



# INDIAN PHARMACOPOEIA COMMISSION



## Annual Report 2011-12

# **ANNUAL REPORT**

## ***2011-2012***



सत्यमेव जयते



INDIAN PHARMACOPOEIA COMMISSION,  
GHAZIABAD, U.P.

**Ministry of Health & Family Welfare**  
**Govt. of India**

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## Preface

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.

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.

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

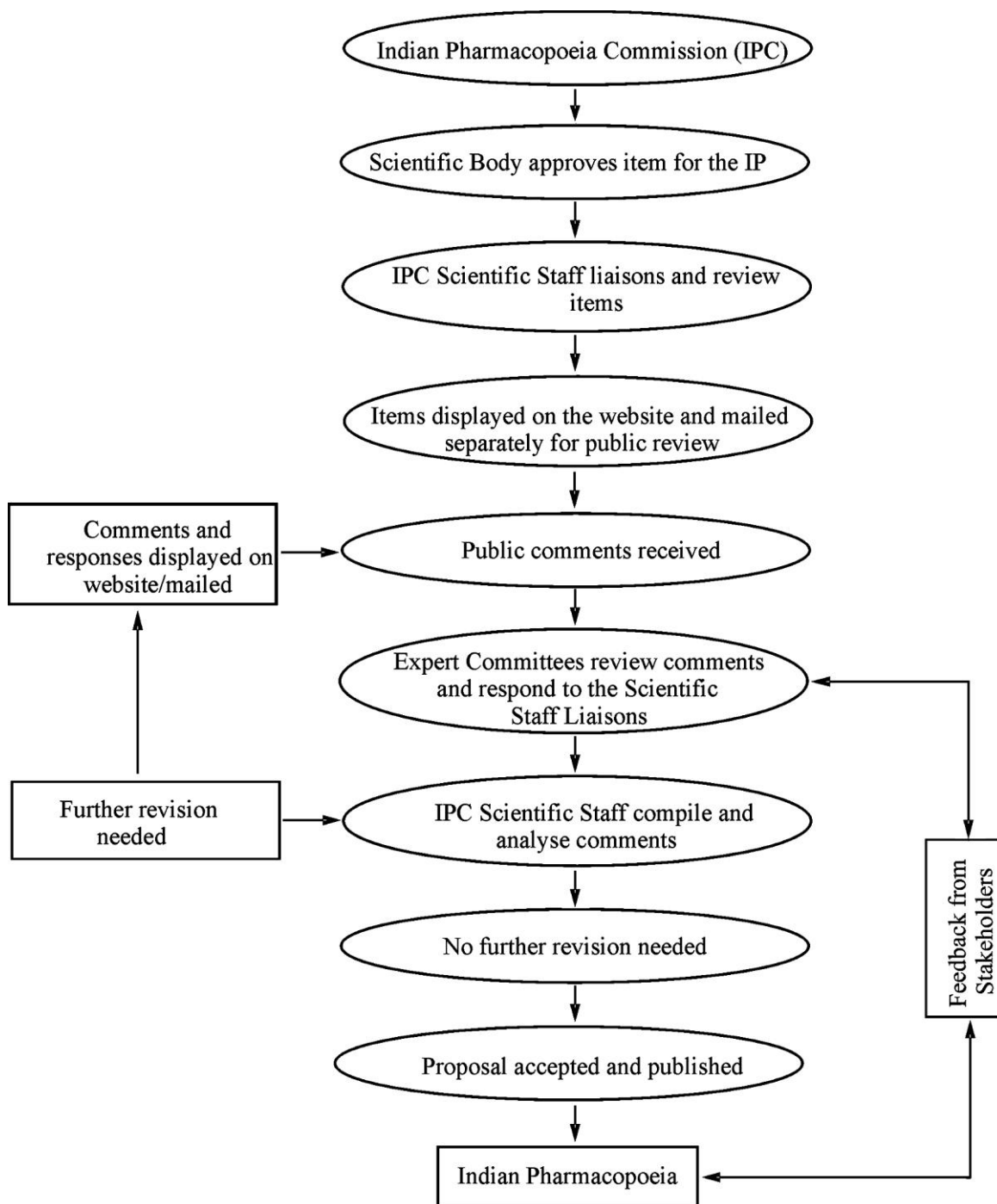
monographs and added monographs based on the therapeutic merit, medical need and extent of use of such articles in the country.

A committee under the chairmanship of Prof. Harkishan Singh was constituted by Government to study and submit its report on the feasibility of constitution of Indian Pharmacopoeia Commission to cope up with international standard to deliver the global expectations at par with USP, BP and European Pharmacopoeia Commission. The Committee submitted its report to the government in the year 1982. On the basis of the recommendations of Prof. Harkishan Singh Committee, the Government after long deliberations and exhaustive examinations established Indian Pharmacopoeia Commission in the 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) was 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 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.

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 Immunoserum 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 Immunoserum are also upgraded in view of development of latest technology in the field. A new chapter on Liposomal products and a monograph 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 is 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.**

To bridge the gap between two editions and familiarize amendments and corrections during the period between two editions, the addendum is published. To address the difficulties faced by stakeholders, Addendum 2012 to 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. It strives to fulfill the objective of the Commission by updating the IP regularly. The



IP is the official book of standards for the drugs included therein in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940 so as to specify the standards of identity, purity and strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. Compliance with these standards by the industry is thus an assurance to the healthcare professionals, patients and consumers of their quality.

As in the past, the choice of new articles has been governed by a system of priorities based on the therapeutic merit, medical need and extent of use of such articles in the country. Modern test methods have also been selected keeping in view the availability of sophisticated instruments and the resources so that the industries and government laboratories can adhere. The principle of 'openness, justice and fairness' is kept into consideration while editing and compiling the addendum. 51 monographs were added in Addendum 2010 to IP 2012.

This Addendum is the outcome of the 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.

## 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 Pharmaceutical Industry in India is valued at Rs. 90,000 crore and is growing at the rate of 12-14% per annum. Exports are growing at 25% compound Annual growth rate every year. The total export of Pharma Products is exceeding the amount of Rs. 40,000 crore. India is also emerging rapidly as a hub of Global Clinical Trials and a destination for Drug Discovery and Development. Further, more and more new drugs are being introduced into the Country which include new chemical entities, high techno pharma products, vaccines as well as new dosage forms, new routes of drug administrations and new therapeutic claims of existing drugs. All medicines (pharmaceutical and vaccines) have side effects some of these side effects are known, while many are still unknown even though that medicine has been in clinical use for several years. 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. It is important to have a standardized and robust Pharmacovigilance and drug safety monitoring programme at national and international level. Collecting this information in a systematic manner and analyzing the data to reach a meaningful conclusion on the continued use of these medicines is the rationale to launch this programme in India. Initially, National Coordination Centre (NCC) of Pharmacovigilance Programme of India was started at All India Institute of Medical Sciences (AIIMS), New Delhi. But, the Government of India has recasted this programme to Indian Pharmacopoeia Commission in order to ensure more safety, efficacy and quality of medicines in the Nation. And now this Pharmacovigilance Programme of India has been included into the mandate of the Commission. The Commission is fully financed by the Central Government with specific budgetary provisions under the administrative control of Ministry of Health and Family Welfare.

