INDIAN PHARMACOPOEIA COMMISSION

PROFILE
Releasing of IP Addendum 2005 to IP 1996 on 23rd March 2006 by Hon'ble Minister, Health & Family Welfare, Govt. Of India

Left to right- Sh. P. Hota (Secretary, Min. of Health & Family Welfare and Chairman, IPC) Dr. Ambumani Ramdoss (Union Minister of Health & Family Welfare, Govt. of India) and Dr. P.R. Pabrai (Vice Chairman, SB of IPC).

Left to right- Sh. Rajesh Bhushan (Director, Drug), Mrs. Rita Teotia (Joint Secretary, Min. of Health & Family Welfare) Sh. P. Hota (Secretary, Min. Of Health & Family Welfare and Chairman, IPC) Dr. Ambumani Ramdoss (Union Minister of Health & Family Welfare, Govt. of India) Dr. P.R. Pabrai (Vice Chairman, SB of IPC).

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Indian Pharmacopoeia Commission (IPC) is an unique organization of the country situated in the National Capital Region just 20 Km. far from New Delhi. It is an Autonomous Institution under the Ministry of Health & Family Welfare, Govt. of India dedicated for setting of standards for drugs, pharmaceuticals & healthcare devices / technologies etc. by publishing the Indian Pharmacopoeia which is an official and legal book of standards for drugs including therein under the Drugs and Cosmetics Act 1940, besides providing Reference Substances and training. The IPC has been registered as a Society under the provisions of the Societies Registration Act. 1860 (Act No. 21 of 1860) for the registration of Literary, Scientific and Charitable Societies on 9th December 2004. The functioning of the Commission is governed by the provisions of the approved Memorandum of Association, Rules and Regulations of the IPC. The Commission has set up its headquarter in the campus of the Central Indian Pharmacopoeia Laboratory (CIPL), Sector-23, Raj Nagar, Ghaziabad, U.P.

The Commission has a three-tier structure comprising of General Body, Governing Body and Scientific Body supported by IPC Secretariat and CIPL (fig. 1)

All the three organs are integral for the smooth functioning of the Commission. The IPC Secretariat coordinates various activities of the Commission while CIPL is constituent laboratory involved in the generation, validation and verification of scientific data of high quality to fulfill the requirements of IPC.

**MISSION, VISION AND OBJECTIVES OF THE IPC**

**Mission**

To 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 of 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 revision on a regular basis.
To develop monographs for herbal drugs, both raw drugs and extracts/formulations therefrom.

To accord priority to monographs of drugs included in the National Essential Medicines 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, which may be accorded 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 of the concerned drug.

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

To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.

To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards.

To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgradation / revision.

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.

**DEPARTMENTS**

Presently, IPC is assisted by the following main departments of CIPL:

**Scientific Wing**
- Research and Development
- Pharmaceutical Chemistry
- Pharmacology
- Microbiology
- Pharmacognosy
- Medical Devices
- Library, Information and Publication
- Sample Warden
- Reference Standard

**Administrative Wing**
- Office Administration
- Accounts
- Stores
- House-keeping

**OPPORTUNITIES FOR HIGHER EDUCATION & RESEARCH**

The institute has got affiliation from CCS University, Meerut, Institute of Technology, Banaras Hindu University, Varanasi and U.P. Tech. University, Lucknow for imparting higher education (Ph.D.) and carrying out research.

**CURRENT ACTIVITIES AND ACHIEVEMENTS**

1. **Publication of IP Addendum 2005**

The first publication of IPC the IP Addendum 2005 to IP 1996 was released by the Union Minister for Health & Family Welfare, Dr. Ambumani Ramdoss at New Delhi on 23rd March 2006. The IP Addendum 2005 is effective from 30th June 2006.
Features of IP Addendum 2005

• Added 46 new monographs including 3 for bulk drugs (Adenine, Fructose and Lopinavir), 22 for large volume parenterals, 10 for antiretroviral formulations, 10 for medicinal plants (herbal drugs), 1 for oxygen 93 per cent.
• Monographs undergone major changes
  • Doxycycline HCl Capsules
  • Intraperitoneal Dialysis Solutions
  • Oral Rehydration Salts
  • Oxygen
• Incorporated a new appendix on gas detector tubes.
• Existing appendix on test for sterility, plastic containers, sterilization and biological indicators replaced by update versions.

2. Salient features for the next edition of the Indian Pharmacopoeia

• Updating and making user’s friendly manner existing monographs of IP 1996.
• First time appearing about 100 new monographs on most frequently used drugs.
• Special emphasized one vaccines and sera monographs
• Special attention to herbal drugs.
• Blood and blood product monographs.
• Monographs for commonly used excipients.
• Fast track approach to the drugs of antiretroviral drugs.
• Updating and harmonizing antituberculosis drugs including fixed dose combination.

