Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare
Government of India

ANNUAL ACHIEVEMENTS 2017-18

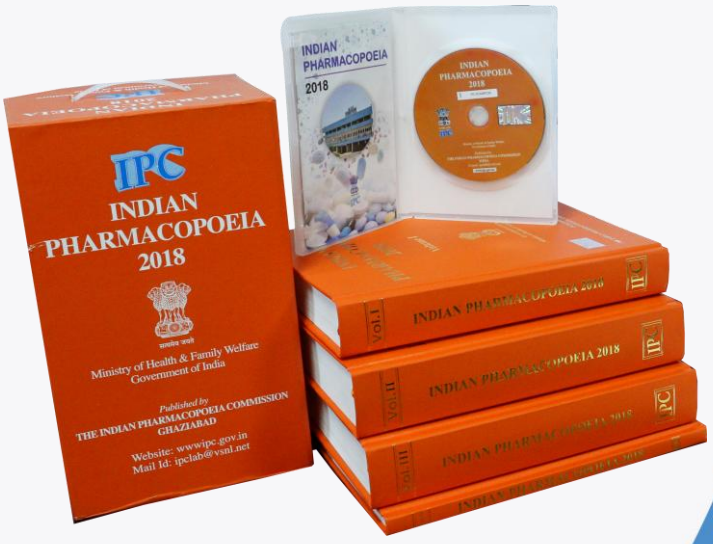
ANNUAL ACHIEVEMENTS DURING THE YEAR 2017-18

The Indian Pharmacopoeia Commission (IPC) is a unique organization committed to set the quality specifications of drugs and pharmaceuticals in the form of Indian Pharmacopoeia (IP) and to promote rational use of medicines by bringing out National Formulary of India (NFI) and to ensure safety of medicines by running Pharmacovigilance Programme of India (PvPI) to protect health of all citizens of our country.

The major achievements of IPC during the year 2017-18 include the following:

A. Indian Pharmacopoeia (IP) – 2018

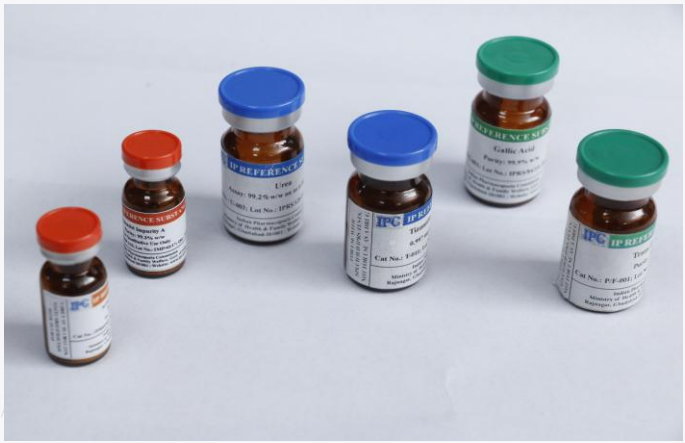
In continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines by publishing the Indian Pharmacopoeia (IP), a legal book of standards for monitoring the quality of Drugs and Pharmaceuticals as per the Drugs and Cosmetics Act, 1945, the Eight Edition of IP-2018 is under printing and expected to be released very soon incorporated with the following salient features:



- IP-2018 contains total 2929 monographs.
- Also incorporates 391 monographs inclusive of 82 monographs of Addendum 2015 to IP-2014; 89 monographs of Addendum 2016 to IP-2014 and 220 newly added monographs of APIs, Excipients and Dosage Forms.
- 10 New General Chapters are also included.
- 25 New Fixed Dose Combination (FDC) Monographs are first time being included in this 8th edition, which are not available in any other Pharmacopoeia of the world.
- 25 New APIs and single formulations are added in IP-2018, which are not available in any other Pharmacopoeia of the world.
- Use of Chromatographic methods has been greatly extended. Classical Chemical Tests for identification of an article have been almost eliminated and more specific IR, UV Spectrophotometer and HPLC Tests have been introduced.
- For the first time Index to make user friendly is also incorporated to Volume-I of IP-2018.

B. Indian Pharmacopoeia Reference Substances (IPRS)

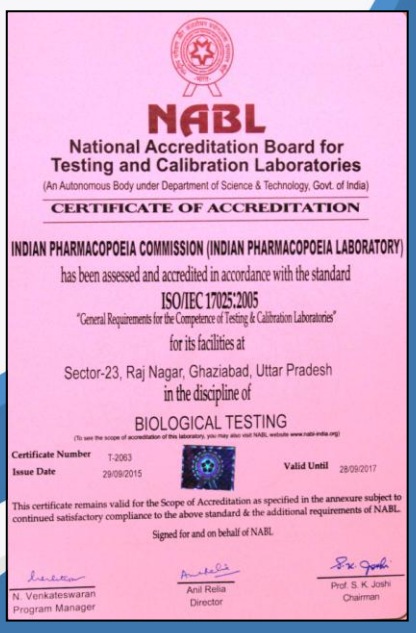
- A total no. of 03 new Impurities were developed and information uploaded on the IPC website (www.ipc.gov.in). Thus, so far 615 IPRS including 78 Impurities are available at IPC.
- To prove the stability of already developed IPRS, retesting is performed initially after two years and then on an annual basis. A total of 158 IPRS were retested for their integrity of potency.
- Total no. of 65 New Candidate Materials for Impurity Reference Standards are under validation to develop the IP Reference Substances.
- Total no. of 20 IPRS issued for changing of their lot numbers due to old number of vials had out of stock or less quantity of vials remains.