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 IP Commission has successfully published IV<sup>th</sup> edition of National Formulary of India (NFI) after a gap of three decades. NFI is a guidance document to medical practitioners, pharmacist, nurses, students of pharmacy and medical streams besides stakeholders and other health care professional. IV<sup>th</sup> edition contains 431 monographs of medicines currently in use.

The IPC has been bestowed with the responsibility of verification of new drug molecules by CDSCO and the Commission has successfully verified 135 molecules and 24 molecules are under verification. The Commission has supplied 900 IPRS vials to Government Laboratories and 98 to Private Laboratories.

To meet expectations of stakeholders, the Commission is working vigorously and the work is rolling satisfactorily to achieve the goals fixed for new edition of IP where exercises for 250 new monographs and up-gradation of 48 monographs have been completed. Roadmap for 5<sup>th</sup> edition of NFI has been chalked out and directives have been flashed to working hands to complete the task well in time. Site survey and soil testing for proposed state-of-the art laboratory has been completed and M/s HLL have been summoned for submission of Detailed Project Report (DPR) after the concurrence of the Ministry.

## **From the Secretary-cum-Scientific Director Desk**

It provides me privilege to present the fourth annual progress report before yourselves. The fiscal year under the report was optimistic for this scientific institution as the National Pharmacovigilance Programme was recasted to this institution from All India Institute of Medical Sciences, New Delhi. The faith which was reposed by the Ministry on this aspect is suitably replied by increasing the number of functional Adverse Drug Reaction (ADR) Centres from 22 to 100. The Commission was also assigned the responsibility of verification of new drugs molecules by CDSCO and the Commission has verified 158 new drug molecules till date. The Commission has also participated in International Proficiency Testing Programme conducted by Federation of International Pharmacists, Hague, the Netherlands and got a certificate in Proficiency Testing. The aspect of preparing, certifying and manufacturing of IP Reference Substances has accelerated the momentum and the Commission has prepared 129 IPRS while 200 IPRS are in pipeline. This will pave the way for saving valuable foreign currency which was till now incurred on the import of Chemical Substances from BP/USP/International Forums. The Commission has successfully published IVth edition of National Formulary of India apart from Addendum 2012 to IP 2010. In the ensuing edition of Indian Pharmacopoeia, we are going to add 20 new monographs on Radiopharmaceuticals while 54 will be the number of such monographs which are not available in any pharmacopoeia of world. This is mainly possible due to the availability of high end instruments like NMR, ICP-MS, LC-MS, GC-MS, GC-HS, IC, AAS, FTIR and installation of Cold Room. The Commission is poised to make available the monographs for the molecules listed in National list of Essential Medicines 2012. The onus of entire performance lies in the principles of transparency, accountability and punctuality adopted by the manpower willingly.

The task of the Commission seems to be more challenging in the coming future as the Country has high expectations from newly created institution to provide upgraded and updated infrastructural facilities required for executing the responsibilities vested with it and to cope up with global standards in this era of kill or get killed competition.

The guidance, blessings and road map prepared by the Ministry and assisting hand provided by the members of Scientific Body and other Scientific fraternity along with the incessant labour of the working staff of the Commission are always praiseworthy. I, on my own and on behalf of my co-workers would like to extend my deep sense of obligation and gratitude to all those visible and invisible who continuously guided during the period and to the Sovereign Government for the unending support mercifully extended to the IP Commission to garner its coveted goals.

With best wishes.

  
(Dr. G. N. Singh)

## MISSION, VISION AND OBJECTIVES

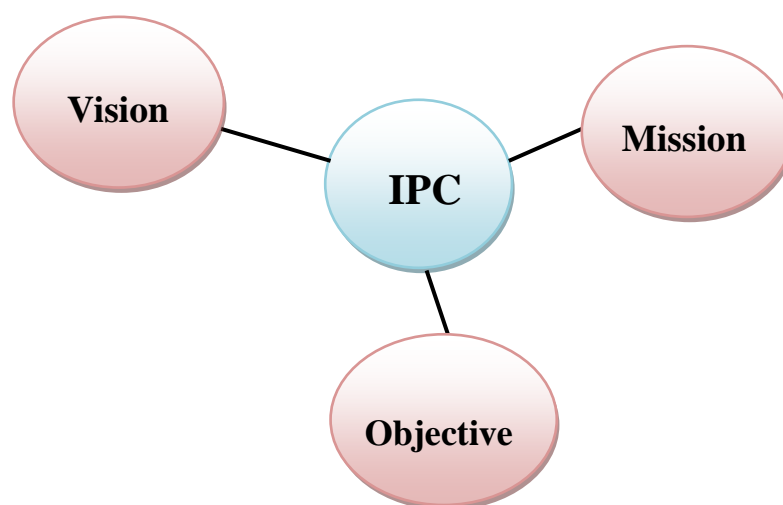


Fig: 2-Functions of IPC

**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.

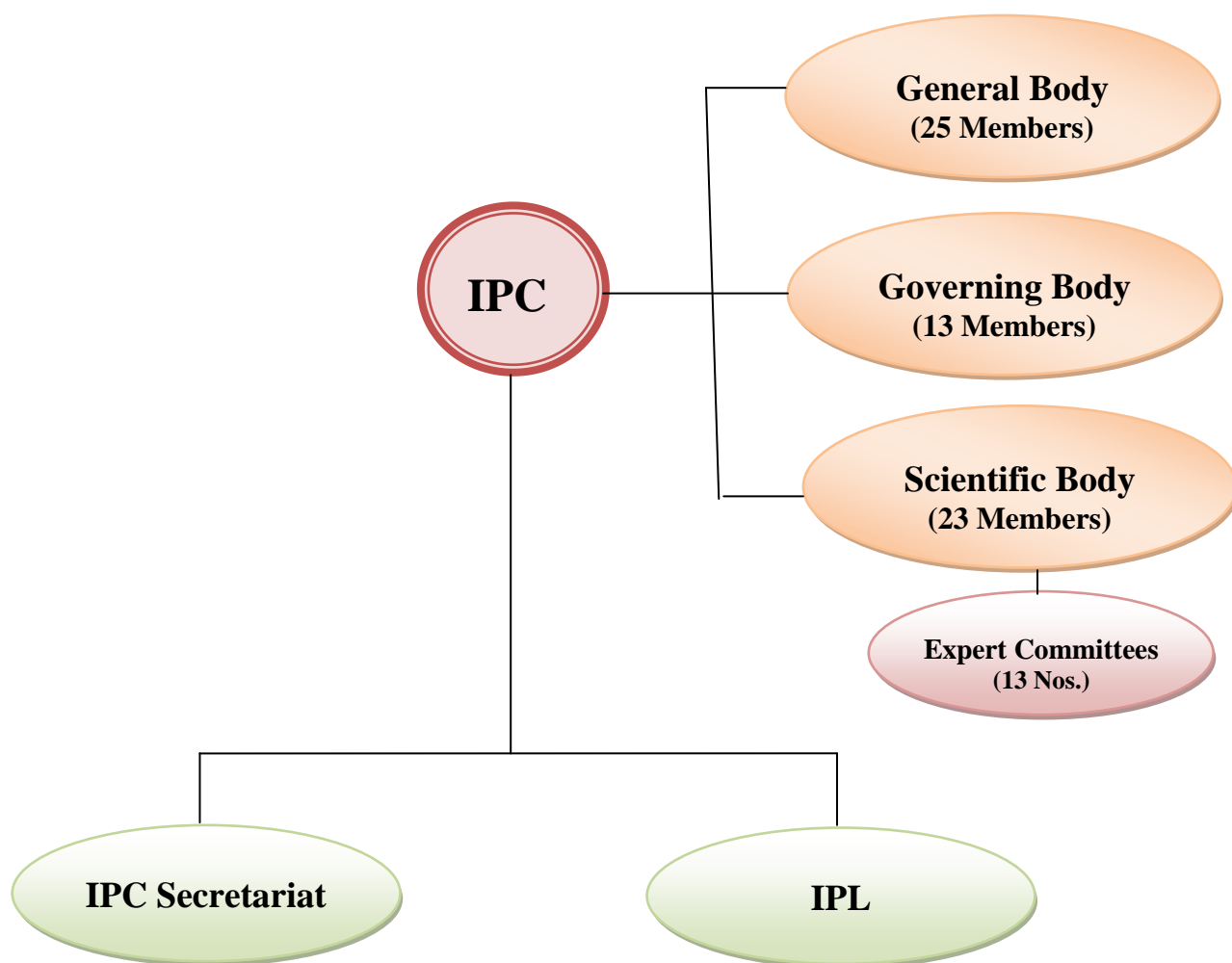
**Vision:** To promote the highest standards for drugs for use in humans and animals within practical limits of the technologies available for manufacture and analysis.

