Annual Report
2013-14

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Ministry of Health & Family Welfare
Government of India
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Foreword

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

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

IPC also functions as National Coordination Centre for Pharmacovigilance Programme of India (PvPI). During the index period various steps have been taken such as recognizing 60 more ADRs monitoring centres (total 150), launching of ‘PvPI – Helpline’ for the healthcare professionals and consumers to provide assistance in ADRs reporting, integration of Revised National Tuberculosis Control Program to monitor the safety of anti TB drugs, development of PvPI toolkit and provided training to more than 8000 healthcare professionals on the concept of PvPI.
IPC is committed to promote the rational use of generic medicines by publishing National Formulary of India (NFI). The process has been started for bringing out 5th edition of NFI. The Commission also poised to make the monographs available for the molecules listed in the National List of Essential Medicines (NLEM) on year to year basis.

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

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

(Dr. G. N. Singh)
INTRODUCTION

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

The fourth mandate is to ensure the safety of medicines by functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). Since more new drugs are being introduced in the Country which include new chemical entities, high techno pharma products, vaccines as well as new dosage forms, new routes of drug administration and new therapeutic claims of existing drugs. They may cause (pharmaceutical and vaccines) adverse effects which may not be captured in clinical trials. It is therefore, important to monitor both the known and hitherto unknown side effects of medicines. Accordingly, any new information available relating to the safety profile of medicines needs to be analysed. Therefore, it is important to have a standardized and robust Pharmacovigilance and drug safety monitoring programme at national and international level. Collecting all the relevant information in a systematic manner and analyzing the data to arrive at a meaningful conclusion about the safety aspect of the medicines is the rationale behind launching this programme in India. Initially, when the programme launched in the year 2010, AIIMS New Delhi was identified as NCC of PvPI. Later on in the year 2011, MoHFW government of India, identified IPC as NCC for PvPI. The Commission is fully financed by the Central Government with specific budgetary provisions under the administrative control of Ministry of Health and Family Welfare.
The Commission has a three-tier structure comprising the General Body, the Governing Body and the Scientific Body, supported by IPC Secretariat and Indian Pharmacopoeial Laboratory. The IPC also provides training and education to the healthcare professionals, research scholars, and medical and paramedical students on Pharmacopoeial and pharmacovigilance at regular intervals. Till date IPC organized several training/education/awareness programs and more than 10,000 healthcare professionals were trained on the concept of compliance of IP standards and Pharmacovigilance.

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

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

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

The seventh edition of the IP 2014 has recently been published by the Indian Pharmacopoeia Commission in fulfillment of the requirements of the Drugs
and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for
drugs produced and / or marketed in India and thus contributes in the control and
assurance of the quality of the medicines. The standards of this pharmacopoeia
are authoritative and legally enforceable. It intends to help in the licensing of
manufacturing, inspection and distribution of medicines. The IP is published in
continuing pursuit of the mission of IPC to improve the health of the people
through ensuring the quality, safety and efficacy of medicines. The Commission
has been receiving significant inputs from regulatory, industrial houses, academic
institutions, national laboratories, individual scientists and others. The Publication
of IP at a regular interval is one of the main mandates of the Commission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Figure: Structure of IPC
### Bodies of the IPC:

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

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<tr>
<th>S. No.</th>
<th>Designation in Committee</th>
<th>Name &amp; Address</th>
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| 1. | Chairman | Shri Lov Verma  
Secretary (Health & Family Welfare)  
Government of India  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011. |
| 2. | Co-Chairman | Prof. B. Suresh  
Vice-Chancellor, J. S. S. University,  
JSS Medical Institution Campus, Sri  
Shivarathreeshwara Nagara,  
Mysore-570 015 |
| 3. | Member | Dr. Jagdish Prasad  
Director General (DGHS)  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011. |
| 4. | Member | Shri R. K. Jain,  
Additional Secretary & Director General (CGHS)  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011. |
| 5. | Member | Shri Gautam Guha  
Additional Secretary & Finance Advisor  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011. |
| 6. | Member | Dr. Arun Kumar Panda  
Joint Secretary (R)  
Ministry of Health & Family Welfare,  
Nirman Bhawan  
New Delhi-110 011. |
| 7. | Member | Shri Shambhu Kalloolikar  
Joint Secretary  
Department of Pharmaceuticals,  
Ministry of Chemicals and Fertilizers  
Shastri Bhawan, New Delhi |
| 8. | Member | Shri Shailendra Kumar  
Director (Drugs)  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011 |
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<th></th>
<th>Member</th>
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<tr>
<td>9</td>
<td>Dr. G. N. Singh</td>
<td>Drugs Controller General (I), Directorate General of Health Services, Ministry of Health &amp; Family Welfare, FDA Bhawan, Kotla Road, New Delhi.</td>
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<td>10</td>
<td>Dr. Surinder Singh</td>
<td>Director, National Institute of Biologicals, B-62, Institutional Area, Noida-201 307</td>
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<tr>
<td>11</td>
<td>President, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Aiwan-E-Ghalib Marg, Post Box No. 7020, New Delhi-110 002</td>
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<tr>
<td>12</td>
<td>Professor (Dr.) Lalji Singh, Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P.)</td>
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<td>13</td>
<td>Dr. Kiran Mazumdar Shaw</td>
<td>C&amp;MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City, Bangalore- 560 100</td>
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<tr>
<td>14</td>
<td>Dr. G. N. Singh</td>
<td>Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector-23, Rajnagar, Ghaziabad-201 002</td>
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The composition of the General Body is as follows:

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<td>Chairman</td>
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<td>14.</td>
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<td></td>
<td>Dr. C. Adithan</td>
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<tr>
<td></td>
<td>Director-Professor</td>
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<td>Department of Pharmacology</td>
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<td>Andhra Pradesh</td>
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<td>17.</td>
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<td>Sikkim</td>
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<tr>
<td>No.</td>
<td>Member</td>
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<tr>
<td>18.</td>
<td>Member</td>
<td>Commissioners in-charge of Drug Control Administration, Gujarat</td>
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<tr>
<td>19.</td>
<td>Member</td>
<td>Commissioner in-charge of Drug Control Administration, Uttar Pradesh</td>
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<tr>
<td>20.</td>
<td>Member</td>
<td>Commissioner in-charge of Drug Control Administration, Himachal Pradesh</td>
</tr>
<tr>
<td>22.</td>
<td>Member</td>
<td>The President, Indian Drug Manufacturers Association (IDMA) 102-B, Poonam Chambers, 'A' Wing' Dr. Annie Besant Road, Worli Mumbai – 400018</td>
</tr>
<tr>
<td>23.</td>
<td>Member</td>
<td>The President, Organization of Pharmaceutical Producers of India (OPPI), Peninsula Corporate Park, Peninsula Chambers, Gr. Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013</td>
</tr>
<tr>
<td>24.</td>
<td>Member</td>
<td>Shri. D. G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), Mumbai</td>
</tr>
<tr>
<td>25.</td>
<td>Member</td>
<td>Dr. Kiran Mazumdar Shaw C&amp;MD, Biocon Ltd., 20th KM, Hosur Road, Electronics City Bangalore- 560 100</td>
</tr>
<tr>
<td>26.</td>
<td>Member-Secretary</td>
<td>Dr. G. N. Singh Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002</td>
</tr>
</tbody>
</table>
The composition of the **Executive Committee** is as follows:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Designation in Committee</th>
<th>Name &amp; Address</th>
</tr>
</thead>
</table>
| 1.    | Chairman                 | Prof. B. Suresh  
Vice-Chancellor, J. S. S. University,  
JSS Medical Institution Campus, Sri Shivarathreeshwara Nagara,  
Mysore-570 015 |
| 2.    | Member                   | Drugs Controller General (I)  
Dte. General of Health Services,  
FDA Bhawan, Kotla Road,  
New Delhi. |
| 3.    | Member                   | Professor (Dr.) Lalji Singh,  
Vice-Chancellor,  
Banaras Hindu University,  
Varanasi -221 005 (U.P). |
| 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:

<table>
<thead>
<tr>
<th>S. No.</th>
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</tr>
</thead>
</table>
| 1.     | Chairman                 | Prof. B. Suresh  
        |              | Vice-Chancellor,  
        |              | J. S. S. University,  
        |              | JSS Medical Institution Campus,  
        |              | Sri Shivarathreeshwara Nagara,  
        |              | Mysore-570 015   |
| 2.     | Member                   | Dr. G. N. Qazi   
        |              | Vice Chancellor,  
        |              | Jamia Hamdard  
        |              | Hamdard University, ‘A’ Category – NAAC,  
        |              | Hamdard Nagar,  
        |              | New Delhi-110 062. |
| 3.     | Member                   | Dr. N. Udupa     
        |              | Principal,  
        |              | Manipal College of Pharmaceutical Sciences,  
        |              | Madhav Nagar,  
        |              | Manipal-576 104.  
        |              | Karnataka  |
| 4.     | Member                   | Professor M. R. Yadav   
        |              | Pharmacy Department,  
        |              | Faculty of Technology and Engineering,  
        |              | The M. S. University of Baroda,  
        |              | Vadodara– 390 001 (Gujarat)  |
| 5.     | Member                   | Dr. Venugopal     
        |              | WHO Temporary Advisor,  
        |              | A 11, Sarvodaya Enclave,  
        |              | New Delhi-110 017.  |
| 6.     | Member                   | Dr. D. B. Anantha Narayana   
        |              | Former Director, Hindustan Lever Research Centre,  
        |              | #15 (Old No 1101/927),  
        |              | 1 “F” Main Road, 2nd Stage,  
        |              | Giri Nagar,  
        |              | Bangalore - 560085  |
| 7.     | Member                   | Professor Praveen Aggarwal,  
        |              | Professor in-charge,  
        |              | Department of Emergency Medicine,  
        |              | All India Institute of Medical Sciences (AIIMS),  
        |              | Ansari Nagar, New Delhi-110 029.  |
| 8.     | Member                   | Professor Y. K. Gupta   
        |              | Head, Department of Pharmacology,  
        |              | All India Institute of Medical Sciences (AIIMS),  
<pre><code>    |              | Ansari Nagar, New Delhi.  |
</code></pre>
<table>
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<th></th>
<th>Member</th>
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</table>
| 9 | Member                                     | Professor (Dr.) Lalji Singh  
Vice-Chancellor,  
Banaras Hindu University,  
Varanasi -221 005 (U.P) India                             |
| 10| Member                                     | Dr. S. M. Mudda  
Executive Director – Technical & Operations,  
Micro Labs Limited,  
27, Race Course Road,  
Bangalore-560 001.                                         |
| 11| Member                                     | Dr. Manish Gangrade  
Head-Analytical Development Lab,  
CIPLA Limited,  
L.B.S. Marg, Vikhroli (W),  
Mumbai-400 083.                                             |
| 12| Member                                     | Dr. J. P. Mehta  
Plant Manager,  
Franco-Indian Pharmaceuticals Pvt. Ltd.,  
20, Dr.E. Moses Road,  
Worli, Mumbai-400 011.                                       |
| 13| Member                                     | Dr. Vinay G. Nayak  
President Technical Operations  
International Business Division  
Alembic Ltd, Alembic Road,  
Vadodara – 390003                                            |
| 14| Member                                     | Mr. Vinod Arora  
Vice President (Pharma Research),  
Ranbaxy Research Laboratories,  
Plot No. 20, Sector 18, Udyog Vihar Industrial Area,  
Gurgaon-122 001.                                             |
| 15| Member                                     | Dr. S. S. Jadhav  
Executive Director,  
Quality Assurance & Regulatory Affairs,  
Serum Institute of India Ltd.,  
212/2, Hadapsar,  
Pune-411 028.                                                 |
| 16| Member                                     | Prof. Rakesh Kumar Sharma  
Additional Director and Head, CBRN Defence  
Institute of Nuclear Medicine and Allied Sciences (INMAS),  
Brig SK Mazumdar Marg,  
Delhi 110 054 INDIA                                           |
| 17| Member                                     | The Joint Commissioner (Testing),  
Food & Drugs Laboratory,  
Nr. Polytechnic,  
Baroda – 390 002 (Gujarat)                                  |
<table>
<thead>
<tr>
<th>Member Number</th>
<th>Name</th>
<th>Position and Details</th>
</tr>
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<tr>
<td>18</td>
<td>Member</td>
<td>Dr. S. Y. Pandey&lt;br&gt;D. Y. Pandey&lt;br&gt;Director&lt;br&gt;Chemistry and Business Development&lt;br&gt;Jai Research Foundation&lt;br&gt;Daman Ganga Bridge, N.H. No. 8, Valvada - 396 108 , Dist. Valsad, Gujarat.</td>
</tr>
<tr>
<td>19</td>
<td>Member</td>
<td>Dr. H. G. Koshia&lt;br&gt;Commissioner&lt;br&gt;Food &amp; Drugs Control Administration&lt;br&gt;Government of Gujarat&lt;br&gt;Block No. 8, 1st Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar-382 010.</td>
</tr>
<tr>
<td>20</td>
<td>Member</td>
<td>Dr. Prasad V. Kanitkar&lt;br&gt;Director, Plant Operations&lt;br&gt;Pfizer Global Manufacturing&lt;br&gt;Pfizer Limited&lt;br&gt;Thane Belapur Road, K.U. Bazar Post, Turbhe, Navi Mumbai-400 705.</td>
</tr>
<tr>
<td>21</td>
<td>Member</td>
<td>Dr. Anurag Rathore&lt;br&gt;Associate Professor&lt;br&gt;Department of Chemical Engineering&lt;br&gt;Indian Institute of Technology&lt;br&gt;Hauz Khas, New Delhi-110 016.</td>
</tr>
<tr>
<td>22</td>
<td>Member</td>
<td>Mr. R. Sridharan&lt;br&gt;603, Sarangi, Lokpuram, Thane (W) – 400 610</td>
</tr>
<tr>
<td>23</td>
<td>Member-Secretary (ex-officio)</td>
<td>Dr. G. N. Singh&lt;br&gt;Secretary-cum-Scientific Director&lt;br&gt;Indian Pharmacopoeia Commission&lt;br&gt;Sector-23, Rajnagar&lt;br&gt;Ghaziabad-201 002</td>
</tr>
<tr>
<td>1</td>
<td>Special Invitee</td>
<td>Dr. B. R. Jagashetty&lt;br&gt;Former Drugs Controller of Karnataka&lt;br&gt;Flat No. 702/402, Ram Sridhar Apts, BTM 2nd Stage, 16th Main, Aicoboonagar, Bangalore-560 076</td>
</tr>
<tr>
<td>2</td>
<td>Special Invitee</td>
<td>Mr. S. S. Venkatakrishnan&lt;br&gt;InviteeFormer Drugs Controller of Kerala&lt;br&gt;12/548, (GNRA 47), Dhanyasree, Vrindavanam Gardens, Old P O Lane, Kodunganoor, Thiruvananthapuram-695 013</td>
</tr>
</tbody>
</table>
The composition of the **National Consultative Committee (NCC) of the Indian Pharmacopoeia Commission** is as follows:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Designation in Committee</th>
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<tbody>
<tr>
<td>1.</td>
<td>Chairman</td>
<td>Dr. Vishwa Mohan Katoch, Secretary to the Govt. of India (DHR), and Director General, Indian Council of Medical Research, Ramalingaswamy Bhawan, Ansari Nagar, New Delhi-110 029.</td>
</tr>
<tr>
<td>2.</td>
<td>Co-Chairman</td>
<td>Mr. R. K. Jain Additional Secretary &amp; Director General (CGHS) Ministry of Health &amp; Family Welfare Nirman Bhawan New Delhi-110 011.</td>
</tr>
<tr>
<td>3.</td>
<td>Member</td>
<td>Dr. Surinder Singh Director (I/C), National Institute of Biologicals B-62, Institutional Area Noida-201 307</td>
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<tr>
<td>4.</td>
<td>Member</td>
<td>Professor (Dr.) Lalji Singh Vice-Chancellor, Banaras Hindu University, Varanasi -221 005 (U.P) India</td>
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<td>6.</td>
<td>Member</td>
<td>Professor C. K. Kokate Vice-Chancellor KLE University Belgaum</td>
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<tr>
<td>7.</td>
<td>Member</td>
<td>Dr. G. N. Qazi Vice-Chancellor, Jamia Hamdard Hamdard University, ‘A’ Category – NAAC, Hamdard Nagar, New Delhi-110 062.</td>
</tr>
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</table>
| Member | Professor Y. K. Gupta  
Head, Department of Pharmacology,  
All India Institute of Medical Sciences (AIIMS),  
Ansari Nagar,  
New Delhi. |
|--------|---------------------------------|
|        | Dr. P. V. Appaji  
Executive Director  
Pharmaceuticals Export Promotion Council (Pharmexcil)  
101, Aditya Trade Centre,  
Ameerpet,  
Hyderabad-500 038. |
|        | Mr. M. Ayyapan  
C&MD  
HLL  
Mahilamandiram Road  
Poojappura  
Thiruvananthapuram-695 1012. |
|        | Drugs Controller General (I) (I/C),  
Directorate General of Health Services  
Ministry of Health & Family Welfare  
FDA Bhawan, Kotla Road,  
New Delhi. |
|        | Dr. B.E. Rao  
WHO Consultant and  
Ex-CMD, IDPL  
906, Amsri,  
Central Court (Old Lancer Road)  
Secunderabad- 500 025. |
|        | Dr. M. Bamji  
Former Director Grade Scientist  
National Institute of Nutrition  
211 Sri Datta Sai Apartments  
RTC Cross Road  
Hyderabad-500 020. |
|        | Mr. Pankaj Patel  
C&MD  
Cadila Health Care  
Zydus Tower  
Satellite Cross Road  
Ahmedabad- 380 015. |
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<td>15.</td>
<td>Dr. Sudershan Arora</td>
<td>President, Ranbaxy Research Laboratory Plot No. 20, Sector 18 Udyog Vihar Gurgaon.</td>
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<th><strong>Member-Secretary</strong></th>
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<td>16.</td>
<td>Dr. G. N. Singh</td>
<td>Secretary-cum-Scientific Director Indian Pharmacopoeia Commission Sector-23, Rajnagar Ghaziabad-201 002</td>
</tr>
</tbody>
</table>
Expert Working Groups

**Review of IP Work**
Mr. J.L. Sipahimalani (*Chair*), Mr. R. Raghunandanana, Mr. R. Sridharan.

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

**Anti-Cancer**
Dr. K.V. Jogi (*Chair*), Dr. B. Nagaraju, Dr. N. Padmaja, Mr. Mohan Jain.

**Anti-Retroviral**
Dr. Manish Gangrade (*Chair*), Dr. Antony Raj Gomes, Ms. Rashmi Srivastava, Dr. Suryanarayana Muluktla.

