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Standards for drugs are of paramount importance for regulating the Quality, Safety and Efficacy of Drugs used in any country. The Indian Pharmacopoeia (IP) is the official book of standards prescribing standards of identity, purity and strength of drugs to be complied with by drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. IP is the book of standard of the country to be relied upon for quality control of the drugs in India by the regulatory bodies of the Central and States Drugs Control Organizations. The Pharmacopoeia contributes to the overall control of the quality of medicinal products by providing authentic norms of quality that a product, material or notified medical device is required to meet at any time during its period of use. The Pharmacopoeial Standards, which are publicly available and legally enforceable, are designed to be adopted for the licensing and quality control processes of drugs and are part of the system for safeguarding the health of consumers of medicinal products. The preparation and publication of pharmacopoeia is an exacting task and the rigors involved in preparing the Pharmacopoeia is extremely demanding as the efforts to work out the contents of the monographs of drugs prescribing parameters of quality, efficacy and efficiency are to be prescribed precisely. The field of drugs and pharmaceuticals change at enormous pace not only in the matter of new molecules and dosage forms being introduced but also in the matter of quality control and assurances as newer methods and techniques of identification and determination of purity and impurities are invented and adopted. The IP monographs are therefore to be reviewed and revised periodically to incorporate the changed needs and the IP itself is to be republished periodically incorporating all updates. Addenda are also to be published in between editions to notify and rectify errors if any, in the preceding edition and to incorporate additional monographs on priority basis. The Pharmacopoeial Standards are required to be upgraded regularly as the safety requirements tend to get more and more stringent also. In our country we had not given sufficient attention to streamline the preparation and publication of the Indian Pharmacopoeia, which has often led to criticism about our book of drug standards, its production and distribution and also had resulted in lack of updated national standards. Realizing the facts and also the administrative and scientific matters involved. After independence, the Indian Pharmacopoeia Committee was constituted in 1948, for publication of IP as its main function, which published the IP in 1955, followed by a Supplement in 1960. This Pharmacopoeia contained both western and traditional system drugs commonly used in India, and the same policy continued while preparing the Pharmacopoeia of India 1966 and its Supplement 1975. There had been a phenomenal growth and development of the Indian Pharma industry since independence, especially from early 1970 both in the range of Active Pharmaceutical Ingredients (APIs) and the dosage forms produced. This had totally transformed the profile of the Indian Pharmaceuticals market. Indian Pharma industry had emerged as one of the important global supplier of pharmaceutical products, both to the developed and developing countries. These developments posed major challenges for the IP to reflect the quality standards of the marketed drugs, which the subsequent editions of IP tried to address.
In view of these rapid advances, it was decided to publish a new edition of the Pharmacopoeia and its Addenda at regular and shorter intervals for which the Indian Pharmacopoeia Committee was reconstituted in 1978. In the Pharmacopoeia of India 1985, its Addenda 1989 and 1991, inclusion of traditional system of drugs were limited. However, most of the new drugs manufactured and/or marketed were included, while only those herbal drugs which had definitive quality control standards had got place in it. In view of the continuing rapid increase in the range of drugs produced in India, the IP 1996, its Addendum 2000, Supplement 2000 for Veterinary Products and Addenda 2002 were published. The Addendum 2005 was published by the IPC which included a large number of antiretroviral drugs, and raw plants commonly used in making medicinal products not covered by any other pharmacopoeias and attracted much global attention. The IP Committee decided to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medical need and extent of use of such articles in the country.

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

The sixth edition of the Indian Pharmacopoeia (IP 2010) has been published in accordance with the principles and designed plan decided by the Scientific Body of the IPC. To establish transparency in setting standards for this edition, the contents of new monographs, revised appendices and other informations have been publicized on the website of the IPC, besides following conventional approach of obtaining comments. The feedback and inputs were reviewed by the relevant Expert Committee to ensure the feasibility and practicability of the standards and methods revised. The principle of “openness, justice and fairness” is kept in mind during compiling and editing the contents of this edition. The IP 2010 incorporates 1918 monographs of drugs out of which 287 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc. 51 monographs were added in Addendum 2012 to IP 2010.

The work on edition of IP 2014 is under active progress. The manuscript has been prepared extensively examined and found worth to be complying with requirements. It is expected that the ensuring edition of IP 2014 will shortly roll out of the press for the usage and reference of stakeholders. The issue of preparation, certification and distribution of IP Reference Substances has been taken on war footing basis and Commission is ready to release 192 IPRS. The Commission is briskly analysing and validating the Certificate of Analysis (COA) of new drugs assigned to it by CDSCO. The Commission has been accredited by various accreditation bodies.
The Central Government established a full-fledged **Indian Pharmacopoeia Commission (IPC)**, an autonomous society registered under the Society Registration Act, 1860, to carry out the important, complicated and arduous job of preparing and publishing the Indian Pharmacopoeia (IP) periodically. While Indian Pharmacopoeia is a book of standards, the National Formulary of India is a book of reference to be used by medicinal practitioners, pharmacists and nurses. The task of publication of National Formulary of India was also assigned to the IP Commission. The work on the next edition of NFI has been commenced and it has optimized that the ensuring edition will come out shortly.
Introduction

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

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

A. “Standards of drugs” –

For drugs included in the Indian Pharmacopoeia:

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.

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

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

B. “Manner of Labelling.”

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

The name of the drug:

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

(a) for drugs included in Schedule F or Schedule F(1), the name given therein;

(b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters ‘I.P.’ or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters ‘N.F.I.’;
(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

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

C. “Use of letters I.P., etc.”

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

The Govt. of India have created a separate, dedicated, autonomous institution in the form of the Indian Pharmacopoeia Commission (IPC) to deal with matters relating to timely publication of the Indian Pharmacopoeia which is the official book of standards for drug included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940 so as to specify the standards of identify, purity and strength of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. The mandate of the Commission is to perform, inter-alia, functions such as revision and publication of the Indian Pharmacopoeia and National formulary of India on a regular basis besides providing Reference Substances for deciding the identity, purity and also detect impurities of drugs and for imparting training to the stakeholders on Pharmacopoeial issues. The Commission has become fully operational from 1st January, 2009 as an Autonomous Body, fully financed by the Central Government with specific budgetary allocations under the administrative control of the Ministry of Health and Family Welfare.

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

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

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

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

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

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

The day is not far when the state-of-the art laboratory will start functioning in the very campus of the Commission under the able guidance, blessings and support of Ministry’s officers.
From the Secretary-cum-Scientific Director’s Desk

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

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

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

With best wishes.

Dr.G.N.Singh
MISSION, VISION AND OBJECTIVES

Fig: 2-Functions of IPC

**Mission:** To protect and promote public health by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients, dosage forms and medical devices for use by health professionals, patients and consumers.

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

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

- To accord priority to monographs of drugs included in the national Essential Drugs List and their dosage forms.

- To prepare monographs for products that have normally been in the market for not less than 2 years except for certain special categories of new drugs like antiretrovirals, antituberculosis and anticancer drugs and their formulations introduced more recently needing priority attention.

- To give special attention to the methods of manufacture used by the indigenous industry in selecting the pharmacopoeial tests for monitoring the toxic impurities as applicable to such drugs.

- To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.
• To accelerate the processes of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products required.

• To collaborate with other pharmacopoeia commissions like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing the national standards with global standards without harming the National interests and concerns.

