INDIAN PHARMACOPOEIA COMMISSION

Annual Report
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INDIAN PHARMACOPOEIA COMMISSION,
GHAZIABAD, U.P.

Ministry of Health & Family Welfare
Govt. of India

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Preface

The sixth edition of the Indian Pharmacopoeia (IP 2010) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare. The Indian Pharmacopoeia (IP) is published in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of this pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines. IP is published in continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines. The Commission has been receiving significant inputs from regulatory, industrial houses, academic institutions, national laboratories, individual scientists and others. Publication of IP at regular and shorter intervals is one of the main mandates of the Commission.

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

The history of the IP began in the year 1833 when a Committee of the East India Company's Dispensary recommended the publication of a Pharmacopoeia, and Bengal Pharmacopoeia and General Conspectus of Medicinal Plants was published in 1844, which mainly listed most of the commonly used indigenous remedies. This was followed by IP 1868, which covered both the drugs of British Pharmacopoeia (BP) 1867 and indigenous drugs used in India, with a Supplement published in 1869 incorporating the vernacular names of indigenous drugs and plants. However, from 1885 the BP was made official in India. A Drugs Enquiry Committee appointed in 1927 by the government recommended the publication of a National Pharmacopoeia.

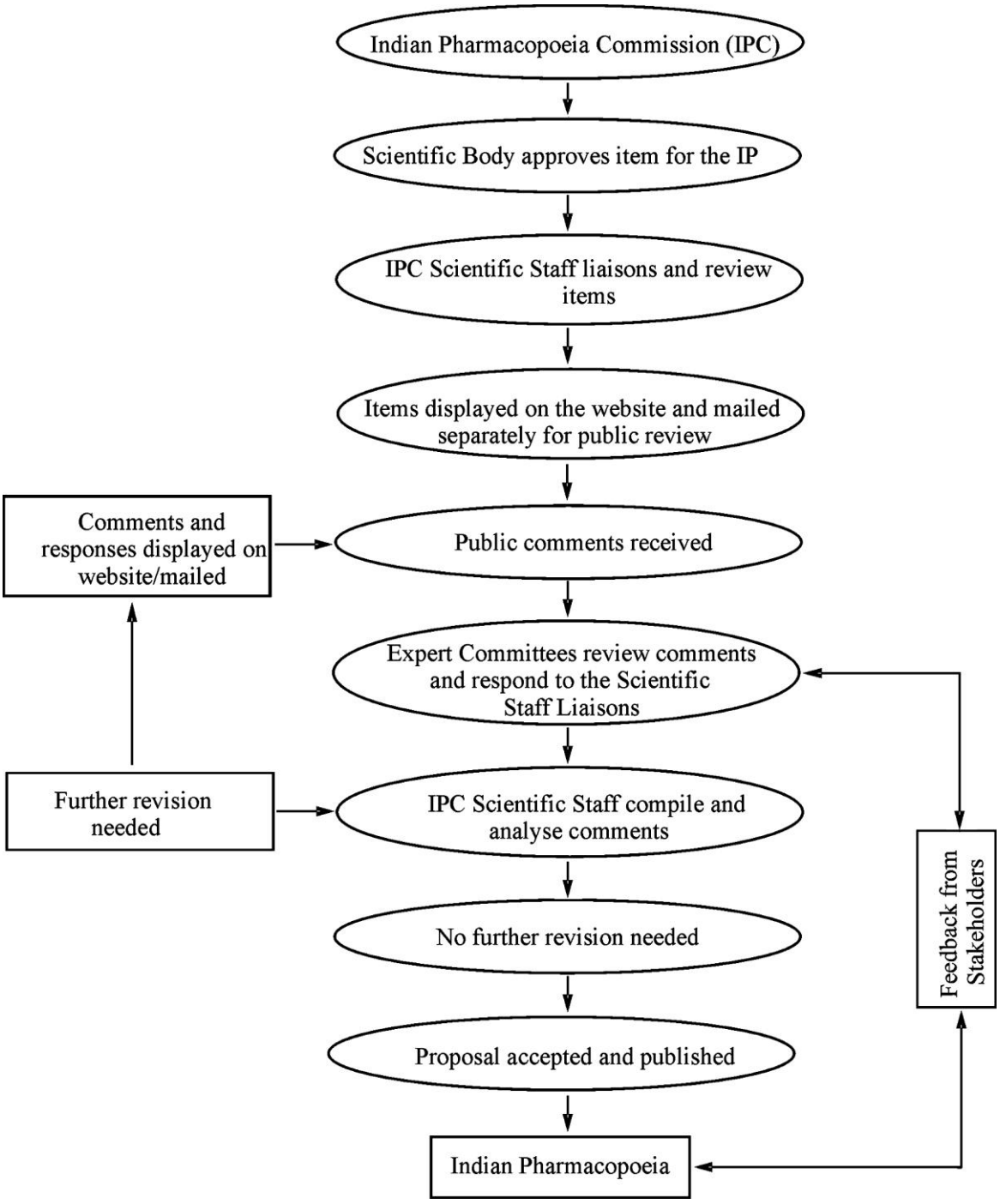
After independence, the Indian Pharmacopoeia Committee was constituted in 1948, for publication of IP as its main function, which published the IP in 1955, followed by a Supplement in 1960. This Pharmacopoeia contained both western and traditional system drugs commonly used in India, and the same policy 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, Immunosera 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 Indian Pharmacopoeia 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.

Public Review and Comment Process for Standards Development related to this edition of the Indian Pharmacopoeia have given special attention to incorporate comments from stakeholders. The methodology adopted is appended below:



The IPC Secretariat and Indian Pharmacopoeia Laboratory (IPL) staff, with the support of different advisory Expert Committees and Expert Members of the Scientific Body have examined the suitability of the standards. In order to make IP 2010 user friendly, the existing formatting pattern has been suitably revised. The standards prescribed in this edition are encouraged to adhere with the concept of harmonization, keeping in view the technological status for manufacture and analysis of drugs and pharmaceuticals in the country without compromising with the quality of the products. It strives to update the existing monographs as well as incorporating the new monographs of drug substances based on clinical use of

medicines in India and improving their test protocols. The IP 2010 has been considerably revised and improved in respect of the requirements of monographs, appendices and testing protocols by introducing advanced technology. The contents of Appendices are by and large revised in consonance with those adopted internationally. The monographs of special relevance diseases of this region have been given special attention.

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

This is the sixth edition of the Indian Pharmacopoeia. It comprises of three volumes. Each volume has got different features.

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

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

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

The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a days are omitted from this edition. The number of monographs of Excipients, Anticancer drugs, Herbal products and Antiretroviral drugs have been increased in this edition. Monographs of Vaccines and Immunosera are also upgraded in view of development of latest technology in the field. A new chapter on Liposomal products and a monographs of Liposomal Amphotericin B injection is delivery. A chapter on NMR is incorporated in Appendices. The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

As in the past, this compendium provides a publicly available statement concerning the quality of a product that can be expected and demonstrated at any time throughout the accepted shelf-life of the article. The standards laid down represent the minimum with which the article must comply and it is inculcate on the manufacturer to ensure that the article is manufactured in accordance with the Good Manufacturing Practices (GMPs). It is essential that sufficiently stringent limits are applied at the time of release of a batch of a drug substance of drug product so that the pharmacopoeia standards are met until its expiry date when stored under the storage conditions specified. It must be noted that a valid interpretation of any requirement of the Pharmacopoeia should be done in the context of the monograph as a whole, the relevant general monograph, where appropriate, the specified tests and methods of analysis including any reference to the relevant General Notices. Familiarity with the General Notices will facilitate the correct application of the requirements.

Keeping in view the essential requirement under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules 1945 made thereunder in the information on category of a drug, dosage and usual available strengths of dosage forms has been re-kept in this edition.

General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued. The use of chromatographic method has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in drug substances and drug products. Most of the existing Assays and Related substances tests are upgraded by liquid chromatography method in view to have more specificity and to harmonise with other International Pharmacopoeias. The test for pyrogens involving the use of animals has been virtually eliminated. The test for bacterial endotoxins introduced in the previous edition in now applicable to more items. The test for abnormal toxicity is now confined to certain vaccines.

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

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

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

It is hoped that this edition would play a significant role in improving the quality of medicines which in turn promote public health and accelerate the growth and development of Pharma Sector.

Introduction

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.

This new edition of the Indian Pharmacopoeia entitled 6th edition (Indian Pharmacopoeia 2010) is published by the Indian Pharmacopoeia Commission (IPC) in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years. It supersedes the 2007 edition but any monograph of the earlier edition that does not figure in this edition continues to be official as stipulated in the Second Schedule of the Drugs and Cosmetics Act, 1940.

