Paracetamol Oral Suspension. Page 2940
Paracetamol Syrup. Page 1860
Pentazocine Hydrochloride. Page 1873
Pilocarpine Eye Drops. Page 2943
Polyoxyl 35 Castor Oil. Page 1931
Polyoxyl 40 Hydrogenated Castor Oil. Page 1931
Psoralen. Page 2001
Quinine Dihydrochloride Injection. Page 2023
Rabeprazole Sodium. Page 2037
Ramipril and Hydrochlorothiazide Tablets. Page 2041
Salbutamol Sulphate. Page 2085
Sildenafil Citrate. Page 2100
Sodium Bicarbonate Injection. Page 2111
Sorbic Acid. Page 2955
Thiopentone Sodium. Page 2216
Tiotropium Bromide Powder for Inhalation. Page 2228
Vinorelbine Injection. Page 2304
Zidovudine, Lamivudine and Nevirapine Tablets. Page 2334
Zinc Sulphate Dispersible Tablets. Page 2970
Zinc Sulphate Oral Solution. Page 2970

8. Verification of Analytical methods for IP

The AR&D team is vigorously involved in analytical verification of various tests in the existing monographs of IP-2010/Addendum 2012 to IP 2010 and the monographs drafted for next edition of IP. Carried out verification of analytical method for drugs samples received from various Stakeholders in the AR&D Division for verification of different tests of IP monographs. During this period following tests in mentioned samples were verified.

1. Verification of related substance of Ampicillin Trihydrate as per IP & BP.
2. Verification of water content in Secnidazole API.
3. Verification of Nevirapine Tablets, identification test by UV.
4. Verification of dissolution test in Escitalopram Tablets.
5. Verification of Solubility test in Rizatriptan Benzoate.
6. Verification of Related Substance test in Amikacin Sulphate.
7. Verification of Assay in Bupivacaine HCl Injection.
8. Verification of Assay of Olanzapine Tablets.
9. Verification of Solubility in Atorvastatin Calcium.
10. Verification of FTIR Spectra of Citric Acid monohydrate & anhydrous citric acid.
11. Verification of solubility of Escitalopram Oxalate.
12. Verification of Disintegration time for Ondansetron Orally Disintegration Tablets.
13. Verification of LOD/Water content in Cefotaxime Sodium.
14. Verification of FTIR spectra of Fumaric Acid.
15. Verification of water content in Imatinib Mesylate.
16. Verification of Assay in Zinc Sulphate Dispersible Tablets.
17. Verification of Uniformity of content in Atorvastatin Tablets.
18. Verification of Solubility in Dapsone.
19. Verification of Related Substance test in Ondansetron Tablet.
20. Verification of Solubility in Cefixime.
21. Verification of Dissolution of Levonorgestrel Tablets.
22. Verification of Appearance of solution, light absorption & description in Irinotecan hydrochloride.
23. Verification of Assay of Sodiumcarboxymethylcellulose Eye Drops.
24. Verification of Assay & related substance in Citicoline.
25. Verification of monograph of Lamivudine & Zidovudine Tablets.
26. Repeated verification of water content of Imatinib Mesylate.
27. Verification of Assay of Psoralen.
28. Verification of Dissolution of Terbutaline Sulphate Tablets.

09. Development of Veterinary Monographs (IVth Vol. of IP-2014)

Organized and coordinated the work related to the development of veterinary monographs for the 4th volume of next edition with the expert group of veterinary manufacturers under the chairmanship of Dr. Rishendra Verma, IVRI, Izatnagar. The first workshop was arranged on 23rd - 24th Jan-2013 at IPC-IPL, GZB.

10. Development of New Drugs Monographs

Reviewed and rechecked more than 30 monographs of New Drugs received and analyzed in Reference Standard Division and developed by them for the next edition of IP.

11. IP Reference Standards Developments:

Organized and co-ordinated for development of IPRS at Reference Standard Division by developing IPRS vial and their packing, cold room facility and for making availability of candidate material from the stakeholders. Co-ordinated the analysis of these candidate material in Reference Standard Division. The list of available IPRS is reached upto 150.

12. WHO Work for International Pharmacopoeia

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

1. Monograph of Fluconazole
2. Monograph of Fluconazole Injection
3. Monograph of Sulphamethoxazole and Trimethoprim Intravenous Infusion
4. Monograph of Sulphamethoxazole and Trimethoprim Oral Suspension

13. NABL (ISO-IEC/17025:2005) Accreditation of IPC-IPL

Worked for accreditation from National Accreditation Board for Testing and Calibration Laboratories of DST, New Delhi. Dr. Raman Mohan Singh was designated as **Quality Manager** for the purpose of Accreditation of IPC-IPL from NABL. Supervised and co-ordinated the work for preparation for the same with AR&D and Reference Standard Division and other Divisions. IPC-IPL assessed successfully for the NABL (ISO/IEC/17025:2005) accreditation for its testing facility in the field of Chemical as well in Biological Testing.

Seminar & Meetings

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

Following meetings / programmes were held during April,2012- March,2013.

1. Attended USP-International Training Programme at USP, Head Quarter, Rockville, M.D.,USA by the delegation of Dr. Raman Mohan Singh, Dr. P.K.Saini and Mr. Anuj Prakash on 29.4.12 to 5.5.12, organized by IPC-USP under MOU of collaboration.
2. 24th Scientific Body meeting was held at IPC, Ghaziabad on 12.05.2012.
3. Delegation from Tanzania Government visited IPC, Ghaziabad on 21.06.2012.
4. USP, CEO Dr. Rogger Williams & other officials of USP visited IPC. They interacted and a brief meeting was held at IPC on 18.07.2012 with the employees of IPC.
5. A meeting/discussion at NIB, Noida on 18.07.2012 on Biological Standards with Scientific Delegation from USP, Rockville was attended by IPC officials.
6. A meeting of expert committee on Radio Pharmaceutical monographs for IP was held on 13.08.2012 at IPC, Ghaziabad.
7. 25th Scientific Body meeting was held at IPC, Ghaziabad on 29.08.2012.
8. Attended seminar on “International Seminar on Patient Safety & Drug Detection Technology” held at New Delhi on dated 10.09.2012 to 11.09.2012 and organized by MOH&FW at India Habitat Centre, N. Delhi.
9. IPC staff attended the IDMA- APA Pharmaceutical Analyst Convention at Hyatt regency, Mumbai on dated 21.09.2012 to 22.09.2012.
10. IPC officials attended a Pharmacopoeial Education Programme on “validation and verification of compendial procedures” at Hyderabad on 05.10.2012 to 06.10.2012 organised by USP, India.
11. Attended 2nd Sceintific Body Meeting of Pharmacopoeial Commission for Indian Medicines (PCIM) on dated 12.10.2012 at CCRAS, N.Delhi.