**Radiopharmaceuticals**
Dr. Rakesh Kumar Sharma (*Chair*), Dr. M.G.R. Rajan, Dr. N.C. Goomer, Dr. N. Shivaprasad, Dr. Aruna Korde, Dr. Sanyog Jain.

**Biologics**
Dr. Surinder Singh (*Chair*), Dr. Anurag Rathore, Dr. S.S. Jadhav.

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

**General Chapters**
Dr. V.G. Nayak (*Chair*), Dr. Sunil Nadkrani, Mr. Antony R. Gomes, Dr. Vinay Aroskar, Dr. Pramod Dalvi, Dr. Sunder Kalyana Balaji, Mr. Kundan D. Patil, Mr. Deepak Jakate, Mr. Sanjay Deshpandey, Dr. V. B. Malkar, Mr. Mohan Jain, Dr. Luis Countinho.

**General Chapters on Dosage forms**
Mr. Vinod Arora (*Chair*), Dr. Prashant Dixit.

**Herbal Products**
Dr. D.B.A. Narayana (*Chair*), Dr. Amit Agrawal, Dr. G. Patani, Dr. Pulok Mukherjee, Dr, M.N. Nanjan, Dr. C.K. Katiyar.

Sub-group on Essential Oils
Dr. Ramakant Harialkha, Mr. B. Murali, Dr. Rahul Singh, Ms. Bhuvana Nageswaran, Dr. Hema Lohani.

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

**Medical Devices**
Dr. Ishwar Reddy (*Chair*).
Microbiology- General
Dr. J.P. Mehta (Chair), Dr. Gopa Ghosh, Mr. S.N. Chavan, Dr. Jadhav, Mr. A.P. Mohan, Dr. P. K. Chitnis, Mr. Ashok Desai.

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

Parenteral Preparation- General
Mr. Satish R. Kulkarni (Chair), Mr. Hemal Patel, Mr. Vijay V. Kshirsagar, Mr. H.T. Nazare, Mr. S.L. Jat, Mr. Sudhir Pandya.

Veterinary Products
Mr. Rishendra Verma (Chair), Dr. V.A. Srinivas.

Vaccines
Mr. S.S. Jadhav (Chair), Dr. Arun Bhardwaj, Dr. V.A. Srinivasan, Dr. Sumant Sharachchandra Karnik, Dr. Sunil Gairola, Dr. Mahesh Bhalgat, Mr. Anil Sood, Mr. P.M. Patel, Mr. Parag P. Nagarkar, Dr. K. Anand Kumar.

Biological and rDNA Products
Dr. Anurag Rathore (Chair), Mr. S.S. Jadhav, Dr. Venkata Ramana, Dr. Sriram Akundi, Mrs. Kinnari Vyas, Mr. Arvind Kukreti, Dr. Renu Jain, Dr. Rahul Kulkarni, Dr. Himanshu Gadgil, Dr. Satyanarayana Subrahmanyam., Ms. Seema Shimpi and Dr. Samir Sangitrao

Website
Dr. D.B.A. Narayana (Chair), Dr. Venugopal, Mr. G.S. Bedi.
1. Preparation of Manuscript of IP 2014

The following admissions, upgradations, changed titles and omissions were made as per the suggestions received from various stakeholders, subject experts and the concerned committees. The final manuscript of IP 2014 was checked by the subject experts and officials of IPC and send for printing.

(i) Admissions

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

**General Chapters**

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

Acamprosate Calcium
Acesulfame Potassium
Acetretin Capsules
Aciclovir Cream
Aciclovir Dispersible Tablets
Aciclovir Eye Ointment
Aciclovir Oral Suspension
Acitretin
Adefovir Dipivoxil
Adefovir Tablets
Adenosine
Adenosine Injection
Adipic Acid
Albendazole Oral Suspension
Alfalcacidol
Alfuzosin Hydrochloride
Alfuzosin Prolonged-release Tablets
Alfuzosin Tablets
Alprazolam Prolonged-release Tablets
Alprostadil
Alprostadil Injection
Aminophylline Prolonged-release Tablets
Amiodarone Intravenous Infusion
Amisulpride
Amisulpride Tablets
Amorolfine Hydrochloride
Aprotinin
Aripiprazole
Ascorbyl Palmitate
Aspirin Gastro-resistant Tablets
Atomoxetine Hydrochloride
Atracurium Besylate Injection
Atracurium Besylate
Azelaic acid
Azelastine Eye Drop
Azelastine Hydrochloride
Bambuterol Hydrochloride
Bambuterol Tablets
Benazepril Hydrochloride
Benazepril Hydrochloride Tablets
Benzoyl Peroxide Cream
Benzoyl Peroxide Gel
Betahistine Mesilate
Betamethasone Valerate Cream
Betaxolol Eye Drops
Betaxolol Hydrochloride
Bezafibrate
Bezafibrate Tablets
Bicalutamide
Bicalutamide Tablets
Bortezomib
Cabergoline
Calciotrol
Calcipotriol Anhydrous
Calcipotriol Ointment
Calcitonin (Salmon)
Calcitonin (Salmon) Injection
Calcium Dextrose Monohydrate
Carboplatin
Carboplatin Injection
Carboxymethylcellulose Calcium
Carboxymethylcellulose Eye Drops
Carisoprodol
Cefipime Injection
Cefipime Sulphate
Ceftiofur Sodium
Cefuroxime
Cilostazol
Cilostazol Tablets
Citicoline Sodium
Clemastine Fumarate
Clemastine Tablets
Clindamycin Injection
Clindamycin Phosphate
Clobetasol Cream
Clobetasol Ointment
Clobetasol Propionate
Clobetasol Butyrate
Clobetasone Cream
Corn Oil
Cottonseed Oil
Crotamiton
Crotamiton Cream
Alfacyclodextrin
Betacyclodextrin
Cyclopentolate Eye Drops
Cyclopentolate Hydrochloride
Cyclosporine
Cyclosporine Capsules
Dalteparin Sodium
Dalteparin Sodium Injection
Desmopressin
Desmopressin Intranasal Solution
Diclofenac Prolonged-release Tablets
Diltiazem Injection
Dipivefrine Eye drops
Dipivefrine Hydrochloride
Dipyridamole
Dipyridamole Tablets
Divalproex Prolonged-release Tablets
Dobutamine Hydrochloride
Dobutamine Injection
Docetaxel Anhydrous
Domperidone Suspension
Dopamine Hydrochloride
Dopamine Injection
Doxapram Hydrochloride
Doxapram Injection
Drotaverine Tablets
Dutasteride
Ebastine
Eberconazole Nitrate
Entacapone
Ephedrine Nasal Drops
Epinastine Eye Drops
Epinastine Hydrochloride
Eplerenone
Eptifibatide
Eptifibatide Injection
Erlotinib Hydrochloride
Erlotinib Tablets
Esmolol Hydrochloride
Ethambutol Injection
Ethanolamine
Ethophylline and Theophylline Tablets
Ethyl Vanillin
Ethylparaben
Etidronate Disodium
Etidronate Tablets
Etoricoxib
Etoricoxib Tablets
Ezetimibe
Ezetimibe Tablets
Famiciclovir
Famiclovir Tablets
Flavoxate Hydrochloride
Flavoxate Tablets
Flucloxacillin Capsules
Flucloxacillin Oral solution
Flucloxacillin Sodium
Fludarabine Phosphate
Fludarabine Phosphate Injection
Flumazenil
Flumazenil Injection
Fluorometholone
Fluorometholone Eye Drops
Flupentixol Decanoate
Flupentixol Injection
Flurazepam Capsules
Flurazepam Hydrochloride
Flurbiprofen Eye Drops
Flurbiprofen Sodium
Flutamide Tablets
Fluticasone Cream
Fluticasone Nasal Spray
Fluticasone Ointment
Fluvastatin Capsules
Fluvastatin Sodium
Fluvoxamine Maleate
Fluvoxamine Tablets
Fosinopril Sodium
Fosinopril Sodium Tablets
Gemcitabine Hydrochloride
Gemcitabine Injection
Gemfibrozil
Gemfibrozil Capsules
Glutaraldehyde Solution
Strong Glutaraldehyde Solution
Glycerin Oral Solution
Diluted Glyceril Trinitrate
Hydrocortisone Ointment
Hydrocortisone Acetate Cream
Hydrogenated Vegetable Oil
Hydroxychloroquine Sulphate
Hydroxychloroquine Tablets
Hydroxyethylcellulose
Hydroxypropyl Methylcellulose Phthalate
Hydroxypropyl Methylcellulose
Hydroxypropyl Methylcellulose Phthalate
Hydroxyzine Hydrochloride
Hydroxyzine Oral Solution
Hydroxyzine Tablets
Imatinib Tablets
Imidurea
Invert Syrup
Iopanoic Acid
Iopanoic Acid Tablets
Irbesartan
Irbesartan and Hydrochlorothiazide Tablets
Irbesartan Tablets
Iron and Folic Acid Syrup
Iron and Folic Acid Tablets
Isopropyl Palmitate
Isopropyl Rubbing Alcohol
Isotretinoin
Tranexamic Acid Injection
Tranexamic Acid Tablets
Triclofos Oral Solution
Triclofos Sodium
Ursodeoxycholic Acid
Ursodeoxycholic Acid Tablets
Vecuronium Bromide
Vecuronium Bromide Injection
Voglibose
Voglibose Dispersible Tablets
Voglibose Tablets
Zonisamide
Zopiclone
Zopiclone Tablets
Zuclopenthixol Acetate
Zuclopenthixol Acetate Injection
New Drugs Substances Monographs
Agomelatine
Arbidol Hydrochloride
Arterolane Maleate
Asenapine Maleate
Atosiban Acetate
Azelnidipine
Azacitidine
Biapenam
Brinzolamide
Choline Fenofibrate
Dapoxetine Hydrochloride
Dexlansoprazole
Dienogest
Eletriptan Hydrobromide
Eslicarbazepine
Fasotecronium Fumarate
Fasudil Hydrochloride
Fenspiride Hydrochloride
Fingolimod Hydrochloride
Fomepizole
Frovatriptan Succinate
Galanthamine Hydrobromide
Ibudilast
Ilaprazole
Iloperidone
Levo Bupivacaine Hydrochloride
Lubiprostone
Moexipril Hydrochloride
Naproxinod
Ramelteon
Rilpivirine
Roflumilast
Rufinamide
Safinamide Methane Sulphonate
Seratrodast
Tapentadol Hydrochloride
Tauroursodeoxycholic Acid
Tofluprost
Tolvaptan
Tranilast
Trimethobenzamide Hydrochloride
Udenafil
Ulipristal Acetate
Antibiotic Monographs
Colistimethate Injection
Colistimethate Sodium
Colistin Sulphate
Colistin Tablets
Gramicidin
Natamycin
Natamycin Ophthalmic Suspension
Netilmicin Sulphate
Sisomicin Sulphate
Sisomicin Sulphate Injection
Teicoplanin
Tyrothricin
Radiopharmaceutical Monographs
Radiopharmaceuticals
(\(^{131}\)I) Meta-Iodobenzyl Guanidine Injection for Diagnostic Use
(\(^{131}\)I) Meta-Iodobenzyl Guanidine Injection for Therapeutic Use
Fluorodeoxyglucose (\(^{18}\)F) Injection
Samarium (\(^{153}\)Sm) Ethylene Diamine Tetramethylene Phosphonate (EDTMP) Injection
Sodium Fluoride (\(^{18}\)F) Injection
Sodium Iodide (\(^{131}\)I) Capsules for Diagnostic Use
Sodium Iodide (\(^{131}\)I) Capsules for Therapeutic Use
Sodium Iodide (\(^{131}\)I) Solution
Sodium Pertechnetate (\(^{99m}\)Tc) Injection (Fission)
Sodium Pertechnetate (\(^{99m}\)Tc) Injection (Non-fission)
Sodium Phosphate (\(^{32}\)P) Injection
Technetium (\(^{99m}\)Tc) DMSA Injection
Technetium (\(^{99m}\)Tc) DTPA Injection
Technetium (\(^{99m}\)Tc) EC Injection
Technetium (\(^{99m}\)Tc) ECD Injection
Technetium (\(^{99m}\)Tc) Glucoheptonate Injection
Technetium (\(^{99m}\)Tc) Mbrofenin Injection
Technetium (\(^{99m}\)Tc) Medronate Complex Injection
Technetium (\(^{99m}\)Tc) MIBI Injection
**Herbal Monographs**

