Azadi Ka Amrit Mahotsav

Role of IPC in Setting Pharmacopoeia Standards for Ensuring Quality of Medicines

Dr. Gaurav Pratap Singh Jadaun
Principal Scientific Officer

November 17, 2023
Chennai

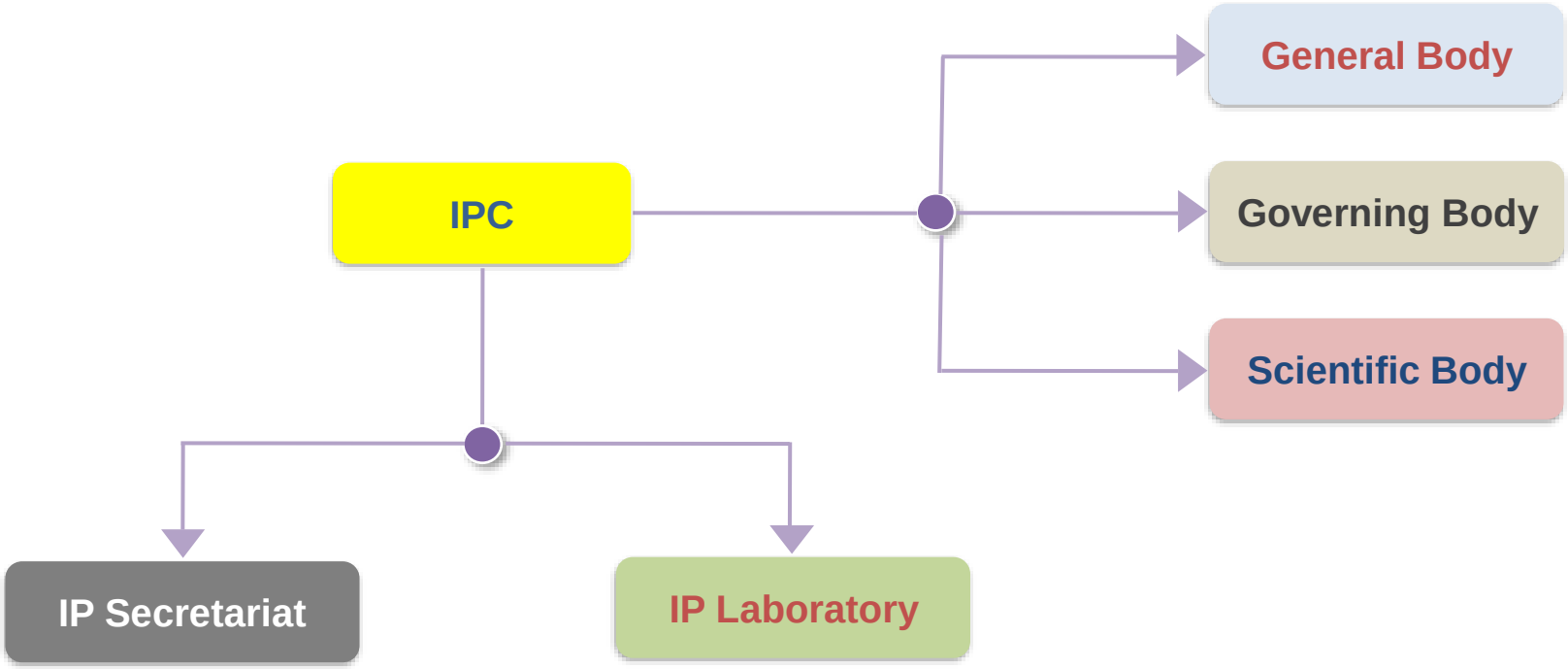
Presentation Disclaimer

The information contained herein represents the current best practices in the field of pharmacopoeial sciences to demonstrate compliance with the existing regulatory requirements. The information contained in this presentation is not intended to alter or modify or supplement or in any other way change the contents of the Indian Pharmacopoeia (IP), but is intended to provide general guidance to all users of the IP to help in ensuring proper compliance with the IP requirements when standards of drugs are to be determined.

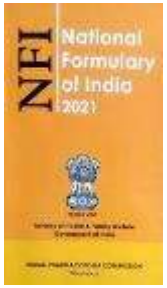
The content of this presentation shall be treated as non-mandatory guidance and the information contained herein is subject to review by the IPC. Approaches and methods other than those described in this presentation may be adopted if found suitable and justified. Where provisions of the law exist, the law as prevailing at the relevant time shall apply.

