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सत्यमेव जयते

IPC

INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

EMPOWERING PUBLIC HEALTH BY PROMOTING QUALITY OF MEDICINES AND PATIENT SAFETY

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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

As we draw the curtain on 2024, it is with immense pride and gratitude that I reflect on the remarkable achievements and milestones of the Indian Pharmacopoeia Commission (IPC). These accomplishments underscore our steadfast dedication to elevating the quality and safety of medical products, both within India and on the global stage.

The latter half of the year has been particularly dynamic, marked by significant progress in our harmonization efforts with the Pharmacopoeial Discussion Group (PDG) and development of IP Reference Substances (IPRS) and impurity standards. These efforts have further strengthened the pharmaceutical industry's ability to ensure regulatory compliance and uphold the highest standards of quality assurance.

Global collaboration has remained at the heart of our mission. In August 2024, we successfully hosted the inaugural Policy Makers' Forum, in partnership with the Ministry of Health & Family Welfare and Ministry of External Affairs. This landmark event brought together delegates from 15 countries to align pharmaceutical policies and foster international cooperation. The recognition of IP standards in five additional countries further highlights the growing trust and synergy in our global partnerships.

The launch of the IP Online Portal has been a transformative step forward, providing stakeholders with seamless access to pharmacopoeial standards and guidelines. This digital innovation has been widely acclaimed across the industry, reflecting our commitment to leveraging technology for greater efficiency and transparency.

Moreover, our active participation in key international events has reinforced India's leadership in shaping the global pharmaceutical landscape. These achievements are a testament to the unwavering dedication of our scientists, staff, and stakeholders, who share IPC's vision of safeguarding patient safety and promoting public health.

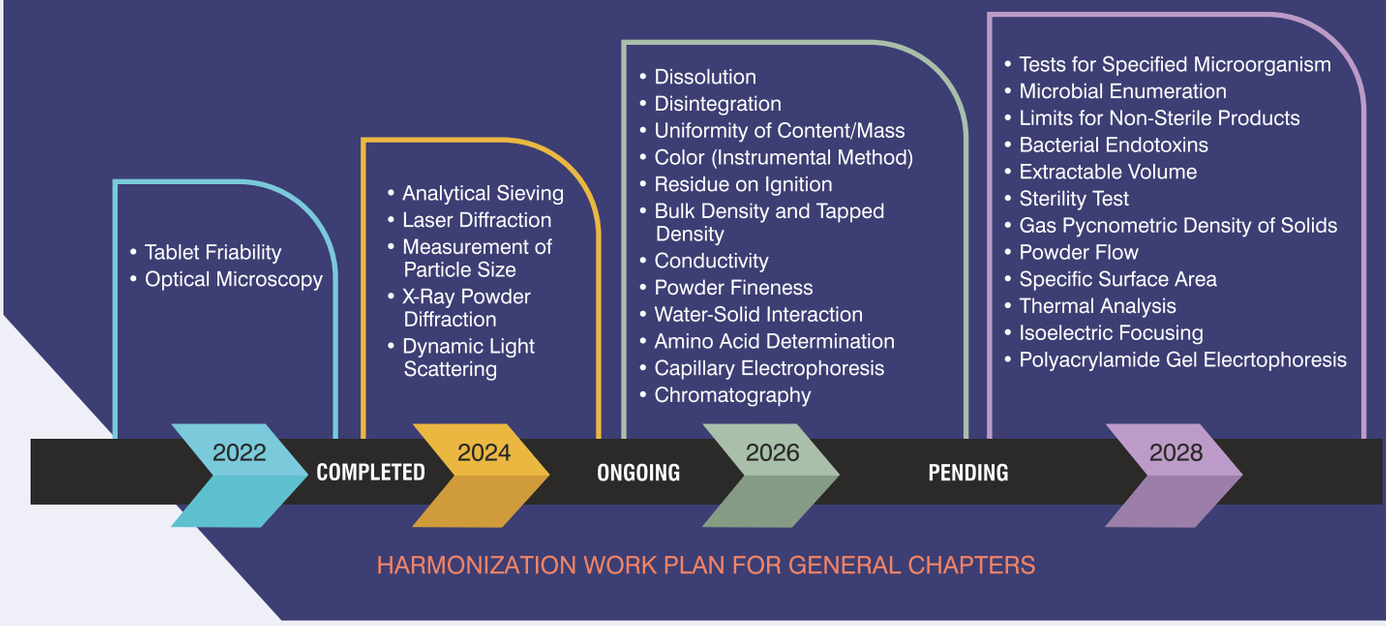
As we look ahead to 2025, we are inspired to build on these successes and reach even greater heights. Together, we will continue to advance pharmaceutical standards, foster global collaborations, and uphold our mission to ensure the highest quality of healthcare for all. The journey ahead is filled with promise, and we are motivated to make an even greater impact in the years to come.