12. A meeting was conducted at RS Iyer Hall, IPC on 27.10.2012 with Padam Shree Dr. Nitya Anand, Ex-chairman of Scientific Body for various scientific and technical issues.
13. Attended 8th meeting for drafting of monographs and General Chapters on Radiopharmaceuticals for IP on dated 10.11.2012 at Tata Memorial Hospital, Mumbai.
14. Attended 64th meeting of Indian Pharmaceutical Congress on 7.12.2012 to 9.12.2012 at SRM University, Chennai.
15. A meeting was held on 01.01.2013 at IPC under the Chairmanship of Prof. B. Suresh, Chairman Scientific Body on the occasion of Foundation Day of IPC.
16. Attended Expert Committee meeting on dated 18.01.2013 at Hyderabad.
17. Attended a meeting on Veterinary monographs for IP on dated 23.01.2013 to 24.01.2013 at IPC, Ghaziabad.
18. Attended a seminar on “Accessibility to Quality Medicine in the supply chain” at New Delhi on dated 15.02.2013.
19. Attended Manipal-IPC Annual Commemoration Symposium and Annual Day on dated 14.02.2013 to 15.02.2013 at Manipal University, Manipal.
20. Attended IPC-USP Joint Pharmacopoeial Education Programme on dated 19.02.2013 at Gateway Hotels Ummed Taj, Gujarat.
21. 26th Scientific Body meeting held at Malviya Bhawan, New Delhi on dated 23.02.2013.
22. A meeting was held at IPC, Ghaziabad with the expert group for developing IP monographs on Radiopharmaceutical preparations on dated 20.03.2013.

LIBRARY AND INFORMATION CENTRE

About the Library & Information Centre:

The IPC Library & Information Centre is one of the leading Pharmacopoeial Library & Information Centre of the country. The library & Information Centre aims to be a leading Library & Information Centre in all the fields of Pharmacopoeial research areas and support IPC in its basic function to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this Country. The IPC Library & Information Centre continues to expand its resource and activities to provide valuable Library & Information Services to support Scientific and Pharmacopoeial work. The Library & Information Centre makes its resources available and useful to the Scientists, Health Professionals and Researchers preserve latest collection of knowledge and creativity for future generations. The Library & Information Centre aims to collect, store, and disseminate information to acquire new products and services. The Library & Information Centre houses an excellent collection of more than 11,000 documents including books, periodicals, Indian & International Standards, CD-ROMs, other Non-Print Materials, and Pharmacopoeias etc. of different Countries. The Library & Information Centre also subscribes 37 national and international scientific journals on different subjects to keep up-to-date knowledge in the field of Pharmacopoeial, Pharmaceuticals and Drugs Standardization etc. It also aims to build a comprehensive collection of back volumes of journals in all these fields and in-house 2720 collection of bound volume journals. The Library & Information Centre apart from users from the IPC is open to other users of other GOI Departments, Universities and Institutes for reference.

Mission:

The mission of Library & Information Centre is to acquire organizes, provide access to, maintain, secure, and preserve all the collections safely. The collection of the Library & Information Centre is constantly being enlarged and enriched every year by acquisition of latest books, reports, serials, bound volumes of journals periodicals and non-book materials etc.

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 (01/04/2012 – 31/03/2013) as appended below: -

S. No.	ITEMS NAME	QUANTITY
1.	Total Books Procured	439

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 (01/04/2012 – 31/03/2013): -

S.No.	ITEMS NAME	QUANTITY
1.	CD/DVD-ROM	6
2.	USB Flash Drive	3
3.	Theses/Dissertations/Training Report	8
4.	Magazines	17
5.	Newspaper	8

SUBSCRIPTION OF JOURNALS:

The Library & Information Centre has subscribed 37 national and international scientific journals on different subjects to keep up-to-date knowledge in the field of Pharmacopoeial, Pharmaceuticals and Drugs Standardization etc.

DIGITALIZATION OF LIBRARY & INFORMATION CENTRE:

As part of the ongoing modernisation exercise, the Library & Information Centre has changed its face by installing FineDocs Document Management Software. The Document Management Software is for 5-Users and preserved Indian Pharmacopoeia with addendum since 1957, National Formulary of India (NFI) and Bound Volume of Journals (All issues of 19 Titles since 1965). The Users can easily access the relevant information through this software and also save the data in mass storage, take print out, copy or edit etc. The software also allows the free text searching.

LIBRARY & INFORMATION CENTRE SERVICES DURING THE YEAR 01/04/2012 – 31/03/2013:

The IPC Library & Information Centre provides the following services during the year 01/04/2012 to 31/03/2013 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 01/04/2012 to 31/03/2013.

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 4854 books has been consulted during the year 01/04/2012 to 31/03/2013.

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 1341 pages during the year 01/04/2012 to 31/03/2013.

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 01/04/2012 to 31/03/2013.

LIBRARY & INFORMATION CENTRE EXPENDITURE:

The total expenditure of the IPC Library & Information Centre is `1,13,23,929/- during the year 01/04/2012 to 31/03/2013.

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 01/04/2012 to 31/03/2013 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.

PUBLICATION DIVISION

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 01.04.2012 to 31.03.2013. The details are as appended below:-

S. No.	TITLE OF THE PUBLICATION
1.	PvPI Newsletter Vol. 2, Issue 2, 2012
2.	Guidance Manual for Compliance of Indian Pharmacopoeia (IP)
3.	PvPI Newsletter Vol. 2, Issue 3, 2012

SALE & DISTRIBUTION OF IPC PUBLICATIONS

The sales and distribution of IPC Publications during the financial year 01.04.2012 to 31.03.2013 are as appended below: -

Status of Sales & Distribution of IPC Publications w.e.f. 01 April 2012- 31 March 2013.

