

NEWSLETTER

2024 | VOL 1



INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA



EMPOWERING PUBLIC HEALTH BY
PROMOTING QUALITY OF MEDICINES AND PATIENT SAFETY

TABLE OF CONTENTS

01. MESSAGE FROM THE SECRETARY-CUM-SCIENTIFIC DIRECTOR
02. PUBLICATION OF THE IP ADDENDUM 2024
03. GLOBAL RECOGNITIONS
04. ESTABLISHMENT OF IPRS
05. COLLABORATIONS
06. SIGNIFICANT ACTIVITIES AND CELEBRATIONS
07. CONFERENCES AND SEMINARS
08. PUBLICATIONS

EDITORIAL TEAM



DR. GAURAV PRATAP SINGH JADAUN - EDITOR

DR. SHRUTI RASTOGI - ASSOCIATE EDITOR

MS. AYSHU BHARDWAJ - ASSOCIATE EDITOR

MR. SAURABH SAHOO - ASSOCIATE EDITOR

FROM THE SECRETARY-CUM-SCIENTIFIC DIRECTOR'S DESK

It is with great delight that we present the first volume of IPC Newsletter 2024, highlighting our ongoing progress and initiatives aimed at enhancing the quality and safety of medical products both in India and globally.

In 2024, IPC remained steadfast in fostering international collaboration and harmonization efforts, aligning our standards with the evolving global healthcare landscape. We have consistently introduced new monographs and general chapters in the IP Addendum 2024, ensuring that pharmacopoeial standards meet the ever-changing needs of the regulatory requirements and healthcare sector.

Our development of IP Reference Substances (IPRS), including impurity standards, has provided critical support to stakeholders in meeting regulatory and quality requirements. These efforts have solidified IPC's reputation as a leading pharmacopoeial body worldwide for making available reference standards.

Patient safety and rational medicine use continue to be at the core of IPC's mission. Through the Pharmacovigilance and Materiovigilance Programmes of India, we have actively ensured patients' safety, rights, and well-being across the nation.

Additionally, IPC has been dedicated to enhancing laboratory competence by conducting and participating in proficiency testing schemes, ensuring reliable and accurate results generated by the laboratory.

None of these achievements would have been possible without the collective dedication of our scientists and staff, who remain committed to advancing public healthcare and contributing to societal welfare.

We look forward to continuing this journey of excellence in years to come.



Dr. Rajeev Singh Raghuvanshi
Secretary-Cum-Scientific Director
Indian Pharmacopoeia Commission

PUBLICATION OF THE IP ADDENDUM 2024

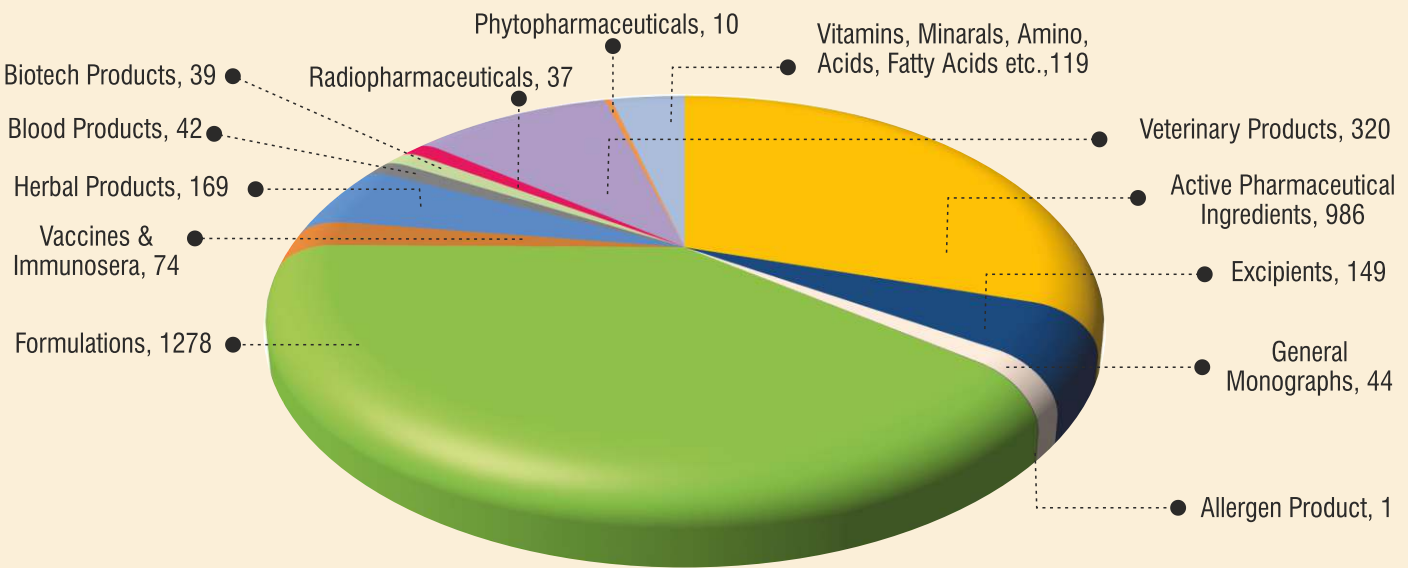
Continuing its commitment to enhancing drug standards, IPC published the IP Addendum 2024 to IP 2022, which was released by Dr. Mansukh Mandaviya, Hon'ble Union Minister of Health and Family Welfare during a function held at CDSCO Bhawan in Indore on 7th January, 2024. IP Addendum 2024 became effective from 1st July 2024.