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

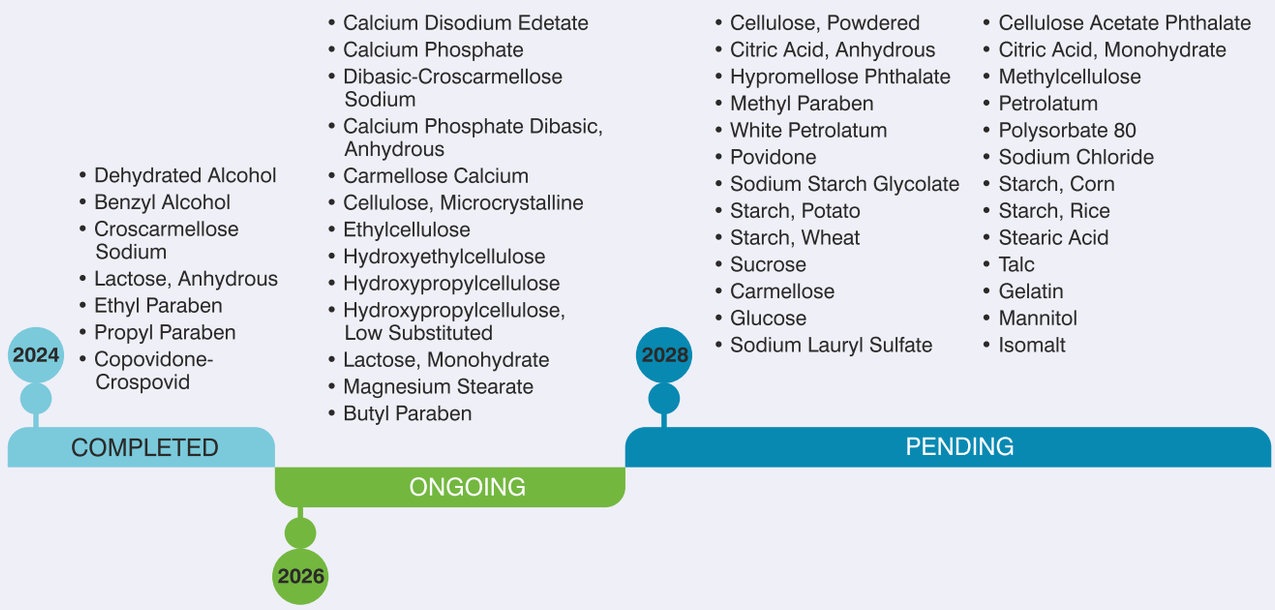
KEY HIGHLIGHTS OF 2024

HARMONIZATION EFFORTS WITH PHARMACOPOEIAL DISCUSSION GROUP (PDG)

As a proud member of the Pharmacopoeial Discussion Group (PDG), IPC is actively working towards harmonizing general chapters and excipient monographs with the standards of PDG pharmacopoeias, including the European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and United States Pharmacopeia (USP). These harmonized texts are targeted for inclusion in forthcoming Indian Pharmacopoeia (IP) editions in a phased manner, reflecting IPC's commitment to aligning with global best practices and ensuring international compatibility. IPC remains actively engaged in collaborating with the EP, JP, and USP to drive the harmonization of pharmacopoeial texts, aiming for their inclusion in the upcoming IP 2026.



