

# ANNUAL ACHIEVEMENTS

2018-19



**Indian Pharmacopoeia Commission**  
**Ministry of Health & Family Welfare**  
**Government of India**

# ANNUAL ACHIEVEMENTS DURING THE YEAR 2018-19

(w.e.f. 01/01/2018 to 31/03/2019)

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 carrying out other related tasks such as preparation, certification and distribution of Indian Pharmacopoeia Reference Substances (IPRS). The Commission also functions as National Coordination Centres (NCCs) for Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI) for ensuring safety of patients/drugs and medical devices, respectively, in the Country.

The major achievements of IPC during the year 2018-19 include the following:

## 1. Publishing of the Indian Pharmacopoeia 2018 (Eighth Edition)

The most significant achievement is the publication of Indian Pharmacopoeia 2018 (Eighth Edition). In continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines, the eighth edition of Indian Pharmacopoeia (IP) in four volumes along with DVD has been published with effective from 1<sup>st</sup> January, 2018. The salient features of IP-2018 are:-

- IP 2018 contains 2928 total monographs, out of which 220 are new monographs, 366 are revised monographs and 07 monographs have been omitted.
- 10 New General Chapters on pharmaceutical, microbiological & biological have been incorporated. General Chapter on Viral safety evaluation of biotechnology products derived from cell lines of Human or Animal origin (2.2.28) has been included for the first time.



- 10 Monographs of Blood grouping reagents have been introduced for first time.

- 53 New Fixed Dose Combination (FDC) monographs have been included, out of which 25 FDC monographs are not available in any other Pharmacopoeia of the world.
- 25 New APIs and single formulations have been included which are not available in any other Pharmacopoeia of the world.
- 34 New IR Spectras have been added and 15 IR spectra have been upgraded.
- 14 Monographs of Insulin and its analogs have been moved from Chemical monographs (Volume-II) to Biotechnology derived therapeutics (Volume-III).

## 2. Progress on Indian Pharmacopoeia (IP) 2018 Addendum 2019

Addendum to the Indian Pharmacopoeia is published in between editions of IP. It takes care of technical/other inadvertent errors as well as incorporates new monographs and omits non-relevant monographs. The Addendum to IP-2018 is under printing. The salient features of IP-2018 Addendum 2019 are:

- IP-2018 Addendum 2019 contains 66 new monographs including Chemical monographs (61), Herbal monographs (03), and Radiopharmaceuticals (02).
- Special emphasis has been given to the dosage forms which are not present in IP 2018.
- Monographs on various life-saving drugs have been introduced in the Addendum 2019.
- General monograph on “Lotions” has been introduced.
- 10 monographs have been upgraded by introducing Dissolution test.

## 3. Increasing Availability of Indian Pharmacopoeia Reference Substances (IPRS) and Impurity Standards

- A total no. of 54 IPRS, 10 Impurities, 01 IPRS (Biologics) and 05 BRS (Botanical Reference Substances) were developed during the index period and information uploaded on the IPC website ([www.ipc.gov.in](http://www.ipc.gov.in)). Thus, so far 580 IPRS including 124 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 482 IPRS were retested for their integrity of potency.
- Total no. of 446 New Drugs Substances were received from the Office of Drugs Controller General (India) for verification and reports generated were submitted to the CDSCO, FDA Bhawan, New Delhi.



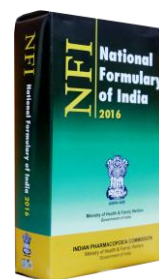
- Total no. of 2491 drug samples received from CDSCO, IGI Cargo Complex, New Delhi and CMSS, New Delhi were analyzed and reports generated were submitted to the respective CDSCO Offices and CMSS in New Delhi.
- The work of impurity synthesis is also being carried out at IPC in collaboration with Indian Institute of Chemical Technology-IICT, Hyderabad and NCL, PUNE. A total of 23 Impurities have been synthesized in NCL Pune & IICT, Hyderabad and submitted to IPC, Ghaziabad

#### 4. Proficiency Testing (PTP) Activities

- A total number of 2 PT programme round “PT Round-01” and “PT Round 02” for the Index Period 2018 were successfully completed in April and December, 2018. A total no. of 39 Laboratories in April, 2018 and 40 Laboratories in December, 2018 participated respectively.

#### 5. National Formulary of India (NFI)

- Core Group and Subject Review Committee were re-constituted for development of 6<sup>th</sup> edition of NFI.
- 1<sup>st</sup> meeting of “Core Group and Subject Review Committee” was held on 24<sup>th</sup> August, 2018 at IPC.



#### 6. Department of Science & Technology (DST) Project

Drugs and Pharmaceuticals Research Programme (DPRP), Department of Science & Technology (DST), Govt. of India sanctioned project entitled “Development of National laboratory facility for setting quality standard for rDNA based therapeutics” for development of laboratory facility at IPC.