S.No.	Publication	Total No. of Copies/Sets Printed	Current Status (As on 01/04/2012 to 31/03/2013		Revenue Generated
1.	I.P. -2007	4894	Sold	2	Total revenue generated = ` 22,500/-
			Comp.	24	
2.	I.P. -2010	3000	Sold	311	Total revenue generated = ` 50,56,000/-
			Comp.	19	
3.	DVD of I.P.- 2010	3000	Sold	23	Total revenue generated = ` 4,60,000/-
			Comp.	26	
4.	I.P. -2010 Addendum 2012	1500	Sold	469	Total revenue generated = ` 11,44,200/-
			Comp.	32	
5.	NFI-2011	30000	Sold	12376	Total revenue generated = ` 57,95,570/-
			Comp.	461	
6.	Guidance Manual for Compliance of IP	1000			Total revenue generated = ` 34,250/-
			Sold Comp.	125 127	

Total = ` 1,25,12,520/-

(Total Revenue Generated = Rupees One Crore Twenty Five Lacs Twelve Thousand Five Hundred Twenty only)

Pharmacovigilance Programme of India

Ministry of Health & Family Welfare, Government of India launched a nationwide Pharmacovigilance Programme of India (PvPI) to monitor the safety of medicine. Indian Pharmacopoeia Commission (IPC) an autonomous institution, under the ministry of Health & Family Welfare, Government of India, Ghaziabad is functioning as National Coordination Centre (NCC) for PvPI since April 15th 2011. ADRs are collected by various ADR Monitoring Centres across the country and reported to NCC. PvPI is functioning with the mission to ensure that the benefits of medicine outweigh the risks and thus safeguard the health of the population. The objective is to

- monitor ADRs in Indian population
- create awareness amongst health care professionals about the importance of ADR reporting in India
- monitor benefit-risk profile of medicines
- generate independent, evidence based recommendations on the safety of medicines
- support the CDSCO for formulating safety related regulatory decisions for medicines

The health care professionals collecting data of adverse events related to drugs marketed in India, can report to their respective ADRs Monitoring Centres (AMCs) which in turn is submitted to NCC through Vigiflow. The submitted data is collated and evaluated for quality by the various panels and groups of NCC-PvPI, IPC Ghaziabad. NCC is responsible for committing the reports to Uppsala Monitoring Centre (UMC) in Sweden and to communicate the scientific outcome to CDSCO for their regulatory intervention.

As on date, there are 90 AMCs spread across the four zonal offices of CDSCO are functioning under NCC. ADRs related to drugs, biologicals including blood and blood related products, recombinant DNA derived therapeutic products, vaccines and medical

devices are being reported to these AMC's, in a specially designed ADR reporting form, which are transmitted to NCC after proper evaluation at each level.

In order to provide training and technical support to the newly inducted AMCs, four Training and Technical Support Centres at regional level were identified by NCC. These include Post Graduate Institute of Medical Education and Research, Chandigarh (North), JSS Medical College, Mysore (South), Institute of Post Graduate Medical Education and Research, Kolkata (East), Seth GS Medical College and KEM Hospital, Mumbai (West).

To disseminate information on suspected adverse reactions to health products occurring in humans and regulatory decisions to the stakeholders NCC publishes "PvPI Newsletter".

Mission

Safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweighs the risks associated with its use.

Vision

To improve patient safety and welfare in Indian population by monitoring the drug safety and thereby reducing the risk associated with use of medicines.

Objectives

To create a nation-wide system for patient safety reporting.

To identify and analyse the new signal (ADR) from the reported cases.

To analyse the benefit - risk ratio of marketed medications.

To generate the evidence based information on safety of medicines.

To support regulatory agencies in the decision-making process on use of medications.

To communicate the safety information on use of medicines to various stakeholders to minimise the risk.

To emerge as a national centre of excellence for Pharmacovigilance activities.

To collaborate with other national centres for the exchange of information and data management.

To provide training and consultancy support to other National Pharmacovigilance Centres located across globe.

Scope

Since there exist considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management “ there is a need to engage healthcare professionals and the public at large, in a well structured programme to build synergies for monitoring adverse drug reactions in the country.

The purpose of the Pharmacovigilance Program of India is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

Implementation of PvPI

Indian Pharmacopoeia Commission understands the need for establishing local hospital based centres across the nation for the better patient safety. It is important to monitor both the known and hitherto unknown side effects of medicines in order to determine any new information available in relation to their safety profile. In a vast country like India with a population of over 1.2 billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust Pharmacovigilance and drug safety monitoring programme for the nation.