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

**Human Vaccines**

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

Rotavirus Vaccine (Live Attenuated, Oral)

**Insulin Products**

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

**Biotechnology Products**

Erythropoietin for Injection

**Veterinary Non-biological Monographs**

Activated Charcoal
Adrenaline Tartrate
Albendazole Oral Suspension
Amitraz Pour-on
Amoxicillin Oral Powder
Amoxicillin Injection
Ampicillin Injection
Ampicillin Sodium
Ampicillin Trihydrate
Benzocaine
Benzyl Benzocate Application
Benzylpenicillin Injection
Benzylpenicillin Potassium
Benzylpenicillin Sodium
Betamethasone Injection
Betamethasone Sodium Phosphate
Buserelin
Buserelin Injection
Calcium Levulinate Injection
Carprofen
Cefoperazone Injection
Cefoperazone Sodium Intramammary Suspension
Cefpodoxime Oral Suspension
Cefpodoxime Tablets
Ceftizoxime for Injection
Ceftizoxime Sodium
Ceftriaxone Injection
Chloramphenicol
Chloramphenicol Sodium Succinate
Chlorpheniramine Injection
Chlorpromazine Hydrochloride
Chlorpromazine Injection
Cholecalciferol
Chorionic Gonadotropin
Ciprofloxacin Injection
Ciprofloxacin Tablets
Cloprednin Injection
Cloprednin Sodium
Closantel Sodium Dihydrate
Cloxacillin Injection
Cloxacillin Sodium
Cynocobalamin
Cynocobalamin Injection
Decoquinate
Decoquinate Premix
Deltamethrin
Deltamethrin Pour-on
Dexamethasone Injection
Dexamethasone Sodium Phosphate
Diacepam
Diacepam Injection
Diclazuril
Dicloxacillin Sodium
Diethylcarbamazine Citrate
Diethylcarbamazine Tablets
Docetaxel Injection
Enrofloxacin
Febantel
Febendazole Granules
Fenbendazole Oral Paste
Fenbendazole Oral Powder
Fenbendazole Oral Suspension
Ferrous Fumarate Tablets
Flunixin Meglumine
Frusemide Injection
Furazolidone
Gentamicin Injection
Iron Dextran Injection
Isoflupredone Acetate
Isoflupredone Acetate Injectable Suspension
Ivermectin Oral Paste
Ivermectin Pour-on
Levamisole Hydrochloride
Levofloxacin Hemihydrate
Light Kaolin
Light Magnesium Carbonate
Lignocaine Hydrochloride
Lignocaine Injection
Lincomycin Hydrochloride
Magnesium Sulphate
Marbofloxacin
Meloxicam Injection
Mepyramine Injection
Mepyramine Maleate
Methyl Ergometrine Injection
Methylprednisolone Acetate
Methylprednisolone Acetate Injection
Monosulfram
Morphine Injection
Morphine Sulphate
Moxidectin
Moxidectin Injection
Neomycin Sulphate
Nicolsamide
Oestradiol Benzoate
Oestradiol Injection
Oxazalone
Oxytetracycline Hydrochloride
Oxytetracycline Hydrochloride Injection
Oxytetracycline Injection
Paclitaxel Injection
Pentobarbitone Sodium
Promethazine Hydrochloride
Promethazine Injection
Pyridoxine Hydrochloride
Sodium Dihydrogen Phosphate Dihydrate
Sodium Thiosulphate
Streptomycin Sulphate
Sulphadiazine and Trimethoprim Tablets (Combination Tablets)
Sulphadimidine
Sulphadimidine Injection
Sulphadimidine Sodium
Sulphadimidine Tablets
Sulphadiazine
Testosterone Propionate
Testosterone Propionate Injection
Thiabendazole
Tinidazole Tablets
Tocopheryl Acetate
Trimethoprim
Xylazine Hydrochloride
Zinc Oxide Cream

**Veterinary Biological Monographs**
Bluettongue Vaccine Inactivated
Brucella Abortus (Strain 19 Vaccine) Live
Brucella Melitensis (Strain Rev. 1) Vaccine, Live,

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

**Veterinary Diagnostic Monograph**
Avian Tuberculin Purified Protein Derivative (PPD)

**Veterinary Immunoserum Monographs**
Clostridium Novyi Alpha Antitoxin
Clostridium Perfringens Antitoxins
Clostridium Perfringens Beta Antitoxin
ii) Amendment List 1 to IP 2014

Worked on the queries/suggestions received from different stakeholders including pharma industries and after discussing and taking views of the subject expert group for IP, the same was finalized and put up on website for appropriate time and released on 31.03.2014 by the Secretary-cum-Scientific Director of IPC. Total more than 100 amendments taken place in the monographs/tests.

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

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

iv) Verification of Analytical methods for IP

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

1. Verified related substance test of Rabeprazole API.
2. Verified related substance of Paracetamol Oral Suspension.
3. Verified assay of Levotrigine Dispersible Tablets.
4. Verified uniformity of content of Indapamide Tablets.
5. Verified assay of Atorvastatin Tablets.
7. Verified full monographs of Citicoline Tablets.
8. Verified related substance of Piroxicam API.
9. Verified full monograph of Torsemide API.
13. Verified full monograph of Dorzolamide API.
15. Verified related substance of Atenolol.
17. Verified dissolution of Nifedipine SR Tablets.
18. Verified assay & uniformity of content of Cyproheptidine Tablets.
19. Verified assay of Thyrroxine Sodium Tablets.
22. Verified assay of Clotrimazole Cream.
24. Verified solubility of Menthol.
27. Verified full monograph of Cisplatin Injection.
28. Verified Uniformity of content of Glibenclamide
29. Verified dissolution of Ormeloxifene HCl Tablets.
30. Verified assay of Lamivudine Tablets.
31. Verified full monographs of Sitagliptin Tablets.
32. Verified assay of Ranitidine Tablets.
33. Verified assay of Diacerein Tablets.
34. Verified full monograph of Raloxifene HCl Tablets.
35. Verified full monograph of Barium Sulphate.
36. Verified assay of Efanavir Capsules.
38. Verified of Misoprostol Tablets.
39. Verified full monographs of Brimonidine Tartrate.
40. Verified assay of Carvedilol Tablets.
41. Verified dissolution of Ursodiol Tablets.
42. Verified full monograph of Natamycin Sodium.
43. Verified related substance of Donepizol HCl.
44. Verified full monograph of Ranitidine Oral Solution.
45. Verified full monograph of Tadalafil Tablets.