The IP Addendum 2024 includes 75 new monographs under the categories of Pharmaceuticals (N=51), Veterinary Medicines (N=20), Phytopharmaceuticals (N=3), and Biotechnology Derived Therapeutic Products (N=1). Additionally, 9 new general chapters were introduced, covering Pharmaceuticals (N=2), Veterinary Biological Products (N=4), Bacterial Endotoxins (N=1), and Phytopharmaceuticals (N=2).

Furthermore, on account of IPC's commitment for harmonization of pharmacopoeial text, a total of 6 general chapters and 9 excipient monographs have been harmonized with the Pharmacopoeial Discussion Group (PDG) text to align with global standards.



RELEASE OF IP ADDENDUM 2024 BY DR MANSUKH MANDAVIYA, HON'BLE MINISTER OF HEALTH & FAMILY WELFARE AT CDSCO BHAWAN, INDORE



STATUS AND DISTRIBUTION OF MONOGRAPHS IN THE CURRENT EDITION OF THE IP

GLOBAL RECOGNITIONS

In pursuit of the efforts by the IPC, supported by the Ministry of Health and Family Welfare, and Ministry of External Affairs, the IP has also been recognized in the following countries:

- **BHUTAN:** An MoU has been exchanged between India and Bhutan on cooperation concerning sharing reference standards, pharmacopoeia, vigilance and testing of medicinal products. The MoU would allow for acceptance of the IP by Bhutan as a book of standards for medicines and supply of generic medicines at affordable prices.



EXCHANGE OF MOU BETWEEN FOREIGN SECRETARIES OF INDIA AND BHUTAN IN THE PRESENCE OF HON'BLE PRIME MINISTER OF INDIA, SH. NARENDRA MODI AND HON'BLE PRIME MINISTER OF BHUTAN, SH. TSHERING TOBGAY

- **NICARAGUA:** The governments of India and Nicaragua have signed a Memorandum of Understanding (MoU) on pharmacopoeia cooperation to accept IP as a book of standards for medicines in Nicaragua. Nicaragua has become the first Spanish-speaking nation to officially recognize the IP standards.



SIGNING OF MOU BY DR. SUMIT SETH, INDIAN AMBASSADOR TO NICARAGUA AND DR. MARTHA REYES, NICARAGUA'S MINISTER OF HEALTH

• MEETINGS WITH INDIAN MISSIONS

Three virtual meetings (morning, afternoon, and evening sessions) were convened by the Ministry of External Affairs (MEA) and Ministry of Health & Family Welfare (MoHFW) on 7th March, 2024 to discuss the proposal of acceptance and recognition of the IP in foreign countries with Indian Missions across the globe. Officials from the MEA, MoHFW, Central Drugs Standard Control Organization (CDSCO), and IPC attended the meeting along with representatives from Indian Missions. These meetings will act as catalysts to push the proposal of IP recognition in countries of the Global South.

ESTABLISHMENT OF IP REFERENCE STANDARDS & IMPURITIES

The IPC continues to strengthen its commitment to ensuring quality in pharmaceuticals by launching new IPRS & impurities.