Short term goals

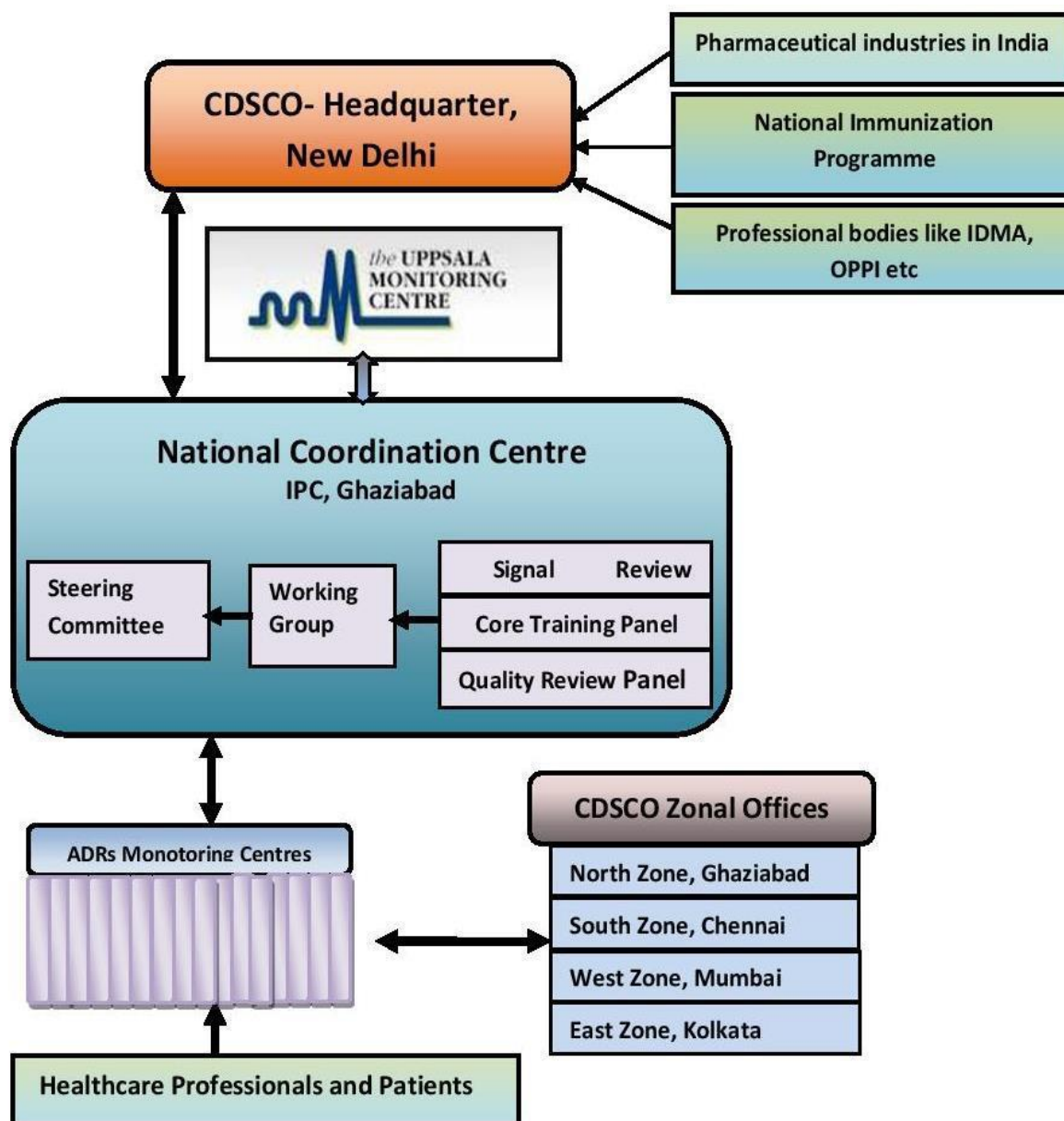
1. To develop and implement Pharmacovigilance system in India.
2. To enroll, initially, all MCI approved medical colleges in the program covering north, south, east and west of India.

3. To encourage healthcare professionals in reporting of adverse reaction to drugs, vaccines, medical devices and biological products.
4. Collection of case reports and data.

Long term goals

1. To expand the Pharmacovigilance programme to all hospitals (govt. & private) and centres of public health programs located across India.
2. To develop and implement electronic reporting system (e-reporting).
3. To develop reporting culture amongst healthcare professionals.
4. To make ADR reporting mandatory for healthcare professionals.

PvPI - Programme Communication



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

- NCC-PvPI officials participated in the ‘National symposium on Translational Pharmacovigilance’ organized by department of Pharmacology, PGIMER, Chandigarh on 14th April 2012.
- NCC-PvPI submitted 30 ICSRs on *Pioglitazone* and 150 ICSRs on *Statins* to CDSCO for regulatory intervention in India.
- NCC-PvPI delivered a lecture on ‘Introduction to Pharmacovigilance and Pharmacovigilance programme of India’ during the workshop on to create awareness among health care professionals organized by Department of Pharmacology, SMS Medical College, Jaipur on September 17, 2012.
- NCC-PvPI delivered a lecture on ‘Appraisal about the PvPI and the modalities of reporting the ADRs’ to the Clinical faculty, PGs and other health care professionals at Department of Pharmacology, UCMS & GTB Hospital, New Delhi on September 19, 2012.
- The Second Working Group-PvPI Meeting was held on September 28, 2012 under the Chairmanship of Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad to discuss and resolve various issues of PvPI.
- The 1st Steering Committee was held on 28th December 2012 at DCG(I) office, FDA Bhawan, New Delhi to give a direction for effective functioning of PvPI.
- NCC-PvPI published Issue-4, Volume-2 PvPI news letter in December 2012 with special emphasis on the ADRs reporting culture in India & Insulin-induced weight gain in diabetic patients.
- The Third Working Group of PvPI meeting was held on 29/01/2013 to discuss the various issues at DCG(I) office, FDA Bhawan, New Delhi.

- NCC-PvPI provided technical support to organize a workshop on ‘National symposium on Pharmacovigilance and ADRs monitoring’ to create awareness among healthcare professionals on 9th and 10th February 2013.
- AEFI division from MOH & FW, Govt of India visited at NCC-PvPI on 28th February 2013 to discuss the various issues on ADRs related to vaccines and for better coordination.
- PGIMER, Chandigarh in collaboration with NCC organized a VigiFlow training for the personnel’s involved in AMCs north zone under PvPI on 22nd February 2013.

IPC Staff (as on 31st March, 2013)

Name	Designation
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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

Statements of Account 2012-13

Auditors Report

1. We have audited the attached balance Sheet of the *Indian Pharmacopoeia Commission* as at 31st March, 2013 and the Income and Expenditure Account along with Receipts & Payment Account for the year ended on that date annexed thereto. These Financial Statements are the responsibility of the Commission's Management. Our responsibility is to express an opinion on these Financial Statement based on our audit.
2. We have conducted our Audit in accordance with Auditing standards generally accepted in India. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the Financial Statements are free of materials misstatement. An Audit included examining on test basis evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing accounting principles used and significant estimates made by management, as well as evaluating the overall Financial Statement presentation. We believe that our audit provide a reasonable basis for expressing our opinion.
3. Attention is invited to:

Note No. (3),(4),(5) & (12).

Re: Non provision of Leave Encashment & Gratuity. The impact of the same on tax liability, if any could not be assessed and quantified because of amount of bonus has not yet been finalized.
4. We report that
 - a) In our opinion, the Balance Sheet and Income & Expenditure dealt with by this report broadly comply with the Accounting Standards issued by the Institute of Chartered Accountants of India.
 - b) We have obtained all the information and explanations, which to the best of our knowledge and belief were necessary for the purpose of our audit.
5. In our opinion proper books of accounts have been maintained by the Commission so far as it appears from our examination of books.

6. The Balance Sheet and the Income & Expenditure Account dealt with by this report are in agreement with the books of accounts.

Subject to our observation / comments in Para 3 above, in our opinion and to the best of our information and according to the explanations given to us, the accounts and the Schedules annexed together with the significant accounting policies and notes thereon exhibit a true and fair view:

- a) Balance Sheet of the state of affairs of the Commission as at 31st March, 2013 and
- b) Income & Expenditure Account for the year ended 31st March, 2013.