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

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

1) Monographs on Herbal Drugs

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

New monographs included in IP 2014 are:

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

New and revised monographs in Addendum 2015 to IP 2014:

<table>
<thead>
<tr>
<th>New Monographs</th>
<th>Revised Monographs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birmi (Taxus wallichiana)</td>
<td>Amaltas (Cassia fistula)</td>
</tr>
<tr>
<td>Asthsmaharta (Cissus quadrangularis)</td>
<td>Vidanga (Embelia ribes)</td>
</tr>
<tr>
<td>Shankhpushpi (Convolvulus pluricaulis)</td>
<td></td>
</tr>
</tbody>
</table>

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

2) Monographs on Biologicals

a. Biotechnology derived Products

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

New monographs included in IP 2014 are:

<table>
<thead>
<tr>
<th>Insulin Monographs</th>
<th>New Monographs</th>
<th>Revised Monographs</th>
<th>General Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Aspart</td>
<td>Biotech Monographs</td>
<td>Monographs</td>
<td>General Chapter</td>
</tr>
<tr>
<td>Insulin Aspart Injection</td>
<td></td>
<td></td>
<td>Biotechnology Derived</td>
</tr>
<tr>
<td>Insulin Lispro</td>
<td></td>
<td></td>
<td>Therapeutic Products</td>
</tr>
<tr>
<td>Insulin Lispro Injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biphasic Insulin Aspart Injection</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Biphasic Insulin Lispro Injection | Interferon Beta 1a Concentration Solution | Recombinant Streptokinase for Injection |                                     |

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

b. **Blood and blood products**

New monographs included in IP 2014 are:

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

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

c. **Human Vaccines**

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

Pharmacopoeial vaccine monographs in IP contain information including the definition of the vaccine relative to the monograph title followed by specifications. The specifications cover the various tests for critical quality parameters of the vaccine, procedures and acceptance criteria.
New monographs included in IP 2014 are:

**New Monographs**

- Diphtheria Vaccine (Adsorbed) for Adults and Adolescents
- Group A Meningococcal Conjugate Vaccine
- Diphtheria Vaccine (Inactivated, Oral)
- Meningococcal Polysaccharide A & C Vaccine
- Rotavirus Vaccine (Live Attenuated, Oral)
- Cholera Vaccine (Inactivated, Oral)
- Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b Conjugate Vaccine (Adsorbed)
- Meningococcal Polysaccharide A & C Vaccine
- Hepatitis B Vaccine (rDNA)
- Rotavirus Vaccine (Live Attenuated, Oral)
- Measles, Mumps and Rubella Vaccine (Live)
- Pneumococcal Polysaccharide Vaccine (Liquid / Adsorbed)
- Poliomyelitis Virus (Inactivated)
- Tetanus Vaccine (Adsorbed)

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

3) **Veterinary Monographs**

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

**New Non Biological Monographs**: 37
- Amitraz Pour-on
- Amoxicillin Oral Powder
- Buserelin
- Buserelin Injection
- Carbpenen
- Cefoperazone Sodium Intramammary Suspension
- Cefizoxime Sodium
- Cefizoxime for Injection
- Cloprostenol Sodium
- Cloprostenol Injection
- Closantel Sodium Dihydrate
- Decoquinante
- Decoquinante Premix
- Dehtamethrin
- Dehtamethrin Pour-on
- Diethyliru
- Enrofloxacin
- Febantel
- Febendazole Granules
- Fenbendazole Oral Paste
- Fenbendazole Oral powder
- Fenbendazole Oral Suspension
- Flunixin Megglumine
- Isoflupredone Acetate
- Isoflupredone Acetate Injectable Suspension
- Ivermectin Oral Paste
- Ivermectin Pour-on
- Marbofloxacin
- Meloxicam Injection
- Moxidectin
- Moxidectin Injection
- Sulphadiazine and Trimethoprim Tablets (Co-trimazine Tablets)
- Sulphadimidine
- Sulphadimidine Sodium
- Sulphadimidine Injection
- Sulphadimidine Tablets
- Xylazine Hydrochloride

**Revised Monograph :14**

**New Biological Monographs**: 13
- Bluetongue Vaccine Inactivated
- Brucella Abortus (Strain 19 Vaccine) Live
- Brucella Melitensis (Strain Rev 1) Vaccine, Live
- Canine Adenovirus Vaccine, Inactivated
- Canine Adenovirus Vaccine, Live
- Haemorrhagic Septicaemia Vaccine-Alum Treated
- Laryngotrichitis Vaccine, Live (Avian Infectious Laryngotrichitis Vaccine, Live)
- Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats
- iudium novyi Alpha Antitoxin
- iudium perfringens Antitoxins
- iudium perfringens Beta Antitoxin
- iudium perfringens Epsilon Antitoxin
- ius Antitoxin (Clostridium Tetani Antitoxin)
- **New Diagnostics Monograph :01**
- Avian Tuberculin Purified Protein Derivative (PPD)
- **New Surgicals Monographs :07**
- Catgut in Distributor
- Non-absorbable Strands in Distributor
- Linen Thread in Distributor
- Poly (ethylene terephthalate) Suture in Distributor
- Polyamide 6/6 Suture in Distributor
- **New General Chapter :01**
- Cultures for the Production of Veterinary Vaccines
- **General Monograph :05**
- Veterinary liquid preparations for cutaneous application
- Intrauterine Preparations
- Veterinary Oral Pastes
- Veterinary Immunsera
- Terminology Used in Monographs on Veterinary Vaccines

38
Infectious Bursal Disease Vaccine, Inactivated
Infectious Chicken Anaemia Vaccine, Inactivated
Infectious Coryza Vaccine, Inactivated
Marek’s Disease Vaccine, Live
Ranikhet Disease Vaccine, Inactivated
Reo Virus Vaccine, Inactivated
Salmonella Vaccine, Inactivated
Salmonella pullorum Antigen to Salmonella pullorum Coloured Antigen
Anthrax Spore Vaccine
Avian Infectious Bronchitis Vaccine, Inactivated
Avian Spirochaetosis Vaccine, Inactivated
Blackquarter Vaccine
Fowl Cholera Vaccine, Inactivated
Inclusion Body Hepatitis (IBH) Vaccine, Inactivated

4) National Formulary of India (2011)
The monographs, chapters and appendices in the 4th Edition of NFI is thoroughly revised for 5th Edition of NFI.

5) New Drug Analysis: 02
Actively participated in analysis of new drug samples related to herbal drugs and veterinary drugs received in the department

6) Microbiological testing of drugs
Microbial Bioassay of candidate reference material of IPRS: 08
- New Drugs Samples: 35 for microbiological testing
- Port Samples: 09 for microbiological testing
- Miscellaneous Drug Samples: 06 for microbiological testing

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

7) National and International audits for accreditation of testing labs
- Pre-qualification audit of microbiological laboratory was conducted by a team of assessors of WHO, as a initial process of WHO accreditation procedure for laboratories.
- Successfully completed NABL Surveillance Audit 2013

8) Monographs and related work from microbiological division
- Addition of new Antibiotics monographs in IP 2014: 13
- New General chapters: 03

New Antibiotics Monographs: 13
- Colistimethate Sodium
- Colistimethate Injection
- Colistin Sulphate
- Colistin Tablet
- Gramicidin
- Natamycin
- Bacterial Endotoxin Test
- Microbial contamination in non sterile products
- Bacterial Endotoxin Test: Included in 47 Parenteral Preparations Monographs in IP 2014,
- 08 Blood and Blood Related Products Monographs,
- 03 Veterinary Monographs
- Test for *Shigella* included in Microbial Contamination Test: 16 Monograph.

9) **Technical coordination with WHO**

- Prepared working document on Good Pharmacopoeial Practices on
  a) Monograph on Herbals
  b) Analytical test procedures and methodologies
Reference Standard Division

Indian Pharmacopoeia Laboratory

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

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

1. LC-MS/MS  Q-TOF Agilent 6520
2. NMR, Agilent 500/54/AR,Cryostat,
3. GC-MS Triple Quad  Agilent 7890A
4. GC-HS  Agilent 7890A
5. ICP –MS 6000, Perkin Elmer , Model: NexION 300X,
6. HPLC, Agilent 1200 Series
7. HPLC, DionexUltimet 3000
8. HPLC, Water 2695
9. UV-VIS, Lamda35
10. Atomic Absorption Spectrometer, Model- Agilent, AA240 series,
11. FT-IR  Spectrum one Perkin Elmer
12. FTIR, Perkin Elmer, FT microscope spotlight 200 & frontier
13. Polarimeter, Perkin Elmer-241
14. Mettler Toledo Autotitrator T-50
15. Mettler Toledo DL55 Titrator
16. Mettler Toledo KF Titrator
17. TGA/DSC Mettler Toledo Model Star è System
18. Coulometric KF Titrator (C-30) Mettler Toledo
19. Digital Tablet Dissolution Test Apparatus, LABINDIA, DISO TEST
20. Tablet Dissolution Tester (USP24), Electrolab
21. Dionex ICS-5000 DC, Ion Chromatograph with VWD, ECD & Conductivity Detectors
22. Euro Vector Elemental Analyser  Model : EURO EA3000
23. Particle Size Analyzer, Model: Microtrac S3000/S3500,
24. Microwave reaction system, Model: Multiwave 3000, Perkin Elmer,
25. pH Meter, Mettler Toledo, Seven Compact 5220
26. pH Meter, Mettler Toledo, Seven Easy
27. Sartorius Microbalance CPA2P  Part I & II
28. Analytical Balance- Mettler Toledo XP205
29. Analytical Balance-Mettler Toledo, XP2U
30. DSC – 6000, Perkin Elmer
31. Vacuum Oven, NSW-251
32. Muffle Furnace, Toshiba
33. NSW-143 Oven
34. Sonar Serlogical Water bath
35. Rei-Services Ultrasonic
36. Prolabo-Ultrasound
37. Water Purifier, Millipore
IP Reference Substances (IPRS)