Indian Pharmacopoeia Commission (IPC)

- An autonomous Institute under Ministry of Health & Family Welfare, Govt. of India
- Established on 1st January, 2009 to set official standards of drugs in India
- Three tier structure comprising of the General Body, Governing Body, and Scientific Body
- Expert Working Groups (EWGs) with subject experts to guide on standards setting



IPC Mandates & Functions



PHARMACOVIGILANCE PROGRAMMES OF INDIA (PvPI)

WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Indian Pharmacopoeia (IP)

Indian Pharmacopoeia (IP)

01 Book of drug standards as per Drugs & Cosmetics Act 1940. Published by the Indian Pharmacopoeia Commission (IPC)

02 Monograph development by public comments and expert consultations

03 IP standards are authoritative and legally enforceable

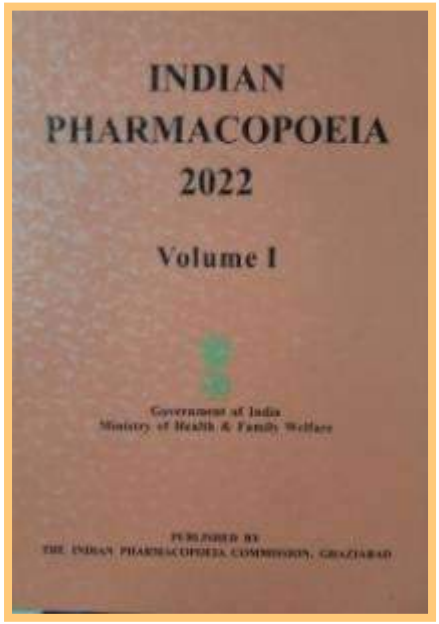
04 Helps ensuring quality of marketed medicinal products in India

05 Contains monographs on APIs, formulations, excipients, veterinary medicines etc.

Monograph Inclusion & Exclusion Criteria

Inclusion Criteria

- Drugs approved by the CDSCO
- Drugs included in the National List of Essential Medicines
- Drugs used in National Health Programs of India
- Drugs considered appropriate by the IPC

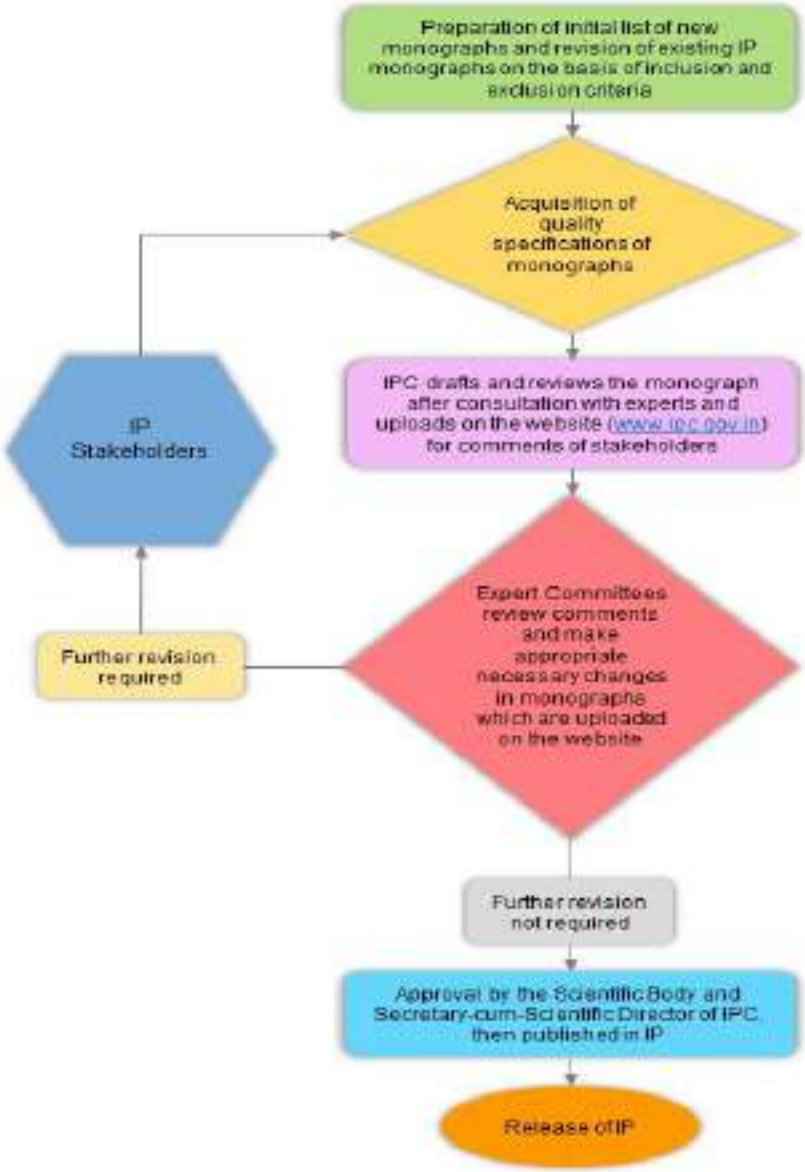


Exclusion Criteria

- Drugs banned in India
- Obsolete drugs
- Drugs considered inappropriate by the IPC

Monograph Development Process

- Selection of monographs based on specific inclusion criteria
- Quality specifications sourced from manufacturers
- Monograph development in consultation with experts of EWGs and stakeholders
- Pharmacopoeia text published on IPC website for inviting public comments
- Approval of the Scientific Body before publication in the IP



EWGs of IP

- Active Pharmaceutical Ingredients
- Anti-Cancer
- Anti-Retroviral
- Excipients
- Fixed Dose Combinations
- Ophthalmic
- Vitamins, Minerals, Amino Acids, Fatty Acids etc.

