

INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health & Family Welfare, Govt. of India)

Sector-23, Raj Nagar, Ghaziabad-201002

MINUTES OF 42nd MEETING OF THE SCIENTIFIC BODY OF IPC

Date : 22nd February, 2020
Venue : RS Iyer Hall, IPC-Ghaziabad
Chairperson : Prof. N. K. Ganguly

The list of participants is appended (Enclosure-I)

Opening of the Meeting

Dr. Jai Prakash, Secretary-cum-Scientific Director (I/c), IPC welcomed the Chairperson and members of the Scientific Body for the 42nd meeting of the Scientific Body. He thanked all the members of the Scientific Body for critically reviewing the activities of IPC and their suggestions for further strengthening the same. He requested Prof. N. K. Ganguly to open the meeting and the same was accepted by the Chairperson.

Prof. N. K. Ganguly, Chairperson-Scientific Body remembered the leadership role of Dr. G. N. Singh, Former Secretary-cum-Scientific Director-IPC in the major success stories of IPC including publication of Indian Pharmacopoeia (IP), development of IPRS and impurities, publication of National Formulary of India (NFI), Pharmacovigilance Programme of India (PvPI), national and international co-operations, certification and accreditation of IPC laboratories, and infrastructure development.

Prof. Ganguly also informed the members that due to emergency family situation he could not attend the last meeting of the Scientific Body scheduled on 22nd October, 2019. Prof. Ganguly further suggested that in such emergency situations the meeting need not be cancelled and the Scientific Body members may elect an alternate Chairperson amongst themselves to complete the proceedings of the meeting in future.

Thereafter, Prof. Ganguly took note of the key achievements of the IPC since the last meeting of the Scientific Body and appreciated that IPC has been doing constant progress in every field. He also desired that the assessment of the progress of each Division of the IPC should be carried out against the assigned work during the index period.

Afterwards, the Scientific Body took-up the agenda items.

Item 1. Confirmation of the Minutes of the 41st Scientific Body (SB) Meeting held on 20th July, 2019

The minutes had been circulated to the Scientific Body members through email vide IPC letter No. IPC/7041 dated 23.07.2019 and no comments were received; therefore, the minutes of the 41st meeting of the Scientific Body were confirmed.

Item 2. Action Taken Report on the Minutes of the 41st Meeting held on 20th July, 2019

Noted and approved by the Scientific Body.

Main Agenda

Item 3. Progress Report of Indian Pharmacopoeia (IP) and AR&D Division

I. Extension of Effective Date of IP Addendum 2019 to IP 2018

Noted by the Scientific Body.

II. Monographs Drafted for IP Addendum 2021

Scientific Body appreciated the work of monograph development for IP Addendum 2021 and suggested that the monographs should be displayed on IPC website for a period of 45 days and comments received on draft monographs may be reviewed by the Expert Working Groups. The concept of harmonization of monographs, if applicable, be applied while reviewing. Thereafter, such monographs to be put up for the approval of the Scientific Body in next meeting.

III. Inclusion of Monograph of Sugar Spheres in IP

Scientific Body opined that considering the use of Sugar Spheres in homeopathic medicines and possible large impact of the monograph of Sugar Spheres on Indian pharma industry, the views of the Ministry of AYUSH may be sought before taking final decision on this issue.

IV. Effective Date of Forthcoming IP Edition, Addendum and Amendment List

Reviewing the historical data of the extensions given by the IPC of effective dates and trends of other pharmacopoeias, it was approved to keep the effective dates as follows:

Publication	Current Effective Date	Approved Effective Date
New Edition of IP	06 months after publication	06 months after publication
IP Addendum	03 months after publication	06 months after publication
Amendment List	Immediately after release	Immediately after release

V. Frequency of Publication of IP Edition and its Addendum

Scientific Body extensively discussed this matter and approved that in future IP Editions to be published at an interval of two years. Also, if needed, amendment list and/or IP Addendum may be published in between two IP Editions to keep IP standards updated.

VI. Amendment List 04 to IP 2018

Scientific Body approved the contents of the Amendment List-04.

VII. NDMA Impurity in Sartan Drugs and Ranitidine

It was suggested by the Scientific Body that in order to address the issue of NDMA impurities, a sub-committee may be constituted by the IPC and the recommendations of the committee may be put up for the approval of the Scientific Body in the next meeting.

VIII. Limit of Ethylene Glycol & Diethylene Glycol in Propylene Glycol Monograph in IP 2018

Scientific Body members discussed the matter and suggested that IPC laboratory may verify these methods as per USP. Also, opinion of the CDSCO to be considered before taking final decision.