**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:

<b>S. No.</b>	<b><i>Designation in Committee</i></b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Mr. P. K. Pradhan 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 L. C. Goyal, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	<i>Member</i>	Shri R. K. Jain 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 (Drugs) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	<i>Member</i>	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 Sanjay Prasad Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	<i>Member</i>	Director National Institute of Biologicals B-62, Institutional Area Noida-201 307



9.	<i>Member</i>	Shri Raja Sekhar Vundru 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>	Dr. Kiran Mazumdar Shaw C&MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100
12.	<i>Member</i>	From Scientific Body, IPC
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:

<b>S. No.</b>	<b><i>Designation in Committee</i></b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Mr. P. K. Pradhan 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 L. C. Goyal, Additional Secretary & Director General (CGHS) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011.
4.	<i>Member</i>	Shri R. K. Jain 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 (Drugs) Ministry of Health & Family Welfare, Nirman Bhawan New Delhi-110 011.
6.	<i>Member</i>	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 Sanjay Prasad Director (Drugs) Ministry of Health & Family Welfare Nirman Bhawan New Delhi-110 011
8.	<i>Member</i>	Director National Institute of Biologicals B-62, Institutional Area Noida-201 307

9.	<i>Member</i>	Shri Raja Sekhar Vundru 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>	Shri P. K. Guha Director Central Drugs Laboratory 3, Kyd Street Kolkata
12.	<i>Member</i>	From Regulatory Bodies Central Drugs Standard Control Organisation Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi.
13.	<i>Member</i>	Dr. C. Adithan Director-Professor Department of Pharmacology Jawaharlal Institute of Postgraduate Medical Education and Research Pondicherry-605 006.
14.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Andhra Pradesh
15.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Sikkim
16.	<i>Member</i>	Commissioners in-charge of Drug Control Administration, Gujarat
17.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Uttar Pradesh
18.	<i>Member</i>	Commissioner in-charge of Drug Control Administration, Himachal Pradesh

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

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

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

<b>S. No.</b>	<b>Designation in Committee</b>	<b>Name &amp; Address</b>
1.	<i>Chairman</i>	Prof. B. Suresh Vice-Chancellor, J. S. S. University, JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara, Mysore-570 015
2.	<i>Member</i>	Dr. G. N. Qazi Vice Chancellor, Jamia Hamdard Hamdard University, 'A' Category – NAAC, Hamdard Nagar, New Delhi-110 062.
3.	<i>Member</i>	Dr. N. Udupa Principal, Manipal College of Pharmaceutical Sciences, Madhav Nagar, Manipal-576 104. Karnataka
4.	<i>Member</i>	Professor M. R. Yadav Pharmacy Department, Faculty of Technology and Engineering, The M. S. University of Baroda, Vadodara– 390 001 (Gujarat)
5.	<i>Member</i>	Dr. 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 <sup>st</sup> Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar-382 010.
20	<i>Member</i>	Dr. Prasad V. Kanitkar Director, Plant Operations, Pfizer Global Manufacturing, Pfizer Limited, Thane Belapur Road, K.U. Bazar Post, Turbhe, Navi Mumbai-400 705.
21.	<i>Member</i>	Dr. Anurag Rathore, Associate Professor, Department of Chemical Engineering, Indian Institute of Technology, Hauz Khas, New Delhi-110 016.
22.	<i>Member</i>	Mr. R. Sridharan 603, Sarangi, Lokpuram, Thane (W) – 400 610
23.	<i>Member-Secretary (ex-officio)</i>	Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002



## **Expert Committee on Biologicals and rDNA products**

Dr. Anurag Rathore (*Chair*); Dr. S.S. Jadhav; Dr. Venkata Ramana; Dr. Tamal Raha; Dr. Anil Kukreja; Dr. Sriram Akundi; Dr. Jaideep Moitra; Mrs. Kinnari Vyas; Dr. Sunil Gairola; Mr. Arvind Kukrety; Dr. Renu Jain; Dr. Sanjeev Kumar; Dr. Yasmeen Shenoy

## **Working Group on**

### **1. Antiretroviral Drugs API's**

Dr. Manish Gangrade (*Chair*); Dr. Antony Raj Gomas; Ms. Rashmi Srivastava; Dr. Jyoti Ganti; Dr. Suryanarayana Mulukutla

### **2. General Chapters**

Dr. Vinay G. Nayak (*Chair*); Dr. Sunil S. Nadkarni; Mr. Antony Raj Gomes; Dr. Vinay J Aroskar; Dr. Pramod Dalvi; Dr. Sundara Kalyana Balaji; Mr. Kundan Dharma Patil; Mr. Deepak Jakate; Mr. Sanjay Deshpande; Dr. V. B. Malkar; Mr. Mohan Jain; Dr. Luis Coutinho

### **3. General Chapters – Dosage Forms**

Mr. Vinod Arora (*Chair*); Dr. Prashant Dikshit

### **4. Herbal Products**

Dr. D. B. Anantha Narayana (*Chair*); Dr. Amit Agarwal; Dr. G. Patani; Dr. Pulok Mukherjee; Dr. M. N. Nanjan; Dr. C. K. Katiyar

### **Sub Group on 'Essential Oils' for the IPC**

Mr. Ramakant Harialka; Mr. B. Murali; Dr. Rahul Singh; Ms. Bhuvana Nageswaran; Dr. Hema Lohani