• To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/materials.
Composition of the Indian Pharmacopoeia Commission

Fig.-1 Structure of IPC
**Bodies of the IPC:**

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

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

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<tr>
<th>S. No.</th>
<th>Designation in Committee</th>
<th>Name &amp; Address</th>
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</thead>
</table>
| 1.     | Chairman                 | Shri Keshav Desiraju  
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                   | Shri R. K. Jain,  
Additional Secretary & Director General (CGHS)  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011. |
| 4.     | Member                   | Shri S. K. Srivastava  
Additional Secretary & Finance Advisor  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi -110 011. |
| 5.     | Member                   | Dr. Arun Kumar Panda  
Joint Secretary (R)  
Ministry of Health & Family Welfare,  
Nirman Bhawan  
New Delhi-110 011. |
| 6.     | Member                   | Dr. G. N. Singh  
Drugs Controller General (I),  
Directorate General of Health Services  
Ministry of Health & Family Welfare  
FDA Bhawan, Kotla Road, New Delhi. |
| 7.     | Member                   | Shri Shailendra Kumar  
Director (Drugs)  
Ministry of Health & Family Welfare  
Nirman Bhawan  
New Delhi-110 011 |
| 8.     | Member                   | Dr. Surinder Singh  
Director  
National Institute of Biologicals  
B-62, Institutional Area  
Noida-201 307 |
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| 9. | **Member** | Shri Shambhu Kallolikar  
Joint Secretary  
Department of Pharmaceuticals,  
Ministry of Chemicals and Fertilizers  
Shastri Bhawan, New Delhi |
| 10. | **Member** | President,  
Pharmacy Council of India,  
Combined Councils' Building,  
Kotla Road, Aiwan-E-Ghalib Marg,  
Post Box No. 7020  
New Delhi-110 002 |
| 11. | **Member** | Professor (Dr.) Lalji Singh,  
Vice-Chancellor,  
Banaras Hindu University,  
Varanasi -221 005 (U.P.) |
| 12. | **Member** | The Director  
Central Drugs Laboratory  
3, Kyd Street  
Kolkata |
| 13. | **Member** | From Regulatory Bodies  
Central Drugs Standard Control Organisation  
Directorate General of Health Services,  
FDA Bhawan, Kotla Road,  
New Delhi. |
| 14. | **Member** | Dr. C. Adithan  
Director-Professor  
Department of Pharmacology  
Jawaharlal Institute of Postgraduate Medical Education and Research  
Pondicherry-605 006. |
| 15. | **Member** | Commissioner in-charge of Drug Control Administration,  
Andhra Pradesh |
| 16. | **Member** | Commissioner in-charge of Drug Control Administration,  
Sikkim |
| 17. | **Member** | Commissioners in-charge of Drug Control Administration,  
Gujarat |
| 18. | **Member** | Commissioner in-charge of Drug Control Administration,  
Uttar Pradesh |
<table>
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<tr>
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<th>Name</th>
<th>Position and Details</th>
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<tr>
<td>19</td>
<td>Member</td>
<td>Commissioner in-charge of Drug Control Administration, Himachal Pradesh</td>
</tr>
<tr>
<td>20</td>
<td>Member</td>
<td>The Director National Institute of Pharmaceutical Education and Research (NIPER) Sector 67, SAS Nagar Mohali-160 062.</td>
</tr>
<tr>
<td>21</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>22</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>23</td>
<td>Member</td>
<td>Shri. D. G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA), Mumbai</td>
</tr>
<tr>
<td>24</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>25</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>
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</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>
<th>Designation in Committee</th>
<th>Name &amp; Address</th>
</tr>
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</table>
| 1.    | Chairman                 | Prof. B. Suresh  
            Vice-Chancellor,  
            J. S. S. University,  
            JSS Medical Institution Campus,  
            Sri Shivarathreeshwara Nagar,  
            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. B. Sesikeran  
            Director,  
            National Institute of Nutrition,  
            Jamai-Osmania Post Office,  
            Tarnaka Road, Hyderabad,  
            Andhra Pradesh 500 007. |
| 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,  
<pre><code>        |
</code></pre>
<table>
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<th>Member</th>
<th>All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi-110 029.</th>
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| 8.     | **Member** Professor Y. K. Gupta  
Head, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi. |
| 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., |
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| 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** | Dr. Patel Bharatkumar Natubhai  
Joint Commissioner (Testing),  
Food & Drugs Laboratory,  
Nr. Polytechnic,  
Baroda – 390 002 (Gujarat) |   |
| 18. **Member** | Dr. S. Y. Pandey  
Director,  
Chemistry and Business Development,  
Jai Research Foundation,  
Daman Ganga Bridge, N.H. No. 8,  
Valvada - 396 108 ,  
Dist. Valsad, Gujarat. |   |
| 19. **Member** | Dr. H. G. Koshia  
Commissioner,  
Food & Drugs Control Administration  
Government of Gujarat,  
Block No. 8, 1st Floor, Dr. Jivraj Mehta Bhavan,  
Gandhinagar-382 010. |   |
| 20 **Member** | Dr. Prasad V. Kanitkar  
Director, Plant Operations,  
Pfizer Global Manufacturing,  
Pfizer Limited,  
Thane Belapur Road,  
K.U. Bazar Post, Turbhe,  
Navi Mumbai-400 705. |   |
| 21. **Member** | Dr. Anurag Rathore,  
Associate Professor,  
Department of Chemical Engineering,  
Indian Institute of Technology,  
Hauz Khas, New Delhi-110 016. |   |
| 22. **Member** | Mr. R. Sridharan  
603, Sarangi,  
Lokpuram,  
Thane (W) – 400 610 |   |
| 23. **Member-Secretary (ex-officio)** | Dr. G. N. Singh  
Secretary-cum-Scientific Director  
Indian Pharmacopoeia Commission |   |
| Sector-23, Rajnagar  
| Ghaziabad-201 002 |
The composition of the **National Consultative Committee (NCC) of the Indian Pharmacopoeia Commission** is as follows:

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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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<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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Head, Department of Pharmacology,  
All India Institute of Medical Sciences (AIIMS),  
Ansari Nagar,  
New Delhi. |
|---|---|---|
|   | **Member** | **Dr. P. V. Appaji**  
Executive Director  
Pharmaceuticals Export Promotion Council (Pharmexcil)  
101, Aditya Trade Centre,  
Ameerpet,  
Hyderabad 500 038. |
|   | **Member** | **Mr. M. Ayyapan**  
C&MD  
HLL  
Mahilamandiram Road  
Poojappura  
Thiruvananthapuram-695 1012. |
|   | **Member** | **Drugs Controller General (I) (I/C),  
Directorate General of Health Services  
Ministry of Health & Family Welfare  
FDA Bhawan, Kotla Road,  
New Delhi.** |
|   | **Member** | **Dr. B.E. Rao**  
WHO Consultant and  
Ex-CMD, IDPL  
906, Amsri,  
Central Court (Old Lancer Road)  
Secunderabad- 500 025. |
|   | **Member** | **Dr. M. Bamji**  
Former Director Grade Scientist  
National Institute of Nutrition  
211 Sri Datta Sai Apartments  
RTC Cross Road  
Hyderabad-500 020. |
|   | **Member** | **Mr. Pankaj Patel**  
C&MD  
Cadila Health Care  
Zydus Tower  
Satellite Cross Road  
Ahmedabad- 380 015. |
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Expert Working Groups

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

**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.
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**Parenteral Preparation- General**
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**Veterinary Products**
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**Vaccines**
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**Biological and rDNA Products**
Dr. Anurag Rathore (*Chair*), Mr. S.S. Jadhav, Dr. Venkata Ramana, Dr. Anil Kukreja, Dr. Sriram Akundi, Dr. Jaideep Moitra, Mrs. Kinnari Vyas, Mr. Arvind Kukreji, Dr. Renu Jain, Dr. Sanjeev Kumar, Dr. Rahul Kulkarni, Dr. Himanshu Gadgil, Dr. Satyanarayana Subrahmanyam.

**Website**
Dr. D.B.A. Narayana (*Chair*), Dr. Venugopal, Mr. G.S. Bedi.
1. **New Monographs Drafted for next VII\textsuperscript{th} edition of IP**