While considering the annual report of any organization, it is imperative to take a look into the objects of its creation, the declared visions and targets, the performance during the year under review and also the plans ahead to achieve the objects of creation, vision, mission and physical targets. If the object of the creation of IPC is to be stated in a nutshell, it is “To function as a National Standards writing institution for drugs and carryout all activities associated with it”. This object, if elaborated, would mean to decide the National standards for all the drugs reaching the hands of the consumers, to notify them in the form of an publication that has statutory and regulatory status and carry out all activities needed to update the document periodically through further publications. The documents of vision, mission and physical targets should spell out the programmes envisaged to achieve the object.

To perform activities of standards writing of drugs, several infrastructure facilities are needed. The facilities inherited from an institution performing different facilities shall necessarily have to be restructured and a report of this nature is to contain the proposals in this regard.

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.

The IPC has also been vested with the work of updating and publishing the National Formulary of India (NFI) after a lapse of about thirty years. The NFI is a book of reference for all those involved in the processes of making them available to the end user to ensure correct and rational handling and use. NFI is also to be revised and republished periodically.

To meet expectations of stakeholders, the Commission is striving very hard and addendum 2012 to IP 2010 is near completion. Preparatory work on National Formulary of India has been completed and it is expected that next edition of NFI will roll out very soon.

From the Secretary-cum-Scientific Director's Desk

I am extremely delighted to present the third annual report before you. The financial year under the report was very challenging for this autonomous institution as the aspect of timely publication of 6th edition of Indian Pharmacopoeia was concerned and this institution has come out marching through deep waters despite paucity of working hands and restricted access to work on high end equipments/instruments when the quality and efficacy is at stake in international terms. The edition of IP 2010 incorporates 287 new monographs consisting of API's, excipients, dosage forms and herbal products etc. Constant efforts have been made to unify the National Drugs Standards and tone up them in line with the international standards progressively, by addition of monographs of new drugs and adopting current methodology. The Commission has also been vested with the work of updating and publishing the National Formulary of India after a lapse of about thirty years. NFI is a book of reference for use of clinicians, pharmacists and nurses alike. The Commission is in the process of certifying, preparing and manufacturing IP Reference substances vigorously. The credit of this whole performance is concealed in the principles of transparency, accountability and punctuality adopted by the workforce voluntarily.

The path of the Commission seems to be more crucial in the coming future as the country has high expectations from institution to provide highly updated and upgraded infrastructure facilities required for executing the responsibilities vested with it and to cope up with international and national standards in this era of throat cut competition.

The blessings, guidance and road map extended by the Ministry and helping hand provided by the members of Scientific Body and other distinguished expert members along with the untiring labour of the hard working staff of the Commission are laudable. I, on my own and on behalf of my co-workers would like to extend my deep sense of gratitude and obligation to all those who guided during the period and to the Government for the continuous support provided to the IP Commission to achieve its coveted goals.

With best wishes.

Dr. G. N. Singh

MISSION, VISION AND OBJECTIVES

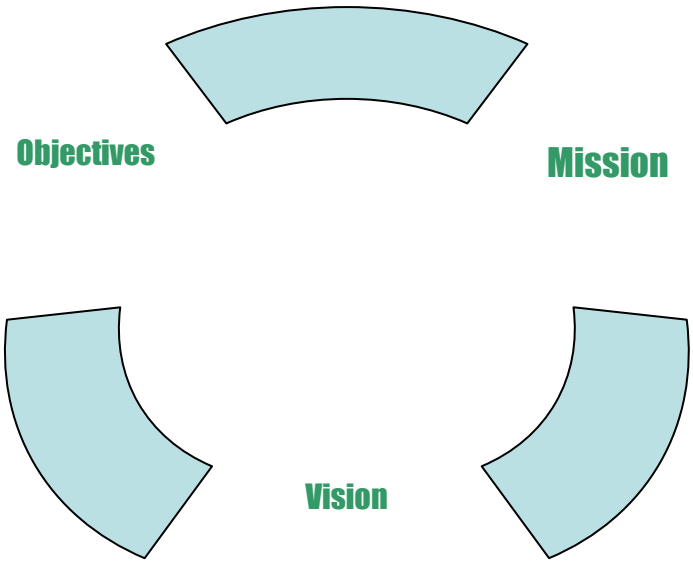


Fig: 2-Functions of IPC

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.

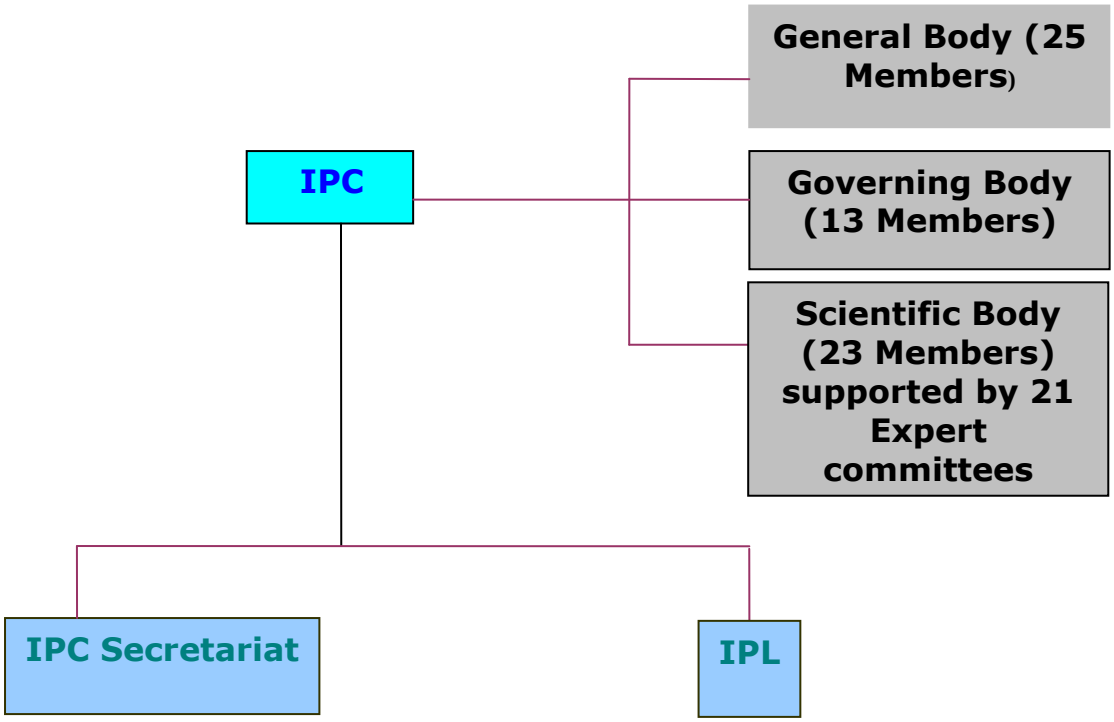
- To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.

- 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.	*Designation in Committee*	Name & Address
1.	*Chairman*	Shri K. Chandramouli Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
2.	*Co-Chairman*	Dr. Nitya Anand Ex-Director Central Drug Research Institute B-62, Nirala Nagar Lucknow-226 020.
3.	*Member*	Shri L. C. Goyal, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	*Member*	Shri Naved Masood Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
5.	*Member*	Dr. Arun Kumar Panda Joint Secretary (Drugs) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	*Member*	Dr. Surinder Singh Drugs Controller General (I), Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road, New Delhi.
7.	*Member*	Shri Sanjay Prasad Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	*Member*	Dr. Jotna Sokhey Director National Institute of Biologicals B-62, Institutional Area Noida-201 307

9.	*Member*	Shri Arun Jha, Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
10.	*Member*	Prof. B. Suresh President, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Aiwan-E-Ghalib Marg, Post Box No. 7020 New Delhi-110 002
11.	*Member*	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
12.	*Member*	Shri P. D. Sheth, Former Executive Director, Ranbaxy E-256, Greater Kailash-I New Delhi-110 048.
13.	*Member-Secretary*	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.	*Designation in Committee*	Name & Address
1.	*Chairman*	Shri K. Chandramouli Secretary (Health & Family Welfare) Government of India Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
2.	*Co-Chairman*	Dr. Nitya Anand Ex-Director Central Drug Research Institute B-62, Nirala Nagar Lucknow-226 020.
3.	*Member*	Shri L. C. Goyal, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	*Member*	Shri Naved Masood Additional Secretary & Finance Advisor Ministry of Health & Family Welfare Nirman Bhawan New Delhi -110 011.
5.	*Member*	Dr. Arun Kumar Panda Joint Secretary (Drugs) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	*Member*	Dr. Surinder Singh Drugs Controller General (I), Directorate General of Health Services Ministry of Health & Family Welfare FDA Bhawan, Kotla Road, New Delhi.
7.	*Member*	Shri Sanjay Prasad Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	*Member*	Dr. Jotna Sokhey Director National Institute of Biologicals B-62, Institutional Area Noida-201 307