### **5. Inhalation Products**

Mr. R. Sridharan (*Chair*); Dr. Jyoti Ganti; Mr. Satish Sharma; Mr. Sanjay Gupta; Mr. Nagesh Shenoy; Mr. Ganadish Kamat; Mr. Amit Sule; Mr. S. G. Belapure

### **6. Medical Devices**

Dr. Ishwar Reddy (*Chair*)

### **7. Microbiology (General)**

Dr. J. P. Mehta (*Chair*); Dr. (Mrs) Gopa Ghosh; Mr. S. N. Chavan; Dr. S. S. Jadhav; Mr. A. P. Mohan; Dr. P. K. Chitnis

**8. Parenteral Preparations (General)**

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

**9. Pharmaceutical Dosage Forms – Anticancer Drugs – including API's**

Dr. K. V. Jogi (*Chair*); Dr. B. Nagaraju; Dr.N.Padmaja; Mr. Mohan Jain

**10. Pharmaceutical Dosage Forms – Biological Drugs**

Dr. Surinder Singh (*Chair*); Dr. Anurag Rathore; Dr. S. S. Yadav

**11. Pharmaceutical Dosage Forms – Excipients**

Dr. Prasad V. Kanitkar (*Chair*); Mr. Subodh Prilokar; Dr. D. B. Anantha Narayana; Dr. Sailesh Nagarsenkar

**12. Pharmaceutical Dosage Forms - Ophthalmic**

Dr. S. M. Mudda (*Chair*); Mr. V. Sivakumar; Ms. Shakila. S. Pai; Mr. R. T. Arasu; Mr. Navneet V. Mehta; Ms. S. Asha; Mr. P. Venkata Reddy; Ms. Aditi Panandikar

**13. Veterinary Products**

Dr. Rishendra Verma (*Chair*); Dr. V. A. Srinivasan

**14. Website Development**

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

## **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**

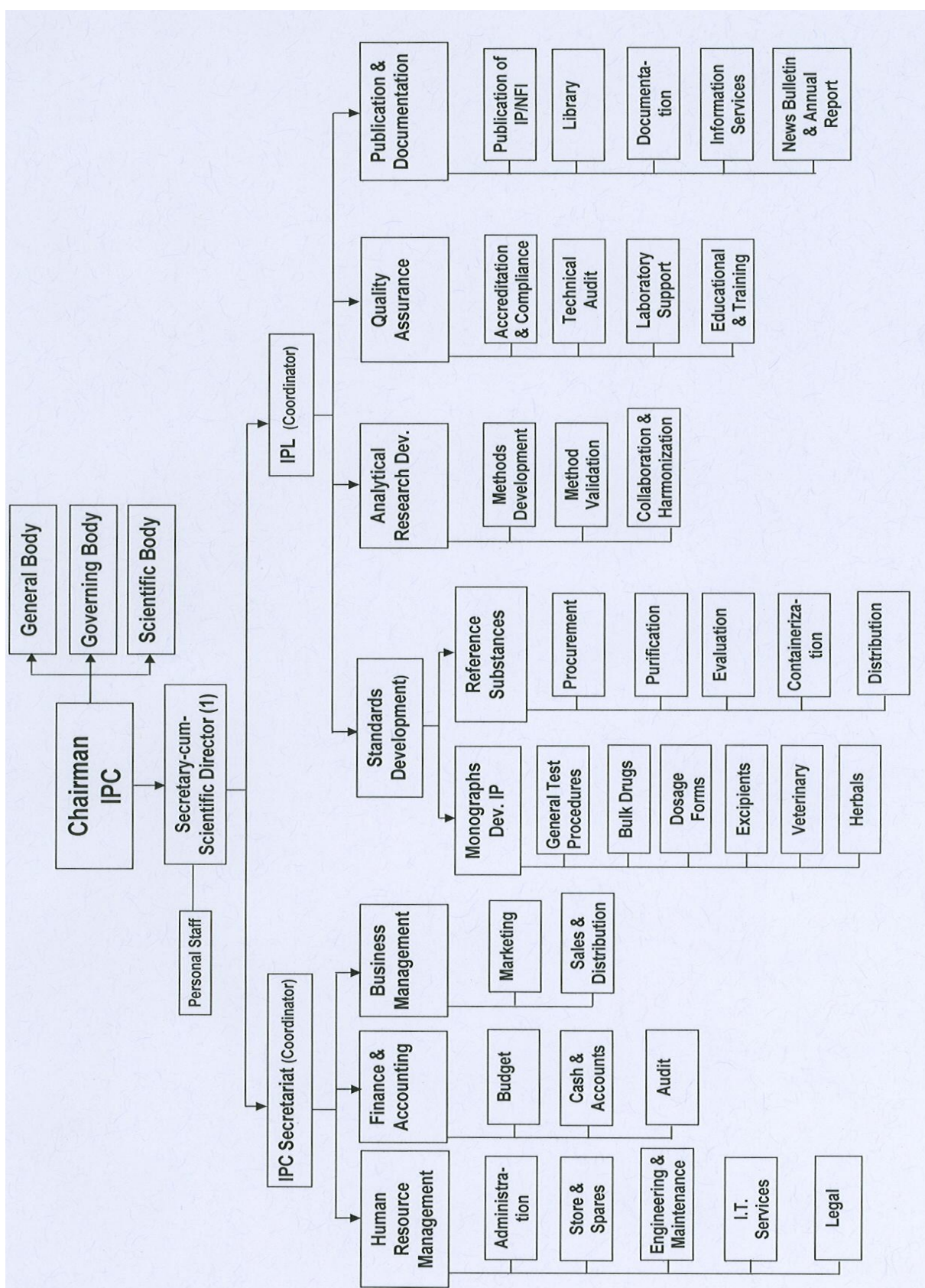
The Indian Pharmacopoeia Laboratory (IPL) has taken over the above infrastructure of the CIPL. As a standards writing institution, the IPL has to validate several methods of analysis and also reference substances and the activities are quite different from those of the CIPL. Restructuring of the laboratory 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



## **Scientific Activities & Achievements**

### **A. Addendum 2012 to Indian Pharmacopoeia 2010:**

#### **1. Releasing of Indian Pharmacopoeia 2010 (6<sup>th</sup> edition)**

The IPC team examined the queries continuously received from different stakeholders related to IP and amendments inserted in the manuscript of Addendum IP 2012. The manuscript was converted into page maker and handed over to NISCAIR in September 2011 for printing. The Manuscript sent by NISCAIR for rechecking of manuscript just before printing was reviewed and the corrected thoroughly. This Addendum 2012 is released on 27.12.2011 by Hon'ble Secretary of Health & Family Welfare, Govt. of India, at Nirman Bhavan New Delhi.

#### **2. Addendum 2012 to Indian Pharmacopoeia 2010**

Total 52 new monographs were included in Addendum 2012. Drafted monographs were sent for wider circulation to the stakeholders, academia and the technical experts. The suggestions received from various sources for revision of the new drafted monographs were re-examined and finally incorporated in Addendum 2012 to Indian Pharmacopoeia 2010.

