

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

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**MINUTES OF 48<sup>th</sup> MEETING OF THE SCIENTIFIC BODY OF IPC**

**Date of Meeting** : 8<sup>th</sup> January 2022  
**Mode of Meeting** : Video Conferencing  
**Chairperson** : Prof. N. K. Ganguly

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The list of participants is appended as Enclosure-I.

**Welcome and Opening of the Meeting**

Dr. Rajeev Singh Raghuvanshi welcomed the Chairperson and members of the Scientific Body for the 48<sup>th</sup> meeting of the SB through video conferencing. With the permission of Prof. N. K. Ganguly, Chairperson-Scientific Body, Dr. Raghuvanshi gave a presentation on the major activities and achievements of the IPC after 47<sup>th</sup> meeting of the Scientific Body.

Prof. N. K. Ganguly took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated the efforts of IPC towards publication and release of National Formulary of India 2021, development of monographs for IP 2022, development of new IP Reference Substances (IPRS) and Impurity Standards, expansion of Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI). It was appreciated that IPC is on the path of developing into a professional organization. Prof. Ganguly suggested that the phytopharmaceuticals testing laboratory shall be strengthened with modern analytical instruments. Also, PvPI shall become a permanent part of the IPC with dedicated staff.

Prof. Ganguly also desired that the long pending FCS proposal shall be implemented at the earliest for timely promotion of the scientific staff of the IPC.

Thereafter, the Member Secretary presented the agenda in following sequence and decisions of the Scientific Body are recorded as below:

**Item 1. Confirmation of the Minutes of the 47<sup>th</sup> Meeting of the Scientific Body held on 3<sup>rd</sup> July 2021**

Confirmed.

**Item 2. Action Taken Report on the Minutes of the 47<sup>th</sup> Meeting of the Scientific Body held on 3<sup>rd</sup> July 2021**

Noted by the Scientific Body.

**MAIN AGENDA**

**Item 3. Progress Report of AR&D Division**

Noted.

Scientific Body appreciated development of new general chapters, monographs, and monograph revisions/upgradations for their publication in the IP 2022. The content was approved for its publication.

Creation of separate category for 'Vitamins, Minerals, Amino acids, Fatty acids etc.' was approved for IP 2022.

Scientific Body also approved deletion of 'Dose' from IP monographs.

**Item 4. Progress Report of Reference Standard Division**

Noted.

Scientific Body appreciated significant increase in the number of IPRS and Impurity standards developed by the Division. Efforts made for procurement of new IPRS and Impurity Standards through tendering process were also noted.

**Item 5. Progress Report of Microbiology Division**

Noted.

Development of new general chapters and monograph revisions/upgradations were appreciated and approved by the Scientific Body for their publication in the IP 2022.

Design layouts for new Microbiology Laboratory in ALRC were put up for comments and it was agreed. Scientific Body suggested that as microbiology is an important Division, therefore, new laboratory should be equipped with latest instrumentation.

Scientific Body also opined that NCCS-Pune may be contacted for making available reference cultures as per the IP.

**Item 6. Progress Report of Phytopharmaceuticals Division**

Noted.

Scientific Body appreciated and approved content of new general chapters, monographs, and monograph revisions/upgradations for publication in the IP 2022.

The proposed monographs as a new category of Phytopharmaceuticals Ingredient (PPI) for IP 2022 was approved by the Scientific Body.

Scientific Body suggested prioritizing the list of PPI monographs for next IP editions and following may be taken up by the Division in gradual manner: *Glyzeriza glabra*, *Ashwaganda*, *Bacopa monneri*, *Phyllanthus emblica*.

**Item 7. Progress Report of Biologics Section**

Noted.

Development of new general chapters, monographs, and monograph revisions/upgradations were appreciated and approved by the Scientific Body for their publication in the IP 2022.