9.	*Member*	Mr. Arun Jha, Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers Shastri Bhawan, New Delhi
10.	*Member*	Prof. B. Suresh President, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Aiwan-E-Ghalib Marg, Post Box No. 7020 New Delhi-110 002
11.	*Member*	Shri P. K. Guha Director Central Drugs Laboratory 3, Kyd Street Kolkata
12.	*Member*	From Regulatory Bodies Central Drugs Standard Control Organisation Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
13.	*Member*	Dr. C. Adithan Director-Professor Department of Pharmacology Jawaharlal Institute of Postgraduate Medical Education and Research Pondicherry-605 006.
14.	*Member*	Commissioner in-charge of Drug Control Administration, Andhra Pradesh
15.	*Member*	Commissioner in-charge of Drug Control Administration, Sikkim
16.	*Member*	Commissioners in-charge of Drug Control Administration, Gujarat
17.	*Member*	Commissioner in-charge of Drug Control Administration, Uttar Pradesh
18.	*Member*	Commissioner in-charge of Drug Control Administration, Himachal Pradesh

19.	*Member*	The Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062.
20.	*Member*	Shri N. R. Munjal, President, Indian Drug Manufacturers Association (IDMA) 102-B, Poonam Chambers, 'A' Wing' Dr. Annie Besant Road, Worli Mumbai – 400018
21.	*Member*	The President, Organization of Pharmaceutical Producers of India (OPPI), Peninsula Corporate Park, Peninsula Chambers, Gr. Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013
22.	*Member*	Shri. D. G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), Mumbai
23.	*Member*	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
24.	*Member*	Shri P. D. Sheth, Former Executive Director, Ranbaxy E-256, Greater Kailash-I New Delhi-110 048.
25.	*Member-Secretary*	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.	*Chairman*	Dr. Nitya Anand Ex-Director Central Drug Research Institute B-62, Nirala Nagar Lucknow-226 020.
2.	*Member*	Dr. Surinder Singh Drugs Controller General (I) Dte. General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
3.	*Member*	Mr. Prafull D. Sheth E-256, Greater Kailash-I New Delhi-110 048.
4.	*Member-Secretary*	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.	*Chairman*	Dr. Nitya Anand Ex-Director Central Drug Research Institute B-62, Nirala Nagar Lucknow-226 020.
2.	*Member*	Mr. Vinod Arora Vice-President (Pharma Research) Ranbaxy Research Laboratories Plot No. 20, Sector 18, Udyog Vihar Industrial Area Gurgaon-122 001.
3.	*Member*	Dr. T. G. Chandrashekhar Vice-President, Global Quality & Analytical Research, Ranbaxy Research Laboratories, Plot No. 20, Sector 18, Udyog Vihar Industrial Area Gurgaon-122 001.
4.	*Member*	Dr. Manish Gangrade Head-ANALYTICAL Development Laqb. CIPLA Limited L.B.S. Marg, Vikhroli (W) Mumbai-400 083.
5.	*Member*	Dr. Parthajyoti Gogoi Director-in-Charge Regional Drugs Testing Laboratory (RDTL) Khana Para, Panjabari, Six mile Guwahati-781 037.
6	*Member*	Dr. Prem K. Gupta Ex-Drugs Controller (I) House No. 95 DDA Flats Pocket ‘B’, Sukhdev Vihar New Delhi -110 025.
7.	*Member*	Professor Y. K. Gupta Head, Department of Pharmacology, All India Institute of Medical Sciences Ansari Nagar New Delhi-110 029.
8.	*Member*	Professor V. K. Kapoor Ex-Dean and Chairman, Pharmaceutical Sciences, Punjab University 1743, Pushpae Complex, Sector 49-B Chandigarh-160 047.

9.	*Member*	Dr. Anand Kumar 553, 7th Main Road, Sadashivanagar, Bangalore-560 080.
10..	*Member*	Dr. D. B. Anantha Narayana Head, Herbal Research Hindustan Lever Research Centre Unilever Research India 64, Main Road, Whitefiled Bangalore- 560 066.
11.	*Member*	Dr. Vinay G. Nayak President, Tech. Operations Watson Pharma Pvt. Ltd. 201/301, HOD Building Corporate Enclave "B" Wing, 100 Link Road, Chakala Andheri (E) Mumbai-400 009.
12.	*Member*	Dr. S. N. Pal Executive Director HSCC E-6(A), Sector-1, Noida -201 301.
13.	*Member*	The Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062.
14.	*Member*	Mr. Prafull D. Sheth E-256, Greater Kailash-I New Delhi-110 048.
15.	*Member*	Dr. P. G. Shrotriya Chief Executive, Elite Pharma Consultants 11/302 Sea Woods, NRI Complex, Nerul Navi Mumbai-400 706
16.	*Member*	Professor Saranjit Singh Professor and Head Department of Pharmaceutical Analysis National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 002.
17.	*Member*	Mr. J. L. Sipahimalani 10-C, Ananta, R. Patel Lane Mumbai-400 026.

18.	*Member*	Dr. V. A. Srinivasan Research Director Indian Immunologicals Ltd. Gachibowli Post Hyderabad-500 032.
19.	*Member*	Dr. R. Sridharan Vice President Corporate Quality Assurance-API Lupin Limited 159, CST Road, Kalina, Santacruz (E) Mumbai-400 098.
20.	*Invitee*	Mr. Gidy Asrani President, Pharmacon, 3, Salmona Ville, North Avenue, Santa Cruze, Mumbai-400 054.
21.	*Invitee*	Dr. B. R. Jagashetty Drugs Controller for the State of Karnataka Office of the Drugs Controller (Karnataka) Post Bag No. 5377, Palace Road, Bangalore-560 001.
22.	*Invitee*	Mr. S. S. Venkatakrishnan Drugs Controller (Retd), Kerala 12/548, Dhanya Sree, Vrindavanam Grardens Kodunganoor Thiruvananthapuram-695 013.
23.	*Member-Secretary*	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002.

Expert Committees:

The IPC has constituted committees which are experts in different fields to assist and advise the Scientific Body in matters pertaining to those fields. The Expert committees are:

(1) Expert Committee on Anti-Retroviral Drugs

Dr. Manish Gangrade (*Chair*), Mr. Anwar, Dr. Pramod Dalvi , Mr. Antony Raj Gomes and Dr. Hemant Kumar.

(2) Expert Committee on Anti-Tuberculosis/Anti Asthma Drugs

Dr. Vinay G Nayak (*Chair*), Mr. Satyawan Hatte, Prof. Saranjit Singh and Dr. Prashant Dikshit.

(3) Expert Committee on Blood and Blood Products

Dr. Prem K. Gupta (*Chair*), Dr. Zareen Bharucha, Dr. Kabita Chatterjee and Mr. Kapil Bhargava.

(4) Expert Committee on Clinical Medicine and Pharmacology

Prof. Y. K. Gupta (*Chair*), Prof. Praveen Agrawal, Dr. Sridhar Dwivedi and Prof. G. C. Khilnani

(5) Expert Committee on Information Technology

Dr. Parthajyoti Gogoi (*Chair*), Dr. A. Ramkishan, Mr. Daara B. Patel, Mr. Milid Joshi, Mr. B. K. Sharma and Dr. Sanjay Singh.

(6) Expert Committee on Devices and Diagnostics

Dr. S. N. Pal (*Chair*), Dr. G. S. Bhuvaneshwar, Sh. M. Mitra and Prof. Alok Ray.

(7) Expert Committee on Drug Nomenclature and Medicinal agents

Professor V. K. Kapoor (*Chair*), Dr. D. Roy and Mr. Sanjeev Kumar Garg.

(8) Expert Committee on General Analytical Methods

Mr. J. L. Sipahimalani (*Chair*), Mr. Shantanu Chobhe, Dr. Y. K. S. Rathore, Dr. R. A. Singh and Mr. R. Sridharan.