The list of finalized monographs are appended below and published in Addendum 2012 to IP 2010.

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

### **3. New Monographs Drafted for seventh edition of IP**

About 31 monographs drafted during this period for next edition and put on the website for stakeholders comments. The list is as follows.

1. Alprazolam SR Tablet
2. Aciclovir Oral Suspension
3. Aciclovir Cream
4. Acitretin Capsules
5. Acamprosate Calcium
6. Clindamycin Injection
7. Dalteparin Sodium
8. Dalteparin Injection
9. Diclofenac SR Tablet
10. Divalproex SR Tablets
11. Dopamine Hydrochloride
12. Dopamine Injection
13. Gemcitabine Injection
14. Gemcitabine Hydrochloride
15. Hydroxychloroquine Sulphate
16. Invert Syrup
17. Levosalbutamol Hydrochloride
18. Levosalbutamol Inhalation
19. Ascorbyl Palmitate
20. Carboxymethylcellulose Calcium
21. Alfacalcidol
22. Aciclovir Dispersible Tablets
23. Aciclovir Eye Ointment
24. Lapatinib Ditosylate
25. Lapatinib Tablets
26. Acitretin
27. Adenosine
28. Albendazole Oral Suspension
29. Cyclosporine Capsules
30. Sorafenib Tosylate
31. Sorafenib Tablets

#### **4. Drafted the following revised tests for next edition of IP**

- |                                 |                                     |
|---------------------------------|-------------------------------------|
| 1. Atropine Sulphate – RS       | 2. Calcium folinate – RS            |
| 3. Ceftazidime – RS             | 4. Clarithromycin Tablets – RS      |
| 5. Micnazole Mitrates – RS      | 6. Norfloxacin – RS                 |
| 7. Omeprazole – RS              | 8. Oxazepam – RS                    |
| 9. Pheniramine Maleate – RS     | 10. Proguanil Maleate – RS          |
| 11. Ranitidine HCL – RS         | 12. Tinidazole                      |
| 13. Ranitidine Tablets          | 14. Ranitidine Injection            |
| 15. Triamterene                 | 16. Bupivacaine HCL                 |
| 17. Caffeine                    | 18. Clofazimine                     |
| 19. Clofazimine Capsules        | 20. Clonidine Hydrochloride         |
| 21. Clotrimazole                | 22. Diazepam                        |
| 23. Cloxacillin Sodium          | 24. Digoxin                         |
| 25. Codeine Phosphate           | 26. Dithranol                       |
| 27. Cyclizine Hydrochloride     | 28. Doxepin HCL                     |
| 29. Dequalinium Chloride        | 30. Econazole Nitrate               |
| 31. Fluphenazine Decanoate      | 32. Fluphenazine HCL                |
| 33. Fluphenazine Injection      | 34. Haloperidol                     |
| 35. Homatropine Hydrobromide    | 36. Hydrochlorothiazide             |
| 37. Hydrochlorothiazide Tablets | 38. Hyoscine Butylbromide           |
| 39. Hyoscine Hydrobromide       | 40. Hyoscine Hydrobromide Injection |
| 41. Hyoscine Hydrobromide Tab.  | 42. Isoprenaline Hydrochloride      |

#### **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 02<sup>nd</sup> July, 30<sup>th</sup> Oct. and 11<sup>th</sup> Feb. 2010

#### **7. Verification of Analytical methods for IP**

The IPC staff is vigorously involved in analytical verification of various tests in the existing monographs of IP and the monographs drafted for Addendum 2012. Carried out verification of analytical method of drugs samples received from various Stakeholders for verification of IP monograph. During this period following sample were verified:-

- |                       |  |
|-----------------------|--|
| 1. Levofloxacin       | 2. Zolmitriptan                          |
| 3. Rabepazole         | 4. Docetaxel injection                   |
| 5. Amlodipine Tablets | 6. Losartan Potassium tablet dissolution |



7. Lamotrigine dispersible tablet	8. Mannitol
9. Atorvastatin Calcium	10. Rizatriptan
11. Telmisartan tablet	12. Rizatriptan Tablets
13. Rifampicin Capsules	14. Tizanidine
15. Levofloxacin	16. Chloroquine sulphate
17. Thyroxine tablet	18. Ketorolac tromethamine
19. Lactose monohydrate	20. Neotame
21. Sucralose	21. Zolmitriptan tablets
22. Ramipril /Hydrochlorthiazide	23. Pralidoxime chloride
24. Isosorbide mono nitrate	25. Isosorbide di nitrate
26. Bupivacaine HCl	27. Travoprost eye drop
28. Ramipril	29. Metronidazole
30. Minoxidil	31. Chloroquine sulphate
32. Thiamine mononitrate	33. Donepezil tablets
34. Rosuvastatin Calcium	35. Rabeprazole tablets
36. Aceclofenac Tablets	37. Primaquine tablets
38. Noradrenaline Bitartrate	39. Dapsone
40. Zoledronic acid	41. Lansoprazole

Amendment lists were prepared from the draft proposal for amendments kept on website for stakeholders comments and released during this period with the consultation of subject experts and concerned committees.

## **B. IP Reference Standards Developments:**

### **1. IPRS Developed At IPL**

During the year 72 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 80 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.

235 IR Spectrum of API are added on IPC website and the same will be included in IP 2014.

### **2. IPRS distributed to various Government Laboratories**

For the year ending 31<sup>st</sup> March, 2012 IPC technical staff have dispatched 900 IPRS vials to Government laboratories and 62 IPRS vials to private laboratories.

### **3. 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.

#### **4. 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 Reference Substances.

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

#### **C. Testing of New Drugs**

- 73 New Drugs Substances (NDS) Sample analysed and reported to CDSCO
- 10 new Monograph of NDS prepared during the financial year.
- 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:
  - L-Glutathione reduced.
  - Mitiglinide Cadhydrate
  - Azicidine.
  - Fomepizole.
  - Ulipristal Aceate.
  - Carbtocine.
  - Coleseuelam HCl.
  - Iloperidone.
  - Fingolimode HCl.
  - Rilpivirine HCl.

#### **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:**

- To strengthen the quality system & documentation, Globally accepted NABL certification ISO 17025 and NABL certification ISO 17025:2005 were achieved by IPC in September 2011 for chemical and biological testing with full devotion of IPC staff within few months after filing the application in very first attempt. Now the IPC is adopting uniform approach for determining laboratory competence, encourage laboratories to adopt internationally accepted testing and reliable result.
- Laboratory participated in Inter Laboratory Comparison for products as per prepared Scope of Accreditation.
- Participated in International Proficiency Testing and got certification.

#### **Quality Assurance**

- To improve the quality of documentation, QA section established & is functioning since Nov' 11.
- Newly joined pharma associate were trained in lab as well as in documentation related to NABL
- Procedures were developed to keep the data of Reference Standard Division in safe custody & are archived in QA section
- New log book of IPC were implemented in lab & other area where required
- Evaluation of about 100 reports received from other labs, participating in validation of IPRS done.

#### **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 2012 to IP 2010 was loaded on IPC Web-site at [www.ipc.gov.in](http://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.