- A total of 69 new Candidate Materials have been received from Stakeholders and CDSCO and have already been indentified to develop new IP Reference Substances.
- Total no. of 104 New Drugs samples were received from the Office of Drugs Controller General (India) for verification and reports generated were submitted to the CDSCO, FDA Bhawan, New Delhi.
- Total no. of 142 port samples received from CDSCO, IGI Cargo Complex, New Delhi were analyzed and reports generated were submitted to the respective CDSCO Offices in New Delhi.

C. Accreditation and Certification

- IPC has been assessed and accredited in accordance with the standard ISO Guide 34:2009 "General Requirements for the Competence of Reference Material Producers" as Reference Material Producer (RMP) by National Accreditation Board for Testing and Calibration Laboratories (NABL).
- IPC has been assessed and accredited in accordance with the standard ISO/IEC 17025:2005 "General Requirement for the Competence of Testing & Calibration Laboratories" in the discipline of Chemical and Biological Testing by National Accreditation Board for Testing and Calibration Laboratories (NABL).


NABL
National Accreditation Board for Testing and Calibration Laboratories
(An Autonomous Body under Department of Science & Technology, Govt. of India)
CERTIFICATE OF ACCREDITATION
INDIAN PHARMACOPOEIA COMMISSION (INDIAN PHARMACOPOEIA LABORATORY)
has been assessed and accredited in accordance with the standard
ISO/IEC 17025:2005
"General Requirements for the Competence of Testing & Calibration Laboratories"
for its facilities at
Sector-23, Raj Nagar, Ghaziabad, Uttar Pradesh
in the discipline of
BIOLOGICAL TESTING
Certificate Number T-2063
Issue Date 29/09/2015
Valid Until 28/09/2017
This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.
Signed for and on behalf of NABL
N. Venkateswaran Program Manager
Anil Relia Director
Prof. S. K. Joshi Chairman

- IPC has been assessed and accredited in accordance with the standard ISO/IEC 17043:2010 as Proficiency Testing (PT) Provider in the field of Chemical by National Accreditation Board for Testing and Calibration Laboratories (NABL).

D. Synthesis of Impurities

The new molecules are being introduced in the global market regularly. The impurity profile is one of the most important issues in modern pharmaceutical analysis in the process of technology development for the production of high-purity substances. The new monographs are introduced in IP which become official standards in India and may be adopted globally.

In order to achieve the goal of providing maximum safety of drugs to the public, the work of Impurity Synthesis is also being carried out at IPC in collaboration with Indian Institute of Chemical Technology (IICT), Hyderabad.

E. Pharmacovigilance Programme of India (PvPI)

Indian Pharmacopoeia Commission (IPC) as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) performs the following activities during the period:

- **WHO-Collaborating Centre for Pharmacovigilance**

Based on quantity, quality of the work carried out by the NCC-PvPI and its significant contribution to WHO-UMC, now IPC is recognized as one of the sixth WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services.

- **Initiated Intensive Drug Monitoring (IDM) under PvPI:**
  - Initiated IDM for the drugs like SGLT-2 Inhibitors, Sofosbuvir & Pioglitazone.
  - Identified total 16 sites for the IDM study for above mentioned drugs.
- **Coordination activities with National Health Programs:**

National ToT for expansion of Bedaquiline Shorter MDR-TB regimen with updated Guidelines for PMDT in India was organized by Central TB Division & WHO-Country Office at New Delhi from 18th to 20th April, 2017.

F. Skill Development Programme

IPC contributes significantly to the skill development of professionals engaged in the quality, safety and rational use of medicines. IPC labs are equipped with the latest analytical instruments and equipments and has qualified, experienced and competent scientists for providing training on a regular basis to the drug analysts/bench chemists, regulatory officials, pharmaceutical and medical academicians, research scholars, students, industry personnel etc.

The subject experts/resource persons are drawn from within IPC and outside.

Total 8893 participants from across the country and from abroad have utilized this opportunity. IPC also conducts induction and in-service training.

G. Production of TV Spots and Radio Jingles

In pursuant to the Ministry's O.M. No. S.11016/01/2017-IEC, dated 13th January, 2017, the Commission has been keeping constant co-ordination with the Directorate of Advertising & Visual Publicity (DAVP), New Delhi and also with Prasar Bharti, New Delhi towards the Production of TV Spots and Radio Jingles for the duration of 60 seconds in bilingual for awareness of IPC.