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

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<td>Dipyridamole</td>
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<td>Divalproex Prolonged-release Tablets</td>
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<td>Flucloxacillin Capsules</td>
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<td>Flucloxacillin Oral solution</td>
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<td>Flucloxacillin Sodium</td>
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28
Ivermectin Injection
Labetalol Injection
Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
Lapatinib Ditosylate
Lapatinib Tablets
Leflunomide
Leflunomide Tablets
Levodropropizine
Levofloxacin Injection
Levosulbutamol Hydrochloride
Levosulbutamol Inhalation Solution
Lithium Carbonate Prolonged-release Tablets
Lorazepam
Lorazepam Injection
Lorazepam Tablets
Meloxicam
Mesalazine
Mesalazine Prolonged-release Tablets
Metoprolol Injection
Midazolam
Midazolam Injection
Midazolam Oral Solution
Mifepristone
Mifepristone Tablets
Misoprostol Tablets
Mitomycin
Mitomycin Injection
Monobasic Sodium Phosphate
Morphine Tablets
Moxifloxacin Eye Drops
Moxifloxacin Hydrochloride
Mupirocin
Mupirocin Ointment
Nicorandil
Nicorandil Prolonged-release Tablets
Nicorandil Tablets
Octyl dodecanol
Ofloxacin Oral Suspension
Ornidazole Injection
Oxacillin Capsules
Oxacillin Sodium
Ozagrel Hydrochloride
Paracetamol Infusion
Paracetamol Paediatric Oral Suspension
Parecoxib Sodium
Paroxetine hydrochloride
Paroxetine Tablets
Petrolatum
Phenylethyl Alcohol
Phenyramidol Hydrochloride
Phenyramidol Tablets
Pitavastatin Calcium
Polacrilin Potassium
Polyvinyl Acetate Phthalate
Polyvinyl Alcohol
Potassium Chloride for Injection
Prednisolone Sodium Phosphate Eye Drops
Premetrexed Disodium
Procarbazine Hydrochloride
Progesterone
Progesterone Injection
Propyl iodone
Propyl iodone Injectable Oil Suspension
Pyridostigmine Bromide
Pyridostigmine Injection
Pyridostigmine Tablets
Racecadotril
Racecadotril Capsules
Racecadotril Sachet
Raloxifene Hydrochloride
Rebamipide
Reboxetine Methanesulphonate
Repaglinide
Repaglinide Tablets
Risendronate Sodium
Ritodrine Hydrochloride
Ritodrine Injection
Ritodrine Tablets
Rupatidine Fumarate
Saquinavir Capsules
Selegiline Hydrochloride
Selegiline Tablets
Sertraline Hydrochloride
Sertraline Tablets
Silver Sulphadiazine
Silver Sulphadiazine Cream
Sodium Nitroprusside
Sodium Nitroprusside injection
Sodium Valproate Gastro-resistant Tablets
Sorafenib Tablets
Sorafenib Tosylate
Soyabean Oil
Strong Glutaraldehyde Solution
Sulpride
Sulpride Tablets
Surgical Spirit
Tenofovir fumarate, lamivudine and efavirenz tablets
Theophylline Prolonged-release Tablets
Tranexamic Acid
Tranexamic Acid Injection
Tranexamic Acid Tablets
Triclofos Oral Solution
Triclofos Sodium
Ursodeoxycholic Acid
2. Revision/Upgradation of existing monographs for VII\textsuperscript{th} edition of IP.

The following monographs were revised/ upgraded for next VII\textsuperscript{th} edition of IP in respect of different tests like Assay, Related substances etc.

1. Amikacin
2. Amikacin Injection
3. Amikacin Sulphate
4. Amiodarone Hydrochloride
5. Amiodarone Tablets
6. Ampicillin Trihydrate
7. Aspirin
8. Azithromycin
9. Azithromycin Tablets
10. Bupivacaine Hydrochloride
11. Bupivacaine Injection
12. Butylparaben
13. Caffeine
14. Cefuroxime Axetil
15. Chloroquine Phosphate
16. Chloroquine Phosphate tablets
17. Cholecalciferol Tablets
18. Clarithromycin
19. Clofazimine
20. Clofazimine Capsules
21. Clonidine Hydrochloride
22. Clotrimazole
23. Cloxacillin Sodium
24. Codeine Phosphate
25. Colchicine Tablets
26. Cyclizine Hydrochloride
27. Cyclophosphamide Injection
28. Diazepam
29  Digoxin  
30  Diphenhydramine Hydrochloride  
31  Dithranol  
32  Docetaxel Injection  
33  Donepezil Tablets  
34  Doxepin Hydrochloride  
35  Econazole Nitrate  
36  Etoposide  
37  Finasteride Tablets  
38  Fluphenazine Decanoate  
39  Fluphenazine Decanoate Injection  
40  Fluphenazine Hydrochloride  
41  Fumaric Acid  
42  Haloperidol  
43  Homatropine Hydrobromide  
44  Hydrochlorothiazide  
45  Hydrochlorothiazide Tablets  
46  Hyoscine Butylbromide  
47  Hyoscine Hydrobromide  
48  Hyoscine Hydrobromide Tablets  
49  Hyoscine Hydrobromide Injection  
50  Ipratropium Bromide  
51  Isoprenaline Hydrochloride  
52  Isoprenaline Injection  
53  Lamivudine  
54  Lamivudine, Nevirapine and Stavudine Dispersible Tablets  
55  Lamivudine and Zidovudine Tablets  
56  Lamotrigine Prolonged-release Tablets  
57  Levamisole Hydrochloride  
58  Levodopa  
59  Levofloxacin Hemihydrate  
60  Levonorgestrel Tablets  
61  Lignocaine and Adrenaline Injection  
62  Mepyramine Maleate  
63  Methadone Hydrochloride  
64  Methotrexate  
65  Methotrexate Injection  
66  Methotrexate Tablets  
67  Methylgermometrine Maleate  
68  Methylparaben  
69  Mexiletine Hydrochloride  
70  Mianserin Hydrochloride  
71  Montelukast Sodium  
72  Nicotinic Acid
73 Nitrazepam
74 Nortriptyline Hydrochloride
75 Ondansetron Oral Solution
76 Ondansteron Tablets
77 Orphenadrine Citrate
78 Orphenadrine Hydrochloride
79 Perphenazine
80 Phenobarbitone
81 Phentolamine Injection
82 Phentolamine Mesylate
83 Phenylephrine Hydrochloride
84 Phenytoin
85 Phenytoin Sodium
86 Pholcodine
87 Pilocarpine Nitrate
88 Pregabalin
89 Primaquine Tablets
90 Propylparaben
91 Pyridoxine Hydrochloride
92 Ramipril and Hydrochlorothiazide Tablets
93 Ranitidine Hydrochloride
94 Ribavirin
95 Salbutamol Syrup
96 Salicylic Acid
97 Salmeterol Xinafoate
98 S-amlodipine Besylate
99 Sodium Methylparaben
100 Sodium Propylparaben
101 Sodium Stibogluconate
102 Terbutaline Tablets
103 Thiotepa Injection
104 Thyroxine Tablets
105 Timolol Maleate
106 Tolbutamide
107 Tolnaftate
108 Travoprost Eye Drops
109 Triamterene
110 Trimethoprim
111 Tropicamide
112 Verapamil Injection
113 Vinorelbine Injection
3. **Revision/upgradation of General chapters for the next VIIth edition of IP.**

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

2.3.51. 2-Ethylhexanoic Acid  
2.3.53. Ammonium  
2.3.55. Fluorides  
2.4.35. Bulk Density and Tapped Density of Powders  
2.4.36. Completeness of Solution  
2.4.37. Crystallinity  
2.4.38. Specific Surface Area  
2.4.39. Mass Spectroscopy  
2.5.11. Polymorphism  
2.4.17. Thin-Layer Chromatography  
2.4.27. Refractive Index  
2.4.29. Weight Per Milliliter and Relative Density (Specific Gravity)  
2.4.34. Nuclear Magnetic Resonance Spectrometry  
2.5.7. Particle Size Distribution Estimation  
2.5.8. Optical Microscopy: Particle Size by Microscopy

4. **Amendment list 3 to IP 2010**

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

**AMENDMENTS**

2.2.10. Microbiological Assay of Antibiotics  
2.3.21. N,N-Dimethylaniline. Page 83  
2.3.27. Hydroxyl Value. Page 85  
Inhalation Preparations. Page 726  
Microbial contamination. Page 740  
Adrenaline Injection. Page 779  
Ampicillin. Page 2879  
Ampicillin Sodium. Page 2880  
Ampicillin Injection. Page 2880  
Ampicillin Trihydrate. Page 2881  
Bupivacaine Hydrochloride. Page 933  
Carvedilol Tablets. Page 992  
Cinnarizine. Page 1088  
Dextrose. Page 1190  
Docetaxel Trihydrate. Page 1242  
Doxycycline Hydrochloride. Page 1257
Specific optical rotation. Line 1
Imipenem. Page 1486
Miconazole Nitrate. Page 2933
Neotame. Page 1769
Ondansetron Oral Solution. Page 1818
Paracetamol Oral Suspension. Page 2940
Phenoxyethanol. Page 2942
Simvastatin Tablets. Page 2104
Streptomycin Sulphate. Page 2161
Sulphadiazine. Page 2169
Sulphadiazine Tablets. Page 2170
Telmisartan Tablets. Page 2960
Thiopentone Sodium. Page 2216
Thiopentone Injection. Page 2217
Travoprost Eye Drops. Page 2251
Zoledronic Acid. Page 2339