- Biological & r-DNA Products
- Blood & Blood-related Products
- Allergen
- Vaccines & Immunosera for Human use
- Anti-Sera

- General Chapters
- General Chapter on Dosage Form
- Microbiology-General
- Parenteral Preparations-General

- Impurity Standard Review
- IPRS Review

- Toxicology
- Phytopharmaceuticals
- Radiopharmaceuticals
- Veterinary Products
- Medical Devices
- Plastic Containers
- IP Digitalization
- Website

Proposing Monograph Development & Revision

Monograph Development

- Need for new monograph
- Proposal submitted to the IPC on lab.ipc@gov.in
- CDSCO approval, validation data, test samples/Ref. Std. required
- Approval by the EWG as per inclusion criteria
- Monograph development through standard process of public comments

Monograph Revision

- Need for revision due to harmonization, modernization or amendment
- Proposal submitted to the IPC on lab.ipc@gov.in
- Test samples/Ref. Std. required for verification
- Inviting public comments on revised text
- Approval by the EWG

Structure of IP Standards

General Notices

- Provide rules to understand pharmacopoeia text for its interpretation and application
- Applicable to all pharmacopoeia texts

General Chapters

- Not mandatory '*per se*'
- Mandatory when referred to in a specific monograph
- Some General Chapters are not referred in monographs and are published as useful guidance
- Can be used for substances not covered by monographs
- May contain validity or equipment-verification requirements

General Monographs

- Containing centralized methods and specifications common to all dosage forms (e.g. tablets, capsules, injections)
- Include aspects that cannot be treated in each specific monograph
- Mandatory for all the products within the scope of definition section
- Usually referred for substances where there is no monograph

Specific Monographs

- Developed based on approved specifications for drug substances or finished products
- Analytical procedures and acceptance criteria to demonstrate that the substance meets required quality standards
- Specifications for pharmaceutical products in commerce (from release through product shelf life)

Reference Standards

- Physical materials to be used in conjunction with the test methods in the monograph
- Assesses specific quality attributes of the drug product or ingredient, including assay and impurities

History of IP Editions

1955 — First Edition
- 1 Volume
- 986 Monographs
- Title of monographs in Latin
- Supplement in 1960

1966 — Second Edition
- 1 Volume
- 890 Monographs
- Title of monographs changed from Latin to English
- Supplement in 1975

1985 — Third Edition
- 1 Volume
- 886 Monographs
- Anti-cancer Monographs Incorporated
- Addenda in 1989 & 1991

1996 — Fourth Edition
- 2 Volumes
- 1149 Monographs
- Addenda in 2000, 2002, and 2005
- Veterinary Supplement in 2000

2007 — Fifth Edition
- 3 Volumes
- Published by CIPL
- 1623 Monographs
- Addendum in 2008

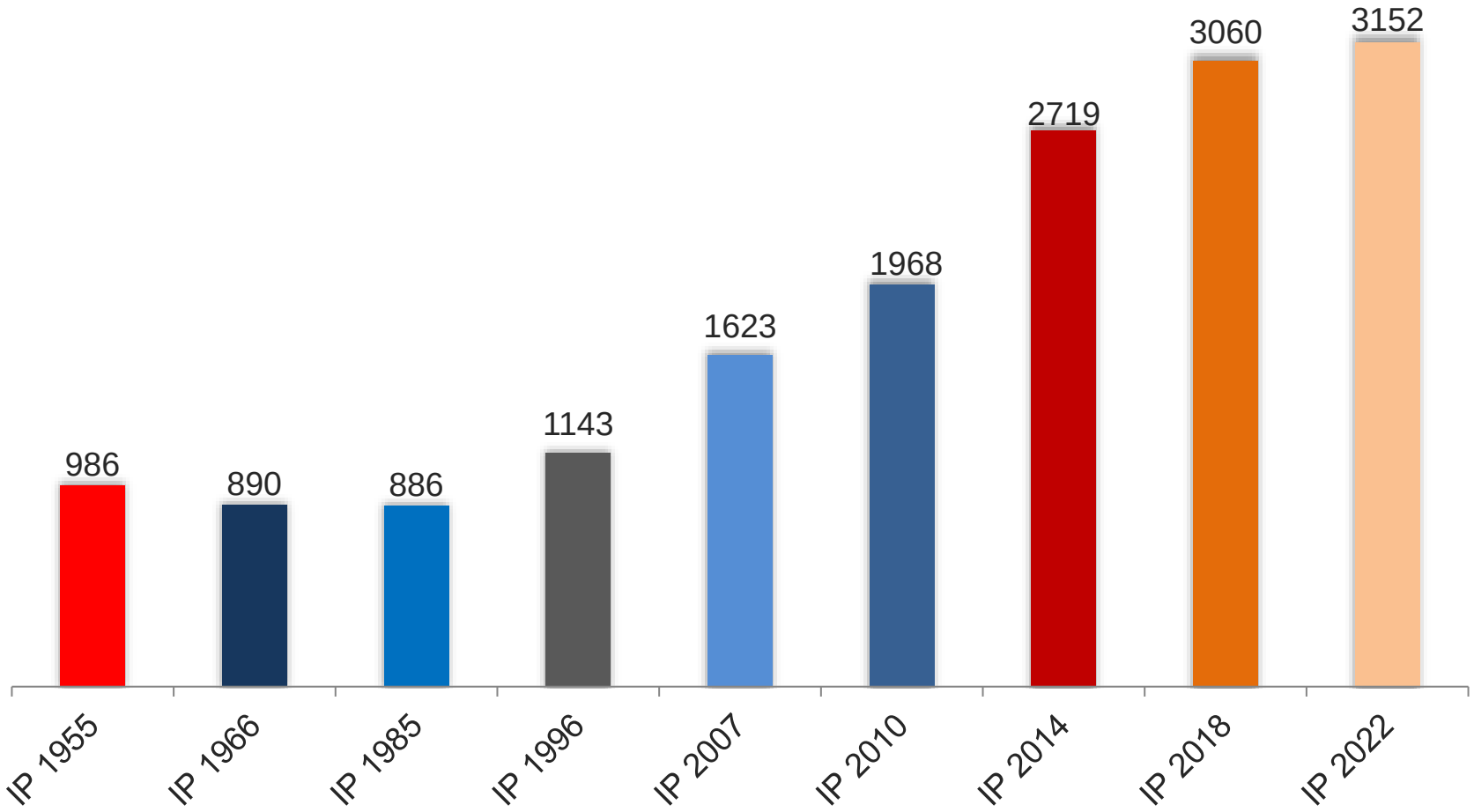
2010 — Sixth Edition
- 3 Volumes
- Published by IPC
- 1968 Monographs
- Biotech Monographs Incorporated
- Addendum in 2012