(9) Expert Committee on General Policies and Planning

Mr. Prafull D. Sheth (*Chair*), Mr. S. D. Jog, Mr. Vijay Kshirsagar, Dr. Shailesh Nagarsenker, Prof. Y. Madhusudan Rao and Mr. B. N. Thakore.

(10) Expert Committee on Herbal Products and Crude Drugs

Dr. D. B. Anantha Narayana (*Chair*), Dr. Amit Agarwal, Dr. C. K. Katiyar, Mr. Ramakant Haralakha and Dr. George Patani.

(11) Expert Committee on Parenteral Products

Dr. P. G. Shrotriya (*Chair*), Dr. Manish Gangrade, Mr. Satish. R. Kulkarni, Mr. Ashok Modi, Dr. A. Prasad and Mr. R. R. Tuljapurkar.

(12) Expert Committee on Pharmaceutical Dosage Forms

Mr. Vinod Arora (*Chair*), Prof. Arvind K Bansal, Dr. Kisan B. Chaudhari, Prof. Roop K. Khar, Dr. Praful R. Naik and Dr Kona Subrahmanya Srinivas.

(13) Expert Committee on Vaccines and Other Biological Products

Dr. V. A. Srinivasan (*Chair*), Dr. Arun Bharadwaj, Dr. S. S. Jadhav, Dr. Surinder Singh, Dr. Rishendra Verma and Dr. J. M. Kataria.

Departments of the IPL

The erstwhile Central Indian Pharmacopoeia Laboratory (CIPL) comprised of the following main departments:-

- **Pharmaceutical Chemistry**
- **Pharmacology**
- **Research & Development**
- **Microbiology**
- **Pharmacognosy**
- **Library & Publication**

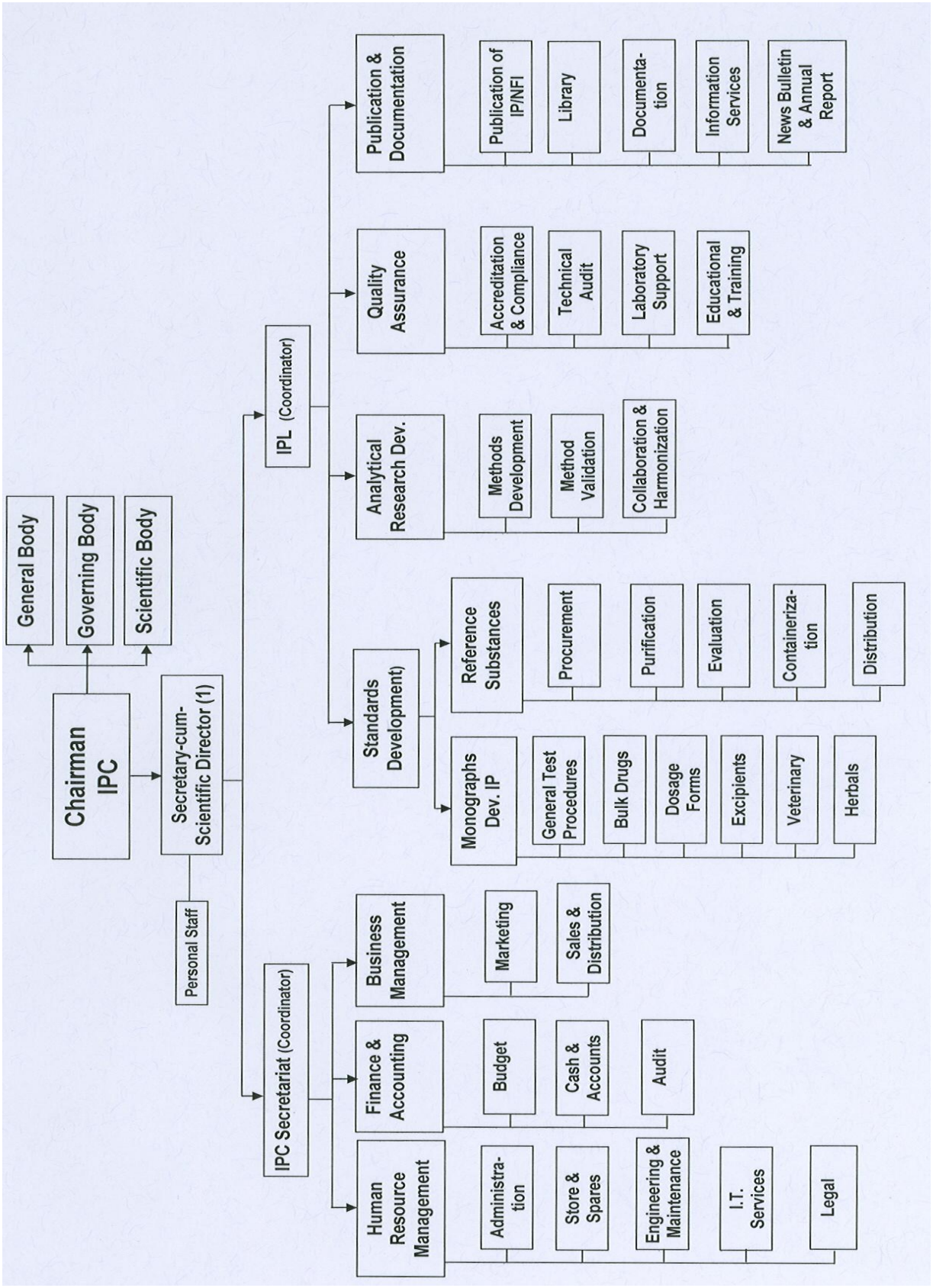
The Indian Pharmacopoeia Laboratory (IPL) has taken over the above infrastructure of the CIPL. As a standards writing institution, the IPL has to validate several methods of analysis and also reference substances and the activities are quite different from those of the CIPL. Restructuring of the laboratory set up was an essential and urgent need and a comprehensive organogram was to be given shape. The organogram prepared by the IPC has the following divisions:

Departments of-

- **Monograph Development**
- **Reference Substances**
- **Research & Development**
- **Quality Assurance**
- **Business Management**
- **Publication & Documentation**
- **Library & Information Services**
- **Finance & Accounts**
- **Engineering Services**
- **Human Resource Development**

The structure needs additional manpower to handle the different activities. At the time of amalgamation of the CIPL with IPC Government had consented for thirteen additional hands in IPC. This is insufficient to meet the needs and an estimated thirty-seven additional hands are now proposed. The organogram of the IPC is presented here under:

Organogram of IPC



Restructuring Plans

The major task of the Commission is preparation of standards for drugs in the form of monographs specifying various parameters of quality, compile these monographs together with related informations and publish these monographs and other compilations in the form of a book, the Indian Pharmacopoeia. The IP is to be published periodically incorporating all up-dating needed and publish Addenda also as may be needed to these publications of IP. Deciding these quality parameters, preparing these monographs and publicizing them as the IP and its Addenda for adoption and application by the regulatory bodies of the country and the drug industry and the task involve services of several scientists and other experts. Prescribing national parameters of quality also involves performing scientific studies in the form of tests, analysis etc on Active Pharmaceutical Ingredients (APIs) and their formulations and these activities need setting up a full-fledged laboratory capable of performing all types of tests that include chemical, instrumental, microbiological, pharmacological, pharmacognotical and other tests and also a well developed Research and Development wing. Supportive technical and non-technical and also administrative activities are also to be performed. All these scientific and non-scientific activities and also supportive activities are to be performed in a timely and very synchronized and coordinated manner. The quality parameters of drugs specified in the IP monographs include conclusive tests for identification, purity and also impurities find ways during synthesis or manufacture of the drug as bye products or related substances or as degenerated substances during storage. For performing these tests, the laboratories across the country and abroad functioning as parts of drugs manufacturing units or otherwise and of regulatory bodies require authentic reference substances. These reference substances are to be provided by the IPC as is done by other pharmacopoeial commissions world wide. The IPC has given shape to the organogram needed at the IPC and its wing IPL for all these purposes and the facilities inherited in the form of CIPL is to be restructured without delay.

As per its approved Bye-Laws, the Commission will be supported by different advisory committees and panels. It shall have its own permanent secretariat which will provide technical information and guidance to the committees and panels. Once a decision is taken to prepare monograph for a particular substance or its preparation taking into account its importance as a therapeutic agent or a pharmaceutical aid, the secretariat will identify the source of availability of the material and seek pertinent information on the material, source, the by-products that might arise while synthesizing the compound or the decomposition products which may be formed on storage etc. The secretariat and laboratory staff will check the details and work on the data and give shape to the criteria of purity to be laid in the monograph and during this process there will be a free flow of information between the Commission and all stake-holders involved and the proposed monograph will be fully examined and reviewed. The report so generated will be submitted to the respective advisory committee to investigate and resolve any unresolved questions. The draft approved by the committee will be presented to the Commission for adoption. One can well imagine the magnitude of work required to be done by the Commission, its committees and staff, when they will be required to prepare anything between 1,800 to 2,200 monographs for the pharmacopoeia. This will be an ongoing process since the

knowledge on physical and chemical characters and analytical procedures continues to expand.