5. Amendment list 4 to IP 2010

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

AMENDMENTS

General Notices. Page 11, 713, 1731
2.2.9. Microbial Contamination in Non Sterile Products. Page 37
4.3. Indicators and Indicator Test Papers. Page 623
4.5. Volumetric Reagents and Solutions.
Amlodipine Tablets. Page 807
S-Amlodipine Besylate. Page 808
Amphotericin B. Page 820
Ampicillin Trihydrate. Page 2881
Aspirin. Page 2882
Azithromycin. Page 857
Barium Sulphate. Page 872
Compound Benzoic Acid Ointment. Page 887
Bupivacaine Injection. Page 934
Butylparaben. Page 942
Cefaclor Oral Suspension. Page 995
Cefuroxime Axetil. Page 1026
Cephalexin. Page 1031
Cholecalciferol Tablets. Page 2896
Ciclesonide Inhalation. Page 1083
Clarithromycin. Page 1101
Clomipramine Capsules. Page 1111
Clopidogrel Tablets. Page 1119
Absorbent Cotton. Page 1137
Crospovidone. Page 1141
Diclofenac Tablets. Page 2900
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Page</th>
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<tr>
<td>Diphenhydramine Hydrochloride.</td>
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<td>Glimepiride Tablets.</td>
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<td>Griseofulvin Tablets.</td>
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<td>Prednisolone Tablets.</td>
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<td>Propylparaben.</td>
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<td>Sorbitol Solution (70 per cent) (Crystallising).</td>
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<td>Sorbitol Solution (70 per cent) (Non-Crystallising).</td>
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6. **Amendment list 5 to IP 2010**

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

**AMENDMENTS**

2.4.22.Optical Rotation and Specific Optical Rotation. Page 143  
2.4.26. Solubility  
2.4.2. Atomic Absorption Spectrometry. Page 109  
2.4.4. Flame Photometry. Page 110  
2.5.2. Dissolution Test. Page 189  
4.2. General Reagents.  
4.3. Indicators and Indicator Test Papers  
4.5. Volumetric Reagents and Solutions.  
5.2. Biological Indicators. Page 639  
Capsules. Page 721  
Alprazolam. Page 786  
Alprazolam Tablets. Page 787  
Ampicillin B. Page 820  
Ampicillin Sodium. Page 824  
Ampicillin Injection. Page 825  
Atenolol. Page 847  
Atenolol Tablets. Page 848  
Atorvastatin Tablets. Page 850  
Azithromycin Oral Suspension. Page 860  
Benzhexol Hydrochloride. Page 884  
Calcitriol Capsules. Page 961  
Cefadroxil Oral Suspension. Page 2891  
Cefotaxime Sodium Injection. Page 1017  
Cefpodoxime Tablets. Page 1020  
Citric Acid Monohydrate. Page 1100  
Colchicine and Probenecid Tablets. Page 1132  
Crosscarmellose Sodium. Page 1139  
Dapsone. Page 1162  
Dicyclomine Tablets. Page 1206  
Activated Dimethicone. Page 1230  
Disodium Edetate. Page 1234  
Donepezil Hydrochloride. Page 1248  
Donepezil Tablets. Page 1249  
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Enoxaparin Injection. Page 1279  
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Fentanyl Citrate. Page 1339
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Framycetin Sulphate. Page 1388
Glibenclamide. Page 1414
Hydrochloric Acid. Page 1450
Dilute Hydrochloric Acid. Page 1450
Hyoscine Butylbromide. Page 1466
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Lithium Carbonate Tablets. Page 1596
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Heavy Magnesium Oxide. Page 1623
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Zidovudine, Lamivudine and Nevirapine Tablets. Page 2334
Zinc Sulphate Dispersible Tablets. Page 2970
Zinc Sulphate Oral Solution. Page 2970
8. **Verification of Analytical methods for IP**

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

1. Verification of related substance of Ampicillin Trihydrate as per IP & BP.
2. Verification of water content in Secnidazole API.
3. Verification of Nevirapine Tablets, identification test by UV.
4. Verification of dissolution test in Escitalopram Tablets.
5. Verification of Solubility test in Rizatriptan Benzoate.
6. Verification of Related Substance test in Amikacin Sulphate.
7. Verification of Assay in Bupivaccine HCl Injection.
8. Verification of Assay of Olanzapine Tablets.
9. Verification of Solubility in Atorvastatin Calcium.
10. Verification of FTIR Spectra of Citric Acid monohydrate & anhydrous citric acid.
11. Verification of solubility of Escitalopram Oxalate.
12. Verification of Disintegration time for Ondansetron Orally Disintegration Tablets.
13. Verification of LOD/Water content in Cefotaxime Sodium.
14. Verification of FTIR spectra of Fumaric Acid.
15. Verification of water content in Imitanib Mesylate.
17. Verification of Uniformity of content in Atorvastatin Tablets.
18. Verification of Solubility in Dapsone.
19. Verification of Related Substance test in Ondansetron Tablet.
20. Verification of Solubility in Cefixime.
21. Verification of Dissolution of Levonorgestrel Tablets.
22. Verification of Appearance of solution, light absorption & description in Irinotecan hydrochloride.
23. Verification of Assay of Sodiumcarboxymethylcellulose Eye Drops.
26. Repeated verification of water content of Imitanib Mesylate.
27. Verification of Assay of Psoralen.
28. Verification of Dissolution of Terbutaline Sulphate Tablets.
09. Development of Veterinary Monographs (IVth Vol. of IP-2014)

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

10. Development of New Drugs Monographs

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

11. IP Reference Standards Developments:

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

12. WHO Work for International Pharmacopoeia

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

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


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

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

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

1. Attended USP-International Training Programme at USP, Head Quarter, Rockville, M.D.,USA by the delegation of Dr. Raman Mohan Singh, Dr. P.K.Saini and Mr. Anuj Prakash on 29.4.12 to 5.5.12, organized by IPC-USP under MOU of collaboration.

2. 24th Scientific Body meeting was held at IPC, Ghaziabad on 12.05.2012.


4. USP, CEO Dr. Rogger Williams & other officials of USP visited IPC. They interacted and a brief meeting was held at IPC on 18.07.2012 with the employees of IPC.

5. A meeting/discussion at NIB, Noida on 18.07.2012 on Biological Standards with Scientific Delegation from USP, Rockville was attended by IPC officials.

6. A meeting of expert committee on Radio Pharmaceutical monographs for IP was held on 13.08.2012 at IPC, Ghaziabad.

7. 25th Scientific Body meeting was held at IPC, Ghaziabad on 29.08.2012.


10. IPC officials attended a Pharmacopoeial Education Programme on “validation and verification of compendial procedures” at Hyderabad on 05.10.2012 to 06.10.2012 organised by USP, India.

12. A meeting was conducted at RS Iyer Hall, IPC on 27.10.2012 with Padam Shree Dr. Nitya Anand, Ex-chairman of Scientific Body for various scientific and technical issues.

13. Attended 8th meeting for drafting of monographs and General Chapters on Radiopharmaceuticals for IP on dated 10.11.2012 at Tata Memorial Hospital, Mumbai.


15. A meeting was held on 01.01.2013 at IPC under the Chairmanship of Prof. B. Suresh, Chairman Scientific Body on the occasion of Foundation Day of IPC.


17. Attended a meeting on Veterinary monographs for IP on dated 23.01.2013 to 24.01.2013 at IPC, Ghaziabad.


22. A meeting was held at IPC, Ghaziabad with the expert group for developing IP monographs on Radiopharmaceutical preparations on dated 20.03.2013.
LIBRARY AND INFORMATION CENTRE

About the Library & Information Centre:

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

Mission:

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

Library & Information Centre (Section):

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

- Circulation Section
- Periodical Section
- Reference Section
- Reprographic Section
- Internet Section
PROCUREMENT OF BOOKS:

The Library & Information Centre houses an excellent collection of more than 11,000 documents including books, Indian & International Standards, and Pharmacopoeias of different Countries. The IPC Library & Information Centre has procured the books to support Scientific, Pharmacopoeial and Administrative work during the year (01/04/2012 – 31/03/2013) as appended below:

<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>439</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 (01/04/2012 – 31/03/2013):

<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>6</td>
</tr>
<tr>
<td>2.</td>
<td>USB Flash Drive</td>
<td>3</td>
</tr>
<tr>
<td>3.</td>
<td>Theses/Dissertations/Training Report</td>
<td>8</td>
</tr>
<tr>
<td>4.</td>
<td>Magazines</td>
<td>17</td>
</tr>
<tr>
<td>5.</td>
<td>Newspaper</td>
<td>8</td>
</tr>
</tbody>
</table>

SUBSCRIPTION OF JOURNALS:

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

DIGITALIZATION OF LIBRARY & INFORMATION CENTRE:

As part of the ongoing modernisation exercise, the Library & Information Centre has changed its face by installing FineDocs Document Management Software. The Document Management Software is for 5-Users and preserved Indian Pharmacopoeia with addendum since 1957, National Formulary of India (NFI) and Bound Volume of Journals (All issues of 19 Titles since 1965). The Users can easily access the relevant information through this software and also save the data in mass storage, take print out, copy or edit etc. The software also allows the free text searching.
LIBRARY & INFORMATION CENTRE SERVICES DURING THE YEAR 01/04/2012 – 31/03/2013:

The IPC Library & Information Centre provides the following services during the year 01/04/2012 to 31/03/2013 to support Scientific, Pharmacopoeial and Administrative work:

i) Document Delivery Services:

The IPC Library & Information Centre has issued/consulted approximately 326 books to its staff during the year 01/04/2012 to 31/03/2013.

ii) Reference Service:

The Library & Information Centre maintains a separate reference collection consisting of rare and costly reference books on various areas of science. The IPC Library & Information Centre provided the reference service to staff members and external users. Approximately 4854 books has been consulted during the year 01/04/2012 to 31/03/2013.

iii) CAS and SDI Service:

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

iv) Indexing and Abstracting:

The Library & Information Centre provided the Index and Abstracts of subscribed national and 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 1341 pages during the year 01/04/2012 to 31/03/2013.

vii) Electronic Information Resource Access:

The Internet Section of Library & Information Centre is equipped with 10 computers with printer and latest configuration. The staff members including PvPI Technical Associates have utilized the service during the year.
viii) CD/DVD-ROM Database search:

The Library & Information Centre provides the CD/DVD-ROM database search facility to their staff members. The CD-ROM of British Pharmacopoeia, European Pharmacopoeia, United State Pharmacopoeia, USB Flash Drive of USP 2013, International Pharmacopoeia, DVD of Indian Pharmacopoeia, and Pharmacokinetic Profiling in Drug Research have been searched during the year 01/04/2012 to 31/03/2013.

LIBRARY & INFORMATION CENTRE EXPENDITURE:

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

TRAINING PROGRAMME:

The Library & Information Centre provided the training programme to students, research scholars and officials from Institutes, Universities and Government Departments during the year 01/04/2012 to 31/03/2013 taking into account their professional background and needs for meeting the challenges of current times. During the year 8 students/research scholars have undergone training from different departments of Indian Pharmacopoeia Commission. Moreover, during the year many students, research scholars and Officials from GOI have visited the Indian Pharmacopoeia Commission like from Karnataka State Drugs Control, CSIR-NISCAIR, DIPSAR, KIET School of Pharmacy, Gitarattan International Business School.
INTRODUCTION

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

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

PUBLICATIONS OF IPC

The following Official Publications are published by the Indian Pharmacopoeia Commission during the financial year 01.04.2012 to 31.03.2013. The details are as appended below:-

<table>
<thead>
<tr>
<th>S. No.</th>
<th>TITLE OF THE PUBLICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Guidance Manual for Compliance of Indian Pharmacopoeia (IP)</td>
</tr>
</tbody>
</table>
SALE & DISTRIBUTION OF IPC PUBLICATIONS

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

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

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

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

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

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

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

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

As on date, there are 90 AMCs spread across the four zonal offices of CDSCO are functioning under NCC. ADRs related to drugs, biologicals including blood and blood related products, recombinant DNA derived therapeutic products, vaccines and medical
devices are being reported to these AMC’s, in a specially designed ADR reporting form, which are transmitted to NCC after proper evaluation at each level.

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

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

Mission

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

Vision

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

Objectives

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

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

To analyse the benefit - risk ratio of marketed medications.

To generate the evidence based information on safety of medicines.

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

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

To emerge as a national centre of excellence for Pharmacovigilance activities.
To collaborate with other national centres for the exchange of information and data management.

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

**Scope**

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

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

**Implementation of PvPI**

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

**Short term goals**

1. To develop and implement Pharmacovigilance system in India.

2. To enroll, initially, all MCI approved medical colleges in the program covering north, south, east and west of India.
3. To encourage healthcare professionals in reporting of adverse reaction to drugs, vaccines, medical devices and biological products.

4. Collection of case reports and data.

**Long term goals**

1. To expand the Pharmacovigilance programme to all hospitals (govt. & private) and centres of public health programs located across India.

2. To develop and implement electronic reporting system (e-reporting).

3. To develop reporting culture amongst healthcare professionals.

4. To make ADR reporting mandatory for healthcare professionals.
PvPI - Programme Communication

CDSCO- Headquarter, New Delhi

National Coordination Centre
IPC, Ghaziabad

Steering Committee
Working Group
Signal Review
Core Training Panel
Quality Review Panel

ADR Monitoring Centres

Healthcare Professionals and Patients

CDSCO Zonal Offices
North Zone, Ghaziabad
South Zone, Chennai
West Zone, Mumbai
East Zone, Kolkata

Pharmaceutical industries in India
National Immunization Programme
Professional bodies like IDMA, OPPI etc
Seminars/ Training Programmes / Symposia / Workshops / Meetings attended:

- NCC-PvPI officials participated in the ‘National symposium on Translational Pharmacovigilance’ organized by department of Pharmacology, PGIMER, Chandigarh on 14th April 2012.
- NCC-PvPI submitted 30 ICSRs on *Pioglitazone* and 150 ICSRs on *Statins* to CDSCO for regulatory intervention in India.
- NCC-PvPI delivered a lecture on ‘Introduction to Pharmacovigilance and Pharmacovigilance programme of India’ during the workshop on to create awareness among health care professionals organized by Department of Pharmacology, SMS Medical College, Jaipur on September 17, 2012.
- NCC-PvPI delivered a lecture on ‘Appraisal about the PvPI and the modalities of reporting the ADRs’ to the Clinical faculty, PGs and other health care professionals at Department of Pharmacology, UCMS & GTB Hospital, New Delhi on September 19, 2012.
- The Second Working Group-PvPI Meeting was held on September 28, 2012 under the Chairmanship of Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad to discuss and resolve various issues of PvPI.
- The 1st Steering Committee was held on 28th December 2012 at DCG(I) office, FDA Bhawan, New Delhi to give a direction for effective functioning of PvPI.
- NCC-PvPI published Issue-4, Volume-2 PvPI news letter in December 2012 with special emphasis on the ADRs reporting culture in India & Insulin-induced weight gain in diabetic patients.
- The Third Working Group of PvPI meeting was held on 29/01/2013 to discuss the various issues at DCG(I) office, FDA Bhawan, New Delhi.
NCC-PvPI provided technical support to organize a workshop on ‘National symposium on Pharmacovigilance and ADRs monitoring’ to create awareness among healthcare professionals on 9th and 10th February 2013.

AEFI division from MOH & FW, Govt of India visited at NCC-PvPI on 28th February 2013 to discuss the various issues on ADRs related to vaccines and for better coordination.

PGIMER, Chandigarh in collaboration with NCC organized a VigiFlow training for the personnel’s involved in AMCs north zone under PvPI on 22nd February 2013.
### IPC Staff (as on 31st March, 2013)

<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. Udaí Pal | Hindi Translator
- Mr. Chandan Kumar | Finance & Accounts Officer
- Ms. Renu Kapoor | Upper Divisional Clerk
- Mr. Satyaveer Singh | Senior Laboratory Attendant
- Mr. Rajendra Kumar Sharma | Peon
Statements of Account
2012-13
Auditors Report

1. We have audited the attached balance Sheet of the Indian Pharmacopoeia Commission as at 31st March, 2013 and the Income and Expenditure Account along with Receipts & Payment Account for the year ended on that date annexed thereto. These Financial Statements are the responsibility of the Commission’s Management. Our responsibility is to express an opinion on these Financial Statement based on our audit.

2. We have conducted our Audit in accordance with Auditing standards generally accepted in India. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the Financial Statements are free of materials misstatement. An Audit included examining on test basis evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing accounting principles used and significant estimates made by management, as well as evaluating the overall Financial Statement presentation. We believe that our audit provide a reasonable basis for expressing our opinion.

3. Attention is invited to:

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

   Re: Non provision of Leave Encashment & Gratuity. The impact of the same on tax liability, if any could not be assessed and quantified because of amount of bonus has not yet been finalized.

4. We report that

   a) In our opinion, the Balance Sheet and Income & Expenditure dealt with by this report broadly comply with the Accounting Standards issued by the Institute of Chartered Accountants of India.

   b) We have obtained all the information and explanations, which to the best of our knowledge and belief were necessary for the purpose of our audit.

5. In our opinion proper books of accounts have been maintained by the Commission so far as it appears from our examination of books.
The Balance Sheet and the Income & Expenditure Account dealt with by this report are in agreement with the books of accounts.

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

a) Balance Sheet of the state of affairs of the Commission as at 31st March, 2013 and

b) Income & Expenditure Account for the year ended 31st March, 2013.

