

# Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare

Government of India



**ANNUAL  
ACHIEVEMENTS  
2015-16**

## PHARMACOPOEIA COMMISSION (IPC)

### A. Indian Pharmacopoeia (IP)

- The Indian Pharmacopoeia Commission is poised to publish periodically the Indian Pharmacopoeia (IP), the official and authentic book of standards.
- IP Addendum-2016 to IP-2014 has been released on 14.11.2015 by Sh. Jagat Prakash Nadda, Hon'ble Union Health & Family Welfare Minister and Gen (Dr.) V.K.Singh (Retd.), Minister of State, Ministry of External Affairs, Overseas affairs and Statistics and Programme Implementation (Independent Charge) Government of India. The IP Addendum 2016 effective from 01<sup>st</sup> January, 2016.



*Left to Right: Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC; Padmashree Dr. Nitya Anand, Scientist; Dr. Jagdish Prasad, Director General, DGHS, MoH&FW; Shri J. P. Nadda, Hon'ble Minister of Health & Family Welfare, GOI, Gen. (Dr.) V. K. Singh (Retd.), Minister of State for - External Affairs, Indian Overseas Affairs, Statistics & Programme Implementation (I/c); Shri K. L. Sharma, Joint Secretary(R), MoH&FW; Prof. B. Suresh, Chairman, SB, IPC*

- To meet the expectations of the stakeholders, the Commission is working energetically and has taken care of amendments to IP 2014 and incorporated 89 New Monographs consisting of 64 Chemical Monographs, 14 Herbal Monographs, 03 Vaccines and Immunsera for Human use, 03 Radiopharmaceuticals Monographs, 01 Blood Related Products, 04 Biotechnology Products Monographs and 02 General Chapters included in this Addendum.
- It is assured that Addendum 2016 play a significant role in improving the quality of medicines which in turn promote public health and accelerate the growth and development of Pharma sector in our Country.



## B. Indian Pharmacopoeia Reference Substances (IPRS)

- The Indian Pharmacopoeia Commission has developed and validated 85 New IP Reference Substances. Total no. of 466 IPRS are made available to the stakeholders.
- Indian Pharmacopoeia Commission has developed 20 new impurities by In-House Synthesis and total no of 30 New Reference Impurities made available to stakeholders.
- IPC is in process of preparing, certifying and distributing Indian Pharmacopoeia Reference Standards which will go a long way to save valuable foreign currency which the Country is forced to incur on account of import of Reference Standards of life saving drugs.
- IPC for the first time has come out with IPRS Impurities, which in turn help in generating more revenue and save foreign currency.
- During the year the Indian Pharmacopoeia Commission was successful in coming out with additional 24 IPRS and 22 Impurities standards. 20 New Botanical Reference Substances are under process to develop as Botanical Reference Standards. 28 New Phytopharmaceutical Reference Standard are under process to develop as Phyto Reference Standards.
- During this period total no. of 35 New Drugs samples were received from the office of Drugs Controller General (India) for verification and 34 New Drugs Samples reported.
- Total no. of 50 port samples were received from CDSCO, IGI cargo complex, New Delhi at IPC, Ghaziabad for the analysis and reports of the 40 samples were successfully submitted to the respective CDSCO Offices.
- 3443 Survey samples were analysed and reported through AKS software.
- The RSD of Indian Pharmacopoeia Laboratory has distributed/Sold total no. of 2928 IPRS Vials worth of 87.84 Lacs and 111 Impurities Standard worth of 4.44 Lacs were sold.
- Total No of 288 vials of IPRS worth Rs. 8.64 Lacs and 22 Impurities Vials worth Rs 0.88 lacs were supplied to Government authorities free of cost.



### C. Prednisone Dissolution Calibrator Tablet

- Prednisone Dissolution Calibrator Tablet is used for calibration of Dissolution Apparatus.
- For the first time Prednisone Dissolution Calibrator Tablet was launched on 14<sup>th</sup> November, 2015 by Hon'ble Union Minister Shri J. P. Nadda, Ministry of Health & Family Welfare, Government of India and Gen. (Dr.) V. K. Singh, Minister of State for External Affairs, Indian Overseas Affairs, Statistics & Programme Implementation (I/c), Government of India, for the use of stakeholders.

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

- The 5<sup>th</sup> edition of NFI – 2016 was released by the Sh. Jagat Prakash Nadda, Hon'ble Union Health & Family Welfare Minister and Gen (Dr.) V.K.Singh (Retd.), Minister of State, Ministry of External Affairs, Overseas affairs and Statistics and Programme Implementaion (Independent Charge) Government of India.



- Several new chapters, appendices, revised chapters and revised appendix and revised introduction in all chapter have been included. It is expected that there will be 32 chapters and more than 450 monographs.

### E. Pharmacovigilance Programme of India (PvPI)

- The Hon'ble Health Minister Shri J P Nadda, inaugurated the “38th annual meeting of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring in collaboration with WHO.



- The meeting was jointly hosted by Indian Pharmacopoeia Commission (IPC), National Coordination Centre-Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, and WHO Country Office.
- In this WHO annual meeting 150 International participants from 57 countries were participated to discuss the various issues on Pharmacovigilance and to make appropriate recommendation to WHO.
- The major outcome of the meeting is IPC recognized as a first WHO Collaborating Centre for safety of medicines and vaccines in the south-East Asia region.