Our country accounts for about 8% of global production of drugs and 2% of the world's drugs & pharmaceutical market. The country meets 95% of its domestic demands through indigenous production covering almost all therapeutic categories and imports only a few high technology products. The size of Indian pharma industry is about Rs.85000 crores, with about 40% i.e. Rs. 35000 crores worth of pharma products being exported. It is among top 20 countries of the world exporting pharma products. Our vaccines and bio-pharma products are exported to about 151 countries. Our country's remarkable achievements in drugs sector is due to the fact that Indian pharma industry produces drugs the highest international quality at the cheapest prices which make our drugs hot demands world wide including in United States. In fact, despite being world's largest Pharma producer, the US procures a large chunk of its medicines needs from Indian manufacturers. Our country holds this position of trust only on its quality assurances of highest standards. This is where the Indian Pharmacopoeia Commission (IPC) plays a significant roll by prescribing quality parameters comparable to international norms without burdening the price structure of the product heavily and by providing the quality reference standards needed at affordable rates.

Though the Indian Pharmacopoeia Commission has come into its present autonomous form only with effect from 1.1.2009, our scientists had already made commendable achievements in the form of publication of IP 2005, IP 2007 and very recently the IP 2008 Addendum by the incessant efforts of scientists at the erstwhile Central Indian Pharmacopoeia Laboratory (which has been converted into the Indian Pharmacopoeia Commission). Given the prestigious position held by the Indian Pharmaceutical Industry, the Commission has a long way ahead to go and has a precise, comprehensive and prestigious agenda to meet the country's present and future needs in the field of setting quality bench marks for drugs of drugs and in its quest to become a pioneering institution of world wide recognition and acceptance. The emphasis these days is more on limiting undesirable impurities in bulk drugs and formulations than by merely ensuring minimum levels and standards of purity. There is rapid progress in the field of drugs analysis with the evolution of more and more sophisticated methods of analysis for more precise and better dependable results. These rapid developments should be reflected in successive editions of pharmacopoeia for implementation and adoption with least delay. A well structured Indian Pharmacopoeia Commission would only be able to meet this need. The developed countries have very strong and autonomous organizations for preparing their pharmacopoeias. The United States Pharmacopoeia (USP) established in 1920 maintains a staff of over 500 Scientists, Professionals, and Administrative personnel at its headquarter alone at Rockville, Maryland. Besides, additional staff members are located at its offices in Basel, Switzerland, and laboratory complexes in Hyderabad (India), Shanghai (China), and Sao Paolo (Brazil). Identified outsource expertise is also available to carry out any task needed in the field there.

Development of a nation is absolutely interlinked with the health of its citizens. Drugs of pure qualities are integral and major parts of the health care system and the task of quality control of drugs is a huge one. To create, sustain

and refurbish the health care sector of the country and in that direction the drug regulatory system is, therefore, one of the most priority sectors of the Government. The pharmacopoeia is a regulatory and statutory document to be complied by drugs manufacturers and to be adopted by the drugs regulatory bodies for their drugs control regulatory activities. An efficient Pharmacopoeia Commission and constantly updated pharmacopoeia are essential for efficient quality regulations of drugs in the country thereby ensuring the efficiency of the health care system of the country. The Ministry of Health & Family Welfare, therefore, aims at converting the Indian Pharmacopoeia Commission into a state of the art institution with a state of the art Pharmacopoeia laboratory. In this regard, the expertise of the US Pharmacopoeia Commission has been solicited to prepare the road map for restructuring activities. The Commission, which is still in a nascent stage having been formally born on 1.1.2009 only, presently has a very scanty manpower with 27 employees only including the scientific personnel against the present sanctioned strength of 93 employees as many had opted to remain in the Government departments rather than the autonomous body at the time of amalgamation of CIPL with IPC. The manpower of the IPC based on the infrastructure availed from CIPL is an insufficient and depleted one. While all measures taken to strengthen the manpower by making recruitments to the sanctioned but vacant positions, restructuring has also to be done on an equally priority basis as otherwise many of the tasks to be accomplished would remain un-attended and this will defeat the very purpose of the creation of this system. Addition of essential posts and abolition of some unnecessary /obsolete posts and other related changes together with redefining and reallocating the work norms and works are part of the restructuring activities needed. The Commission has already prepared an **Organogram** containing its visions and physical targets to be accomplished. As per the proposed organogram, the IPC would have a total of 8 main divisions consisting of employees at different levels and in 33 different fields. This is the **minimum** basic organisational framework proposed by the Commission to perform its duties and responsibilities and to enable it in its quest to achieve the status of a pharmacopoeial body of national international standards and repute and acceptance.

Scientific Activities & Achievements

A. Indian Pharmacopoeia 2010:

1. Releasing of Indian Pharmacopoeia 2010 (6th edition)

The IPC staff has examined the queries continuously received from different stakeholders related to IP and amendments inserted in the manuscript of IP 2010. The manuscript was converted into page maker and handed over to NISCAIR in May 2010 for printing. The Manuscript sent by NISCAIR for rechecking of manuscript just before printing was reviewed and corrected thoroughly. This 6th edition of Indian Pharmacopoeia 2010 is released on 4th Aug.2010 by Hon'ble Minister for Health & Family Welfare, Govt. of India, Mr. Gulam Nabi Azad at Nirman Bhavan New Delhi.

2. Addendum 2012 to Indian Pharmacopoeia 2010

During the period, the IPC staff has examined lot of queries received from different stakeholders related to Indian Pharmacopoeia 2010 having up gradation of the tests, technical and typographical errors. Total 52 new monographs were selected out of which 30 were drafted. Drafted monographs were sent for wider circulation to the stake holders, academia and the technical experts. The suggestions received from various sources for revision of the drafted monographs were re-examined and finally decided to be incorporated in Addendum 2012 to Indian Pharmacopoeia 2010.

Amendment list 1 and 2 was prepared during this period. The draft amendments to IP 2010 was circulated to the stakeholders, put up on the website and discussed with the subject experts before finalization.

The following monographs were prepared for Addendum 2012 to IP 2010 during this period.

a) Additions

A list of New Appendices/ Monographs added to the Indian Pharmacopoeia 2010 through this Addendum is given below.

Appendices

2.3.50. Fatty Acid Composition by Gas Chromatography

2.8.13. Assay of Human Anti- thrombin III

2.8.14. Anti-A and Anti-B Haemagglutinins (Indirect Method)

2.8.15. Assaay of Human Coagulation Factor XI

2.8.16. Assay of Human Protein C

2.8.17. Assay of Human Protein S

2.8.18. Assay of Human Plasmin Inhibitor ($\alpha 2$ –Antiplasmin)

Monographs

Calcium Carbonate Tablets
Cetrimide Emulsifying Ointment
Cholecalciferol Injection
Cholecalciferol Tablets
Divalproex Sodium
Docusate Tablets
Efavirenz, Emtricitabine and Tenofovir Tablets
Ergocalciferol
Ergocalciferol Tablets
Fenofibrate Capsules
Fusidic Acid Cream
Indapamide
Ipratropium Inhalation
Ipratropium Powder for Inhalation
Levonorgestrel Tablets
Magnesium Sulphate Injection
Medroxyprogesterone Injection
Medroxyprogesterone Tablets
Mefloquine Tablets
Methyl Salicylate Ointment
Ondansetron
Paracetamol Oral Suspension
Pilocarpine Eye Drops
Promazine Hydrochloride
Rizatriptan Benzoate
Rizatriptan Tablets
Salicylic Acid Ointment
Sodium Citrate Eye Drops
Sodium Citrate Irrigation Solution
Sumatriptan Succinate
Vasopressin
Vitamin A Capsules
Vitamin A Paediatric Oral Solution
Zinc Chloride Injection
Zinc Oxide and Salicylic Acid Paste
Zinc Sulphate Monohydrate
Zinc Sulphate Oral Solution
Zinc Sulphate Tablets
Zolmitriptan

Zolmitriptan Tablets

Herbs and Herbal Products

Bhuiamla Dry Extract

Gudmar Dry Extract

Kunduru Dry Extract

Mandukaparni Dry Extract

Blood and Blood-related Products

Antithrombin III Concentrate

Hepatitis B Immunoglobulin

Tetanus Immunoglobulin

Rabies Immunoglobulin

Plasma (Pooled and Treated for Virus Inactivation)

Anticoagulant Heparin Solution

Factor IX Complex

Blood Grouping Serums

b) Revisions

A list of Appendices/ Monographs revised (technically) to the Indian Pharmacopoeia 2010 through this Addendum is given below.