2014 — Seventh Edition
- 4 Volumes
- Separate Veterinary Volume
- 2586 Monographs
- Radiopharmaceutical Monographs Incorporated
- Addenda in 2015 & 2016

2018 — Eighth Edition
- 4 Volumes
- 3060 Monographs
- Allergen Monograph Incorporated
- Addenda in 2019 & 2021

2022 — Ninth Edition
- 4 Volumes
- 3152 Monographs
- Phytopharmaceuticals Monographs Incorporated
- General Chapters on Elemental Impurities & Nitrosamines

IP Monograph Development



IP 2022: Monograph Status

92

New Monographs

12

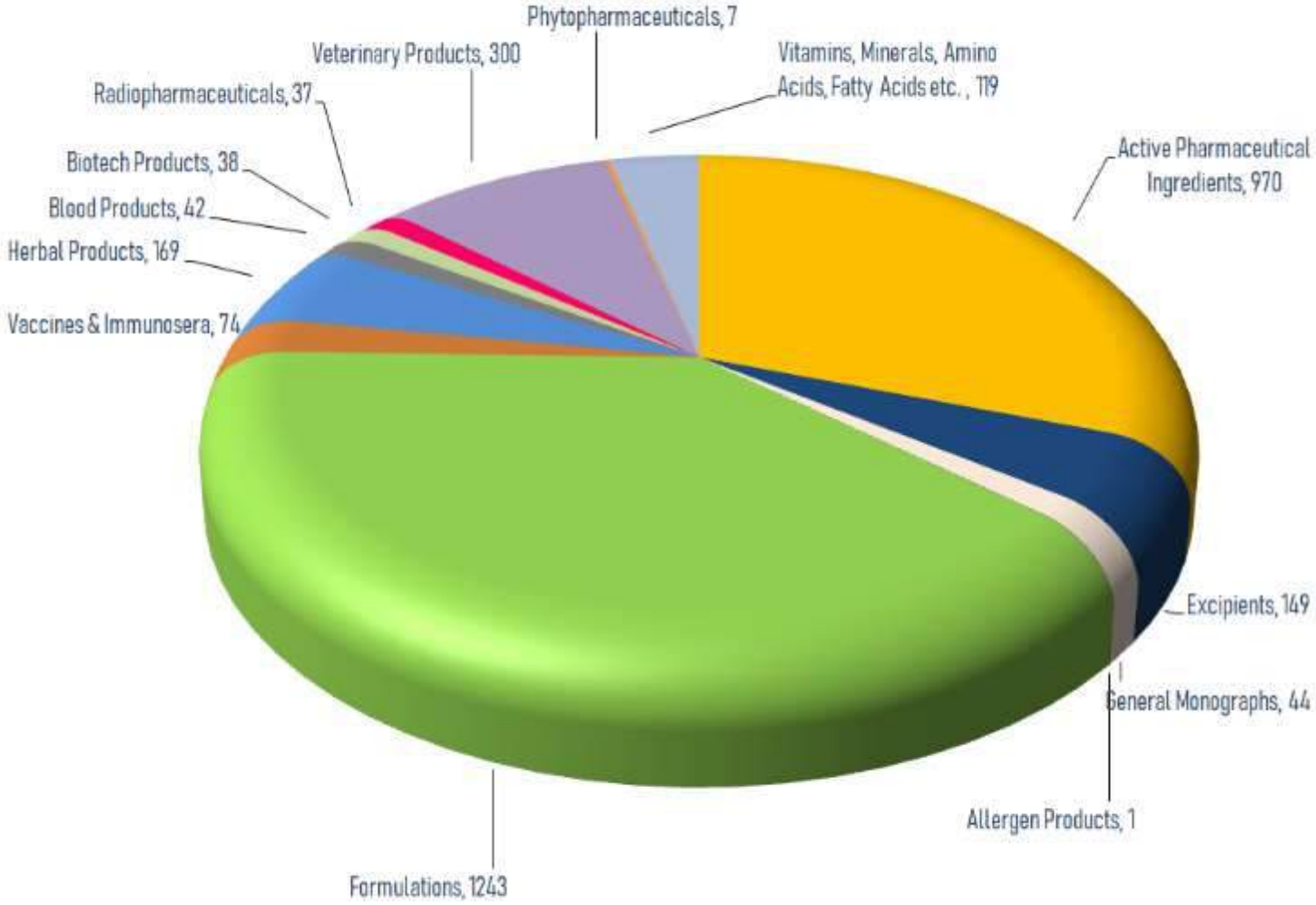
New General Chapters

415

Monograph Revisions

32

General Chapter Revisions



Response to COVID-19

Pharmacopoeia Monographs

- Developed monographs on COVID-19 drugs (Remdesivir, Favipiravir,Ivermectin)
- IP became first Phamacopoeia to have monographs on Remdesivir and Favipiravir

Guidance to Industry

- Developed guidance on 'Rapid Microbiological Methods' for early batch release of COVID-19 related drugs during pandemic

Reference Standards

- Developed IPRS on COVID-19 related drug and made available to stakeholders (Remdesivir, Favipiravir, Ivermectin, Azithromycin, Hydroxychloroquine sulphate, Doxycycline hydrochloride, Dexamethasone)

Clarification on General Chapters

- **Elemental Impurities**
  - Non-mandatory requirement
  - Stakeholders may adopt and implement as an alternative to heavy metals
  - Test on heavy metals to be replaced with Elemental impurities in next IP edition (i.e. IP 2026)
- **Nitrosamine Impurities**
  - For guidance of stakeholders and referred in sartan API monographs
  - Expected that stakeholders adopt for determining nitrosamine impurities in other drugs as well

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F.No. T.11015/01/2020-AR&D

Date: October 27, 2022

NOTICE

Subject: Clarification on General Chapters of the Indian Pharmacopoeia (IP) 2022-regarding.

Indian Pharmacopoeia Commission (IPC) has published the Indian Pharmacopoeia (IP) 2022 and Hon'ble Union Health Minister released the 9th edition of IP 2022 on 1st July, 2022 in Vigyan Bhawan, New Delhi. In IP 2022, several new monographs and general chapters have been introduced while several others are revised to meet the current analytical and regulatory requirements.

After the release of IP 2022, IPC has received several enquiries from the stakeholders on implementation and compliance of new and/or revised pharmacopoeial text. In order to address the enquiries of the stakeholders, clarification on following general chapters of the IP 2022 is compiled and issued:

S. No.	General Chapter in IP 2022	IPC's Clarification