#### **F. Skill Development Programme**

- IPC is contributing significantly to the skill development of professionals engaged in quality, safety and rational use of medicines.
- IPC has labs equipped with latest analytical instruments/equipments and has qualified, experienced and competent scientists for providing training on regular basis to the drug analysts/bench chemists, regulatory officials, pharmaceutical and medical academicians, research scholars, students, industry personals etc.
- The subject experts/resource persons are drawn from within IPC and outside. Presentations included power point slides followed by explanations and daily life examples as well as hands on training in the laboratory.
- In the current year, 923 participants from across the country and from abroad have utilized this opportunity. IPC also conducts induction and in service training.

The skill development programmes conducted during the year are listed below:-

| <b>S. No.</b> | <b>Duration</b>                | <b>Title</b>   | <b>Nature of Participants</b>   | <b>No. of Participants</b> |
|---------------|--------------------------------|--|---|----------------------------|
| 1.            | 01/06/2015<br>to<br>12/06/2015 | Training programme for newly Promoted Assistant Drugs Controllers of CDSCO for strengthening National Regulatory Authority (NRA) | Newly promoted Asst. Drugs Controller   | 14                         |
| 2.            | 24/06/2015<br>to<br>24/06/2015 | PvPI Sensitization programme   | Healthcare professionals, postgraduate and undergraduate students of medical colleges and hospitals | 100                        |
| 3.            | 20/07/2015<br>to<br>21/07/2015 | Refreshment course on updates on PvPI for existing Technical Associates  | Technical Associates  | 11                         |
| 4.            | 18/08/2015<br>to<br>22/08/2015 | Induction-cum-Training programme for newly recruited Technical Associates  | New Technical Associates  | 25                         |



|                |                                |   |  |            |
|----------------|--------------------------------|---|--|------------|
| 5.             | 22/08/2015<br>to<br>22/08/2015 | Continuing Medical Education (CME)<br>on Pharmacovigilance  | Healthcare professionals<br>working under Integrated<br>counseling and Testing<br>Centre, National AIDS<br>Control Organization<br>(ICTC-NACO) | 60         |
| 6.             | 24/08/2015<br>to<br>28/08/2015 | Induction-cum-Training programme for<br>newly recruited Technical Associates  | New Technical<br>Associates  | 25         |
| 7.             | 03/09/2015<br>to<br>04/09/2015 | Induction-cum-Training programme on<br>Pharmacovigilance for Coordinators of<br>newly recognized AMCs under PvPI        | Coordinators of newly<br>recognized AMCs under<br>PvPI   | 30         |
| 8.             | 07/09/2015<br>to<br>01/10/2015 | 4 <sup>th</sup> Training programme on various<br>Analytical Instruments & Techniques for<br>Government Drugs Analysts   | Government Drugs<br>Analysts/Bench Chemists  | 35         |
| 9.             | 07/10/2015<br>to<br>07/10/2015 | Workshop on awareness programme of<br>Indian Pharmacopoeia and Indian<br>Pharmacopoeia Reference Substance              | Stakeholders and<br>Scientific Staff and<br>Students of NMIMS  | 225        |
| 10.            | 05/10/2015<br>to<br>08/10/2015 | Pharmacovigilance Programme of India<br>(PvPI) – Uppsala Monitoring Centre<br>(UMC), Joint Signal Detection<br>Workshop | Staff of NCC-PvPI &<br>Drugs Inspectors of<br>CDSCO  | 33         |
| 11.            | 12/10/2015<br>to<br>15/10/2015 | 1 <sup>st</sup> Training programme on ISO<br>17025:2005 for State Drugs Testing<br>Laboratories                         | Laboratory Persons   | 37         |
| 12.            | 16/11/2015<br>to<br>27/11/2015 | Training programme for Medicine<br>Control Laboratory Analysts from<br>Mongolia   | Drugs Analysts and<br>Regulators from<br>Mongolia  | 6          |
| 13.            | 27/11/2015<br>to<br>27/11/2015 | East Zone Training programme on<br>Pharmacovigilance  | Healthcare professionals<br>& delegates  | 100        |
| 14.            | 30/11/2015<br>to<br>03/12/2015 | 2 <sup>nd</sup> Training programme on ISO<br>17025:2005 for State Drugs Testing<br>Laboratories                         | Laboratory Personnel   | 33         |
| 15.            | 08/12/2015<br>to<br>09/12/2015 | Training & awareness programme on<br>Pharmacovigilance  | Healthcare Professionals   | 75         |
| 16.            | 02/02/2016<br>to<br>05/02/2016 | 3 <sup>rd</sup> Training programme on ISO<br>17025:2005 for State Drugs Testing<br>Laboratories                         | Laboratory Persons   | 35         |
| 17.            | 05/02/2016<br>to<br>05/02/2016 | Training for Nursing professionals  | Nursing Staff  | 30         |
| 18.            | 15/02/2016<br>to<br>19/02/2016 | Induction-cum-Training programme for<br>newly recruited Technical Associates  | Technical Associates   | 7          |
| 19.            | 19/03/2016<br>to<br>19/03/2016 | Advanced Level Training in<br>Pharmacovigilance   | Existing Coordinators &<br>Technical Associates of<br>west zone  | 30         |
| 20.            | 01/04/2015<br>to<br>31/03/2016 | <b>Project Trainees</b>   |  | 12         |
| <b>TOTAL =</b> |                                |   |  | <b>923</b> |