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

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

PLACE: GHAZIABAD
DATE: 02.09.2013
## Balance Sheet as at 31st March 2013

### Corpus/Capital Fund and Liabilities

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Current Year</th>
<th>Previous Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>86,35,10,074.00</td>
<td>85,36,92,868.00</td>
</tr>
<tr>
<td>2</td>
<td>60,82,100.00</td>
<td>47,58,532.00</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>86,95,92,174.00</strong></td>
<td><strong>85,84,51,400.00</strong></td>
</tr>
</tbody>
</table>

### Assets

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Current Year</th>
<th>Previous Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross Block</td>
<td>87,63,89,794.00</td>
<td>83,37,50,720.00</td>
</tr>
<tr>
<td>Less : Depreciation</td>
<td>8,78,20,737.00</td>
<td>5,91,31,244.00</td>
</tr>
<tr>
<td>Net Block</td>
<td>78,85,69,057.00</td>
<td>77,46,19,475.00</td>
</tr>
<tr>
<td>Investment in Fixed Deposits</td>
<td>2,44,18,504.00</td>
<td>5,49,21,915.00</td>
</tr>
<tr>
<td>Interest Accrued on Investment</td>
<td>1,99,926.00</td>
<td>14,05,696.00</td>
</tr>
<tr>
<td>Current Assets, Loans &amp; Advances</td>
<td>5,64,04,687.00</td>
<td>2,75,04,314.00</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>86,95,92,174.00</strong></td>
<td><strong>85,84,51,400.00</strong></td>
</tr>
</tbody>
</table>

### Significant Accounting Policies and Notes on Accounts

As per our report of even date attached.

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

FOR INDIAN PHARMACOPOEIA COMMISSION

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

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner
M. No. 074635
Chandan Kumar
( Finance & Accounts Officer)

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

Place: Ghaziabad
Date: 02.09.2013
## INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31st MARCH 2013

### (Amount in Rs)

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

#### As per our report of even date attached.

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

FOR INDIAN PHARMACOPOEIA COMMISSION

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

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

Chandan Kumar  
(Finance & Accounts Officer)

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

Place: Ghaziabad  
Date: 02.09.2013
### Indian Pharmacopoeia Commission

**Ministry of Health & Family Welfare**  
**Sector-23, Raj Nagar Ghaziabad-201002**

#### Receipts and Payments Account for the Year Ended 31st March 2013

<table>
<thead>
<tr>
<th>Category</th>
<th>Current Year</th>
<th>Previous Year</th>
<th>Category</th>
<th>Current Year</th>
<th>Previous Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receipts</strong></td>
<td></td>
<td></td>
<td><strong>Payments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1. Opening Balance</strong></td>
<td></td>
<td></td>
<td><strong>1. Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cash in Hand</td>
<td>62,847.00</td>
<td>51,655.00</td>
<td>- Establishment Expenses</td>
<td>4,30,12,082.00</td>
<td>3,59,87,218.00</td>
</tr>
<tr>
<td>- Bank Balance</td>
<td>82,10,159.00</td>
<td>8,53,85,928.00</td>
<td>- Administrative Expenses</td>
<td>2,06,07,968.00</td>
<td>2,04,36,567.00</td>
</tr>
<tr>
<td>- Stamps in Hand</td>
<td>50,433.00</td>
<td>-</td>
<td>- Lab Services &amp; O&amp;M Exp</td>
<td>54,59,991.00</td>
<td>31,33,632.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Prior Period Expenses</td>
<td>1,82,708.00</td>
<td>17,39,882.00</td>
</tr>
<tr>
<td><strong>2. Grants Received</strong></td>
<td></td>
<td></td>
<td><strong>2. Payments made against funds</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- From Government of India</td>
<td>11,21,60,000.00</td>
<td>10,36,20,000.00</td>
<td>- Advance to HLL Lifecare Limited</td>
<td>1,03,67,307.00</td>
<td>98,85,777.00</td>
</tr>
<tr>
<td><strong>3. Interest Received</strong></td>
<td></td>
<td></td>
<td>- Advance to A &amp; A Periodicals</td>
<td>39,96,619.00</td>
<td>31,40,786.00</td>
</tr>
<tr>
<td>- Advance to A &amp; A Periodicals</td>
<td>2,06,07,968.00</td>
<td>2,04,36,567.00</td>
<td>- Advance to W.H.O</td>
<td>10,00,000.00</td>
<td>20,00,000.00</td>
</tr>
<tr>
<td>- On Savings Account</td>
<td>3,42,847.00</td>
<td>20,14,434.00</td>
<td>- Advance to CPWD Ghaziabad</td>
<td>81,07,366.00</td>
<td>73,504.00</td>
</tr>
<tr>
<td>- Prior Period Expenses</td>
<td>1,82,708.00</td>
<td>-</td>
<td>- Advance to others</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>4. Other Income</strong></td>
<td></td>
<td></td>
<td><strong>3. Expenditure on Fixed Assets &amp; Capital Work-in-Progress</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Sale of I.P Books</td>
<td>62,22,700.00</td>
<td>1,31,05,240.00</td>
<td>- Books</td>
<td>81,97,366.00</td>
<td>13,37,921.00</td>
</tr>
<tr>
<td>- Sale of IPRS</td>
<td>7,58,150.00</td>
<td>-</td>
<td>- Building</td>
<td>36,90,954.00</td>
<td>89,88,497.00</td>
</tr>
<tr>
<td>- Sale of NFI</td>
<td>57,95,570.00</td>
<td>-</td>
<td>- Computer &amp; Pheripheral</td>
<td>20,96,983.00</td>
<td>11,01,652.00</td>
</tr>
<tr>
<td>- Others</td>
<td>4,94,250.00</td>
<td>-</td>
<td>- Cycle</td>
<td>-</td>
<td>2,900.00</td>
</tr>
<tr>
<td>- Other Income</td>
<td>1,93,992.00</td>
<td>20,91,313.00</td>
<td>- Furniture &amp; fixture</td>
<td>69,74,860.00</td>
<td>20,86,996.00</td>
</tr>
<tr>
<td>- Sale of Tender Forms</td>
<td>14,600.00</td>
<td>-</td>
<td>- Office Equipment</td>
<td>15,30,359.00</td>
<td>64,27,750.00</td>
</tr>
<tr>
<td>- Other Income</td>
<td>2,400.00</td>
<td>3,100.00</td>
<td>- Plant Machinery &amp; Equipment</td>
<td>70,35,672.00</td>
<td>11,01,81,061.00</td>
</tr>
<tr>
<td><strong>5. Other Receipts</strong></td>
<td></td>
<td></td>
<td>- Vehicle</td>
<td>-</td>
<td>4,93,365.00</td>
</tr>
<tr>
<td>- Advances to Contractors &amp; Suppliers</td>
<td>61,96,566.00</td>
<td>9,52,70,786.00</td>
<td><strong>4. Refund of surplus money/loans</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Increase in amounts payable to creditors</td>
<td>31,500.00</td>
<td>34,000.00</td>
<td>- To the MOH &amp; FW</td>
<td>3,90,00,000.00</td>
<td>4,50,00,000.00</td>
</tr>
<tr>
<td>- Tour Advance</td>
<td>4,19,025.00</td>
<td>-</td>
<td>- increase in Investments during the year</td>
<td>-</td>
<td>63,27,611.00</td>
</tr>
<tr>
<td>- Festival Advance</td>
<td>40,875.00</td>
<td>30,300.00</td>
<td>- License Fee Recovered</td>
<td>5,100.00</td>
<td>-</td>
</tr>
<tr>
<td>- License Fee Recovered</td>
<td>1,93,992.00</td>
<td>20,91,313.00</td>
<td>- Decrease in Investments during the year</td>
<td>3,17,09,181.00</td>
<td>-</td>
</tr>
<tr>
<td>- Scooter Advance</td>
<td>-</td>
<td>-</td>
<td>- Increase in Security Deposit/ Retention Money</td>
<td>1,32,000.00</td>
<td>-</td>
</tr>
<tr>
<td>- Decrease in Security Deposit/ Retention Money</td>
<td>-</td>
<td>-</td>
<td>- Increase in Security Deposit/ Retention Money</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>5. Other payments</strong></td>
<td></td>
<td></td>
<td>- TCS Paid</td>
<td>4,50,00.00</td>
<td>-</td>
</tr>
<tr>
<td>- Security deposit with Electricity Deptt.</td>
<td>-</td>
<td>-</td>
<td>- To the MOH &amp; FW</td>
<td>-</td>
<td>1,21,738.00</td>
</tr>
<tr>
<td>- Festival Advance</td>
<td>30,00.00</td>
<td>33,750.00</td>
<td>- Tour Advance</td>
<td>4,18,733.00</td>
<td>38,225.00</td>
</tr>
<tr>
<td>- Scooter Advance</td>
<td>-</td>
<td>-</td>
<td>- Amount Recoverable From Debtors</td>
<td>-</td>
<td>61,000.00</td>
</tr>
<tr>
<td><strong>6. Closing Balances</strong></td>
<td>17,79,64,614.00</td>
<td>30,58,63,967.00</td>
<td><strong>5. Other payments</strong></td>
<td>57,68,040.00</td>
<td>-</td>
</tr>
<tr>
<td>- Cash in Hand</td>
<td>39,284.00</td>
<td>62,847.00</td>
<td>- Advance to CPWD Ghaziabad</td>
<td>81,07,366.00</td>
<td>73,504.00</td>
</tr>
<tr>
<td>- Bank Balance</td>
<td>63,58,994.00</td>
<td>82,10,159.00</td>
<td>- Advance to Others</td>
<td>73,504.00</td>
<td>-</td>
</tr>
<tr>
<td>- Stamps in Hand</td>
<td>11,324.00</td>
<td>-</td>
<td>- TCS Paid</td>
<td>4,50,00.00</td>
<td>-</td>
</tr>
<tr>
<td><strong>As per our report of even date attached.</strong></td>
<td>17,79,64,614.00</td>
<td>30,58,63,967.00</td>
<td><strong>FOR INDIAN PHARMACOPOEIA COMMISSION</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Yogesh Malik  
F.C.A, D.I.S.A (ICA)  
Sr. Partner  
M. No. 074635  
Place: Ghaziabad  
Date: 02.09.2013