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

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

Activity of Indian Pharmacopoeia Laboratory

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

1- IPRS Development

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

1. Abacavir Sulphate
2. Acebutolol Hydrochloride
3. Acetaminophen
4. Acetazolamide
5. Aciclovir
6. Allopurinol
7. Alprazolam
8. Amantadine Hydrochloride
9. Ambroxol Hydrochloride
10. Amiloride Hydrochloride
11. Aminophylline
12. Amiodarone Hydrochloride
13. Amitriptyline Hydrochloride
14. Amlodipine Besylate
15. Amodiaquine Hydrochloride
16. Amoxycillin Sodium
17. Amoxycillin Trihydrate
18. Ampicillin
19. Ampicillin Sodium
20. Ampicillin Trihydrate
21. Anastrozole
22. Artemether (Artemether)
23. Artesunate
24. Ascorbic Acid (Vit. C)
25. Aspirin
26. Atazanavir Sulphate
27. Atenolol
28. Atorvastatin Calcium
29. Atropine Sulphate
30. Azathioprine
31. Baclofen
32. Beclomethasone Dipropionate
33. Benzhexol Hydrochloride
34. Benzocaine
<p>| 35. | Betahistine Hydrochloride |
| 36. | Betamethasone Dipropionate |
| 37. | Betamethasone Valerate |
| 38. | Bisacodyl |
| 39. | Bromhexine Hydrochloride |
| 40. | Bronopol |
| 41. | Buclizine Hydrochloride |
| 42. | Budesonide |
| 43. | Buspirone Hydrochloride |
| 44. | Caffeine |
| 45. | Calcium Gluconate |
| 46. | Calcium Levulinate |
| 47. | Capecitabine |
| 48. | Captopril |
| 49. | Carbazepine |
| 50. | Carbipil |
| 51. | Carvedilol |
| 52. | Cefaclor |
| 53. | Cefadroxil |
| 54. | Cefepime Hydrochloride |
| 55. | Cefixime |
| 56. | Cefoperazone Sodium |
| 57. | Cefotaxime Sodium |
| 58. | Cefpodoxime Proxetil |
| 59. | Cefuroxime Axetil |
| 60. | Cefuroxime Sodium |
| 61. | Cephalexin |
| 62. | Cetirizine Dihydrochloride |
| 63. | Chloramphenicol |
| 64. | Chloramphenicol Palmitate |
| 65. | Chlorhexidine Hydrochloride |
| 66. | Chlorhidrosepoxide |
| 67. | Chlorhexidine Hydrochloride |
| 68. | Chloroquine Phosphate |
| 69. | Chloroquine Sulphate |
| 70. | Chlorpheniramine Maleate |
| 71. | Chlorothalidone |
| 72. | Clindamycin Clofazimine |
| 73. | Clindamycin Hydrochloride |
| 74. | Clotrimazole |
| 75. | Clofazimine |
| 76. | Cloflamoxacin Hydrochloride |
| 77. | Clembaline Hydrobromide |
| 78. | Clarithromycin |
| 79. | Clindamycin Clofazimine |
| 80. | Clofazimine |
| 81. | Clomipramine Hydrochloride |
| 82. | Clomipramine Hydrochloride |
| 83. | Clonazepam |
| 84. | Clopidogrel Bisulphate |
| 85. | Cntrolazol |
| 86. | Cloxacillin Sodium |
| 87. | Cyanoobalamin (Vit. B12) |
| 88. | Cycloheximide Hydrochloride |
| 89. | Cycloserine |
| 90. | Cyproheptadine Hydrochloride |
| 91. | Cyproterone Acetate |
| 92. | Cytarabine |
| 93. | Dexamethasone Sodium Phosphate |
| 94. | Dextromethorphan Hydrobromide |
| 95. | Diacerein |
| 96. | Diazeppam |
| 97. | Dalcolfenac Sodium |
| 98. | Dicloxacillin Sodium |
| 99. | Diclofenac Sodium |
| 100. | Dimethoate Maleate |
| 101. | Donepezil Hydrochloride |
| 102. | Doflumoxime Hydrochloride |
| 103. | Doxepin Hydrochloride |
| 104. | Doxofylline |
| 105. | Disodium Edetate |
| 106. | Disosulpham |
| 107. | Divalproex Sodium |
| 108. | Divalproex Sodium |
| 109. | Divalproex Sodium |
| 110. | Divalproex Sodium |
| 111. | Divalproex Sodium |
| 112. | Divalproex Sodium |
| 113. | Divalproex Sodium |
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| 130. | Divalproex Sodium |
| 131. | Divalproex Sodium |
| 132. | Divalproex Sodium |
| 133. | Divalproex Sodium |
| 134. | Divalproex Sodium |
| 135. | Divalproex Sodium |
| 136. | Divalproex Sodium |
| 137. | Divalproex Sodium |
| 138. | Divalproex Sodium |
| 139. | Divalproex Sodium |
| 140. | Divalproex Sodium |
| 141. | Divalproex Sodium |
| 142. | Divalproex Sodium |
| 143. | Divalproex Sodium |
| 144. | Divalproex Sodium |
| 145. | Divalproex Sodium |
| 146. | Divalproex Sodium |</p>
<table>
<thead>
<tr>
<th>No.</th>
<th>Compound</th>
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<tbody>
<tr>
<td>147.</td>
<td>Furazolidone</td>
</tr>
<tr>
<td>148.</td>
<td>Fusidic Acid</td>
</tr>
<tr>
<td>149.</td>
<td>Gatifloxacin</td>
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<tr>
<td>150.</td>
<td>Gefitinib</td>
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<td>151.</td>
<td>Gemifloxacin Mesylate</td>
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<tr>
<td>152.</td>
<td>Gentamicin Sulphate</td>
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<tr>
<td>153.</td>
<td>Glibenclamide</td>
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<tr>
<td>154.</td>
<td>Glycine</td>
</tr>
<tr>
<td>155.</td>
<td>Glyceryl Salicylate</td>
</tr>
<tr>
<td>156.</td>
<td>Griseofulvin</td>
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<tr>
<td>157.</td>
<td>Guaiphenesin</td>
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<td>158.</td>
<td>Haloperidol</td>
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<tr>
<td>159.</td>
<td>Homatropine Methylbromide</td>
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<tr>
<td>160.</td>
<td>Hydralazine Hydrochloride</td>
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<tr>
<td>161.</td>
<td>Hydrochlorothiazide</td>
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<tr>
<td>162.</td>
<td>Hydrocortisone Acetate</td>
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<tr>
<td>163.</td>
<td>Hydralazine Sulfate</td>
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<tr>
<td>164.</td>
<td>Hyosine Butyl Bromide</td>
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<tr>
<td>165.</td>
<td>Ibuprofen</td>
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<tr>
<td>166.</td>
<td>Imatinib Mesylate</td>
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<tr>
<td>167.</td>
<td>Imipramine Hydrochloride</td>
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<td>168.</td>
<td>Indapamide</td>
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<td>169.</td>
<td>Indomethacin</td>
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<tr>
<td>170.</td>
<td>Isoniazid</td>
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<tr>
<td>171.</td>
<td>Isosorbide Dinitrate Diluted (40 %)</td>
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<tr>
<td>172.</td>
<td>Isoxsuprin Hydrochloride</td>
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<tr>
<td>173.</td>
<td>Ivermectin</td>
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<td>174.</td>
<td>Ivermectin Hydrochloride</td>
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<td>175.</td>
<td>Ketamine Hydrochloride</td>
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<td>Ketoconazole</td>
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<td>Ketoprofen</td>
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<td>178.</td>
<td>Ketorolac Tromethamine</td>
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<td>Labelotol Hydrochloride</td>
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<td>Lamivudine</td>
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<td>Lansoprazole</td>
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<td>183.</td>
<td>Levamisole Hydrochloride</td>
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<td>Levamisole Sulfate</td>
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<td>185.</td>
<td>Levodopa</td>
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<td>186.</td>
<td>Levofloxacin Hemihydrate</td>
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<td>Levodilum Sulphate</td>
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<td>188.</td>
<td>Lignocaine Hydrochloride</td>
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<tr>
<td>189.</td>
<td>Lindane (Gama Benzene Hexachloride)</td>
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<td>190.</td>
<td>Linzolid</td>
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<td>191.</td>
<td>Lisinopril</td>
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<td>Lithium Carbonate</td>
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<td>Loperamide Hydrochloride</td>
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<td>Lopinavir</td>
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<td>195.</td>
<td>Losartan Potassium</td>
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<td>Magaldrate</td>
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<td>197.</td>
<td>Mannitol</td>
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<td>199.</td>
<td>Mebeverine Hydrochloride</td>
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<td>200.</td>
<td>Meclizine Hydrochloride</td>
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<td>Mefenamic Acid</td>
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<td>202.</td>
<td>Mefloquine Hydrochloride</td>
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<td>203.</td>
<td>Meropenem</td>
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<td>204.</td>
<td>Metformin Hydrochloride</td>
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<td>205.</td>
<td>Methotrexate</td>
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<td>206.</td>
<td>Methyl Prednisolone</td>
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<td>207.</td>
<td>Methyl Salicylate</td>
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<td>208.</td>
<td>Methylprednisolone Acetate</td>
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<td>209.</td>
<td>Metoclopramide Hydrochloride</td>
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<td>210.</td>
<td>Metoprolol Tartrate</td>
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<td>211.</td>
<td>Metronidazole</td>
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<tr>
<td>212.</td>
<td>Metronidazole Benzoate</td>
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<tr>
<td>213.</td>
<td>Micofenolate Sodium Sesquihydrate</td>
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<td>214.</td>
<td>Micronidazole Nitrate</td>
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<td>215.</td>
<td>Minoxidil</td>
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<td>216.</td>
<td>Mometasone Furoate</td>
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<td>217.</td>
<td>Montelukast Sodium</td>
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<td>218.</td>
<td>Mosapride Citrate Dihydrate</td>
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<td>219.</td>
<td>Mycophenolate Mofetil</td>
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<td>220.</td>
<td>Nandrolone Phenyl Propionate</td>
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<td>221.</td>
<td>Naproxen</td>
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<td>222.</td>
<td>Nebivolol Hydrochloride</td>
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<td>223.</td>
<td>Neomycin Sulphate</td>
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<td>224.</td>
<td>Nevirapine</td>
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<tr>
<td>225.</td>
<td>Nicotinamide (Niacinamide)</td>
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<tr>
<td>226.</td>
<td>Nicotinic Acid (Niacin)</td>
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<td>227.</td>
<td>Nicoumalone</td>
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<td>228.</td>
<td>Nifedipine</td>
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<td>229.</td>
<td>Nitrazepam</td>
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<td>230.</td>
<td>Nitrofurantoin</td>
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<td>231.</td>
<td>Norethisterone</td>
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<td>232.</td>
<td>Norfloxacin</td>
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<td>233.</td>
<td>Nystatin</td>
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<td>234.</td>
<td>Ofloxacin</td>
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<td>235.</td>
<td>Olanzapine</td>
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<td>236.</td>
<td>Omeprazole</td>
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<td>237.</td>
<td>Ondansetron</td>
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<td>238.</td>
<td>Ondansetron Hydrochloride</td>
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<td>239.</td>
<td>Ornidazole</td>
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<td>240.</td>
<td>Orphenadrine Citrate</td>
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<td>241.</td>
<td>Oseltamivir Phosphate</td>
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<td>242.</td>
<td>Oxcarbazepine</td>
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<td>243.</td>
<td>Pantoprazole Sodium Sesquihydrate</td>
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<td>244.</td>
<td>Paracetamol</td>
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<tr>
<td>245.</td>
<td>Penicillamine</td>
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<td>246.</td>
<td>Pentazocine</td>
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<td>247.</td>
<td>Pheniramine Maleate</td>
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<td>248.</td>
<td>Phenobarbitalone</td>
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<td>249.</td>
<td>Phenoxylethanol</td>
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<td>Phenoxymethylpenicillin Potassium</td>
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<td>251.</td>
<td>Phenylephrine Hydrochloride</td>
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<td>252.</td>
<td>Phenylpropanolamine Hydrochloride</td>
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<td>253.</td>
<td>Phenyltoin Sodium</td>
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<tr>
<td>254.</td>
<td>Piroglitazone Hydrochloride</td>
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<td>255.</td>
<td>Pipercillin</td>
</tr>
<tr>
<td>256.</td>
<td>Piracetam</td>
</tr>
<tr>
<td>257.</td>
<td>Piroxicam</td>
</tr>
</tbody>
</table>
During the year 2013, additional 171 new IPRS including 8 Impurities were developed and updated on our website. 78 more candidate materials are under development for IPRS. To prove the stability of already developed IPRS, retesting of the IPRS are being done initially after 2 year than annually. Total 97 IPRS were retested for their integrity of potency.
- No. of IPRS/Impurity vials dispatched to Govt. drugs testing laboratories
  \[= 3426 \text{ and } 39\]
  \[= 3465 \text{ (Rs. 1, 04, 3400/- IPRS Supplied free of cost)}\]