**FOR PARY & CO.
CHARTERED ACCOUNTANTS
(FR No. 007288C)**

**Yogesh Malik
F.C.A., D.I.S.A. (ICA)
Sr. Partner
M.No. 074635**

**PLACE: GHAZIABAD
DATE: 02.09.2013**

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare
Sector - 23, Raj Nagar Ghaziabad - 201002

BALANCE SHEET AS AT 31st MARCH 2013

(Amount in Rs.)

CORPUS/CAPITAL FUND AND LIABILITIES	Schedule	Current Year	Previous Year
Corpus / Capital Fund	1	86,35,10,074.00	85,36,92,868.00
Current Liabilities and Provisions	2	60,82,100.00	47,58,532.00
TOTAL		86,95,92,174.00	85,84,51,400.00

ASSETS	Schedule	Current Year	Previous Year
Fixed Assets	3		
Gross Block		87,63,89,794.00	83,37,50,720.00
Less : Depreciation		8,78,20,737.00	5,91,31,244.00
Net Block		78,85,69,057.00	77,46,19,475.00
Investment in Fixed Deposits		2,44,18,504.00	5,49,21,915.00
Intrest Accrued on Investment		1,99,926.00	14,05,696.00
Current Assets, Loans & Advances	4	5,64,04,687.00	2,75,04,314.00
TOTAL		86,95,92,174.00	85,84,51,400.00
SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS	12		

As per our report of even date attached.

For P A R Y & CO.
Chartered Accountants
(FR No. 007288C)

FOR INDIAN PHARMACOPOEIA COMMISSION

Dr. G. N. Singh
(Secretary cum scientific Director)

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635

Chandan Kumar **I.J.S Oberoi**
(Finance & Accounts Officer) **(Administrative Officer)(i/c)**

Place:Ghaziabad
Date: 02.09.2013

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare
Sector - 23, Raj Nagar Ghaziabad - 201002

INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31st MARCH 2013

(Amount in Rs)			
PARTICULARS	Schedule	Current Year	Previous Year
INCOME			
Receipts from Sales	5	1,32,85,270.00	1,31,05,240.00
Grants/Subsidies	6	7,00,81,360.00	6,28,90,577.00
Interest Earned	7	32,57,211.00	83,45,145.00
Other Income	8	1,93,992.00	20,913.00
Depreciation (as per contra)		2,48,91,966.00	2,08,89,467.00
TOTAL (A)		11,17,09,799.00	10,52,51,342.00
EXPENDITURE			
Establishment Expenses	9	4,30,12,082.00	3,72,11,395.00
Adminstration Expenses	10	2,14,26,579.00	2,16,34,672.00
Lab Services - Operation & Maintainance Exp	11	54,59,991.00	23,04,628.00
Depreciation (as per contra)		2,48,91,966.00	2,08,89,467.00
TOTAL (B)		9,47,90,618.00	8,20,40,162.00
Balance being Surplus/(Deficit)		1,69,19,181.00	2,32,11,180.00
Add/(Less): Prior Period Expenses		(1,82,708.00)	(17,39,882.00)
Current year Income paid to MOH & FW		1,67,36,473.00	2,14,71,298.00
Surplus/(Deficit) carried to Corpus/Capital Fund (Total A - B)		-	-
SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS	12		

As per our report of even date attached.

For P A R Y & CO.
Chartered Accountants
(FR No. 007288C)

FOR INDIAN PHARMACOPOEIA COMMISSION

Dr. G. N. Singh
(Secretary cum Scientific Director)

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635

Chandan Kumar
(Finance & Accounts Officer)

I.J.S Oberoi
(Administrative Officer)(i/c)

Place:Ghaziabad
Date: 02.09.2013

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare
SECTOR-23,RAJ NAGAR GHAZIABAD-201002

RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31ST MARCH 2013

		(Amount in Rs)			
Receipts	Current Year	Previous Year	Payments	Current Year	Previous Year
1. Opening Balance			1. Expenses		
-Cash in Hand	62,847.00	51,655.00	- Establishment Expenses	4,30,12,082.00	3,59,87,218.00
-Bank Balance	82,10,159.00	8,53,85,928.00	- Administrative Expenses	2,06,07,968.00	2,04,36,567.00
-Stamps in Hand	50,433.00	-	- Lab Services- O&M Exp	54,59,991.00	31,33,632.00
			-Prior Period Expenses	1,82,708.00	17,39,882.00
2. Grants Received			2. Payments made against funds		
-From Government of India	11,21,60,000.00	10,36,20,000.00	-Advance to HLL Lifecare Limited	1,03,67,307.00	98,85,777.00
			-Advance to A & A Periodicals	39,96,619.00	31,40,786.00
3. Interest Received:			-Advance Payment to W.H.O	-	14,200.00
-Intrest Accrued on Investment	29,11,964.00	63,27,611.00	-Advance to GPF-IPC	10,00,000.00	20,00,000.00
-On Savings Account	3,42,847.00	20,14,434.00	-Advances to CPWD Ghaziabad	81,07,366.00	-
-Interest Recovered from Scooter advance	2,400.00	3,100.00	-Advances to Others	73,504.00	-
4. Other Income			3. Expenditure on Fixed Assets & Capital Work-in-Progress		
-Sale of I.P Books	62,22,700.00	1,31,05,240.00	-Books	81,97,366.00	13,37,921.00
-Sale of IPRS	7,58,150.00	-	-Building	36,90,954.00	89,88,497.00
-Sale of NFI	57,95,570.00	-	-Computer & Pheripheral	20,96,983.00	11,01,652.00
-Others	4,94,250.00	-	-Cycle	-	2,900.00
-Other Income	1,93,992.00	20,913.00	-Furniture & fixture	69,74,860.00	20,86,996.00
-Sale of Tender Forms	14,600.00	-	-Office Equipments	15,30,359.00	64,27,750.00
5. Other Receipts			-Plant Machinery & Equipment	70,35,672.00	11,01,81,061.00
-Advances to Contractors & Suppliers including prior period adjustments adjusted during the year	61,96,566.00	9,52,70,786.00	-Vehicle	-	4,93,365.00
-Scooter Advance	31,500.00	34,000.00	4. Refund of surplus money/loans		
-Tour Advance	4,19,025.00	-	- To the MOH & FW	-	3,90,00,000.00
-Festival Advance	40,875.00	30,300.00	-To the MOH & FW	4,30,00,000.00	4,50,00,000.00
-License Fee Recovered	5,100.00	-	-Increase in Investments during the year	-	63,27,611.00
-Decrease in Investments during the year	3,17,09,181.00	-	5.Other payments		
-Increase in Security Deposit/ Retention Money	1,32,000.00	-	-TCS Paid	4,500.00	-
-Increase in amount payable to creditors	22,10,455.00	-	-Security deposit with Electricity Deptt.	-	1,21,738.00
			-Festival Advance	30,000.00	33,750.00
			-Tour Advance	4,18,733.00	38,225.00
			-Scooter Advance	-	61,000.00
			-Amount Recoverable From Debtors	57,68,040.00	-
			6.Closing Balances		
			-Cash in Hand	39,284.00	62,847.00
			-Bank Balance	63,58,994.00	82,10,159.00
			-Stamps in Hand	11,324.00	50,433.00
	17,79,64,614.00	30,58,63,967.00		17,79,64,614.00	30,58,63,967.00