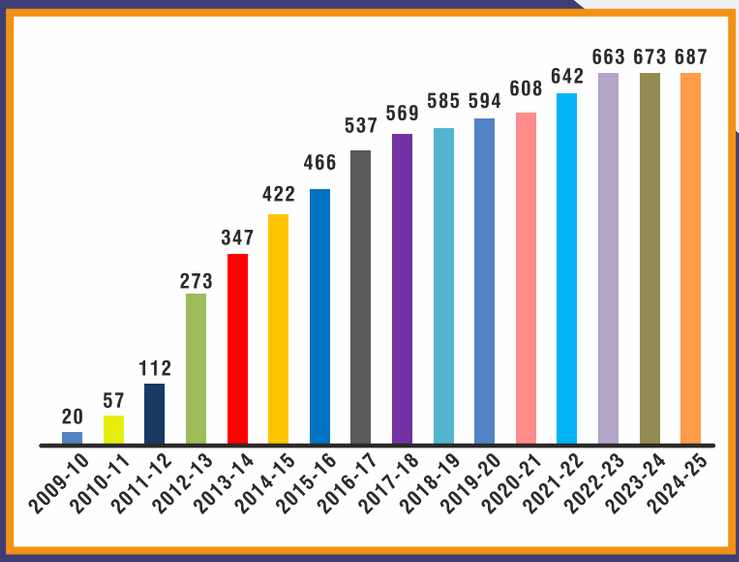
HARMONIZATION WORK PLAN FOR GENERAL CHAPTERS



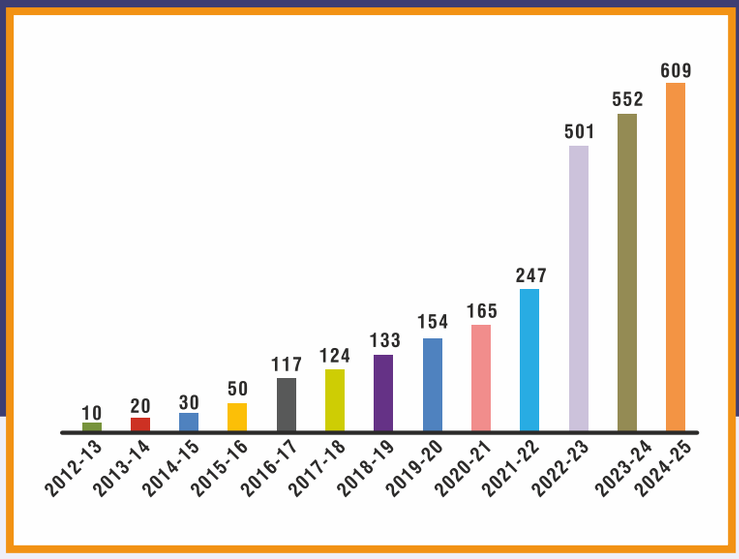
HARMONIZATION WORK PLAN FOR EXCIPIENT MONOGRAPHS

DEVELOPMENT OF IP REFERENCE STANDARDS (IPRS) AND IMPURITY STANDARDS

As one of its key mandates, IPC establishes the IP Reference Standards (IPRS) and Impurity Standards through rigorous testing and validation processes. These reference standards are official primary standards enforced by the regulatory authorities to ensure the quality control of marketed medicinal products across India. To date, IPC has developed 687 IPRS and 609 Impurity Standards, with the complete list available on the official IPC website (www.ipc.gov.in). During the reporting period, 120 IPRS and Impurity Standards were developed. This included 10 new IPRS, 58 new Impurity Standards, 47 lot-changed IPRS, and 5 lot-changed Impurity Standards. A total of 513 IPRS and Impurity Standards were retested during the year to ensure their stability. Notably, IPC has established over 1250 reference standards, which is the third highest number of standards available from any pharmacopoeia body.