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

Chandan Kumar  
I.J.S Oberoi  
( Finance & Accounts Officer)  
( Administrative Officer)(i/c)
(A) SIGNIFICANT ACCOUNTING POLICIES

1. Basis of Accounting

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

2. Fixed Assets and Depreciation

a) Fixed assets are stated at cost less accumulated depreciation.

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

<table>
<thead>
<tr>
<th>FIXED ASSETS</th>
<th>RATES OF DEPRECIATION CHARGED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery &amp; Equipment</td>
<td>-</td>
</tr>
<tr>
<td>Office Equipment</td>
<td>-</td>
</tr>
<tr>
<td>Building</td>
<td>-</td>
</tr>
<tr>
<td>Furniture &amp; Fixtures</td>
<td>-</td>
</tr>
<tr>
<td>Lab Equipments</td>
<td>-</td>
</tr>
<tr>
<td>Vehicles</td>
<td>-</td>
</tr>
<tr>
<td>Cycle</td>
<td>-</td>
</tr>
<tr>
<td>D.G Sets</td>
<td>-</td>
</tr>
</tbody>
</table>

c) In respect of additions to fixed assets made during the year, depreciation has been provided for the full year and in respect of sale/disposal of fixed assets, no depreciation has been provided but it has no financial implication due to this deviation from the prescribed provisions of the ICAI.

d) The depreciation has been charged to the grant Corpus Fund and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item as per AS-12 Prescribed by ICAI.

3. Grant In Aid
a) The grants in aid received from Ministry of Health & family Welfare, Government of India is accounted for on accrual basis. Accordingly, any deficit/surplus of grant has been shown as Grant receivable/payable to the MOH & FW.

b) Grant is charged to the revenue to the extent of expenditure incurred as all the Incomes received by the IPC have been transferred to the MOH & FW.

c) The grants utilized for the purchase of fixed assets have been shown under the head of Corpus Fund.

d) Further grants utilized for Purchase of Fixed Assets have also been shown under the head of Corpus Fund.

4. Employee Remuneration & Benefits

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

5. Revenue Recognition

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

6. Provision

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

7. Contingent Liabilities and Contingent Assets

A disclosure for a contingent liability is made when there is a possible obligation that may, but probably will not, require an outflow of resources. Where there is a possible obligation or a present obligation but the likelihood of outflow of resources is remote, no provision or disclosure is made.
1. The depreciation of Rs.2,48,91,966.00 has been charged to the Income & Expenditure account. Since the institute is fully aided by the Government of India, therefore depreciation is charged to the grant Corpus Fund and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item.

2. During the current year corpus fund was credited by Rs. 37, 97,527.00 on account of excess depreciation charged and Rs.1,31,93,745.00 excess amount written off on books in previous year. Further, during the previous years IPC has charged depreciation on Gross Block of Assets instead of charging Depreciation individually. (i.e. Asset-wise Depreciation)

3. Provision for Leave Encashment and gratuity has not been made during the year.

4. Party balances are subject to confirmation.

5. Cheques being amount of Rs. 20,06,640.00 have been issued to the Parties but not presented before the bank till date.

6. Liabilities are recognized to the extent information available.

7. Internal Control system of IPC needs to be Strengthen.

8. The institute has not gathered any information from suppliers/service providers about their status under Micro, Small and Medium Enterprises (Development) Act, 2006. Therefore the required information, regarding the dues outstanding to Micro, Small and Medium Enterprises as on 31.03.2013 and interest payable, if any, are not considered.

9. Financial effect of pending Court Cases cannot be ascertained on the Balance Sheet Date therefore neither the provision nor the amount of the same has been disclosed in the notes to accounts. The pending court cases are on account of C.G.H.S facility to be provided to employees, so there is no financial impact of the same on the Balance Sheet date.

10. During the F.Y a sum of Rs 2,62,63,527.00 has been charged to the Corpus fund because in the Previous Years amount Payable/Recoverable to the Ministry has been added to the Corpus Fund.
11. During the year, IPC has transferred all the receipts to MOH & FW, GOI which are earned by way of Sale of I.P Books & other misc. receipts. Further, IPC has transferred a sum of Rs 4,30,00,000.00 to the MOH & FW, which includes Income of current year as well as of previous year.

12. Advance payments in excess of actual requirement not only blocked the Government money but also results into financial loss to the Government, as the IPC is not getting any interest on these advances. The details of same are as follows:

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

13. During the year IPC has given advance amounting to Rs.10,00,000.00 to “IPC GPF”.

14. The previous year figures have been regrouped/reclassified/rearranged, wherever necessary.

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

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

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

Chandan Kumar  
(Finance & Accounts Officer)

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

Place: Ghaziabad  
Date: 02.09.2013

AUDITORS REPORT
To,
The Members,
General Provident Fund,

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

1. We have audited the attached Balance Sheet of the Indian Pharmacopoeia Commission, General Provident Fund as at 31st March 2013 and Income & Expenditure Account along with Receipts & Payment Account for the year ended on that date annexed thereto. These Financial Statements are the Responsibility of the “IPC-GPF” Management. Our Responsibility is to express an opinion on this Financial Statements Based on our Audit.

2. Further we report that:
   a) We have obtained all the information and explanations which to the best of our knowledge and belief were necessary for the purpose of our audit.

   b) In our opinion proper books of accounts as required by law have been kept by the Institute so far as it appears from our examination of books.
c) The Balance Sheet and the Income & Expenditure Account dealt with by this report are in agreement with the books of accounts.

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

   a) In the case of Balance Sheet of the state of affairs as at 31st March 2013; and
   b) In the case of the Income & Expenditure Account Excess of Income over Expenditure for the year ended 2013.

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

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

Place: Ghaziabad
Date: 02.09.2013
## INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund

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

(Amount in Rs)

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

As per our report of even date attached.

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

FOR INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund

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

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

Chandan Kumar
(Finance & Accounts Officer)

Place : Ghaziabad
Date : 02.09.2013

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

INDIAN PHARMACOPOEIA COMMISSION GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)
# Income & Expenditure Account for the year Ended 31.03.2013

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

**Significant Accounting Policies and Notes to Accounts**

As per our report of even date attached.

