

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad 201002

Minutes of 58th Meeting of the Scientific Body of the IPC

Date of Meeting : September 4, 2025

Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

The 58th meeting of the IPC Scientific Body started with opening remarks by Dr. V.M. Katoch, Chairperson, Scientific Body, IPC. Thereafter, the main agenda was presented in the following sequence, and the decisions of the Scientific Body were recorded as below:

Item 1. Introduction and Brief Presentation by the Member Secretary

Dr. V. Kalaiselvan welcomed the members of the Scientific Body and presented the progress and major achievements of the IPC since its previous meeting. The Scientific Body noted and appreciated these accomplishments, which included signing of MoUs on recognition of the IP in foreign countries; successfully conducting 2nd Policymakers' Forum; the launch of a multilingual IVRS helpline to strengthen patient safety; participation in the WHO-SEARN Assembly held in Thimphu, Bhutan; the launch of the IVD reporting form; establishment of new IPRS and impurity standards; the expansion of the Pharmacovigilance and Materiovigilance Programmes of India; initiation of audit activities for medical devices; scientific publications; and revenue generation.

The Scientific Body further appreciated the significant progress achieved by the IPC, both globally and domestically, over the past four years. However, considering the limited opportunities for career advancement of the scientific staff, it reiterated its recommendation for the early implementation of the Modified Flexible Complementary Scheme (MFCS) for IPC's scientific personnel.

Item 2. Confirmation of the Minutes of the 57th Meeting of the SB held on May 13, 2025

Confirmed by the Scientific Body.

Item 3. Action Taken Report on the Minutes of the 57th Meeting of the SB held on May 13, 2025

Noted by the Scientific Body.

MAIN AGENDA

Item 4. Progress of AR&D Division

The Scientific Body reviewed the progress of the AR&D Division with respect to the development of new monographs/general chapters and upgradations of monographs/general chapters and approved the same for the forthcoming IP 2026. Further, Scientific Body noted updates on the IP Online portal, activities related to the international recognition of the IP, IPC's participation in the Pharmacopoeial Discussion Group (PDG), and the organization of Expert Working Group (EWG) meetings. Scientific Body appreciated the activities undertaken.

Scientific Body approved the development and implementation of a robust and user-friendly Laboratory Information Management System (LIMS). The Scientific Body also approved proposals for conducting interactive meets for IP 2026 updates for the stakeholders and with partner countries to ensure effective implementation of MOUs.

Scientific Body suggested to make efforts for the inclusion of dissolution tests in remaining IP monographs, in collaboration with NIPER Ahmedabad and also to develop monographs on rational fixed-dose combinations (FDCs).

Scientific Body suggested to make efforts to address the concern regarding the absence of osmolarity parameters in the monographs for ophthalmic preparations. It was advised that collaborative efforts may be made with the RP Center, AIIMS to include osmolarity as a standard testing parameter in the monographs for ophthalmic formulations.

Item 5. Progress of Microbiology Division

Scientific Body noted the progress made by Microbiology Division with respect to development of new general chapter, upgradation of monographs and approval of the work done for the IP 2026, analytical testing and Proficiency Testing Programme (PTP) in biological domain. Scientific Body noted the gap analysis done by Expert Committee and approved creation of biobank facility at IPC.

Item 6. Progress of Biologics Section

The Scientific Body noted the work progress of the Biologics Division regarding development and upgradation of General Chapters and monographs of biologicals for Veterinary and human use for the IP 2026, EWG and stakeholders' meetings, analytical testing, international participation, trainings of IPC officials and students.

Scientific body member noted the initiatives taken to create awareness about Blood and Blood Components monographs included in upcoming edition of IP 2026 and suggested to present a detailed roadmap plan in the next SB meeting. It was advised to understand development process for Regional Reference Standards from WHO officials. For smooth execution of the MoU with NIPER, Mohali, it was suggested to explore modalities between both the institutions. It was also suggested to constitute a separate Working Group for developing monographs of combination vaccines for veterinary use.

Item 7. National Formulary of India (NFI) 7th Edition

Scientific Body noted the work progress of the NFI 2026.

Item 8. Progress of Reference Standard Division (RSD)

The Scientific Body noted the progress made by the Division in the development of new IPRS and impurity standards, updates related to lot changes in reference standards, drug analysis, and revenue generation. The scientific body also recommended exploring the establishment of a dedicated laboratory for impurity synthesis and also seek new partnerships to achieve the targets.

Item 9. Progress of Quality Assurance (QA) Division

The Scientific Body noted the considerable progress achieved by the Division in maintaining accreditation certifications in accordance with ISO standards. This progress encompasses the execution of proficiency testing (PT) programs, methodical internal quality evaluations, and the provision of extensive training for students.