The first, second and third editions of National Formulary of India (NFI) were published in 1960, 1966 and 1979 respectively by the Ministry of Health, Govt. of India. In the past 3 decades there has been vast expansion in the range of new drugs and their formulations. To address the need of publication of an updated version of NFI, Ministry of Health and Family Welfare, Govt. of India vide their Notification No. F.No.X.11035/2/06-DFQC dated 8th May, 2008 assigned this mandatory responsibility to the Indian Pharmacopoeia Commission (IPC), Ghaziabad and hence the NFI is being published by the IPC on behalf of the Govt. of India, Ministry of Health and Family Welfare. For this purpose, an Apex Body and a Core Group with the following composition were constituted:

**Chairman:** Secretary, Ministry of Health and Family Welfare, Govt. of India

**Apex Body (in alphabetical order)**

1. Dr Nitya Anand, Ex-Director, CDRI, Lucknow
2. Mr L. C. Goyal, Additional Secretary & DG (CGHS), Ministry of Health and Family Welfare, Govt. of India
3. Prof. Y. K. Gupta, Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi
4. Dr A. K. Panda, Joint Secretary (Regulation), Ministry of Health and Family Welfare, Govt. of India
5. Mr Debasish Panda, IAS, Joint Secretary (Human Resource), Ministry of Health and Family Welfare, Govt. of India
6. Mr Sanjay Prasad, Director, Ministry of Health and Family Welfare, Govt. of India
7. Mr P. D. Sheth, Vice-President, The International Pharmaceutical Federation, The Hague, The Netherlands
8. Dr G.N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad
9. Dr Surinder Singh, Drugs Controller General of India, New Delhi
10. Prof. B. Suresh, Chairman, Scientific Body, Indian Pharmacopoeia Commission, Ghaziabad

**Core Group (in alphabetical order)**

1. Mr A. K. Adhikari, Chief, Pharmacy Services, St. Stephen's Hospital, Delhi
2. Prof. Praveen Aggarwal, Department of Emergency Medicine, All India Institute of Medical Sciences, New Delhi
3. Dr Veena Gupta, Consultant, Department of Radiotherapy, Safdarjung Hospital, New Delhi
4. Prof. Y. K. Gupta, Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi

5. Dr G. N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad
6. Prof. S. K. Kabra, Paediatric Pulmonology Division, Department of Paediatrics, All India Institute of Medical Sciences, New Delhi
7. Prof. G. C. Khilnani, Department of Medicine, All India Institute of Medical Sciences, New Delhi
8. Dr Jai Prakash, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad
9. Mr P. D. Sheth, Vice-President, The International Pharmaceutical Federation, The Hague, The Netherlands
10. Prof. Pramil Tiwari, Head, Department of Pharmacy Practice, National Institute of Pharmaceutical Education &

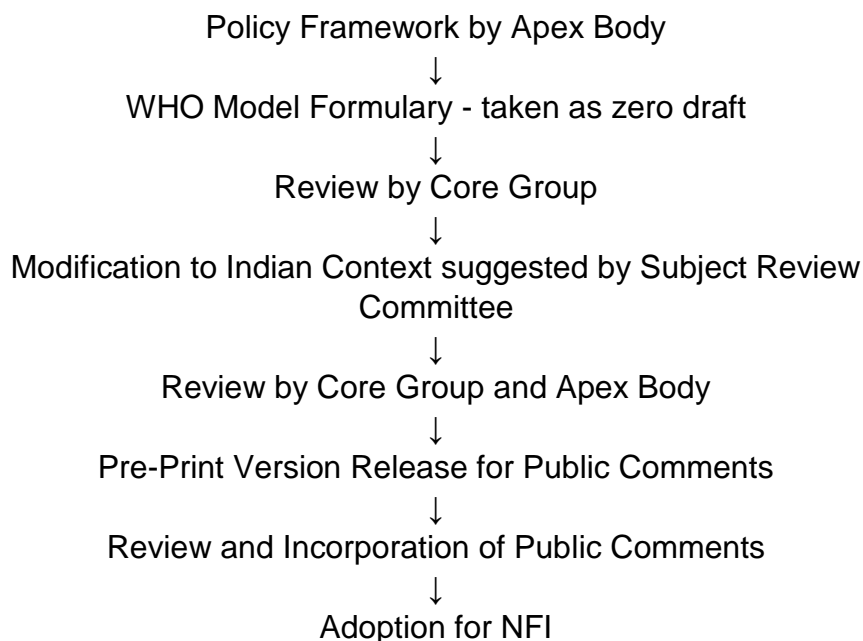
### **Research, Mohali, Punjab, India**

The Criteria for Inclusion of Drugs in NFI:

- Drugs in National List of Essential Medicines 2011, India
- Drugs used in National Health Programmes
- Drugs listed in Indian Pharmacopoeia
- Drugs not covered but recommended by panel of experts
- Any drug (s) considered appropriate by the IPC

### **NFI Review Process**

To fulfil the mandate of publishing the NFI, the following process has been adopted:



### **Subject Review Committee (in alphabetical order)**

The manuscript was reviewed and the contents updated to suit Indian context by the Subject Review Committee.

1. Dr Hemant Singh Bhadauria, Pharmacology, All India Institute of Medical Sciences, New Delhi
2. Dr Arun Kumar Dahiya, Pharmacology, All India Institute of Medical Sciences, New Delhi
3. Dr Aman Goyal, Pharmacology, All India Institute of Medical Sciences, New Delhi
4. Dr Sheffali Gulati, Pediatric Neurology, All India Institute of Medical Sciences, New Delhi
5. Dr Pooja Gupta, Pharmacology, All India Institute of Medical Sciences, New Delhi
6. Dr Madhur Gupta, WHO-India (Country Office), New Delhi
7. Dr Nirmal Gurbani, SMS Medical College, Jaipur
8. Dr Ashish Kakkar, Pharmacology, All India Institute of Medical Sciences, New Delhi
9. Dr V. Kalaiselvan, Indian Pharmacopoeia Commission, Ghaziabad
10. Dr D.B.A. Narayana, Delhi Pharmaceutical Trust
11. Dr Biswa Mohan Padhey, Pharmacology, All India Institute of Medical Sciences, New Delhi
12. Dr Jai Prakash, Indian Pharmacopoeia Commission, Ghaziabad
13. Dr Aarohan Pruthi, Pharmacology, All India Institute of Medical Sciences, New Delhi
14. Dr R.K. Sanghavi, Indian Drugs Manufacturers Association, Mumbai
15. Dr Sudhir Chandra Sarangi, Pharmacology, All India Institute of Medical Sciences, New Delhi
16. Dr P.G. Shrotriya, Elite Pharma Consultancy Services, Ahmedabad
17. Dr Pramil Tiwari, National Institute of Pharmaceutical Education and Research, Mohali, Punjab, India
18. Mr S. S. Venkatakrishnan, Thiruvananthapuram, Kerala
21. Dr Rakesh Yadav, Cardiology, All India Institute of Medical Sciences, New Delhi

NFI is not a regulatory document. Physicians are supposed to use their professional judgement. Inclusion/Exclusion of monographs in NFI is a dynamic process. The drugs contained in NFI have been chosen for rational and economic prescribing. NFI would serve as a guidance document to medical practitioners, pharmacists, nurses, medical and pharmacy students, and other healthcare professionals and stakeholders in healthcare system. The feedback from stakeholders is invited.