• **New IPRS Launched:**

IPC has introduced Sodium L Lactate as a new IPRS.

• **New Impurities Introduced:**

IPC has also launched the following impurities to enhance analytical testing capabilities:

- Promethazine Related Compound B
- Dolutegravir Impurity E
- Buprenorphine Impurity A
- Atenolol Related Compound E
- Tazobactam Related Compound A



COLLABORATIONS

Memoranda of Understanding (MOUs)

The IPC signed multiple MOUs to strengthen collaborations with national and international organizations.

Signing of MoU between IPC and USP

On 14th March 2024, an important MoU was signed between the IPC and United States Pharmacopeia (USP) at the USP headquarters in Rockville, Maryland. The MoU was signed by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director of IPC, and Dr. Ronal T. Piervincenzi, CEO of the USP Convention. This collaboration aims to strengthen the global harmonization of pharmaceutical standards, further enhance the quality of medicines, and foster research and development between the two organizations. On the occasion, Dr. Rajeev also addressed the USP assembly and participated in the panel discussion.



CSIR-IMTech, Chandigarh and IPC

An MoU was signed between the Council of Scientific & Industrial Research (CSIR)-Institute of Microbial Technology (IMTech), Chandigarh, and IPC on 24th April 2024 at CDSCO Bhawan, New Delhi. The agreement aims to fulfil the requirements of Microbial Reference Cultures for stakeholders in accordance with the IP 2022.



SIGNIFICANT ACTIVITIES AND CELEBRATIONS

16TH FOUNDATION DAY CELEBRATION OF IPC

The 16th Foundation Day of IPC was celebrated on 17th January 2024. Dr. Radha Rangarajan, Director, CSIR-Central Drug Research Institute, Lucknow was the Chief Guest on the occasion. During her visit, Dr. Radha interacted with the scientific staff of the IPC and took a round of the IPC laboratory facilities. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC welcomed Dr. Radha Rangarajan, Prof. Y. K. Gupta, and other guests present at the Foundation Day celebrations. Dr. Rajeev gave a presentation summarizing IPC activities in the field of pharmaceutical standardization and pharmacovigilance to promote the quality and safety of medicinal products in the country. Key achievements made by the IPC were also presented. On the occasion, Dr. Radha Rangarajan also delivered a Foundation Day lecture.



INAUGURATION OF ADVANCE LEVEL RESEARCH CENTRE (ALRC) AT IPC

The Hon'ble Prime Minister virtually inaugurated the Advance Level Research Centre (ALRC) on 25th February 2024. The ALRC aims to enhance research capabilities and foster innovation in various scientific and technological fields. The inauguration marks a significant step towards promoting advanced research in the country, supporting the development of new solutions to address emerging challenges in healthcare, pharmaceuticals, and other sectors.



WOMEN'S DAY CELEBRATION

Women's Day was celebrated at IPC on 8th March 2024 to honour the invaluable contributions of women to the organization's growth and success. The event featured inspiring activities and recognition of women employees.



INTERNATIONAL YOGA DAY

IPC celebrated International Yoga Day on 21st June 2024. A special yoga session was conducted, emphasizing physical and mental well-being. Participants engaged in various yoga practices, promoting a healthy lifestyle.



CONFERENCES AND SEMINARS

Dr. M. Kalaivani delivered a talk at the International Symposium on the theme "Animal Virus, Vaccines & Immunity" on 09th -11th February, 2024 at the Institute of Veterinary Science & Animal Husbandry (IVSAH), under the banner of Siksha O Anusandhan, Bhubaneswar, Odisha.



Dr. Gaurav Pratap Singh attended the Pharma Live Expo in Mumbai on January 18, 2024 and delivered a talk on "Role of IPC in Setting Indian Pharmacopoeia Standards". Dr. Gaurav also participated in a panel discussion.





On February 2, 2024 Dr. Gaurav Pratap Singh delivered a lecture on “Role of IPC in Setting Pharmacopoeia Standards for Ensuring Quality of Medicines” at the Capacity Building Programme on “Importance of Quality Compliance and Patient Safety” organized by Pharmexcil in Indore.

IPC organized a workshop on “Scientific writing and Systematic Review” on April 6, 2024. Prof. Bikash Medhi and Dr. Ajay Prakash from Post Graduate Institute of Medical Education and Research, Chandigarh conducted this session with participation of IPC scientific staff.