- No. of IPRS / Impurity vials dispatched to Private companies / laboratories
  \[= (1629 \times 3000) = 48,8700/-\]
  \[+ (31 \times 40000) = 1,24,000/-\]

Grand Total
\[= 50,11,000/-\]
2- **New Drug analysis**

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

3- **Port Sample Analysis**

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

4- **Monograph Verification and Development for IP**

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

1. Agomelatine
2. Arbidol Hydrochloride
3. Arterolane Maleate
4. Asenapine Maleate
5. Atosibane Acetate
6. Azacitidine
| 7. | Azelnidipine                      | 26. | Lubiprostone                      |
| 8. | Biapenem                          | 27. | Mitiglinide Calcium Dihydrate     |
| 11. | Dapoxetine Hydrochloride          | 30. | Ramelteon                         |
| 12. | Dexlansoprazole                   | 31. | Rilpivirine                       |
| 13. | Dienogest                         | 32. | Roflumilast                       |
| 14. | Eletriptan Hydrobromide           | 33. | Rufinamide                        |
| 15. | Eslicarbazepine Acetate           | 34. | Safinamide Methane Sulphonate     |
| 16. | Fasoterdine Fumarate              | 35. | Seratrodast                       |
| 17. | Fasudil Hydrochloride             | 36. | Tapentadol Hydrochloride          |
| 18. | Fenspiride Hydrochloride          | 37. | Tauroursodeoxycholic Acid         |
| 19. | Fingolimod Hydrochloride          | 38. | Tofluprost                        |
| 20. | Fomepizole                        | 39. | Tolvaptan                         |
| 21. | Frovatriptan Succinate            | 40. | Tranilast                         |
| 22. | Galanthamine Succinate            | 41. | Trimethobenzamide Hydrochloride   |
| 23. | Ibudilast                         | 42. | Udenafil                          |
| 24. | Ilaprazole                        | 43. | Ulipristal Acetate                |
| 25. | Iloperidone                       |
Radiopharmaceutical Monographs

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

➢ TRAINING PROGRAMS:

1- Induction Training Program for newly recruited Drug Inspectors of CDSCO was organised by Indian Pharmacopoeia Commission, Ghaziabad in two phases from 15th July, 2013 to 02nd August, 2013 and 02nd September, 2013 to 20th September, 2013.

2- IPC Ghaziabad has successfully organised TRAINING PROGRAMME ON VARIOUS ANALYTICAL INSTRUMENTS & TECHNIQUES FOR GOVERNMENT DRUG ANALYSTS” from 25th November to 06th December 2013. Approx forty government analysts from various State Laboratories pan India had attended the same.

➢ ACCREDITATION:

1- NABL
To strengthen the quality system & documentation, globally accepted NABL certification ISO 17025 and NABL certification ISO 17025:2005 were achieved by
IPC in September 2011 for Chemicals and Biological Testing with full devotion of IPC staff within few months after filling the application in very first attempt. Recently NABL has extended their accreditation for two years after auditing RSD by their auditor for the 2 days (10th to 11th August, 2013) at IPC. Now the IPC is adopting uniform approach for determining laboratory competence, encourage laboratories to adopt internationally accepted testing and reliable results.

2- WHO

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

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

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

➢ QUALITY ASSURANCE

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

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

### List of Updated SOP

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Name of SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SOP for Change Control Procedure</td>
</tr>
<tr>
<td>2.</td>
<td>SOP for Internal Audit</td>
</tr>
<tr>
<td>3.</td>
<td>SOP for pH Meter</td>
</tr>
<tr>
<td>4.</td>
<td>SOP for Internal Proficiency Testing</td>
</tr>
</tbody>
</table>
Seminars/ Training Programmes / Symposia / Workshops / Meetings attended:

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

1. A meeting with Dr. Rishendra Verma, Joint Director, IVRI, Izzat Nagar wak held on 08.04.2013 on Veterinary monographs at IPC.


3. IPC team attended the WHO II\textsuperscript{nd} World Pharmacopoeia meeting at Oberoi Hotel, New Delhi on 18.04.2013 and 19.04.2013.

4. A meeting with experts Sh. J.L. Sipahimalani & Sh. R. Sridharan and Mr. V.K. Kapoor was held for reviewing IP-2014 manuscript volume-I and IV at IPC, from 13.05.2013 to 15.05.2013.

5. Meeting with Prof. B. Suresh, Chairman, Scientific Body and Dr. Nitya Anand, Ex-chairman, SB of IPC on 16.05.2013 at IPC for reviewing and planning IPC activities.

6. A meeting with experts Sh. J.L. Sipahimalani, Sh. R. Raghunandanand and Sh. R. Sridharan was held for reviewing IP-2014 Volume-II and III at IPC, from 29.05.2013 to 31.05.2013.

7. A meeting was held with Dr. K.V. Surindernath, Vice-President and Dr. Ashok Dang, Director from USP (India), Hyderabad at IPC on 27.06.2013.

8. “First Training Programme of Induction of Drug Inspector of CDSCO from 15.07.2013 to 02.08.2013” held at IPC. Dr. Jagdish Prasad, DGHS was Chief Guest and visited the IPC-IPL Facilities.

9. Sh. Desi Raju, Secretary, Ministry of Health & Family Welfare and Chairman, IPC was Chief Guest for the concluding session of the training Programme of Drug Inspectors of CDSCO and visited the IPC-IPL Facilities.