As per our report of even date attached.

For P A R Y & CO.

Chartered Accountants

(FR No. 007288C)

FOR INDIAN PHARMACOPOEIA COMMISSION

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635

Dr. G. N. Singh
(Secretary cum scientific Director)

Place:Ghaziabad
Date: 02.09.2013

Chandan Kumar
(Finance & Accounts Officer)

I.J.S Oberoi
(Administrative Officer)(i/c)

(A) SIGNIFICANT ACCOUNTING POLICIES

1. Basis of Accounting

The financial statements have been prepared as prescribed by ICAI in accordance with generally accepted accounting principles. The Indian Pharmacopoeia Commission (here and after referred as IPC) adopts accrual system of accounting but interest on advances to Employees are recognized on Cash basis.

2. Fixed Assets and Depreciation

- a) Fixed assets are stated at cost less accumulated depreciation.
- b) Depreciation has been provided to the extent of 95% on straight line method on the basis of rates as prescribed in schedule XIV of the Companies Act 1956. Depreciation on Library Books has been charged @ 40% on straight line method. The depreciation rates applied on various assets is given below –

FIXED ASSETS	RATES OF DEPRECIATION CHARGED
Machinery & Equipment	- 4.75%
Office Equipment	- 7.07%
Building	- 1.63%
Furniture & Fixtures	- 6.33%
Lab Equipments	- 7.07%
Vehicles	- 9.50%
Cycle	- 7.07%
D.G Sets	- 4.75%

- c) In respect of additions to fixed assets made during the year, depreciation has been provided for the full year and in respect of sale/disposal of fixed assets, no depreciation has been provided but it has no financial implication due to this deviation from the prescribed provisions of the ICAI.
- d) The depreciation has been charged to the grant Corpus Fund and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item as per AS-12 Prescribed by ICAI.

3. Grant In Aid

- a) The grants in aid received from Ministry of Health & family Welfare, Government of India is accounted for on accrual basis. Accordingly, any deficit/surplus of grant has been shown as Grant receivable/payable to the MOH & FW.
- b) Grant is charged to the revenue to the extent of expenditure incurred as all the Incomes received by the IPC have been transferred to the MOH & FW.
- c) The grants utilized for the purchase of fixed assets have been shown under the head of Corpus Fund.
- d) Further grants utilized for Purchase of Fixed Assets have also been shown under the head of Corpus Fund.

4. Employee Remuneration & Benefits

All Retirement and other Terminal Benefits such as Gratuity, Leave Encashment and Bonus etc are not accounted on year to year basis and the same are recognized in the year of retirement.

5. Revenue Recognition

Income and expenditure are accounted for on accrual basis, as they are earned or incurred. Further all the income received by way of Sale of I.P Books & other misc. receipts has been transferred to the MOH & FW

6. Provision

A provision is recognized when an enterprise has a present obligation as a result of past event; it is probable that an outflow of resources will be required to settle the obligation, in respect of which a reliable estimate can be made. Provisions are not discounted to present value and are determined based on best estimate required to settle the obligation at the balance sheet date. These are reviewed at each balance sheet date and are adjusted to reflect the current best estimates.

7. Contingent Liabilities and Contingent Assets

A disclosure for a contingent liability is made when there is a possible obligation that may, but probably will not, require an outflow of resources. Where there is a possible obligation or a present obligation but the like hood of outflow of resources is remote, no provision or disclosure is made.

(B) NOTES ON ACCOUNTS

1. The depreciation of Rs.2,48,91,966.00 has been charged to the Income & Expenditure account. Since the institute is fully aided by the Government of India, therefore depreciation is charged to the grant Corpus Fund and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item.
2. During the current year corpus fund was credited by Rs. 37, 97,527.00 on account of excess depreciation charged and Rs.1,31,93,745.00 excess amount written off on books in previous year. Further, during the previous years IPC has charged deprecation on Gross Block of Assets instead of charging Depreciation individually. (i.e. Asset-wise Depreciation)
3. Provision for Leave Encashment and gratuity has not been made during the year.
4. Party balances are subject to confirmation.
5. Cheques being amount of Rs. 20,06,640.00 .have been issued to the Parties but not presented before the bank till date.
6. Liabilities are recognized to the extent information available.
7. Internal Control system of IPC needs to be Strengthen.
8. The institute has not gathered any information from suppliers/service providers about their status under Micro, Small and Medium Enterprises (Development) Act, 2006. Therefore the required information, regarding the dues outstanding to Micro, Small and Medium Enterprises as on 31.03.2013 and interest payable, if any, are not considered.
9. Financial effect of pending Court Cases cannot be ascertained on the Balance Sheet Date therefore neither the provision nor the amount of the same has been disclosed in the notes to accounts. The pending court cases are on account of C.G.H.S facility to be provided to employees, so there is no financial impact of the same on the Balance Sheet date.
10. During the F.Y a sum of Rs 2,62,63,527.00 has been charged to the Corpus fund because in the Previous Years amount Payable/Recoverable to the Ministry has been added to the Corpus Fund.