DEVELOPMENT OF IP REFERENCE STANDARDS



DEVELOPMENT OF IMPURITY STANDARDS

DRUG ANALYSIS

A total of 686 new drug samples were tested, while 144 miscellaneous and CMSS port samples were analyzed. Additionally, 1277 cough syrup samples were received for testing. Reports for all these samples were successfully submitted to the respective offices.

FLAGSHIP PROGRAMS AND GLOBAL RECOGNITIONS

IPC HOSTS 1ST POLICY MAKERS' FORUM

In a collaborative effort to elevate the nation's stature in the global pharmaceutical arena, the IPC, in association with the Ministry of Health & Family Welfare and Ministry of External Affairs, successfully hosted a delegation of Policy Makers and Drug Regulators from 15 countries at the 1st Policy Makers' Forum organized from August 19 to 22, 2024.

The event witnessed participation from 15 countries, fostering dialogue and collaboration on shaping global pharmaceutical policies. This landmark forum provided an invaluable platform for sharing insights, aligning regulatory frameworks, and strengthening international partnerships to enhance the quality and safety of medical products worldwide.

Later in the day, the delegates embarked on an in-depth tour of the IPC's state-of-the-art laboratories and facilities in Ghaziabad. During the visit, they were provided with a comprehensive overview of the Commission's rigorous processes and protocols that ensure the highest standards in pharmacopoeial practices. The tour offered a detailed glimpse into India's robust framework for quality control in pharmaceuticals, showcasing the advanced technologies and methodologies employed in the development, testing, and standardization of medicinal products. This experience significantly enriched the delegates' understanding of India's contributions to global healthcare standards.

LAUNCH OF INDIAN PHARMACOPOEIA (IP) ONLINE PORTAL

The IP Online portal was officially launched by the Hon'ble Minister of Health and Family Welfare, Shri J.P. Nadda, on 19th August 2024 during the inauguration session of the 1st Policy Makers' Forum organized at Dr. Ambedkar International Centre, New Delhi. This innovative platform has quickly become an invaluable resource for the pharmaceutical industry, offering seamless access to standards and guidelines.

With its real-time updates, digital resources, and user-friendly interface, the portal has empowered stakeholders to stay informed and compliant with the latest IP standards. Widely embraced across the industry, the portal represents a significant step forward in enhancing accessibility and supporting pharmaceutical quality and safety in India.

INTERNATIONAL RECOGNITION OF THE IP

In pursuit of the efforts by IPC, supported by the Ministry of Health and Family Welfare, Department of Pharmaceuticals, and Ministry of External Affairs, the Indian Pharmacopoeia (IP) has achieved recognition in 13 countries. Notably, Soloman Islands, Mozambique, Malawi, Guyana, and Nauru have joined the list of countries recognizing IP standards, further enhancing its global acceptance.

Signing of MoU by High Commissioner of India to Mozambique, Mr. Robert Shetkintong, and Ms. Tania Vuyeya Sitoie, President, ANARME, Mozambique

Signing of MoU between PMRA Board Chairman, Mrs. Frider Chimimba, and Indian High Commissioner to Malawi, Mr. S. Gopalakrishnan, representing the Pharmacy and Medicines Regulatory Authority (PMRA) and Indian Pharmacopoeia Commission (IPC), respectively.

RECOGNITION OF THE IP IN LATIN AMERICA, AFRICA, ASIA, AND PACIFIC COUNTRIES

COLLABORATIONS

MEMORANDA OF UNDERSTANDING (MoUs)

During the financial year, the IPC signed multiple Memoranda of Understanding to strengthen collaborations with national and international organizations.