10. The Reassessment of NABL (ISO/IEC 17025:2005) accreditation of IPL of IPC was held from 10\textsuperscript{th} to 11\textsuperscript{th} August, 2013.

11. The Second Training Programme ‘Induction of Drug Inspectors of CDSCO from 02.09.2013 to 20.09.2013” was held at IPC.

12. The 27\textsuperscript{th} Scientific Body meeting was held at FDA, Bhawan, New Delhi on 14.09.2013.

14. A meeting with Chief Architect at Nirman Bhawan, New Delhi regarding clearance of DPR of proposed New Building of IPL at IPC was held on 14.10.2013.

15. 7th edition of Indian Pharmacopoeia IP-2014 was released by Hon’ble Health Minister, Mr. Gulab Navi Azad on 04.11.2013 at Nirman Bhawan, New Delhi.

16. Training Programme of Government Laboratory Analyst of Central and States was held in IPC from 25.11.2013 to 06.12.2013.

17. IPC technical team received Best Research Paper Award for the Year, 2015 in the field for Pharmaceutical Analysis on 04.01.2014.

18. The Second Scientific Body meeting of Pharmacopoeial Commission for Indian Medicine (PCIM) at CCRAS, New Delhi was attended by IPC technical staff on 3.01.2014.

19. WHO-QCL Pre-qualification Programme, Assessment by WHO, Geneva Team of IPC-IPL was held from 10th to 14th, Feb., 2014.

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

1. **Establishment of ADRs monitoring Centre**
   MCI approved medical institutions and corporate hospitals showed their willingness to participate in PvPI Programe. Several institutions submitted their letter of Intent to participate in PvPI. After assessing the suitability, 4th Working Group meeting held on 18th October recommended to induct 60 more ADRs monitoring centre (AMC) under PvPI.
   In total 150 AMCs are functioning to monitor and report ADRs to NCC.

2. **Generation of ADRs during the period of April 2013 to March 2014**
   Individual Case Safety Reports (ICSRs) submitted to NCC for the mentioned period was 36,651. (Total ICSRs in national drug safety database is 99,587).

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

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

5. **Documentation grading and Completeness Score for Indian ICSRs**
   As per the WHO-UMC assessment, the documentation and completeness score for Indian ICSRs for the above period was 0.83 (Annexure 3).
6. **Collaboration with Revised Tuberculosis Control Programme to monitor the safety of anti TB drugs**

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

7. **Assisting in Vaccine safety**

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

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

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

9. **Education and Training**

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

a. 1st CME was organized at the Department of Clinical Pharmacology, Sher-I-Kashmir Institute of Medical Science (SKIMS), at Srinagar (J&K) on 23rd October 2013. 150 delegates attended the Programme.

b. 2nd CME was organized at Dr. Rajendra Prasad Government Medical College Tanda (Kanagra), H.P. on 31st October 2013. 280 delegates had participated in the Programme.

c. 3rd CME was organized at U.P. Rural Institute of Medical Sciences and Research, Safai, Etawah, Uttar Pradesh on 8th November 2013. Over 210 delegates participated in the Programme.
d. 4th CME was organized at the Rajendra Institute of Medical Sciences at Ranchi, Jharkhand, on 30th November 2013. Over 260 delegates attended the Programme.
e. 5th CME was organized at Jawaharlal Nehru Medical College, Aligarh Muslim University, at Aligarh, U.P on 7th Nov. 2013. Over 80 delegates attended the Programme.
f. 6th CME was Organized by Indian Medical Association in Collaboration with NCC-PvPI at Chennai, Tamil Nadu on 22Feb. 2014. Over 60 delegates were educated in the Programme for Pharmacovigilance.

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

a. Induction cum training programme for the newly recruited Technical Associates (TAs) was organized by NCC from 10-13th February 2014 at IPC Ghaziabad. During this training programme 30 TAs participated and experienced on Pharmacovigilance practices and hands on training on VigiFlow.

b. 3rd Training cum meeting of coordinators and Technical Associate of North Zone was held on 27th July 2013 at Lecture Theatre Complex, PGIMER, Chandigarh. 20 participants participated in the programme.

c. East Zone Regional centre for Training and Technical Support organized a training programme at Auditorium of College of Nursing, IPGMER, Kolkata on 23 April 2013. Over 115 participants was present in the training programme.

d. A Training Programme on VigiFlow was organized by Regional Centre KEM on dated 15 April 2013 at KEM, Mumbai. 6 participants were present in the Programme.

10 Signal Review Panel Meeting

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

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

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

PROCUREMENT OF BOOKS:

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>ITEMS NAME</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Total Books Procured</td>
<td>322 (appx.)</td>
</tr>
</tbody>
</table>

PROCUREMENT OF NON-BOOK MATERIALS:

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

<table>
<thead>
<tr>
<th>S.No.</th>
<th>ITEMS NAME</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>CD/DVD-ROM</td>
<td>11</td>
</tr>
<tr>
<td>2.</td>
<td>Theses/Dissertations/Training Report</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>Magazines</td>
<td>17</td>
</tr>
<tr>
<td>4.</td>
<td>Newspaper</td>
<td>8</td>
</tr>
</tbody>
</table>
SUBSCRIPTION OF JOURNALS:

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

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

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

i) Document Delivery Services:

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

ii) Reference Service:

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

iii) CAS and SDI Service:

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

iv) Indexing and Abstracting:

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

v) News Paper Clipping:

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

vi) Reprographic Services:

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

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

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

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

**TRAINING PROGRAMME:**

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

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

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

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

PUBLICATIONS OF IPC

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Title of the Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Indian Pharmacopoeia (IP) 2014 (along with DVD)</td>
</tr>
<tr>
<td>2.</td>
<td>PvPI Pamphlets</td>
</tr>
<tr>
<td>3.</td>
<td>Brochure of Indian Pharmacopoeia (IP) 2014</td>
</tr>
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</table>
SALE & DISTRIBUTION OF IPC PUBLICATIONS

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

<table>
<thead>
<tr>
<th>S/N</th>
<th>IPC Publications</th>
<th>Total Copies Printed</th>
<th>Status</th>
<th>Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I.P. -2007</td>
<td>4894</td>
<td>Sold</td>
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<td></td>
<td></td>
<td></td>
<td>Compl.</td>
<td>1133</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total revenue generated = <strong>Rs. 31,500/-</strong></td>
</tr>
<tr>
<td>2.</td>
<td>I.P.-2007 Addendum 2008</td>
<td>1500</td>
<td>Sold</td>
<td>01</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Compl.</td>
<td>37</td>
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<tr>
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<td>Total revenue generated = <strong>Rs. 21,00/-</strong></td>
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<td>3.</td>
<td>I.P. -2010</td>
<td>3000</td>
<td>Sold</td>
<td>15</td>
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<td>Compl.</td>
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<td>Total revenue generated = <strong>Rs. 3,00,000/-</strong></td>
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<td>4.</td>
<td>DVD of I.P.- 2010</td>
<td>3000</td>
<td>Sold</td>
<td>17</td>
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<td></td>
<td></td>
<td></td>
<td>Compl.</td>
<td>162</td>
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<td>Total revenue generated = <strong>Rs. 3,50,000/-</strong></td>
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<td>Compl.</td>
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<td>Total revenue generated = <strong>NIL</strong></td>
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<td>6.</td>
<td>NFI-2011</td>
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<td>Sold</td>
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<td>Compl.</td>
<td>235</td>
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<td>Total revenue generated = <strong>Rs. 64,672/-</strong></td>
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<td>Compl.</td>
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<td></td>
<td>Total revenue generated = <strong>Rs.15,145/-</strong></td>
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<tr>
<td>8.</td>
<td>I.P. -2014</td>
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<tr>
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<td></td>
<td></td>
<td>Compl.</td>
<td>58</td>
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<td>Total revenue generated = <strong>Rs. 2,74,25,000/-</strong></td>
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<tr>
<td>9.</td>
<td>DVD of IP 2014</td>
<td>500</td>
<td>Compl.</td>
<td>36</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Total revenue generated = <strong>NIL</strong></td>
</tr>
</tbody>
</table>

Total = **Rs. 2,81,88,422/-**

Rupees Two Crore Eighty One Lakhs Eighty Eight Thousand Four Hundred Twenty Two Only
PHOTOGRAPHS OF IPC AT A GLANCE

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

Inauguration of Second Induction Course for Drug Inspectors of CDSCO in collaboration with IPC from 02-09-2013 to 20-09-2013 by Sh. S. K. Srivastava, Additional Secretary & Fin. Advisor, Min. of H&FW
Visit of Mr. Lahouari Belgharbi, WHO on 15-07-2013

New Modern Laboratory, IPC Visit of Dr. (Prof.) Jagdish Prasad, DG, DGHS, Min. of H&FW on 15-07-2013
**IPC STAFF (as on 31st March, 2014)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Gyanendra Nath Singh</td>
<td>Secretary-cum-Scientific Director</td>
</tr>
</tbody>
</table>

**Technical Staff**

**Research & Development Division**

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

**Pharmacology and Microbiological Division**

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

**Pharmaceutical Chemistry & Reference Substances Division**

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

Library and Publication Division

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

Store Division

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

Administration and Cash Division

Mr. I. J. S. Oberoi  Admn. Officer (I/C)
Mr. Udai Pal  Hindi Translator
Mr. Chandan Kumar  Finance & Accounts Officer
Ms. Renu Kapoor  Upper Divisional Clerk
Mr. Satyaveer Singh  Senior Laboratory Attendant
Mr. Rajendra Kumar Sharma  Peon
Statements of Account
2013-14