11. During the year, IPC has transferred all the receipts to MOH & FW, GOI which are earned by way of Sale of I.P Books & other misc. receipts. Further, IPC has transferred a sum of Rs 4,30,00,000.00 to the MOH & FW, which includes Income of current year as well as of previous year.
12. Advance payments in excess of actual requirement not only blocked the Government money but also results into financial loss to the Government, as the IPC is not getting any interest on these advances. The details of same are as follows:

Sl. No.	Party's Name	Amount in Rs.
1.	M/s Hindustan Life Care Limited (HLL)	2,02,53,084.00
2.	M/s A & A Periodical Subscription Agency (P) Ltd.	34,18,295.00
3.	Central Public Works Department (CPWD)	81,07,366.00

13. During the year IPC has given advance amounting to Rs.10,00,000.00 to “IPC GPF”.
14. The previous year figures have been regrouped/reclassified/rearranged, wherever necessary.

For P A R Y & CO.

**Chartered Accountants
(FR No. 007288C)**

**Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
(M. No. 074635)**

**Place: Ghaziabad
Date: 02.09.2013**

FOR INDIAN PHARMACOPOEIA COMMISSION

**Dr. G.N Singh
(Secretary-cum -Scientific Director)**

**Chandan Kumar
(Finance & Accounts Officer)**

**I.J.S. Oberoi
(Administrative Officer)(i/c)**

AUDITORS REPORT

To,
The Members,
General Provident Fund,

Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare
Government of India,
Sector-23 Raj Nagar,
Ghaziabad-201002

1. We have audited the attached Balance Sheet of the Indian Pharmacopoeia Commission, General Provident Fund as at 31st March 2013 and Income & Expenditure Account along with Receipts & Payment Account for the year ended on that date annexed thereto. These Financial Statements are the Responsibility of the "IPC-GPF" Management. Our Responsibility is to express an opinion on this Financial Statements Based on our Audit.
2. Further we report that:
 - a) We have obtained all the information and explanations which to the best of our knowledge and belief were necessary for the purpose of our audit.
 - b) In our opinion proper books of accounts as required by law have been kept by the Institute so far as it appears from our examination of books.

c) The Balance Sheet and the Income & Expenditure Account dealt with by this report are in agreement with the books of accounts.

3. In our opinion and to the best of our information and according to the explanations given to us, the said accounts exhibit a true and fair view.

a) In the case of Balance Sheet of the state of affairs as at 31st March 2013; and

b) In the case of the Income & Expenditure Account Excess of Income over Expenditure for the year ended 2013.

**For P A R Y & CO.
Chartered Accountants
(FRN 007288C)**

**Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
(M. No. 074635)**

**Place: Ghaziabad
Date: 02.09.2013**

INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund
RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31ST MARCH 2013

(Amount in
Rs)

Receipts	Current Year	Previous Year	Payments	Current Year	Previous Year
Opening Balance			Payments made out of GPF Fund		
- Bank Balance	15,96,140.00	5,93,502.00	- Towards Withdrawals	42,03,000.00	27,68,000.00
GPF Receipts			- Towards Final Settlement	-	4,86,852.00
- Contribution received during the year	19,47,200.00	19,50,235.00	Payments made towards Investments		
- Interest on GPF	8,99,810.00	8,29,658.00	- Fixed Deposit	12,24,869.00	9,84,383.00
Interest Received			Other payments		
- On Bank deposits	83,702.00	47,055.00	- Advance paid during the year	-	-
- Interest on Investment	12,24,869.00	9,84,383.00	- Interest on subscription	8,99,810.00	8,29,658.00
Other Receipts			Closing Balances		
- Advance recovered during the year from members	-	2,60,200.00	- Bank Balance	4,24,042.00	15,96,140.00
- Loan from IPC	10,00,000.00	20,00,000.00			
Total	67,51,721.00	66,65,033.00	Total	67,51,721.00	66,65,033.00

As per our report of even date attached.

**For P A R Y & CO.
Chartered Accountants
(FR No. 007288C)**

**FOR INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund**

**Dr. G.N. Singh
(secretary-cum -Scientific Director)**

**Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635**

**Chandan Kumar
(Finance & Accounts Officer)**

**I.J.S Oberoi
(Administrative Officer)(i/c)**

**Place : Ghaziabad
Date : 02.09.2013**

**INDIAN PHARMACOPOEIA COMMISSION GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)**

Income & Expenditure Account for the year Ended 31.03.2013

(Amount in Rs)

Expenditure	Current Year	Previous Year	Income	Current Year	Previous Year
Interest on subscription	8,99,810.00	8,29,658.00	Interest on Investment	10,20,199.00	12,89,016.00
Excess of Income over Expenditure	2,04,091.00	5,06,413.00	Interest on Saving A/c	83,702.00	47,055.00
Total	11,03,901.00	13,36,071.00	Total	11,03,901.00	13,36,071.00

Significant Accounting Policies and Notes to Accounts 4

As per our report of even date attached.

For P A R Y & CO.

Chartered Accountants
(FRN. 007288C)

FOR INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635

Place : Ghaziabad
Date : 02.09.2013

Dr. G.N. Singh
(secretary-cum -Scientific Director)

Chandan Kumar
(Finance & Accounts Officer)

I.J.S Oberoi
(Adminstrative Officer)(i/c)

INDIAN PHARMACOPOEIA COMMISSION GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)
Balance Sheet as at 31.03.2013

(Amount in Rs)

Liabilities	Schedule	Current Year	Previous Year	Assets	Schedule	Current Year	Previous Year
<u>Capital</u> Subscription & Contributions	1	1,00,63,762.00	1,14,19,752.00	<u>Investment</u> Fixed Deposit with Bank	3	1,22,09,252.00	1,09,84,383.00
Balance being Excess of Income/Expenditure	2	(3,30,505.00)	(5,34,596.00)	<u>Current Assets</u> Accrued Interest(Investment) Balance in super saving Account		99,963.00 4,17,430.00	3,04,633.00 15,89,528.00
<u>Current Liability</u> IPC Loan		30,00,000.00	20,00,000.00	Bank Balance 310		6,612.00	6,612.00
Total		1,27,33,257.00	1,28,85,156.00	Total		1,27,33,257.00	1,28,85,156.00

Significant Accounting Policies and Notes to Accounts

4

As per our report of even date attached.

For P A R Y & CO.