1.	General Chapter 2.5.4 (i) Uniformity of Dosage Units	IPC has introduced a general chapter on 'Uniformity of Dosage Units' in harmonization with other pharmacopoeias under section 2.5.4 (i) on page 361, Volume I of IP 2022. This chapter is presently introduced in IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs and, therefore, remains non-mandatory requirement. However, stakeholders may adopt this chater before its implementation is made mandatory by IPC.
2.	General Chapter 5.10 Elemental Impurities	IPC has introduced new general chapter on 'Elemental Impurities' on page 1204, Volume I of IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs. Therefore, it remains non-mandatory requirement. However, stakeholders may adopt and implement this general chapter as an alternative to test on heavy metals as per the provisions of the IP General Notices. IPC will gradually replace test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of IP (i.e. IP 2026).
3.	General Chapter 5.11 Nitrosamine Impurities	IPC has introduced new general chapter on 'Nitrosamine Impurities' on page 1210, Volume I of IP 2022 for guidance of the stakeholders which is also referred in sartan API monographs of the IP. However, it is expected that stakeholders adopt this general chapter for determining the nitrosamine impurities in other drugs as well, wherever deemed appropriate and necessary.

Yours sincerely,

(Dr. Rajeev Singh Raghuvanshi)

Clarification on Elemental Impurities

डॉ.राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2023-AR&D

Date: August 1, 2023

NOTICE

Subject: Ensuring Compliance with the Indian Pharmacopoeia General Chapter (5.10) on Elemental Impurities-reg.

This is in continuation of IPC's Notice No. T.11015/01/2020-AR&D dated October 27, 2022 wherein clarification was issued on the subject mentioned above. This is once again brought to the notice of all concerned that:

1. IPC has introduced a new General Chapter on 'Elemental Impurities' in the IP 2022 for information of the stakeholders which is not yet referred in the individual monographs and; therefore, it remains a non-mandatory requirement. However, stakeholders are encouraged to adopt and implement this general chapter as an alternative to the test on heavy metals as per the provisions of the IP General Notices.
2. Meanwhile, IPC has started working on gradually replacing test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of the IP (i.e. IP 2026). IPC will discuss such changes with the Expert Working Group(s) along with publishing the same on IPC website prior to their adoption in the IP 2026.
3. Accordingly, the general chapter on elemental impurities (5.10) shall be referred in the General Requirements of Active Pharmaceutical Ingredients and in individual monographs of drug products in the IP 2026 so as to make it a mandatory requirement.