## Acknowledgements

We are pleased to present the 4th Edition of National Formulary of India. It has materialized after a gap of 3 decades. During this period, there have been tremendous advancements in therapeutic strategies and newly available drugs. This edition incorporates the changes based on the current knowledge.

Valuable inputs that emerged during the meetings of the Core Group and the inputs received in response to the pre-print version circulated have given this edition a unique feature by incorporating value added information. The Commission is greatly indebted to the Members of the Core Group and the Subject Review Experts from diverse fields who consented to review the manuscript of the Formulary. The services of all these experts are appreciated.

The inspiration and the historical perspective were made available by Dr Nitya Anand, Dr. Harkishan Singh, and Dr B. D. Miglani with close involvement of Mr. P. D. Sheth, Vice- President, FIP. The initial inputs in the form of list of drugs to be incorporated was compiled based on drugs available in IP and NLEM at a short notice by Dr Pramil Tiwari and his team.

The Commission is especially indebted to Mr. P. D. Sheth for providing the infrastructural facilities required to carry out this work uninterruptedly. During the preparation of pre-print version, important guidance was received from Mr. Duncan Enright of BNF. We are thankful to Dr Richard Laing and Dr Suzanne Hill at WHO Geneva and Dr Krisantha Weerasuria at WHO-SEARO for their suggestions, support and encouragement. Thanks are due to Dr P. Venugopal for his participation and guidance. Mr. P. D. Sheth engaged a technical team consisting of Mr. S. C. Bhasin, Mr. M. Ahmed Khan and Mr. Syed Jalal Q. Rahman in the initial compilation of the NFI.

Special thanks go to the members who prepared Appendices which have added value to this fourth edition of NFI.

Prof. Y. K. Gupta deserves a special mention for his crucial role in preparing and enriching the contents of the formulary by closely coordinating with his colleagues throughout the course of preparation of this Formulary.

The Commission is highly appreciative of the encouragement and support received from Mr L. C. Goyal, Additional Secretary & DG (CGHS), Mr Debasish Panda, Joint Secretary (HR), Dr A. K. Panda, Joint Secretary (Regulation), Mr Sanjay Prasad, Director (Drugs) and Dr Surinder Singh, DCG (I) and other officials of Ministry of Health & Family Welfare. The Commission appreciates the comments offered on the pre-print version of NFI by the stakeholders. The inputs received from the institutions, state governments and stakeholders have helped to shape the 4th Edition. Their names figure on website of the Commission ([www.ipc.gov.in](http://www.ipc.gov.in)).

## 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. General Chapter on Sulphated Ash
  2. General Chapter on Disintegration Test
  3. General Chapter on Extractable Volume
  4. General Chapter on Particulate contamination
  5. Monograph of Pyrantel Embonate Oral Suspension
  6. Monograph of Pyrantel Embonate Chewable Tablets
  7. Monograph of Zinc Dispersible Tablets
  8. Monograph of Ritonavir Tablet
  9. Monograph of Artesimol
  10. Monograph of Artesunate
  11. Monograph General method of Friability Test
  12. General Chapter on Dissolution test for solid oral dosage form
  13. General Chapter on Bulk Density and Tapped density of powders
  14. Monograph of Medroprogesterone acetate Injection
  15. Monograph of Albendazole Tablets
  16. Monograph of Levonorgestrel and Ethinylloestradiol Tablets
  17. Monograph of Mefloquine Hydrochloride
  18. Monograph of Chewable Albendazole Tablets
  19. Monograph of Rifampicin

## **Library and 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 documents 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 about 10,500 old and latest books, periodicals etc. and Pharmacopoeias of different countries. The Library & Information Centre also subscribes national and international scientific journals on different subjects to keep up-to-date knowledge in the field of Pharmacopoeial, Pharmaceuticals and Drugs Standardization. It also aims to build a comprehensive collection of back volumes of journals in all these fields. 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**

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 about 10,500 old and latest books, periodicals etc. and Pharmacopoeias of different countries. The collection consists of books, periodicals, pamphlets, manuscripts, photographs & electronic resources etc. The IPC Library & Information Centre has procured the books to support Scientific, Pharmacopoeial and Administrative work during the year (01/04/2011 – 31/03/2012) as appended below: -

Sl. No.	ITEMS NAME	QUANTITY
1.	Total Books Procured	193

## PROCUREMENT OF NON-BOOK MATERIALS

The IPC Library & Information Centre has also procured the following non-book materials during the year (01/04/2011 – 31/03/2012): -

Sl. No.	ITEMS NAME	QUANTITY
1.	CD-ROM	08
2.	DVD	16
3.	Photographs	187
4.	Theses/Dissertations/Training Report	13
5.	Magazines	17
6.	Newspaper	6

## SUBSCRIPTION OF JOURNALS

The Library & Information Centre has subscribed 39 national and international scientific journals on different subjects to keep up-to-date knowledge in the field of Pharmacopoeial, Pharmaceuticals and Drugs Standardization. The subscriptions during the year (01/04/2011 – 31/03/2012) are as follows: -

### International Journals

1. Analyst
2. Analytical Abstracts
3. British Medical Journal (International)
4. Bulletin of the WHO
5. Drugs
6. Drug Development & Industrial Pharmacy
7. Drug Safety
8. European Journal of Pharmaceutical Science
9. International Pharmaceutical Abstracts
10. Journal of AOAC International
11. Journal of Analytical Chemistry
12. Journal of Controlled Release

13. Journal of Pharmacy and Pharmacology
14. Journal of Pharmaceutical and Biomedical Analysis
15. Journal of Pharmaceutical Science
16. Journal of the American Pharmacists Association
17. Microbiology
18. New England Journal of Medicine
19. Pharmaceutical Research
20. Pharmacoepidemiology & Drug Safety
21. Phytochemistry
22. Planta Medica
23. Trends in Analytical Chemistry
24. Trends in Biotechnology
25. Trends in Microbiology
26. Trends in Pharmacological Sciences
27. WHO Drug Information

### **National Journals**

1. Annals in Library & Information Studies
2. Current Science
3. Drugs Today
4. Indian Journal of Biochemistry & Biophysics
5. Indian Journal of Chemistry –A
6. Indian Journal of Chemistry-B
7. Indian Journal of Experimental Biology
8. Indian Journal of Physiology & Pharmacology
9. Indian Journal of Pharmacology
10. Journal of Scientific & Industrial Research
11. Medicinal & Aromatic Plants Abstracts
12. MIMS India

### **LIBRARY & INFORMATION CENTRE SERVICES DURING THE YEAR (01/04/2011 – 31/03/2012)**

The IPC Library & Information Centre provides the following services during the year (01/04/2011 - 31/03/2012) to support Scientific, Pharmacopoeial and Administrative work: -

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

The IPC Library & Information Centre has issued approximately 292 books to its staff during the year (01/04/2011 - 31/03/2012).