SIGNING OF MoU BETWEEN IPC AND PCIMH

On 6th August 2024, an MoU was signed between the IPC & Pharmacopoeia Commission for Indian Medicine and Homeopathy (PCIMH), Ministry of AYUSH.

The MoU was signed by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC, and Dr. Raman Mohan Singh, Director, PCIMH, in the presence of Sh. Prataprao Jadhav, Hon'ble Minister of State for Health & Family Welfare and AYUSH. This collaboration marks a milestone in enhancing the quality and safety of Indian medicines through the harmonization of standards and joint initiatives.

IPC COLLABORATES WITH FSBI "SCEEMP"

On 8th July 2024, IPC and Federal State Budgetary Institution 'Scientific Centre for Expert Evaluation of Medicinal Products' of the Ministry of Health of the Russian Federation (FSBI "SCEEMP") signed an MoU and entered into a significant partnership to strengthen mutual understanding of pharmacopoeial frameworks, foster technical cooperation, and advance monograph and reference standard development. The collaboration emphasizes information exchange, practical evaluations, joint publications, and hosting scientific events to enhance global regulatory harmonization and innovation in medicinal standards.

NATIONAL AND INTERNATIONAL ENGAGEMENTS

VISIT OF US PHARMACOPEIA (USP) LEADERSHIP TEAM

IPC hosted the leadership team from the US Pharmacopeia (USP) on 16th December, 2024. An engaging session was held with Dr. Ronald Piervincenzi, CEO-USP, Dr. Jaap Venema, CSO-USP, and other senior leaders. The discussions focused on supply chain resiliency, medicine quality, and opportunities for collaboration, including capability building, industry partnerships, and joint events.

IPC'S PARTICIPATION IN ICDRA 2024

On the sidelines of International Conference of Drug Regulatory Authorities (ICDRA) 2024, meetings were conducted between officials from the IPC and representatives from different nations to strengthen pharmacopoeial cooperation. On 16th October, 2024, IPC officials met with regulatory officials of Nepal, Bhutan, Sri Lanka, Mauritius, Mozambique, and Solomon Islands to discuss the recognition of IP standards, review updates, gather expectations, and consider suggestions from each partner country to strengthen pharmacopoeial cooperation. The establishment of an annual forum between the IPC and partner countries was also discussed.

A meeting was also conducted on 16th October, 2024 with regulatory officials of Fiji to discuss IPC's proposal for recognition and acceptance of the IP. During the meeting, Dr. Kiran Karlapu, Director (Drugs), Ministry of Health & Family Welfare, and Ms. Bhumika Kaushik, Under Secretary, Ministry of External Affairs, were also present.

UZBEK DELEGATION AT IPC

A delegation of drug regulators from Uzbekistan visited the IPC on 16th October 2024 to explore collaboration on pharmaceutical standards. The visit focused on discussions about the IP, IP Reference Standards (IPRS), and potential training programs for capacity building in Uzbekistan's pharmaceutical sector. Both sides expressed commitment to strengthening cooperation in these areas and enhancing regulatory frameworks.

PDG ANNUAL MEET AT EDQM, FRANCE

Dr. Gaurav Pratap Singh and Dr. Shruti Rastogi participated in the PDG Annual Meeting held at the European Directorate for Quality of Medicines (EDQM) in Strasbourg, France, from 1st-2nd October 2024. Discussions were held on the following topics: update of activities from each pharmacopoeia, transition from heavy metal tests to elemental impurities, inclusion of dissolution tests for prolonged-release dosage forms, nitrosamines, improving pharma environmental footprint, future of PDG, and bacterial endotoxin testing using recombinant reagents.

On 3rd October 2024, IPC scientists attended the PDG Stakeholders Meeting at EDQM in Strasbourg, France. The meeting provided an opportunity to engage with global stakeholders, discuss emerging challenges, and contribute to the ongoing efforts for harmonizing pharmacopoeial standards.