In view of the above, all concerned are requested to start working on required necessary changes in their quality systems for the readiness and ensuring compliance with the revised elemental impurities standards of the IP 2026. For further information, please keep on visiting IPC website (www.ipc.gov.in).

(Dr. Rajeev Singh Raghuvanshi)

Using Alternative Methods

Alternative Methods. The tests and assays described are the official methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorised manufacturer of substance or product.

In the event of doubt or dispute, the methods of analysis of the Pharmacopoeia are alone authoritative and only the result obtained by the procedure given in this Pharmacopoeia is conclusive.

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar, Ghaziabad 201 002

F. No. T.11013/02/2018-AR&D **Date:** 26th February 2021

NOTICE

Subject: Clarification on Alternative Methods in the Indian Pharmacopoeia-regarding

Indian Pharmacopoeia Commission (IPC) has been receiving many enquiries on the subject of use of alternative methods instead of official methods included in the Indian Pharmacopoeia (IP). General Notices of IP (Volume I, Page 12) have the provision to use alternative methods and the same is reproduced below:

Alternative Methods. The tests and assays described are the official methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacturer of substance or product.

2. For removal of doubts, it is clarified that the authority competent to authorise manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval.

3. All concerned are requested to bring the above clarification to the notice of all authorities under their control.

(Dr Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director

Other FAQs

Is 'Solubility' mandatory?

Solubility. Statements on solubility are given in Chapter 2.4.26 and are intended as information on the approximate solubility at a temperature between 15° and 30°, unless otherwise stated, and are not to be considered as official requirements. However, a test for solubility stated in a monograph constitutes part of the standards for the substance that is the subject of that monograph.

Is 'Description' part mandatory?

Description. The statements under the heading Description are not to be interpreted in a strict sense and are not to be regarded as official requirements.

What is 'Usual Strength'?

Usual strength. The statement on the usual strength(s) of a preparation given in the individual monograph indicates the strength(s) usually marketed for information of the pharmacist and the medical practitioner. It does not imply that a strength other than the one(s) mentioned in the individual monograph meeting all the prescribed requirements cannot be manufactured and marketed with the approval of the appropriate authority.

Monograph Development for Next IP Edition

डॉ.राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D

Date: September 13, 2023

Subject: Sharing the list of marketed drug products along with their test specifications for development of monographs for the Indian Pharmacopoeia-reg.

Dear all,

As you are aware that, in order to fulfill requirements of the Drugs and Cosmetics Act, 1940 and Rules 1945 there under, the Indian Pharmacopoeia Commission (IPC) functions as an autonomous Institute under the Ministry of Health & Family Welfare to publish the Indian Pharmacopoeia (IP) at regular intervals.

2. Accordingly, IPC has come up with the publication of the 9th edition of the IP 2022 which was released on 1st July, 2022 by the Hon'ble Union Minister of Health and Family Welfare and became effective from 1st December, 2022. This edition contains a total of 3152 monographs.

3. Meanwhile, IPC has started working on developing monographs for the next edition of the IP in 2026 with the aim to include monographs to cover drugs included in the National List of Essential Medicine (NLEM), National Health Programmes (NHPs), and other drugs which are widely prescribed and marketed in India.

4. In India, the Central and State Drugs Testing Laboratories are involved in the regulatory quality analysis of marketed drug products and have a repository of the test specifications of many drug products which are widely prescribed but their monographs are not available in the IP. There is a need to utilize this repository as a source for the development of monographs for their inclusion in the IP.

5. In view of the above, it is requested that Central and State Drugs Testing Laboratories shall share the list of non-IP drug products with the IPC (email: lab.ipc@gov.in) along with their test specifications for initiating monograph development for the IP 2026.

I am sure each laboratory will join hands with the IPC for this national cause towards strengthening the drug standards in the IP.

Thanking you.