3. Collaboration with USP

A MoU has been signed between IP Commission and USP Convention on 1st August 2006 at New Delhi. Sh. P. Hota, Union Secretary, Ministry of Health & Family Welfare, and Chairman of IP Commission and Dr. Roger William, CEO, USP Convention have been the signatory from both the side. This will further strengthen both, the IPC as well as USP.

4. Proficiency Testing

Participated in LMCS Proficiency Testing of the samples received from the Laboratory of the Dutch Pharmacist WinAP, Netherland and analytical results meeting with other international participants.

5. Training

Provided training to undergraduates, postgraduates and scientific staff of various pharmacy and biotechnology colleges from different Universities and drugs testing laboratories.

6. Regulatory Testing

Carried out regulatory testing of the drug samples received from the States Drug Inspectors, survey samples from CDSCO Drug inspector and including new drugs through DCG(II) Office.

7. Ministry of Health & Family Welfare-Capacity Building Project sponsored Testing for spurious Drugs

Carrying out testing of drug samples sent through Ministry of Health & Family Welfare and World Bank assisted Capacity Building Project (CBP) to check the quality of marketed drugs in the country.

8. WHO Work

Regularly participating in the development of Anti-retroviral drugs and Anti-tubercular drugs monographs for the WHO International Pharmacopoeia time to time. Successfully organised verification testing of basic tests for Bulk Drug Dosage Forms received from WHO, Geneva from time to time.

9. Seminars and Meetings

Organised seminars and meetings of scientific interest. The series of and seminars organised in collaboration with USP, IDMA, BDMA, Pharmexcil, IPA etc to enhance visibility of the IPC and active participation of the stakeholders on its various ongoing activities. The following meetings of different bodies of the IPC were held along with other several meetings of Scientific Body committees.
**General Body:**
20th April, 2005 - First meeting

**Governing Body:**
20th April, 2005 - First meeting
5th October, 2005 - Second meeting
10th May, 2006 - Third meeting
08th March, 2007 - Fourth meeting

**Scientific Body:**
16th January, 2006 - First meeting
8th April, 2006 - Second meeting
8th July, 2006 - Third meeting
7th October, 2006 - Fourth meeting
20th January, 2007 - Fifth meeting
06th April, 2007 - Sixth meeting
09th June, 2007 - Seventh meeting

10. Exposure of Staff
The staff participated in various seminars, symposia, workshops and in training programme etc. within the country relating to scientific and administrative upgradation.

11. Research Activity/Research Project
The R&D Division has guided 08 students of M.Pharm from Jamia Millia Hamdard University, Delhi, Bundelkhand University, Jhansi etc. for their six months/one year project work on new drugs and on other topics.

12. Research Papers Published
We have published 18 research papers in different reputed national/international journals.

13. Research papers Presented in Indian Pharmaceutical Congress

14. BIS Work
Regularly participating as members in different council/committees/Subcommittees of Bureau of Indian Standards, Manak Bhawan, New Delhi.

15. Appellate Laboratory for Condom Testing
CIPL is the appellate laboratory for the condom testing. The sample from the Ministry of Health & Family Welfare and from other sources regularly tested alongwith all other medical devices in the Medical Devices Section.

16. IPC Web-Site
Web-Site of the IPC has been launched on 20th January, 2007 with the address: www.ipc.gov.in

**CHALLENGES AHEAD:**

- Timely publication of Indian Pharmacopoeia and its Addenda.
- Certification & providing IP Reference Substances to the stakeholders. In this attempt, Commission has identified the priority items amongst the Reference Substances and is taking firm steps to meet this demand.
- Synthesis and characterization of impurities (mainly toxic ones), degradations products etc.
- International collaboration with other similarly placed institution like British Pharmacopoeia Commission, European Pharmacopoeia Commission, Chinese Pharmacopoeia Commission and WHO etc.
- International recognition and acceptance of Indian Pharmacopoeia.
- To be recognized as an institution of excellence for standards setting.
- To develop state-of-the-art facilities in Library to cater the needs of south East Asia Region for dissemination of information.
Signing of Memorandum of Understanding between IPC and USP on 1st August 2006

Left to right- Dr. Roger Williams (CEO, USP Convention), Dr. G.N. Singh (Member Secretary, IPC), Sh. P. Hota (Secretary, Min. of Health & Family Welfare and Chairman, IPC) and Dr. Nitya Anand (Chairman, SB of IPC)

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