Appendices

2.2.3. Bacterial Endotoxins

2.2.9. Microbiological Contamination in Nonsterile Products

2.2.11. Sterility

2.4.14. Liquid Chromatography

2.4.29. Weight Per Millilitre and Relative Density

2.5.6. Contents of Packaged Dosage Forms

2.5.10. Validation of Analytical Procedures

5.4. Residual Solvents

Monographs

Acarbose

Acebutolol Hydrochloride

Aceclofenac

Aciclovir

Adrenaline

Adrenaline Tartrate

Albendazole

Allopurinol

Allopurinol Tablets

Amikacin

Amikacin Injection
Amikacin Sulphate
Amiloride Hydrochloride
Amiloride Tablets
Amiodarone Hydrochloride
Amiodarone Tablets
Amitriptyline Hydrochloride
Liposomal Amphotericin B Injection
Ampicillin
Ampicillin Injection
Ampicillin Sodium
Ampicillin Trihydrate
Aspirin
Aspirin Tablets
Atropine Sulphate
Atropine Injection
Atropine Eye Ointment
Atropine Tablets
Azithromycin Oral Suspension
Beclomethasone Inhalation
Benzalkonium Chloride
Benzhexol Hydrochloride
Benzyl Alcohol
Betamethasone Sodium Phosphate
Betamethasone Cream
Bisacodyl Suppositories
Bisacodyl Tablets
Bromhexine Hydrochloride
Bromocryptine Mesylate
Bromocryptine Capsules
Bromocryptine Tablets
Bupivacaine Hydrochloride
Calcitriol
Calcium Folinate
Calcium Folinate Injection
Calcium Stearate
Capsules
Cefadroxil
Cefadroxil Oral Suspension
Cefotaxime Sodium

Cefotaxime Injection
Ceftazidime
Cefuroxime Sodium
Cellulose Acetate Phthalate
Cetosteryl Alcohol
Cetyl Alcohol
Chlordiazepoxide
Chlorhexidine Gluconate Solution
Chloroquine Sulphate Tablets
Chlorthalidone Tablets
Cinnarizine Tablets
Citric Acid
Citric Acid Monohydrate
Clarithromycin Tablets
Clopidogrel Bisulphate
Clozapine
Absorbent Cotton
Danazol Capsules
Desferrioxamine Mesylate
Desferrioxamine Injection
Dextromethorphan Hydrobromide
Diclofenac Injection
Diclofenac Tablets
Diethylcarbamazine Citrate
Divalproex Sustained-release Tablets
Docetaxel Injection
Domperidone Maleate
Donepezil Hydrochloride
Enalapril Maleate
Enalapril Maleate Tablets
Enoxaparin Sodium
Enoxaparin Injection
Esomeprazole Tablets
Famotidine
Fentanyl Injection
Finasteride Tablets
Fluconazole
Flutamide
Folic Acid
Formoterol Fumarate and Budesonide Powder for Inhalation

Fumaric Acid
Gefitinib
Glibenclamide
Glimepiride
Glimepiride Tablets
Guaiphenesin
Heparin Sodium
Hyoscine Butylbromide Injection
Hyoscine Butylbromide Tablets
Indapamide Tablets
Human Insulin
Biphasic Isophane Insulin Injection
Ketamine Injection
Ketoconazole
Ketoconazole Tablets
Labetalol Tablets
Lactulose
Lamotrigine Dispersible Tablets
Lamotrigine Sustained-release Tablets
Lansoprazole Sustained- release Capsules
Lopinavir
Losartan Potassium and Amlodipine Tablets
Losartan Potassium and Hydrochlorothiazide Tablets
Light Magnesium Oxide
Magnesium Stearate
Malic Acid
Metformin Hydrochloride Sustained-release Tablets
Methylparaben
Miconazole Nitrate
Miconazole Cream
Mometasone Furoate
Monothioglycerol
Montelukast Tablets
Mycofenolate Mofetil
Nandrolone Decanoate
Nelfinavir Tablets
Neomycin Sulphate
Neomycin Eye Drops
Neomycin Eye Ointment
Nevirapine

Norfloxacin
Omeprazole
Ondansetron Orally Disintegrating Tablets
Ondansetron Oral Solution
Oxazepam
Oxytocin
Oxytocin Injection
Pantoprazole Sodium
Pantoprazole Sustained-release Tablets
Paracetamol
Paracetamol Tablets
Pethidine Hydrochloride
Pheniramine Maleate
Phenoxyethanol
Pioglitazone Tablets
Piroxicam
Poloxamers
Pregabalin Capsules
Proguanil Hydrochloride
Propofol
Propofol Injection
Rabeprazole Tablets
Ramipril and Hydrochlorothiazide Tablets
Ranitidine Hydrochloride
Ranitidine Injection
Ranitidine Tablets
Roxithromycin
Salbutamol
Salbutamol Sulphate
Salbutamol Inhalation
Serratiopeptidase
Simvastatin
Simvastatin Tablets
Sodium Dihydrogen Phosphate Dihydrate
Sodium Methylparaben
Sodium Valproate
Sorbic Acid
Sorbitol Solution (70 per cent) (Crystallising)
Sorbitol Solution (70 per cent) (Non-Crystallising)
Stavudine

Stearic Acid
Stearyl Alcohol
Telmisartan Tablets
Terazosin Hydrochloride
Terbutaline Sulphate
Terbutaline Tablets
Thiocolchicoside
Tinidazole
Tolnaftate
Tolterodine Tartrate
Triamterene
Trimetazidine Hydrochloride
Valproic Acid
Valsartan
Valsartan and Hydrochlorothiazide Tablets
Vancomycin Hydrochloride
Vasopressin Injection
Verapamil Hydrochloride
Vinblastine Injection
Vincristine Injection
Warfarin Sodium Clathrate
Water for Injections in Bulk
Xylometazoline Hydrochloride
Zinc Stearate
Zoledronic Acid

3. Amendments in Monographs of Indian Pharmacopoeia, 2010

Complied with all referred Pharmacopoeial problems, amendments and suggestions pertaining to IP existing monographs/proposed monographs, received in the division. The same were incorporated in the amendment lists 1&2 release through website and in coming Addendum 2012 to IP 2010.

4. Verification of Analytical method of IP

The IPC has already started analytical verification of various monographs of IP 2010 and the monographs drafted for Addendum 2012. Various verifications were carried out of analytical method of drugs samples received from various Stakeholders in the Commission for verification of IP monograph. During this period following samples were verified.

Assays verified by HPLC

a) Acarbose tablets
b) Emtricitabine
c) Rosiglitazone maleate tablets
d) Efavirenz tablets
e) Indinavir Sulphate capsules
f) Oseltamivir Phosphate
g) Paclitaxel
h) Gallic acid
i) Arbidol Hydrochloride (New drug)
j) Donepezil HCl
k) Didanosine tablets
l) Irinotecan Hydrochloride
m) Zoledronic acid
n) Triamcinolone
o) Triamcinolone
p) Cloxacillin Sodium
q) Tizanidine HCl
r) Citalopram HBr

Related substances verified by HPLC

- Atorvastatin tablets
- Efavirenz tablets
- Didanosine tablets
- Indinavir Sulphate capsules
- Oseltamivir Phosphate
- Paclitaxel
- Arbidol HCl
- Clozapine
- Nimorazole by GC

Uniformity of content verified

- Isosorbide Dinitrate
- Rosiglitazone
- Triamcinolone

Dissolution Tests verified

a) Acarbose tablets
b) Rosiglitazone Maleate tablets
c) Didanosine tablets
d) Emtricitabine Capsules
e) Indinavir Capsules
f) Efavirenz tablets

5. Development of Herbal Monographs for IP Addendum-2012

The IPC staff in association with Dr. DBA Narayana for development of Herbal monographs for the Addendum 2012 to IP-2010. 04 extracts monographs for Herbs will be added in this Addendum and participated in the meetings held at IPC-IPL during this period with Dr. DBA Narayana, which is mentioned in the last.