#### 7. Accreditation and Certification at IPC

- Indian Pharmacopoeial Laboratory (IPL) is WHO prequalified and also NABL Accredited in the field of Chemical and Biological Testing as per ISO 17025:2005. It has also got Reference Material Producer Accreditation as per ISO 17034:2016 and Proficiency Test Provider Accreditation as per ISO 17043:2010.



- IPC got renewal as a Scientific & Industrial Research Organization (SIROs) from the Department of Scientific and Industrial Research (DSIR), Ministry of Science and Technology, Government of India.

## 8. Pharmacovigilance Programme of India (PvPI)

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

- **Adverse Drug Reactions (ADRs) Reporting**

During the index period, the NCC-PvPI had received 103004 Individual Case Safety Reports (ICSRs).

- **Recommendations for Regulatory Action**

Signal Review Panel (SRP) of PvPI recommended 18 Drugs-ADRs combinations to CDSCO, New Delhi for the change of Package insert. The details as appended below:

Sr. No.	Drugs	ADRs
1	Carbamazepine	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)
2	Meropenem	Hypokalaemia
3	Artemether + Lumefantrine	Stevens Johnson syndrome (SJS)
4	Diclofenac	Nicolau Syndrome
5	Lamivudine	Hearing Loss
6	Amlodipine	Alopecia
7	Cefixime	Mouth Ulceration
8	Carvedilol	Hyperkalaemia
9	Amlodipine	Gingival Hypertrophy
10	Cefotaxime	Angioedema
11	Ofloxacin	Stevens-johnson syndrome
12	Tranexamic acid	Seizure/convulsion
13	Quetiapine	Urinary incontinence
14	Sulfasalazine	DRESS syndrome
15	Tramadol	Hiccups
16	Phenobarbital	DRESS Syndrome
17	Cefepime	Urticaria
18	Glibenclamide	Palpitation

- **Drug Alerts:** PvPI also issued 11 Drug Alerts to the stakeholders.

## 9. Materiovigilance Programme of India (MvPI)

Indian Pharmacopoeia Commission (IPC) as a National Coordination Centre (NCC) for Materiovigilance Programme of India (MvPI) performed the following activities during the period:

- **MvPI Reporting Tools and Reference Manual**

To ensure effective implementation of MvPI as well as to promote safety of Medical Devices, the NCC-MvPI had launched Reporting Tools and Documents on 8<sup>th</sup> February, 2019 at IPC, Ghaziabad. All reporting tools and documents are made available on the official website of IPC ([www.ipc.gov.in](http://www.ipc.gov.in)). The details are as follows:

- An updated Medical Device Adverse Event Reporting Form.
- A Field Safety Corrective Action (FSCA) Form.
- Registered Medical Devices Information Sharing Portal ([www.mvpi.co.in](http://www.mvpi.co.in)).
- A Reference Manual for Medical Devices.
- A Handbook for MvPI.

- **Medical Devices Adverse Event (MDAE)**

The NCC-MvPI had received total no. of 972 Medical Devices Adverse Event (MDAE) Reports during index period from all over the country.

## **10. Reflection in the National and International Arena**

The Indian Pharmacopoeia Commission (IPC) is evolving as a centre of excellence for the standards of medicines by global authorities like the World Health Organization (WHO), European Directorate for the Quality of Medicine & Healthcare (EDQM), United States Pharmacopoeia (USP), and the British Pharmacopoeia (BP).

### **International Arena**

- Subsequent upon obtaining “Observer” Status by European Directorate for the Quality of Medicine & Healthcare (EDQM), Council of Europe, France, the Indian Pharmacopoeia Commission (IPC) in collaboration with EDQM/European Pharmacopoeia (Ph. Eur.) has organized “IPC-EDQM Symposium on Drug Standards and Regulatory Updates” from 26<sup>th</sup> – 27<sup>th</sup> April, 2018 at Hotel Courtyard Marriott, Mumbai, India. More than 150 stakeholders and professionals from Pharma Industry, API Manufacturers, Associations, Academicians, Individuals, Regulators, etc. actively participated.
- The IPC along with World Health Organization (WHO) HQ, Geneva organized “6<sup>th</sup> WHO Bi-annual inter-Regional Seminar for Quality Control Laboratories (QCLs) involved in WHO Pre-qualification” from 23<sup>rd</sup> - 25<sup>th</sup> October, 2018 at New Delhi. The 58 participants from 30 countries participated in the seminar. The inaugural event of this seminar was held on 23<sup>rd</sup> October, 2018; Ms. Preeti Sudan, Secretary, Ministry of Health & Family Welfare, Government of India inaugurated this event as Chief Guest. She highlighted that Indian Pharmacopoeia Commission is the only WHO pre-qualified laboratory in the public sector and stressed a need for more number of laboratories to be accredited by WHO.
- IPC represented in “160<sup>th</sup> Session of European Pharmacopoeia Commission” held at EDQM Premises, Council of Europe, Strasbourg, France from 20<sup>th</sup> - 21<sup>st</sup> March, 2018.