Dr. Gaurav Pratap Singh participated in Analytica Anacon held in Mumbai on April 17, 2024 and participated in a panel discussion on “Regulatory Compliance in Pharmaceutical Technical Operations”. Dr. Gaurav also delivered a talk on “Role of IPC in Setting Pharmacopoeia Standards for Ensuring Quality of Medicines”.



Dr. Gaurav Pratap Singh visited Accra, Ghana to participate in the “Fourth Session of the India-Ghana Joint Trade Committee (JTC)” which was held from May 2-3, 2024. The Ghanaian delegation was led by Hon. Michael Okyere-Baafi, Deputy Minister of Trade and Industry, Republic of Ghana. The Indian delegation was led by Mr. Amardeep Singh Bhatia, Additional Secretary, Ministry of Commerce and Industry, Government of India.

During the meeting, the Indian side proposed to extend the approval of the IP as a reference book of drug standards alongside other recognized pharmacopoeias in Ghana. Both sides recognized that accepting this proposal would further promote the availability of affordable and high-quality medicines for the citizens of Ghana by eliminating duplication of regulatory testing, labelling, and other regulatory requirements.



Dr. Gaurav Pratap Singh participated in the “2nd India-Myanmar Joint Working Group (JWG) Meeting on Cooperation in Health Sector”, which was held on 17th May 2024 at Civil Services Officers’ Institute, New Delhi. The Myanmar delegation was led by Dr. Myat Wunna Soe, Director General, Ministry of Health & Sports while Ms. V. Hekali Zhimomi, Additional Secretary, Ministry of Health & Family Welfare led the Indian delegation. During the JWG meeting, a presentation was made by Dr. Gaurav on the proposal of recognition and acceptance of the IP in Myanmar.



Dr. Gaurav Pratap Singh participated in the “PharmaLytica Expo 2024”, which was held on 30th May 2024 at HITEX, Hyderabad. PharmaLytica Expo 2024 witnessed a gathering of industry experts, technical heads, quality control and clinical researchers, purchase and packaging professionals, policy advisors, and other key stakeholders to engage in discussions covering the full spectrum of pharma machinery and packaging, lab analytical and cleanroom solutions, and pharmaceutical ingredients. During the conference, Dr. Gaurav made a presentation on the topic “Role of Indian Pharmacopoeia Standards for Ensuring Quality of Medicines”. This Expo was extremely beneficial as it helped to create more awareness about the IP standards among new stakeholders who attended the above session.



Dr. Gaurav Pratap Singh attended the IPEC India Annual Conference 2024 held in Hyderabad on May 31, 2024 and participated in a panel discussion on “Evolving Trends in Quality and Regulatory”. The panel discussion served as an excellent platform to exchange ideas and learn about regulatory and compendial requirements for pharmaceutical operations and created more awareness among the stakeholders about the IP standards.

The 2nd meeting of India-Cambodia Joint Working Group on Trade & Investment (JWGTI) was hosted by India in Vanijya Bhawan, New Delhi on June 19, 2024. The meeting was co-chaired by the Joint Secretary, Department of Commerce, Ministry of Commerce and Industry, Government of India, Shri Siddharth Mahajan and the Director General for International Trade, Ministry of Commerce, Kingdom of Cambodia, Mr. Long Kemvichet. The representatives of stakeholder Ministries also participated in the meeting. During the meeting, Dr. Gaurav made a presentation on the proposal for recognition and acceptance of the IP in Cambodia.



PARTICIPATION IN PHARMA EXPOS FOR THE PROMOTION OF IPC PRODUCTS

IPC actively participated in various Pharma Expos throughout 2024.

Stalls were set up to showcase and promote IPC's diverse range of products and services, and to engage with stakeholders.