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

FOR INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund

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

Chandan Kumar
(Finance & Accounts Officer)

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

INDIAN PHARMACOPOEIA COMMISSION GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)
Balance Sheet as at 31.03.2013
<table>
<thead>
<tr>
<th>Liabilities</th>
<th>Schedule</th>
<th>Current Year</th>
<th>Previous Year</th>
<th>Assets</th>
<th>Schedule</th>
<th>Current Year</th>
<th>Previous Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Capital</strong></td>
<td>1</td>
<td>1,00,63,762.00</td>
<td>1,14,19,752.00</td>
<td><strong>Investment</strong></td>
<td>3</td>
<td>1,22,09,252.00</td>
<td>1,09,84,383.00</td>
</tr>
<tr>
<td>Subscription &amp; Contributions</td>
<td></td>
<td></td>
<td></td>
<td>Fixed Deposit with Bank</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Balance being Excess of Income/Expenditure</strong></td>
<td>2</td>
<td>(3,30,505.00)</td>
<td>(5,34,596.00)</td>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current Liability</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPC Loan</td>
<td></td>
<td>30,00,000.00</td>
<td>20,00,000.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>1,27,33,257.00</td>
<td>1,28,85,156.00</td>
<td><strong>Total</strong></td>
<td></td>
<td>1,27,33,257.00</td>
<td>1,28,85,156.00</td>
</tr>
</tbody>
</table>

Significant Accounting Policies and Notes to Accounts

As per our report of even date attached.
For P A R Y & CO.
Chartered Accountants
(FR No. 007288C)

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

FOR INDIAN PHARMACOPOEIA COMMISSION
General Provident Fund

Yogesh Malik
F.C.A, D.I.S.A (ICA)
Sr. Partner

Place : Ghaziabad

Chandan Kumar
(Finance & Accounts Officer)

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

SCHEDULE FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2013
SCHEDULE - 1 : List of Members Who Contributed towards subscriotion of "IPC-GPF"

(Amount in Rs)
<table>
<thead>
<tr>
<th>Sl.No</th>
<th>GPF A/c No.</th>
<th>Name &amp; Designation</th>
<th>Opening Balance as on 1.04.2012 (A)</th>
<th>Subscription/Contribution (B)</th>
<th>Recovery (C)</th>
<th>Advance (D)</th>
<th>Withdrawal (E)</th>
<th>Final Settlement (F)</th>
<th>Interest (G)</th>
<th>Balance as on 31.03.2013 (A)+(B)+(C)-(D)-(E)-(F)+(G)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IPC/01</td>
<td>Dr. Jai Prakash</td>
<td>6,73,654.00</td>
<td>60,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>7,95,796.00</td>
</tr>
<tr>
<td>2</td>
<td>IPC/02</td>
<td>Dr. R.M. Singh</td>
<td>4,33,572.00</td>
<td>1,35,000.00</td>
<td>-</td>
<td>-</td>
<td>2,55,000.00</td>
<td></td>
<td></td>
<td>3,44,741.00</td>
</tr>
<tr>
<td>3</td>
<td>IPC/03</td>
<td>Shri K. K. Singh</td>
<td>3,66,173.00</td>
<td>60,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>4,61,256.00</td>
</tr>
<tr>
<td>4</td>
<td>IPC/04</td>
<td>Smt. Savita Shukla</td>
<td>47,821.00</td>
<td></td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>47,821.00</td>
</tr>
<tr>
<td>5</td>
<td>IPC/05</td>
<td>Dr. S. C. Mathur</td>
<td>15,68,656.00</td>
<td>1,20,000.00</td>
<td>-</td>
<td>-</td>
<td>12,00,000.00</td>
<td></td>
<td>1,00,128.00</td>
<td>5,88,784.00</td>
</tr>
<tr>
<td>6</td>
<td>IPC/06</td>
<td>Km. Sangeeta Bhatnagar</td>
<td>20,59,305.00</td>
<td>78,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>23,22,242.00</td>
</tr>
<tr>
<td>7</td>
<td>IPC/07</td>
<td>Sh. Alok Sharma</td>
<td>75,682.00</td>
<td>36,000.00</td>
<td>-</td>
<td>-</td>
<td>70,000.00</td>
<td></td>
<td>4,783.00</td>
<td>46,465.00</td>
</tr>
<tr>
<td>8</td>
<td>IPC/08</td>
<td>Sh. M. K. Panday</td>
<td>2,86,149.00</td>
<td>60,000.00</td>
<td>-</td>
<td>-</td>
<td>1,95,000.00</td>
<td></td>
<td>10,881.00</td>
<td>1,62,030.00</td>
</tr>
<tr>
<td>9</td>
<td>IPC/09</td>
<td>Sh. Y. K. Kush</td>
<td>10,267.00</td>
<td>24,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>36,314.00</td>
</tr>
<tr>
<td>10</td>
<td>IPC/10</td>
<td>Sh. Satya Prakash</td>
<td>7,52,257.00</td>
<td>1,08,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td>9,31,604.00</td>
</tr>
<tr>
<td>11</td>
<td>IPC/11</td>
<td>Dr. D. K. Sharma</td>
<td>13,36,816.00</td>
<td>1,20,000.00</td>
<td>-</td>
<td>-</td>
<td>12,50,000.00</td>
<td></td>
<td>59,926.00</td>
<td>2,66,742.00</td>
</tr>
<tr>
<td>12</td>
<td>IPC/12</td>
<td>Sh. Pawan Kr. Saini</td>
<td>1,07,575.00</td>
<td>1,14,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>14,901.00</td>
<td>2,36,476.00</td>
</tr>
<tr>
<td>13</td>
<td>IPC/13</td>
<td>Sh. Satyaveer Singh</td>
<td>4,36,857.00</td>
<td>1,65,200.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>46,245.00</td>
<td>6,48,302.00</td>
</tr>
<tr>
<td>14</td>
<td>IPC/14</td>
<td>Sh. B. Dayal Sharma</td>
<td>3,70,456.00</td>
<td>1,12,000.00</td>
<td>-</td>
<td>-</td>
<td>2,50,000.00</td>
<td></td>
<td>18,139.00</td>
<td>2,50,595.00</td>
</tr>
<tr>
<td>15</td>
<td>IPC/15</td>
<td>Smt. Ritu Tiwari</td>
<td>4,43,239.00</td>
<td>1,31,000.00</td>
<td>-</td>
<td>-</td>
<td>1,80,000.00</td>
<td></td>
<td>35,624.00</td>
<td>4,29,863.00</td>
</tr>
<tr>
<td>16</td>
<td>IPC/16</td>
<td>Sh. Udai Pal</td>
<td>40,345.00</td>
<td>24,000.00</td>
<td>-</td>
<td>-</td>
<td>40,000.00</td>
<td></td>
<td>2,934.00</td>
<td>27,279.00</td>
</tr>
<tr>
<td>17</td>
<td>IPC/17</td>
<td>Sh. I. J. S. Oberoi</td>
<td>70,163.00</td>
<td>84,000.00</td>
<td>-</td>
<td>-</td>
<td>63,000.00</td>
<td></td>
<td>5,162.00</td>
<td>96,325.00</td>
</tr>
<tr>
<td>18</td>
<td>IPC/18</td>
<td>Km. Renu Kapoor</td>
<td>10,63,587.00</td>
<td>1,04,000.00</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>98,318.00</td>
<td>12,65,905.00</td>
</tr>
<tr>
<td></td>
<td>PARTICULARS</td>
<td>As on 31.03.2013</td>
<td>As on</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Sh. Bijendra Kumar</td>
<td>4,94,302.00</td>
<td>1,20,000.00</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IT/C19</td>
<td>-</td>
<td>-</td>
<td>49,219.00</td>
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</tr>
<tr>
<td>20</td>
<td>Sh. R. K. Sharma</td>
<td>62,619.00</td>
<td>52,000.00</td>
<td>-</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>IT/C20</td>
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<td>-</td>
<td>7,402.00</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Dr. Anil Kr. Teotia</td>
<td>7,20,257.00</td>
<td>2,40,000.00</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IT/C21</td>
<td>-</td>
<td>7,00,000.00</td>
<td>59,423.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1,14,19,752.00</td>
<td>19,47,200.00</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-</td>
<td>42,03,000.00</td>
<td>8,99,810.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,00,63,762.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

SCHEDULE - 2: Excess of Income/Expenditure for the year
SCHEDULE - 3: INVESTMENTS

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

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Welfare
General Provident Fund

SCHEDULE - 4

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

A. SIGNIFICANT ACCOUNTING POLICIES
1. **Method of accounting:**
   The accounts have been prepared under the Historical cost convention on accrual basis.

2. **Revenue Recognition:**
   The Revenue has been recognized on accrual basis.

3. **Fixed Assets:**
   There are no fixed assets.

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

**B. NOTES TO ACCOUNTS**

1. “IPC – GPF” is not yet registered with the desired Govt. Authorities.

2. The investments of “IPC-GPF” have been invested in Fixed Deposit with Nationalized bank.

3. The accounting standards issued by ICAI wherever applicable have been complied to the extent possible.

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

For P A R Y & CO.                                       FOR INDIAN PHARMACOPOEIA COMMISSION
Dr. G.N. Singh
(Secretary-cum-Scientific Director)

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

Chandan Kumar
(Finance & Accounts Officer)

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

Place: Ghaziabad
Date: 02.09.2013