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

The Library & Information Centre maintains a separate reference collection consisting of rare and costly reference books on various areas of sciences. The IPC Library & Information Centre provided the service to staff members and external users. Approximately 5134 books have been consulted during the year (01/04/2011 - 31/03/2012).

**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 throughout 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 throughout 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 throughout the year.

**vi) Reprographic Services**

The Library & Information Centre provided the photocopy service to their users. This section has officially photocopied approximately 2812 pages during the year (01/04/2011 - 31/03/2012).

**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 have utilized the service throughout the year.

**viii) CD-ROM Database search**

The Library & Information Centre provides the CD-ROM database search facility to their staff members. During the year 01/04/2011 - 31/03/2012 the CD-ROM of British Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia and DVD of Indian Pharmacopoeia 2010 have been searched.

**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 (01/04/2011 - 31/03/2012) taking into account their professional background and needs for meeting the challenges of current times. During this year 9 students/research scholars have undergone training from different departments of Indian Pharmacopoeia Commission. Moreover, during the year many students, research scholars and Officials like from DIPSAR, JSS College of Pharmacy, Central Council for Research in Ayurvedic Sciences, Swamy Vivekanand College of Pharmacy, and CTL State Drugs Laboratory have visited the Indian Pharmacopoeia Commission.

## **PUBLICATION DIVISION**

Indian pharmacopoeia Commission (IPC) also publishes Newsletter on **Pharmacovigilance Programme of India (PvPI)** on half-yearly 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, Ghaziabad: -

<b>S. No.</b>	<b>TITLE OF THE PUBLICATION</b>
1.	IPC Profile
2.	IP-2007
3.	IP-2007Addendum 2008
4.	IP-2010
5.	IP-2010 Addendum 2012
6.	DVD of IP 2010
7.	NFI-2011
8.	CD of NFI-2011
9.	NFI-2011 Mobile Application
10.	PvPI Newsletter Vol. 1, Issue 1,2011
<b>S. No.</b>	<b>TITLE OF THE PUBLICATION</b>
11.	PvPI Newsletter Vol. 2, Issue 1,2012
12.	PvPI Newsletter Vol. 2, Issue 2,2012
13.	Guidance Manual for Compliance of Indian Pharmacopeia (IP)

## SALE & DISTRIBUTION OF IPC PUBLICATIONS

The sales and distribution of IPC Publications during the financial year 01/04/2011 to 31/03/2012 are as appended below: -

### STATUS (w.e.f. 01/04/2011-31/03/2012)

S. No.	Publications	Total Sets /Copies published	Current Status ( As on 01/04/2011 to 31/03/2012		Total Revenue Generated
1.	IP-2007	5000 Sets	Sale	00	NIL
			Complementary	09	
2.	IP-2010	3000 Sets	Sale	601	Rs. 98,08,040/-
			Complementary	67	
3.	DVD of IP-2010	3000 copies	Sale	44	Rs. 8,95,000/-
			Complementary	121	
4.	NFI- 2011	30000 copies	Sale	297	Rs. 1,12,000/-
			Complementary	90	
5.	IP-2010 Addendum 2012	1500 Copies	Sale	932	Rs. 22,48,200/-
			Complementary	64	
TOTAL =					Rs. 1,30,63,240/-

(Total Revenue Generated in Indian Rupees = One Crore Thirty Lacs Sixty three Thousand Two Hundred Forty only)

## **Seminar & Meetings**

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

Following meetings/programmes were held during April 2011 to March 2012.

1. Meeting with Dr. R. K. Sharma, Dr. Sanjog Jain, Dr. N. Gopal Rajan and Dr. Goomer on Radiopharmaceutical monographs for coming edition of IP on 19<sup>th</sup> April, 2011.
2. Meeting with Dr. Y.K. Gupta at AIIMS, New Delhi to Finalize the Monographs for IP Addendum 2012 on 21<sup>st</sup> April, 2011.
3. Inspection audit by Dr. S.K. Raza, NABL Accessor on 18<sup>th</sup> June, 2011 at IPC, Ghaziabad.
4. Visit of Ms. Kiran Mazumdar Shah, CMD of Biocon on 09<sup>th</sup> August, 2011.
5. Visit of Sh. Chandramouli, Secretary Health & Family Welfare on 14<sup>th</sup> August, 2011.
6. Attended the 14<sup>th</sup> IDMA-PAC-APT Seminar/Convention at Mumbai from 22<sup>nd</sup> to 24<sup>th</sup> September, 2011.
7. Attended Seminar on IP-GLP compliance at IPC Campus, Ghaziabad organized by IPC-WHO on 23<sup>rd</sup> to 24<sup>th</sup> November, 2011.
8. Meeting/Lecture by Dr. C.L. Kaul, Ex-Director of NIPER, Mohali at IPC on 2<sup>nd</sup> January, 2012 on the occasion of Foundation Day of IPC.
9. Meeting/Workshop on pharmaceutical water organized by USP and USFDA at Banjara Hills, Hyderabad on 18-19<sup>th</sup> January, 2012.
10. BIS Meeting at Manak Bhavan, New Delhi on Analytical Method Validation for inorganic chemicals on 20<sup>th</sup> January, 2012.



## **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



Addendum 2012 to IP 2010 is released by Mr. P. K. Pradhan, Secretary (Health & Family Welfare) on 27<sup>th</sup> December, 2012 in presence of



Mr. P. K. Pradhan, Secretary (Health & Family Welfare) looking into detail of Addendum



Induction-cum-Training Workshop on Pharmacovigilance Programme of India (PvPI) on 20<sup>th</sup> & 21<sup>st</sup> July, 2011 at IPC, Ghaziabad



(Dr. G. N. Qazi, Dr. G. N. Singh, Dr. Y. K. Gupta, Prof. B. Suresh and Dr. S. K. Gupta)  
IPC-WHO Collaborative Workshop-cum-Symposium on 'Rational Prescribing of medicines role of National Formulary of India' on 2<sup>nd</sup> & 3<sup>rd</sup> November, 2011 at Malviya Bhawan, New Delhi





(Dr. G. N. Singh, Dr. Surinder Singh and Dr. S. K. Gupta)  
IPC-WHO Collaborative Workshop-cum-Symposium on 'Good Laboratory Practices: From Concept to Implementation' on 23<sup>rd</sup> and 24<sup>th</sup> November, 2011 at IPC, Ghaziabad



Visit of Dr. Kiran Mazumdar Shaw, C&MD, Biocon Ltd., at IPC on 09-08-2011

## **IPC Staff (as on 31<sup>st</sup> March, 2012)**

<b>Name</b>	<b>Designation</b>
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
Mrs. Meenakashi Dahiya	SSO
Ms. Sangeeta Bhatnagar	SA
Mr. Y. K. Kush	SA
Mr. Satya Prakash Tyagi	SA
Smt. Ritu Tiwari	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

## **Non-Technical Staff**

### **Store Division**

Mr. Manish Jain	SO
Mr. Bijender Kumar	LA

### **Administration and Cash Division**

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

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# **Statements of Account 2011-12**