MR. ARVIND SHARMA & MR. MUNEER JAVED MUHAMMED PARTICIPATED IN PHARMA LIVE EXPO IN MUMBAI ON JANUARY 17-19, 2024



MR. LALIT SHARMA PARTICIPATED IN PHARMEXCIL SESSION IN INDORE ON FEBRUARY 2, 2024

PUBLICATIONS

1. Sharma A.K., Rastogi S., Ali F., Yadav A.P., Goyal R.K. "A comprehensive quality control and cost comparison study of branded and generic angiotensin receptor blockers" *Saudi Pharmaceutical Journal*. 2024;32(3):101985. <https://doi.org/10.1016/j.jsps.2024.101985>
2. Teotia A.K., Singh A.C., Thota P., Kumari B., Kumar P., Verma O.M., Phathak C., Pandey M.K., Raghuvanshi R.S. "Engineering advances in safe laboratory design for pharmaceutical microbiology and assessment of their biohazard risk measures" *Safety Science*. 2024:174,106458. <https://doi.org/10.1016/j.ssci.2024.106458>
3. Pratap G.S., Kalaivani M., Kumar M., Singh G.N., Raghuvanshi R.S., Jain P. "Report of a collaborative study to establish the first Indian Pharmacopoeia reference standard for teriparatide" *Biologicals*. 2024;86:101755. <https://doi.org/10.1016/j.biologicals.2024.101755>
4. Saini P.K. "Indian Pharmacopoeia monographs updates and future roadmap" *Spinco Biotech Cutting Edge*. 2024;13(11):30-35. <https://www.spincotech.com/epub/2024/march2024/index-h5.html#page=31>
5. Rastogi S., Jadaun G.P.S. "Regulatory aspects of quality control in pharmaceuticals" *Quality Control and Regulatory Aspects for Biologicals*. 2024:Chapter1,1-14. <https://doi.org/10.1201/9781032697444>
6. Tiwari R., Chauhan A., Patel M., Patel K. "Determination of pesticide residues and heavy metals in Adhatoda Vasaka Linn" *Journal of Pharmaceutical and Biopharmaceutical Research*. 2024;5(2):412-416. <https://doi.org/10.25082/JPBR.2023.02.001>
7. Tiwari R., Pandaya A., Gulati P., Chahuan A. "A big threat: Aflatoxin" *Journal of Pharmaceutical and Biopharmaceutical Research*. 2024;5(2):417-423. <https://doi.org/10.25082/JPBR.2023.02.002>
8. Singh K.K., Raghuvanshi R.S., Asif M. "The exploring role and responsibility of Indian Pharmacopoeia Commission: An introduction" *Journal of Education Technology in Health Sciences*. 2024;10(3):64-68. <https://doi.org/10.18231/j.jeths.2023.015>



INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

Sector - 23, Raj Nagar, Ghaziabad, Uttar Pradesh - 201002 (India)

Tel.: +91-120-2783392, 2783400, Mob.: +91-9654631395, Email: lab.ipc@gov.in, Website: www.ipc.gov.in

DIGITAL ACCESS TO INDIAN PHARMACOPOEIA MONOGRAPHS AND REFERENCE SUBSTANCES



REGULAR UPDATES | EASY CROSS REFERENCING
DOWNLOAD AND PRINT OPTIONS | TECHNICAL SUPPORT
ADVANCE SEARCH FUNCTIONALITY | USER-FRIENDLY INTERFACE
COMPREHENSIVE DATABASE | SECURE ACCESS
INVENTORY OF 1200+ REFERENCE SUBSTANCE | PREDNISONE TABLETS

HOW TO REGISTER AND SUBSCRIBE ON IP ONLINE PORTAL

STEP 1: FREE REGISTRATION

1. Visit the IP Online portal at <https://iponline.ipc.gov.in/>.
2. Click on "Register/Login."
3. Select "Sign Up" and enter your name and email ID, then click on "Sign Up" again.
 - Individual User: Choose this option if you do not have a GST number and want to subscribe for one user only.
 - Organization: Choose this option if you have a GST number and want to subscribe for more than one user.
4. Fill in all the details in the registration form and verify your account using the OTP sent to your email.
5. Once OTP verification is complete, your free registration process will be finalized.

STEP 2: LOGIN AND SUBSCRIPTION ACTIVATION

1. Visit the IP Online portal at <https://iponline.ipc.gov.in/>.
2. Click on "Register/Login."
3. Enter your registered email ID and password to sign in.
4. Click on "Welcome" (displayed with your username) in the top-right corner, and select "Account Management."
5. Navigate to "Manage Subscription" and choose the subscription slab you wish to purchase.
6. Click on "Buy Now" and complete the payment process.
7. After successful payment, your subscription will be automatically activated.
8. Use the search bar at the top to locate and access monographs included in your subscription.

PURCHASE



IP & IP ONLINE



IPRS