- IX. Monographs of 'Lorcaserin Hydrochloride' and 'Lorcaserin Tablets' in IP 2018 and FDA's Request for Withdrawal of 'Lorcaserin'**
Scientific Body deferred the matter as this issue is also under discussion at CDSCO. It was suggested that an appropriate decision may be taken once CDSCO takes a stand on this issue.
- X. Technical Meetings Organized**
Scientific Body noted the work carried out by various Expert Working Groups and suggested that the decisions taken by various Expert Working Groups may also be forwarded to the members of the Scientific Body.
- XI. Organizing Trainings/Seminars/Conferences**
Noted by the Scientific Body.
- Item 4. Progress Report of Microbiology Division**
Scientific Body noted and appreciated the work done by Microbiology Division in the areas of drug analysis, organizing meetings of the Expert Working Group-Microbiology, skill development, and participation in proficiency testing.
Scientific Body also approved the proposed amendments in the Microbiology monographs and the same will be included in Amendment List-04.
- Item 5. Progress Report of Phytopharmaceutical Division**
Scientific Body noted and appreciated the work done by Phytopharmaceutical Division in the areas of development of monographs and general chapters, and development of reference standards for herbal products and phytopharmaceuticals.
- Item 6. Progress Report of Biologics Section**
Scientific Body noted and appreciated the work done by Biologics Section in the areas of monograph development and up-gradation, organizing meetings of the Expert Working Groups, organizing trainings, and participation in ILC.
The proposal for deletion of test for Abnormal Toxicity was also discussed and Scientific Body accepted the proposal in line with WHO guidelines. Scientific Body also approved the proposed amendments in the Biologics monographs and the same will be included in Amendment List-04.
- Item 7. Progress Report of Reference Standard Division**
The work for the development of IP Reference Substances (IPRS) and Impurity Standards, analysis of New Drug Substances, and revenue generated was reviewed by the Scientific Body.
Issue of sale of IPRS and Impurity Standards through authorized distributors was also discussed and it was suggested to qualify such distributors considering the requirements of IPRS storage and distribution and following the best practices adopted by USP and BP.
- Item 8. Progress Report of Quality Assurance (QA) Division**
Scientific Body noted the work progress of the QA Division in the area of maintaining certification and accreditation, organizing PT studies for international laboratories, review of reports and quality documents, and providing training to various stakeholders.

Scientific Body appreciated the new proposal of National Quality Assurance Assessment Scheme (NQAAS) and noted that launch of NQAAS would help strengthening the quality of results produced by participant laboratories across India.

Item 9. Progress Report of National Formulary of India (NFI)

The work of NFI was presented and Scientific Body noted and appreciated the progress.

Item 10. Working Relationships with National and Other Institutes of Repute

Noted by the Scientific Body.

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

The activities of PvPI were presented and Scientific Body Members reiterated that under current drug regulations PvPI has important role to play in the public health. Dr. Jai Prakash informed that 45 new AMCs are being enrolled under the PvPI and the total number will increase to 315 after the consent is obtained from the centers. It was desired by the Scientific Body that efforts should be made to strengthen the activities of PvPI across the country.

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

The progress made under MvPI was noted and it was suggested to gradually increase the Medical Device Adverse Events Monitoring Centres across the country.

Item 13. Release of Annual Report of IPC for the Financial Year 2018-19

Noted by the Scientific Body.

Item 14. Status of Sale and Distribution of IPC Publications

Noted by the Scientific Body.

Item 15. Other Agenda Items

With the permission of the Chairperson following agenda items were also discussed:

(i) IPC Action Plan 2020-2025

Considering the important role of IPC in the field of pharmaceutical field, Scientific Body suggested that IPC should prepare 2020-2025 plan with clear strategy to achieve set goals.

(ii) Replacement of Scientific Body Members

Also, issue of continuous absence of few members of the Scientific Body in its meetings came for discussion and it was desired by the Secretary-cum-Scientific Director that suitable replacements of the members may be find out so that we can have important contributions in IPC work.

Meeting ended with thanks to the Chairman and Members of the Scientific Body of IPC.

List of Scientific Body Members Participated

1. Prof. N. K. Ganguly
2. Dr. R. M. Singh
3. Dr. Sunil Gairola
4. Dr. Praveen Khullar
5. Dr. Hemant K. Sharma
6. Mr. Salim Veljee
7. Dr. Anil Kumar Tyagi
8. Dr. Arun K. Mishra
9. Dr. Nitin Bhatia
10. Dr. Jai Prakash

Leave of Absence

1. Prof. Sanjay Singh
2. Dr. Ram A. Vishwakarma
3. Dr. A. K. Singh
4. Dr. Amulya K. Panda
5. Prof. Ramesh Kr. Goyal
6. Mr. A. K. Pradhan
7. Dr. Naresh Bhatnagar
8. Dr. D. Srinivasa Reddy
9. Prof. Vinod Kumar Dixit
10. Prof. Naveet Wig
11. Dr. Rakesh N. Tirpude
12. Dr. Nithya Gogtay
13. Dr. V. Satyanarayana

IPC Staff who attended the meeting

1. Dr. V. Kalaiselvan
2. Dr. Anil K. Teotia
3. Dr. Robin Kumar
4. Dr. Anuj Prakash
5. Dr. Meenakshi Dahiya
6. Dr. Gaurav Pratap Singh
7. Dr. M. Kalaivani
8. Dr. Shashi Bhushan
9. Dr. Manoj K. Pandey
10. Dr. Pawan K. Saini
11. Dr. K. K. Singh