6. Preparation of Radiopharmaceuticals Monographs for next edition of IP.

Started the drafting work for introducing a chapter and 20 Monographs identified for the next edition of Indian Pharmacopoeia. Supervising and coordinating 03 meetings of expert committee on Radiopharmaceuticals held at IPC-IPL on 02nd July, 30th Oct. and 11th Feb. 2010

B. IP Reference Standards Developments:

1. IPRS Developed At IPL

32 IPRS prepared and listed in IPC website by chemical section by developing IPRS vial and their packing, cold room facility and for making availability of candidate material from the stakeholders. Supervised the analysis of 71 candidate material and checked the generated reports from chemical department. The Scientists identified the list of IPRS required as per IP 2010 and addendum 2012 and along with impurities required.

2. IPRS Developed Through IFPRESS

The development of IPRS by verification in the Indian Pharmaceutical Laboratory received from IFPRESS, Mumbai. Checked all the reports generated in the laboratory.

3. Testing of IP Reference Substance for Certification

Organized and actively involved in analysis and verification of Reference substances received in IPC from IFPRESS for their certification through IPL-IPC.

The following substances received from Indian Foundation for Pharmaceutical Reference Standard Substances (IFPRESS), Mumbai were verified in IPC during this period for the development of Indian Pharmacopoeia Reference Substances.

1. Prednisolone
2. Prednisone
3. Hydrocortisone
4. Nitrofurazone
5. Efavirenz
6. Cephalexin
7. Cyanacobalamin
8. Chloroquine Sulphate
9. Levofloxacin
10. Levofloxacin
11. Ramipril
12. Metoprolol tartarate
13. Minoxidil

C. Testing of New Drugs

- Efforts were made for starting the new drugs testing at IPC-IPL by meeting and co-ordinating with the officials of CDSCO.

- 28 NDS Sample analysed and reported to CDSCO

- 10 new Monograph of NDA prepared

- Organised testing of new drugs molecules received from DCG (I) office and prepared the protocol bank at IPC. The new drugs API received during this period were as follows:

- Arbidolol Hydrochloride Monohydrate.
- Agomelatine.
- Dexlansoprozole.
- Eslicarbazepine.
- Tramilast.
- Fasudil Hydrochloride Hemihydrate.
- Biapenem.
- Trimethobenzamide.
- Safinamide Methane Sulfonate.
- Asenapine Maleate.
- Dienogest.
- Fenspiride Hydrochloride.
- Ilaprazole.
- Indomethacin Copper.
- Brinzolamide.

- Tiemenium Methyl Sulphate.
- Mitiglinide Calcium Dihydrate.
- Etravirine.
- Tapendadol.
- Maclofenamate Sodium.
- α- Glutathione Reduced.
- Nimorazole.

Testing of IP Reference substance Certification:

IPC Organized and was actively involved in the analysis and verification of reference substances received from IFPRESS for their certification through IPL-IPC.

The following substances received from Indian Foundation for Pharmaceutical Reference Standard Substances (IFPRESS), Mumbai were verified in the laboratory of the Commission during this period for developing Indian Pharmacopoeia Reference Substances.

- Levofloxacin
- Ofloxacin
- Citalopram
- Pioglitazone Hydrochloride
- Escitalopram Oxalate

NABL Accreditation:

The IPL is in the process of complying with the requirements for accreditation by National Accreditation Board for Laboratories of DST, New Delhi.

IPC Web-Site:

The official Web-Site of the IPC is constantly updated with the view to notify the intended monographs, secure data or information needed, disseminate information to the stakeholders etc. Data related to IP Addendum 2008 was loaded on IPC Web-site at www.ipc.gov.in. Now details of activities and work related to next edition of IP are updated and uploaded from time to time to get feedbacks.

National Formulary of India: The National Formulary of India was last published about thirty years back. This is the official compendia and book of reference for drugs. IPC has undertaken the task of updating and republishing the book.

Research Papers Published, Accepted and Communicated by IPC Staff:

Research Papers Published

The IPC staff has published 08 research papers and 01 communicated in different scientific journals during this period. The list of research papers is as follows.

1. Development and Validation of a RP-HPLC method for estimation of Montelukast Sodium in Bulk and in Tablet Dosage Form

2. A Simple and Sensitive HPTLC Method for Quantitative Analysis of Artemether and Lumefantrine in Tablets

3. A Rapid and Sensitive RP-UPLC Method for Simultaneous Determination of Zidovudine, Lamivudine and Nevirapine in Tablet Dosage Form

4. Quantification of Vinorelbine in Bulk Drug and its Injection Dosage Form by RP-UPLC Method.

5. Development and validation of Spectrophotometric method for estimation of Emtricitabine in bulk and capsule dosage form

6. Application of High Performance Liquid Chromatography to the Determination and Validation of Levodopa in Methanolic extract of *Mucuna utilis*.

7. Development and Validation of RP-HPLC method for estimation of Efavirenz in bulk and in tablet dosage forms.

8. A Simple and Sensitive HPTLC Method for Quantitative Analysis of Prulifloxacin in Tablets

9. Development and Validation of a RP-HPLC Method for Estimation of Prulifloxacin in Tablet Dosage Form

WHO Work for International Pharmacopoeia

- Organised the verification of methods for basic tests of Bulk Drugs and Dosage Forms received from WHO, Geneva from time to time.

- Participated regularly for the development of the monographs related to Anti-retroviral, Anti-tubercular and Radio pharmaceutical 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. Capreomycin Sulphate
    2. Artesunate for Injection
    3. Sodium Biocarbonate Intravenous Injection
    4. Emtricitabine and Tenofovir Tablets
    5. Amoxicillin Oral Suspension
    6. Emtricitabine Capsules
    7. Amoxicillin Oral Suspension
    8. Metronidazole Oral Suspension
    9. Mefloquine Tablets
    10. Paracetamol Oral Solution
    11. Levamisole Tablets
    12. Retinol Concentrate , oily form
    13. Paracetamol Oral Suspension
    14. Sulphamethoxazole and Trimethoporim Tablets
    15. Levonorgestrel Tablets
    16. Sulphamethoxazole & Pyrimethamine Tablets
    17. Paediaric Retinol Capsules
    18. Kenamycin Injection

Study of the interactions of herbal extracts in combination against the free radical scavenging activity.

1. Isoflavonoids from *Flemingia Strobilifera* (L) R.Br. Roots**.**
2. Development and validation of HPLC method for the determination of Donepezil hydrochloride in bulk and tablet dosage form.
3. Simultaneous HPTLC method for estimation of Domperidone and Paracetamol in bulk and its tablet dosage forms.
4. Simultaneous estimation of Lamivudine and Zidovudine in combined dosage form using RPLC method.
5. Simultaneous Determination of Lamivudine and Zidovudine by HPTLC Method in Tablet Dosage Form
6. Simultaneous Determination of Simvastatin and Ezetimibe by RP-HPLC Method in Tablet Dosage Form
7. Reverse Phase-Ultra Performance Liquid Chromatographic (UPLC) Method for determination and validation of Irinotecan Hydrochloride in Bulk and its Injection Dosage Form.
8. A Simple and Sensitive HPTLC Method for Quantitative Analysis of Artemether and Lumefantrine in Tablets
9. A simple and sensitive HPTLC method for simultaneous determination of abacavir sulphate and lamivudine in pharmaceutical dosage form
10. A sensitive and selective RP-HPLC method for the determination of lamivudine and stavudine in tablets
11. Development and Validation of a RP-HPLC method for estimation of Montelukast Sodium in Bulk and in Tablet Dosage Form.
12. A Rapid and Sensitive RP-UPLC Method for Simultaneous Determination of Zidovudine, Lamivudine and Nevirapine in Tablet Dosage Form.
13. Quantification of vinorelbine in bulk drug and its injection dosage form by RP-UPLC method.
14. Development and validation of a HPLC method for the simultaneous analysis of abacavir sulphate and lamivudine in combined tablet dosage forms.
15. Development and validation of spectrophotometric method for estimation of Emtricitabine in bulk and capsule dosage form**.**
16. Quantification of vinorelbine in bulk and injection dosage form by spectrophotometric method.
17. Application of High Performance Liquid Chromatography to the Determination and Validation of Levodopa in Methanolic extract of *Mucuna utilis*.
18. A Simple and Sensitive HPTLC Method for Estimation of Efavirenz in Bulk and Tablet Dosage forms.
19. Development and validation of RP-HPLC method for estimation of Efavirenz in bulk and in tablet dosage forms.
20. Simultaneous quantification of artemether and lumefantrine in tablets dosage form by high performance liquid chromatographic method.