- IPC represented in “41<sup>st</sup> Annual Meeting of Representatives of National Pharmacovigilance Centres participating in WHO International Programme of Drug Monitoring” held at Geneva, Switzerland from 5<sup>th</sup> – 8<sup>th</sup> November, 2018.
- IPC represented in “2018 Special Meeting for the European Pharmacopoeia Observers, the Benefits of the European Pharmacopoeia Network of Observers” held at EDQM Premises, Council of Europe, Strasbourg, France from 21<sup>st</sup> – 22<sup>nd</sup> November, 2018.
- IPC represented in “10<sup>th</sup> International Meeting of World Pharmacopoeias (IMWP)” held at World Health Organization (WHO) HQ, Geneva from 4<sup>th</sup> – 5<sup>th</sup> March, 2019.
- The IPC in collaboration with Uppsala Monitoring Centre (UMC), Sweden had organized “5<sup>th</sup> Asia Pacific Pharmacovigilance Training Course” from 4<sup>th</sup> - 15<sup>th</sup> March, 2019 at the Hotel Fortune, Ghaziabad. The 30 participants, from 14 countries were participated in the course.

### **National Arena**

- The IPC had organized 1<sup>st</sup> IPC workshop on “Therapeutic proteins: Regulatory and Quality Considerations” at IPC Regional office Hyderabad on 23<sup>rd</sup> February, 2018.
- First time IPC had conducted training programme titled “Training Programme for Analysts of MSMEs on Analytical Instruments used in Drugs & Pharma Analysis” from 5<sup>th</sup> - 8<sup>th</sup> June, 2018”. Total no. of 40 participants attended the training programme.
- NCC-MvPI had organized First National Workshop on “Ensuring Quality and Safety of Medical Devices” at Indian Pharmacopoeia Commission (IPC), Ghaziabad from 19<sup>th</sup> – 20<sup>th</sup> July, 2018. Total no. of 44 participants attended the workshop.
- The Library & Information Centre of IPC had organized National Seminar on “Health Information Resources and Searching Techniques” on 27<sup>th</sup> July, 2018 at IPC Campus. Total no. of 64 participants actively participated across the country and abroad in the said seminar.
- The IPC had organized the “1<sup>st</sup> Residential Course on Phytopharmaceuticals and Herbal Drugs Monographs Drafting, Verification and Validation” from 26<sup>th</sup> - 30<sup>th</sup> November, 2018. This Workshop was inaugurated by Dr. Mandeep Kumar Bhandari, Joint Secretary (R), Ministry of Health & Family Welfare, Government of India on 26<sup>th</sup> November, 2018 at IPC, Ghaziabad.
- The IPC had organized 1<sup>st</sup> IPC Workshop on “Human Vaccines & Immunoserum: Regulatory and Quality Considerations” held at IPC Regional Office Hyderabad on 29<sup>th</sup> January, 2019.
- The IPC had organized the “1<sup>st</sup> IPC Interactive Meet on Pharmacopoeia Standards: Regulatory and Quality Considerations” at CSIR-IMTECH, Chandigarh on 4<sup>th</sup> February, 2019 and 60 participants registered for the event. This event focused to create awareness about setting IP standards, to address the IP compliance issues, monograph modernization, and understanding the regulatory pathways.

- The IPC in collaboration with CSIR-National Botanical Research Institute (NBRI), Lucknow and Society of Pharmacognosy co-organized the 23<sup>rd</sup> National Convention of Society of Pharmacognosy - International Conference on New Age Opportunities and Challenges for Quality, Safety and GMPs in Herbal Drug Development at CSIR-NBRI, Lucknow from 22<sup>nd</sup> – 23<sup>rd</sup> February, 2019.
- The IPC co-hosted two days “Pharmacovigilance Programme for Ayurveda, Siddha, Unani & Homoeopathy Drugs”, with All India Institute of Ayurveda (AIIA), Delhi at IPC, Ghaziabad from 19<sup>th</sup> – 20<sup>th</sup> March, 2019.
- First Zonal Awareness Programme (North Zone) on “Herbal Drugs and Phytopharmaceutical Standards” organized to create awareness and upgrade the knowledge of participants, about standard setting procedures adopted by IPC, at Lovely Professional University, Phagwara, Punjab, on 30<sup>th</sup> March, 2019.

### **11. 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 equipment 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.

IPC has conducted nearly 09 induction-cum-training/advance-level training/skill development programmes during the index period.

Total 541 Continuing Medical Education (CMEs) were organized at AMCs of IPC-PvPI.

Total 35906 participants from across the country and from abroad have utilized this opportunity. IPC also conducts induction and in-service training.

### **12. Publications**

- 08 No. of research articles in National and International Journals.
- 05 Issues of IPC-PvPI Newsletter.
- Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical products.
- MvPI Quality Manual and Handbook on Medical Device Safety.