TRAININGS & CONFERENCES

Dr. Robin Kumar, Principal Scientific Officer, IPC, engaged with newly recruited drug regulators during their induction training program at the National Institute of Health and Family Welfare, New Delhi. His session focused on strategies to ensure product quality, emphasizing the importance of regulatory vigilance, adherence to standards, and proactive measures in safeguarding public health.

Dr. M. Kalaivani participated in a conference on “The refinement towards medication safety compliance with pharmacy practice and Pharmacovigilance” as a Speaker-Resource Person on the topic of “Quality and safety aspects for Biological-derived therapeutics” organized by Senghundhar College of Pharmacy, Tamil Nadu on 21st - 23rd November 2024.

Dr. Gaurav Pratap Singh participated in a panel discussion at Asia Labex and Labotica on July 3, 2024, in Ahmedabad.

Visit of Fiji delegation on 27th August 2024 to IPC under the leadership of the Director, Fiji Pharmaceutical and Biomedical Services (FPBS), Mr. Jeremaia Mataika. Discussions were held around recognition and acceptance of the IP in Fiji, followed by a lab tour.

A guest lecture was delivered by Dr. Archana Bahuguna on the title of "Nitrosamine impurities" at IPC on 11th September 2024.

Dr. Gaurav participated in IDMA Pharmaceutical Analysts Convention held in Mumbai on 24th-25th October 2024 and delivered a talk on “IPC’s Role in Setting Pharmacopoeial Standards and their Harmonization”.

On 30th November 2024, Dr. Gaurav Pratap Singh attended CDSCO-IDMA Workshop in Ahmedabad and made a presentation on “Indian Pharmacopoeia (IP) Updates and IP Online Portal”.

IPC’s stall setup at the 23rd IDMA Pharmaceutical Analysts' Convention (PAC) 2024 in Mumbai from 24th to 25th October 2024

IPC's stall during Asia Labex and Labotica 2024 in Ahmedabad

56th meeting of the Scientific Body of IPC was organized on 23rd December 2024 at IPC to discuss and review the progress made by IPC regarding its functions.

AWARDS & RECOGNITIONS

INDIA PHARMA AWARD

IPC has been conferred a Special Recognition award under "Outstanding Contribution to Pharmaceutical Research by Academic Institutes" at the CPHI India Pharma Awards 2024 held at India Expo Centre, Greater Noida on 26th November 2024.

The award acknowledges IPC's remarkable contributions such as the publication of IP 2022, launch of the IP Online portal, harmonization of IP standards through IPC's membership in the Pharmacopoeial Discussion Group, and acceptance of IP standards in various foreign countries.

OTHER ACTIVITIES

Hindi Pakhwada was observed to promote the use and importance of the Hindi from 14th to 27th September 2024

Vigilance Awareness Week on Capacity Building Programme was observed from 16th August 2024 to 15th November 2024 at IPC, which aimed at fostering transparency, accountability, and integrity in organizational practices. The Capacity Building Programme provided a structured approach to enhance awareness, encourage ethical practices, and strengthen vigilance mechanisms across various sectors.

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5. Kumar P., Rastogi S., Saini P.K., Sahoo S., Raghuvanshi R.S., Jadaun G.P.S. “Minimizing the risk of ethylene glycol and diethylene glycol poisoning in medications: A regulatory and pharmacopoeial response” *Regulatory Toxicology and Pharmacology*. 2024:155,10574. https://doi.org/10.1016/j.yrtph.2024.105741
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11. Tiwari R., Gulati P., Solanki P., Dhobi M. “Analytical quality-by-design guided development of a novel and robust HPTLC method for quantifying plumbagin from Plumbago species” *Journal of Liquid Chromatography & Related Technologies*. 2024,1-8. https://doi.org/10.1080/10826076.2024.2435651

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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

सत्यमेव जयते
IPC

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Govt. of India
Sector 23, Raj Nagar, Ghaziabad 201002
Website: www.ipc.gov.in, E-mail: lab.ipc@gov.in
Phone No.: +91-120-2783392, 2783400