Chartered Accountants

(FR No. 007288C)

FOR INDIAN PHARMACOPOEIA COMMISSION

General Provident Fund

Yogesh Malik

F.C.A, D.I.S.A (ICA)

Sr. Partner

Place : Ghaziabad

Dr. G.N. Singh
(secretary-cum -Scientific Director)Chandan Kumar
(Finance & Accounts Officer)I.J.S Oberoi
(Adminstrative Officer)(i/c)SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2013
SCHEDULE - 1 : List of Members Who Contributed towards subscription of "IPC-GPF"

(Amount in Rs)

Sl.No	GPF A/c No.	Name & Designation	Opening Balance as on 1.04.2012 (A)	Subscription/ Contribution (B)	Recovery (C)	Advance (D)	Withdrawal (E)	Final Settlement (F)	Interest (G)	Balance as on 31.03.2013 (A)+(B)+(C)-(D)-(E)-(F)+(G)
1	IPC/01	Dr. Jai Prakash	6,73,654.00	60,000.00	-	-	-	-	62,142.00	7,95,796.00
2	IPC/02	Dr. R.M. Singh	4,33,572.00	1,35,000.00	-	-	2,55,000.00	-	31,169.00	3,44,741.00
3	IPC/03	Shri K. K. Singh	3,66,173.00	60,000.00	-	-	-	-	35,083.00	4,61,256.00
4	IPC/04	Smt. Savita Shukla	47,821.00	-	-	-	-	-	-	47,821.00
5	IPC/05	Dr. S. C. Mathur	15,68,656.00	1,20,000.00	-	-	12,00,000.00	-	1,00,128.00	5,88,784.00
6	IPC/06	Km.Sangeeta Bhatnagar	20,59,305.00	78,000.00	-	-	-	-	1,84,937.00	23,22,242.00
7	IPC/07	Sh. Alok Sharma	75,682.00	36,000.00	-	-	70,000.00	-	4,783.00	46,465.00
8	IPC/08	Sh. M. K. Panday	2,86,149.00	60,000.00	-	-	1,95,000.00	-	10,881.00	1,62,030.00
9	IPC/09	Sh. Y. K. Kush	10,267.00	24,000.00	-	-	-	-	2,047.00	36,314.00
10	IPC/10	Sh. Satya Prakash	7,52,257.00	1,08,000.00	-	-	-	-	71,347.00	9,31,604.00
11	IPC/11	Dr. D. K. Sharma	13,36,816.00	1,20,000.00	-	-	12,50,000.00	-	59,926.00	2,66,742.00
12	IPC/12	Sh. Pawan Kr. Saini	1,07,575.00	1,14,000.00	-	-	-	-	14,901.00	2,36,476.00
13	IPC/13	Sh. Satyaveer Singh	4,36,857.00	1,65,200.00	-	-	-	-	46,245.00	6,48,302.00
14	IPC/14	Sh. B. Dayal Sharma	3,70,456.00	1,12,000.00	-	-	2,50,000.00	-	18,139.00	2,50,595.00
15	IPC/15	Smt. Ritu Tiwari	4,43,239.00	1,31,000.00	-	-	1,80,000.00	-	35,624.00	4,29,863.00
16	IPC/16	Sh. Udai Pal	40,345.00	24,000.00	-	-	40,000.00	-	2,934.00	27,279.00
17	IPC/17	Sh. I. J. S. Oberoi	70,163.00	84,000.00	-	-	63,000.00	-	5,162.00	96,325.00
18	IPC/18	Km. Renu Kapoor	10,63,587.00	1,04,000.00	-	-	-	-	98,318.00	12,65,905.00

19	IPC/19	Sh. Bijendra Kumar	4,94,302.00	1,20,000.00	-	-	-	-	49,219.00	6,63,521.00
20	IPC/20	Sh. R. K. Sharma	62,619.00	52,000.00	-	-	-	-	7,402.00	1,22,021.00
21	IPC/21	Dr. Anil Kr. Teotia	7,20,257.00	2,40,000.00	-	-	7,00,000.00	-	59,423.00	3,19,680.00
		Total	1,14,19,752.00	19,47,200.00	-	-	42,03,000.00	-	8,99,810.00	1,00,63,762.00

SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2013

SCHEDULE - 2 : Excess of Income/Expenditure for the year

PARTICULARS	As on 31.03.2013	As on
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		31.03.2012
Opening Balance As on	(5,34,596.00)	(10,41,009.00)
Add/Less: Income/Expenditure for the year	2,04,091.00	5,06,413.00
TOTAL	(3,30,505.00)	(5,34,596.00)

SCHEDULE - 3: INVESTMENTS

FDR / Receipt NO	DATE OF INVESTMENT	AMOUNT INVESTED (Rs.)	PERIOD OF DEPOSIT	RATE OF INTEREST(%)	DATE MATURITY / REDEMPTION	AMOUNT DUE ON MATURITY (Rs.)
A- SHORT TERM DEPOSIT WITH BANK OF BARODA						
21860300022595	01.03.2013	1,22,09,252.00	1 Year	9.31%	01.03.2014	1,33,86,237.00
TOTAL OF SCHEDULE -3	-	1,22,09,252.00				1,33,86,237.00

INDIAN PHARMACOPOEIA COMMISSION Ministry of Health and Welfare General Provident Fund

SCHEDULE - 4

Significant accounting policies and Notes to accounts.
(Forming part of the Financial Statements for the year ended 31st March 2013)

A. SIGNIFICANT ACCOUNTING POLICIES

1.Method of accounting:

The accounts have been prepared under the Historical cost convention on accrual basis.

2.Revenue Recognition:

The Revenue has been recognized on accrual basis.

3.Fixed Assets:

There are no fixed assets.

4.Investments:

Investments are stated at cost and are held in the name of the "Indian Pharmacopoeia Commission General Provident Fund" (herein after referred to as "IPC – GPF").

B. NOTES TO ACCOUNTS

1. "IPC – GPF" is not yet registered with the desired Govt. Authorities.
2. The investments of "IPC-GPF" have been invested in Fixed Deposit with Nationalized bank.
3. The accounting standards issued by ICAI wherever applicable have been complied to the extent possible.

4. The previous year's figures have been regrouped/reclassified/rearranged, wherever necessary to confirm to the current period presentation.

For P A R Y & CO.

FOR INDIAN PHARMACOPOEIA COMMISSION

**Chartered Accountants
(FR No. 007288C)**

**Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
(M. No. 074635)**

**Place: Ghaziabad
Date: 02.09.2013**

**Dr. G.N. Singh
(Secretary-cum -Scientific Director)**

**Chandan Kumar I.J.S. Oberoi
(Finance & Accounts Officer) (Administrative Officer)(i/c)**