Item 10. Progress of Phytopharmaceuticals Division

The Scientific Body noted the progress made by the Division. SB noted the reinitiation of the development of monographs for Phytopharmaceutical Ingredients (PPI) and the proposal to develop Phytochemical Reference Substances for both existing and upcoming PPI monographs. Key activities contributing to advancements within the Phytopharmaceuticals Division included organising stakeholder meetings, meetings with MoU partners, and meetings of the Think Tank on Phytopharmaceuticals, as well as the publication of research articles.

Dr. Inder Pal Singh, chairperson of the Think Tank on Phytopharmaceuticals, and esteemed members Dr. Karuna Shanker, Dr. C. K. Katiyar, Dr. T. Narender, Dr. Lal Hingorani, Dr. Amit Agarwal, and Dr. A. K. Pradhan, collaborated to prepare a guidance document titled "Phytopharmaceutical Drugs: General Guidance for Development." The Scientific Body approved this document for upload to the IPC and CDSCO websites to enhance clarity regarding phytopharmaceutical products.

Item 11. Progress of Pharmacovigilance Programme of India (PvPI)

The Scientific Body noted the progress of PvPI for reporting of Adverse Drug Reactions (ADR), expansion of ADR Monitoring Centres across India, issuing drug safety alerts, and stakeholders' meetings.

Item 12. Progress of Medical Device Division/Materiovigilance Programme of India (MvPI)

Scientific Body members reviewed the proposal of establishing a Medical Device Testing Laboratory at IPC and recommended that the newly formed Medical

Device Division should strategically plan the scope and nature of medical device testing activities in alignment with the currently available infrastructure, existing facilities, and in-house technical competencies.

Pertaining to the development and upgradation of medical device monographs, Scientific Body suggested to work closely with Bureau of Indian Standard (BIS) so that duplication of developing medical device standard can be avoided. They also emphasized that list of monographs needs to be developed or upgraded should also be shared with Expert Working Group and their comments should be considered.

Scientific Body also noted progress of MvPI activities on reporting of MDAEs and expansion of MDMCs across India.

Item 13. Progress of Publication Division

Scientific Body accepted the proposal of selling price of the 10th edition of IP 2026 and subsidized/nominal rates for IP Online subscription for CDSCO and State Licensing Authorities, if approved by the competent authority.

Item 14. Revenue Generation

Noted by the Scientific Body.

Item 15. Any Other Item with the Permission of the Chairperson

None.

The meeting ended with a vote of thanks to the Chairperson and Members of the Scientific Body of IPC by the Member Secretary.

List of Scientific Body Members Participated

1. Dr. V. M. Katoch, Former DG-ICMR cum Secretary-Department of Health Research and Chairperson, Scientific Body-IPC
2. Prof. Sanjay Singh, Vice Chancellor, Dr Shakuntala Misra University, Lucknow (connected through VC)
3. Dr Ajay Sachan [Nominee of the Drugs Controller General (I), CDSCO, New Delhi]
4. Mr. A. K. Pradhan [Nominee of the Drugs Controller General (I), CDSCO, New Delhi] (connected through VC)
5. Dr. D. Srinivasa Reddy, Director, IICT, Hyderabad (connected through VC)
6. Dr. Ravi P. Singh, Provost. Adani University, Ahmedabad (connected through VC)
7. Dr. A. K. Singh, Former Director General (LS), DRDO, New Delhi (connected through VC)
8. Dr. Bikash Medhi, Dept. of Pharmacology, PGIMER, Chandigarh
9. Prof. Sanjeev Sinha, Dept. of Medicine, AIIMS, New Delhi (connected through VC)
10. Dr. Naresh Bhatnagar, Dept. of Mechanical Eng., IIT, Delhi (connected through VC)
11. Dr. Inder Pal Singh, Dept. of Natural Products, NIPER, Mohali
12. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration, Mumbai (connected through VC)
13. Dr. C. Hariharan, Director, CDTL, Mumbai (connected through VC)
14. Dr. Sunil Gairola, Executive Director, Serum Institute, Pune (connected through VC)
15. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma Ltd., New Delhi
16. Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt, Aurangabad (connected through VC)
17. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd., Ahmedabad (connected through VC)
18. Dr. V. Kalaiselvan, Secretary-cum-Scientific Director-IPC and Member Secretary

Special Invitees

1. Dr. Ravi Shah, NIPER, Ahmedabad (connected through VC)

Leave of Absence

1. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration, Ahmedabad
2. Dr. Amulya K. Panda, Former Director, NII, Delhi
3. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER, Mohali
4. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI, New Delhi