Library and Information Centre

The IPC library continues to expand its resources and activities to provide valuable library & information services to support scientific, Pharmacopoeial work. The mission of IPC library and information centre is to make its resources available and useful to the users and researchers preserve latest collection of knowledge and creativity for future generations. The library aims to collect, store and disseminate information to acquire new products and services.

The IPC library is fully automated library and use Libware to make users experience in the library smooth and efficient. The library use open access system for self arrangement for users. The library uses open access system for the users. The Library is divided into 4 Divisions:

- Circulation section
- Periodical Section
- Reference and documentation section
- Technical work and internet search section

The mission of IPC is to organise, provide access to, maintain, secure and preserve all the collections safely. The collections of the library 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.
The collection of the Library is :

S. No.	Item Name	Collection
1.	Total Books	4970
2.	Bound Journals	2700
3.	Annually subscribed journals	31 National-10 International-21
4.	Magazine	16
5.	Annual reports	25
6.	Project reports	100
7.	CD	200
8.	Annual Intake	140 Books

Services of IPC library:

OPAC:

The IPC provides online public access facility to its members or users through LAN or on demand. By this facility user can search the information which is required by them as and when needed.

SDI and CAS:

The information centre of library gives the facility of selective dissemination of information (SDI) and Current Awareness services (CAS) to the members of IPC and to visitors. As part of these services the information centre of IPC provides

abstracts of subscribed journals, news clipping and other news items to the officials of the IPC. The other kind of information needed can be downloaded from internet or different web-sites.

Online information resource:

All the users can use web-based online information resources from the library. The IPC library has its own internet search section. In this section we have 10 computers with printer and latest configuration. The users of library use these computers to search their valuable information through internet to get the informations needed. The IPC library and information centre also provides the facility of MEDLAR services. IPC subscribes to this service for use of its members.

CD-ROM and Database search:

The technical section of IPC gives the facility of CD-ROM search to its members. Members can search all kinds of CD's and databases in the library. The library uses CDs which mostly comes with the books.

Reprographic Services:

The IPC library also provides the photocopy service to its authorised users. The library has its own photocopy section. Users can take the photocopy of any book, reference book, report or journals needed for their works related to IP.

Document Delivery Services:

The library provides documents to outside users such as students, researchers from different universities and institution in print form on request.

Inter Library Loan:

The library has a very good collection of books and other study materials so a vast number of user comprising Drug & Pharmaceuticals community, Government officials, teachers students, research scholars from different Colleges, Universities and Academic Institutions visit the library to collect their required information.

Seminar & Meetings

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

Following meetings/programmes were held during April 2010 to March 2011.

1. Meeting with US FDA officials visited at IPC on 05th April, 2010.
2. Review meeting of all officials and Director to discuss the progress and planning for current session at IPC on 07th April, 2010.
3. Meeting with Mr. Sanjay Prasad, Director (Drugs) visited IPL on 13th April 2010.
4. Meeting on 20th April & 29th April, 2010 at IPC to discuss preparing the technical specification for procurement of Instruments for IPL.
5. Attended 19th SB meeting at INSA, New Delhi for finalization of Addendum 2011 on 01.05.2010.
6. First Meeting of experts committee for developing Radiopharmaceuticals at IPC on 2nd July, 2010.
7. Attended meeting with DCGI, ADC, IDMA, BDMA and OPPI representatives alongwith Director regarding the New Drugs Testing at Nirman Bhavan New Delhi on 16th July, 2010.
8. Attended the meeting/presentation of Dr. Lal ji Singh Ex.-Director, CCMB on 23rd July, 2010 at IPC.
9. Meeting with USP delegation at India International Centre, New Delhi on 3rd August, 2010 alongwith Director and Chairman Scientific Body of IPC.
10. Attended release of IP 2010 by Ghulam Nabi Azad, Honorable Minister of Health and Family welfare at Nirman Bhawan New Delhi on 4th August, 2010.
11. Attended 20th Scientific Body meeting at IPC Campus Ghaziabad on 21.8.2010.
12. Second meeting of experts committee at IPC on 30th Oct. 2010 regarding Radiopharmaceutical monographs development.
13. Meeting/Lecture by Dr. B.E. Rao, Ex-CMD, IDPL on the occasion of Foundation Day of IPC.

14. Attended meeting with USP delegation headed by Dr. Roger Williams, CEO, USP alongwith Director and other IPC officials at Malviya Bhavan, New Delhi to discuss further collaborative issues on 20th Jan. 2011.

15. Third meeting of expert committee on Radio pharmaceutical at IPC on 11th Feb. 2011.

16. Review progress meeting on 4th March, 2011 at IPC.

17. National Seminar on 'Recent Trends in Pharmacy Education and Practice'.

18. National Work Shop on veterinary Monographs in IP.

19. Workshop on Pharmacopoeial Standards in Ensuring Quality of Medicines

20. 2011 - IPC-USP 10th Science & Standards Symposium, Theme "Global Quality Standards for Biologicals and Chemical Drugs"

Challenges Ahead

- ✓ Timely publication of further editions of the Indian Pharmacopoeia and its Addendum.

- ✓ Certification & providing IP Reference Substances to the stakeholders. In this attempt, Commission has identified the priority items amongst the Reference Substances and is taking firm steps to meet this demand. IPC is to provide reference substances for all tests for which use of such substances are prescribed in IP monographs. This requires setting up of dedicated facilities.

- ✓ Synthesis and characterization of impurities (mainly toxic ones), degradations products etc.

- ✓ Develop infrastructure facilities needed and carry out the restructuring programme initiated.

- ✓ International collaboration with other similarly placed institution like British Pharmacopoeia Commission, European Pharmacopoeia Commission, Chinese Pharmacopoeia Commission and WHO etc.

- ✓ International recognition and acceptance of Indian Pharmacopoeia.

- ✓ To be recognized as an institution of excellence for standards setting.

- ✓ To develop state-of-the art facilities in Library to cater the needs of south East Asia Region for dissemination of information.

- ✓ Publication of the next edition of NFI and carry the work forward.

Photographs of IPC at a Glance

Hon'ble Union Minister for Health & Family Welfare Shri Ghulam Nabi Azad, releasing the Indian Pharmacopoeia 2010 at Nirman Bhawan, New Delhi in the presence of officials and stakeholders on 4th August, 2010

Hon'ble Union Minister for Health & Family Welfare Shri Ghulam Nabi Azad signing the Indian Pharmacopoeia 2010 at Nirman Bhawan, New Delhi on 4th August, 2010

Ms. K. Sujatha Rao, Secretary, Health & F W, Govt. of India and Chairperson IP Commission launching the Indian Pharmacopoeia 2010 and IP Reference Substances.

Ms. K. Sujatha Rao, Secretary, Health & F W, Govt. of India and Chairperson IP Commission signing the Indian Pharmacopoeia 2010 at Nirman Bhawan, New Delhi

20th Scientific Body Meeting at IPC, Ghaziabad on 21-08-2010

Visit of Dr. Sibu Chakrabarti from USA at IPC, Ghaziabad on 10-08-2010

IPC Staff (as on 31st March, 2011)

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

Technical Staff

Pharmaceutical Chemistry & Reference Substances Division

Dr. Manish Kr. Dare	PSO
Dr. Robin Kumar	SSO
Dr. Anil Kr Teotia	SSO
Mr. Anuj Prakash	SSO
Ms. Sangeeta Bhatnagar	SA
Smt. Ritu Tiwari	SA
Mr. Satya Prakash Tyagi	SA

Research & Development Division

Dr. Raman Mohan Singh	PSO
Dr. S. C. Mathur	SA
Mr. Dinesh Kumar Sharma	SA
Mr. Pawan Kumar Saini	SA

Pharmacology and Microbiological Division

Dr. Jai Prakash	PSO
Dr. Nishant Dafale	SSO
Dr. V. Kalaiselvan	SSO
Mr. Alok Sharma	SA
Mr. Manoj Kumar Pandey	SA

Library and Publication Division

Mr. K. K. Singh	Library & Information Officer
Mr. B. D. Sharma	SLA

Store Division

Mr. Manish Jain	SO
Mr. Y. K. Kush	SA
Mr. Bijender Kumar	LA

Non-Technical Staff

Administration and Cash Division

Mr. R. C. Saxena	Admn. Officer
Mr. Udai Pal	Hindi Translator
Mr. Chandan Kumar	F&AO
Mr. I. J. S. Oberoi	UDC
Ms. Renu Kapoor	UDC
Mr. Satyaveer Singh	SLA
Mr. Rajendra Kumar Sharma	Peon

Statements of Account
2010-11