Scientific Body suggested that IPC should review to mention biological reference standards as National Reference Standards (NRS) instead of IPRS. The suggestion will be discussed in respective expert working group before finalization.

It was also opined to keep bioassay based analysis as part of IP monographs for ensuring the functional identity of the biotherapeutics. IPC may also evaluate possibility of developing general chapter/monograph on futuristic biotherapeutics (e.g. gene therapy, cell therapy etc.)

Scientific Body appreciated and agreed for sale of separate volume of IP having veterinary products.

**Item 8. Progress Report of National Formulary of India (NFI)**

Noted.

Scientific Body suggested efforts to be made to get NFI popularized in India and recognized outside India also.

**Item 9. Mutual Cooperation with National and International Organizations**

Noted.

Scientific Body suggested briefing about the major outcomes of the MoUs in next meeting.

**Item 10. Progress Report of Quality Assurance (QA) Division**

Noted.

Scientific Body appreciated International PT programme conducted by the Division.

It was also opined that retesting plan shall be based on the stability of the API molecule. It was also suggested to organize more training programmes for the stakeholders.

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

Noted.

Scientific Body appreciated the expansion plan of PvPI and suggested to integrate PvPI activities with the National Health Programmes.

Regarding adverse events due to Doxycycline, it was suggested that holistic view should be made after considering global adverse events data.

It was again recommended making PvPI as permanent part of the IPC with permanent staff structure.

**Item 12. Progress Report of Materiovigilance Programme of India (MvPI)**

Noted.

Scientific Body appreciated expansion of MvPI and increase in the reporting of MDAEs to the programme. The progress report of WHO Collaborating Centre was also noted.

Scientific Body suggested while reviewing the Miltefosine related ICSRs dose and duration of the drug also to be taken into consideration.

**Item 13. Progress Report of Publication Division**

Noted.

**Item 14. Other Points for Discussion**

Scientific Body suggested IPC to prioritize new areas to work upon.

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

There was no other agenda.

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

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**List of Scientific Body Members Participated through Video Conferencing**

1. Prof. N. K. Ganguly, Former DG-ICMR and Chairperson, Scientific Body-IPC
2. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
3. Dr. Amulya K. Panda, Former Director, NII-Delhi
4. Mr. A. K. Pradhan, DDC(I), CDSCO-Delhi
5. Dr. Raman M. Singh, Director, CDTL-Mumbai
6. Dr. Sunil Gairola, Director-QC, Serum Institute-Pune
7. Dr. Praveen Khullar, Head-Global Development Centre, Sanofi-Goa
8. Dr. Hemant K. Sharma, Senior Vice President, Aurobindo Pharma-Hyderabad
9. Dr. Nitin Bhatia, Assistant Vice President, Intas Pharma-Ahmedabad
10. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

**Leave of Absence**

1. Prof. Ramesh Kr. Goyal, Vice Chancellor, DPSRU-Delhi
2. Dr. D. Srinivasa Reddy, Director, IIIM-Jammu
3. Dr. A. K. Singh, Former Director General (LS), DRDO-Delhi
4. Dr. Ram A. Vishwakarma, Former Director, IIIM-Jammu
5. Dr. Naresh Bhatnagar, Professor, IIT-Delhi
6. Prof. Naveet Wig, Head-Deptt. of Medicine, AIIMS-Delhi
7. Dr. Nithya Gogtay, Deptt. of Clinical Pharmacology, KEM-Mumbai
8. Dr. Arun K. Mishra, Head-Global Regulatory Affairs, Unilever-Gurugram
9. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram
10. Prof. Vinod Kumar Dixit, Former Dean, Dr. Hari Singh Gaur Univ., Sagar
11. Mr. Salim Veljee, Former Commissioner, FDA-Goa
12. Dr. Rakesh N. Tirpude, Assistant Commissioner, FDA-Maharashtra
13. Dr. V. Satyanarayana, Managing Director, Sipra Labs-Hyderabad