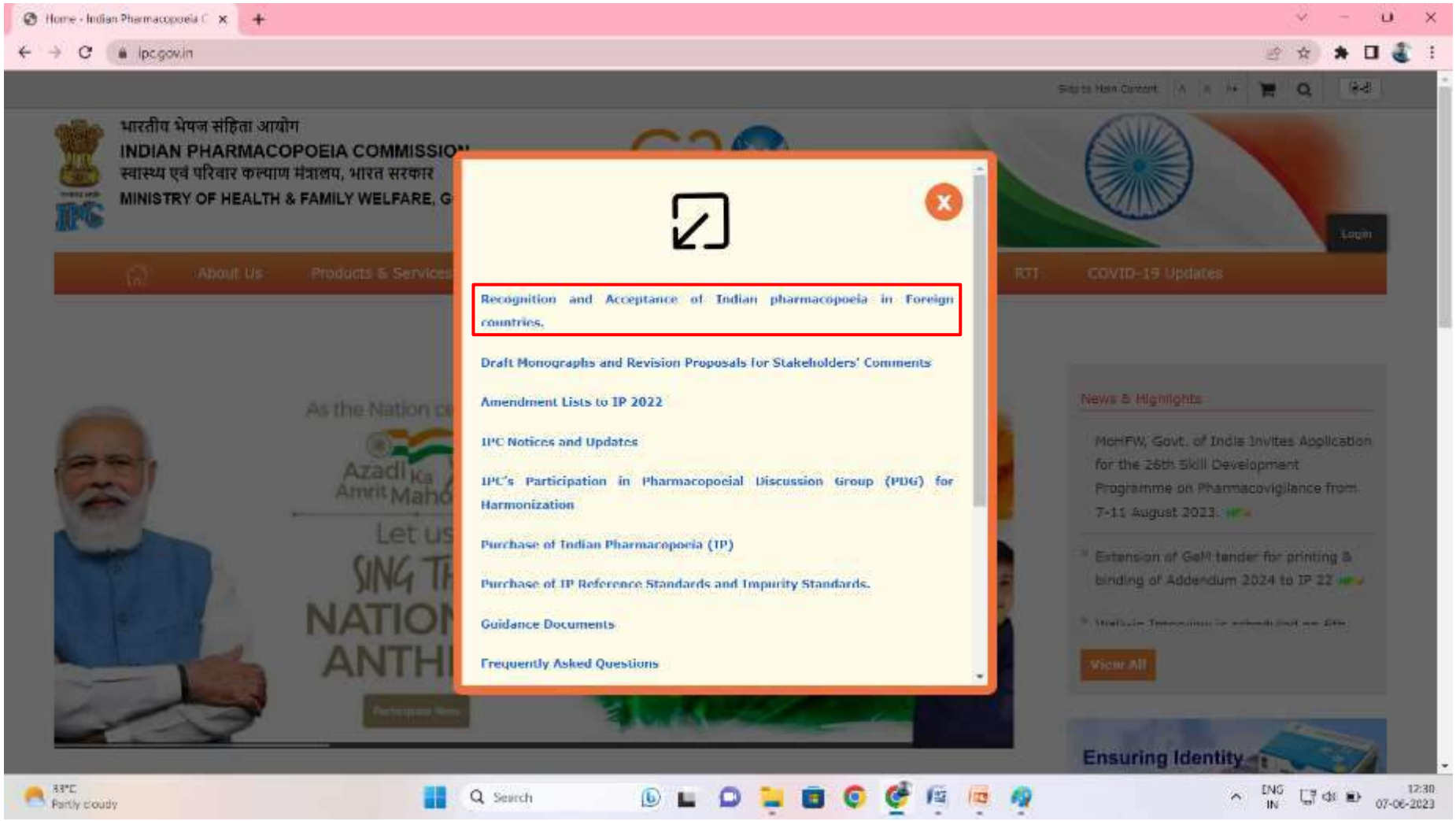
Yours sincerely,

(Dr. Rajeev Singh Raghuvanshi)

Future Updates

- Publication of IP Addendum 2024 (by end of 2023)
- Developing IP on-line Platform (by Feb 2024)
- Participation in PDG for Pharmacopoeial Harmonization (ongoing)
- Introduction of Elemental Impurities and Dissolution Specifications (ongoing)
- Monograph Revisions (ongoing)

Accessing IPC Website



Update on Recognition of IP

IPC Updates

June 13, 2023

Status of Recognition and Acceptance of Indian Pharmacopoeia in Foreign Countries

As per the Second Schedule of the Drugs and Cosmetics Act 1940, Indian Pharmacopoeia (IP) is designated as the official book of standards for drugs imported and/or manufactured for sale, stock or exhibition for sale or distribution in India. In order to ensure the quality of medicinal products, the legal and scientific standards of IP are published at regular intervals by the Indian Pharmacopoeia Commission (IPC). Standards prescribed in the IP are authoritative in nature and are enforced by the regulatory authorities for quality control of medicines in India. IPC has been making sincere efforts towards recognition and acceptance of IP in foreign countries and proposals in this regard have been submitted to various countries through Ministry of Health & Family Welfare, Department of Commerce, Department of Pharmaceuticals, and Ministry of External Affairs.

It is a matter of delight to share that in pursuant to sincere efforts and guidance provided by the Hon'ble Union Minister of Health & Family Welfare to get IP recognized in foreign countries, IP has been accepted as a book of standards in a total of five countries with details as apended below:

- **Afghanistan**
  IP has been recognised formally by the National Department of Regulation of Medicines and Health Products of the Ministry of Public Health of Islamic Republic of Afghanistan and also will be used based on the requirement as reputable pharmacopoeia in the laboratory of medicines and health products quality. With this, a new beginning has been made as Afghanistan has become the first country to recognize the IP. (Click here to view letter issued by Ministry of Foreign Affairs of Afghanistan)
- **Ghana**
  IP is considered as an approved reference when its monograph compares with the monographs in recognized pharmacopoeias in the Fourth Schedule of the Public Health Act. (Click here to view letter issued by Food & Drugs Authority of Ghana)
- **Nepal**
  IP is recognised as the book of standards in Drugs Category Rules 1986 of Nepal. As per the list of pharmacopoeia or encyclopedia related to the category of drugs under Schedule 1 (related to Rule 5) of the Drugs Category Rules 1986, "Pharmacopoeia of India" published by the Ministry of Health of Government of India has been included at Sr. No. 3. (Click here to view Drugs Category Rules 1986 of Nepal)
- **Mauritius**
  In order to include IP in the standards of pharmaceuticals authorized in Mauritius, Section 2 of the Pharmacy Act 1983 has been amended through Section 50 of the legal supplement published in August 2020 and in the definition of "specified standards" of the Section 2 of the Pharmacy Act, the word "or European" has been deleted and replaced with the words "European or Indian". Accordingly, the amended section reads as: "specified standards" means such standards as are specified in the British, French, United States, Europoean or India Pharmacopoeia; (Click here to view Pharmacy Act 1983 of Mauritius and its amendment)

Indian Pharmacopoeia Commission

E-mail: lab.ipc@gov.in
Website: www.ipc.gov.in

Recognition of IP in Suriname

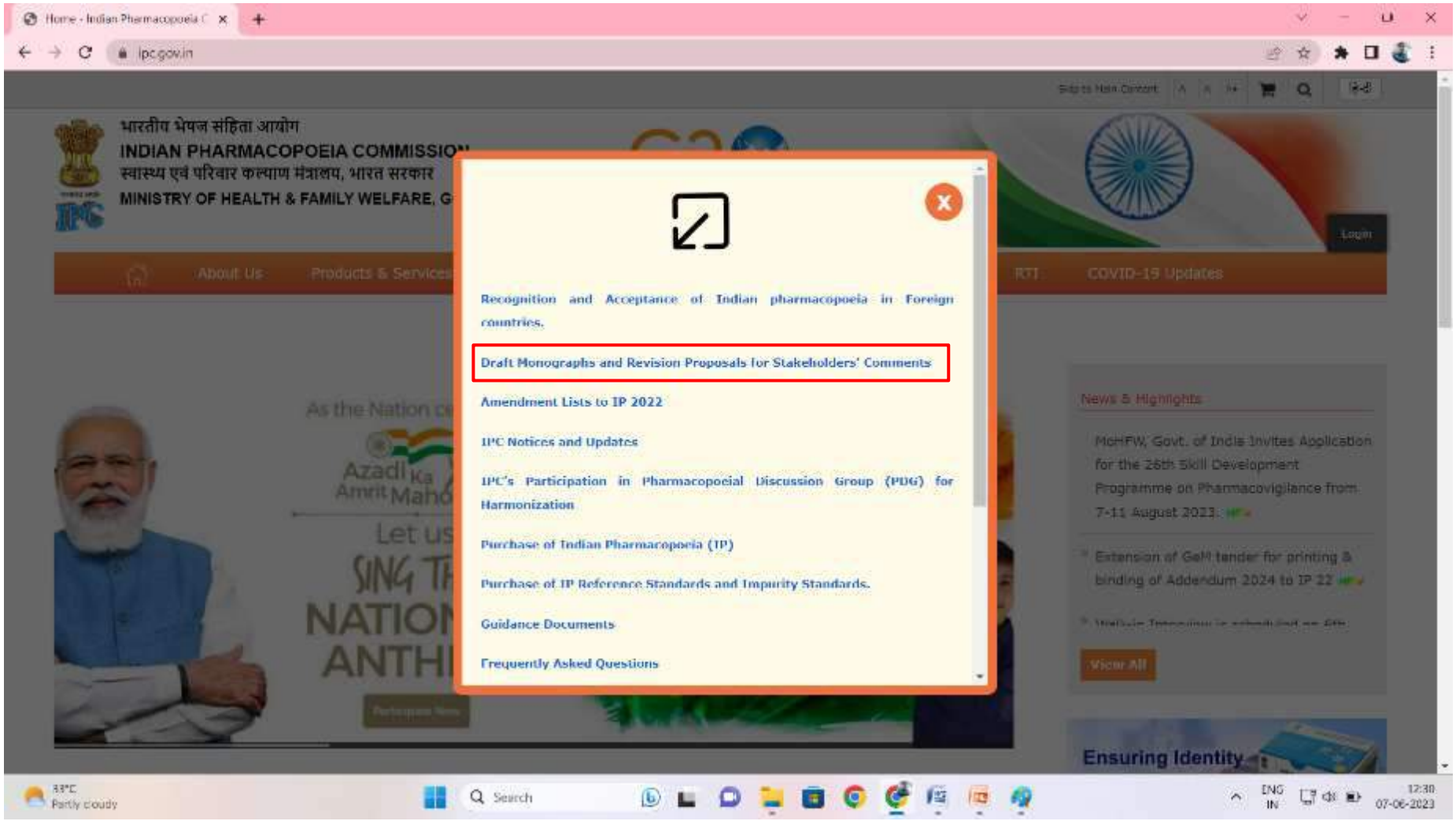
Jun 05, 2023, 9:05PM

President Murmu holds talks with Suriname President; 3 MoUs signed in Agriculture and Health sectors

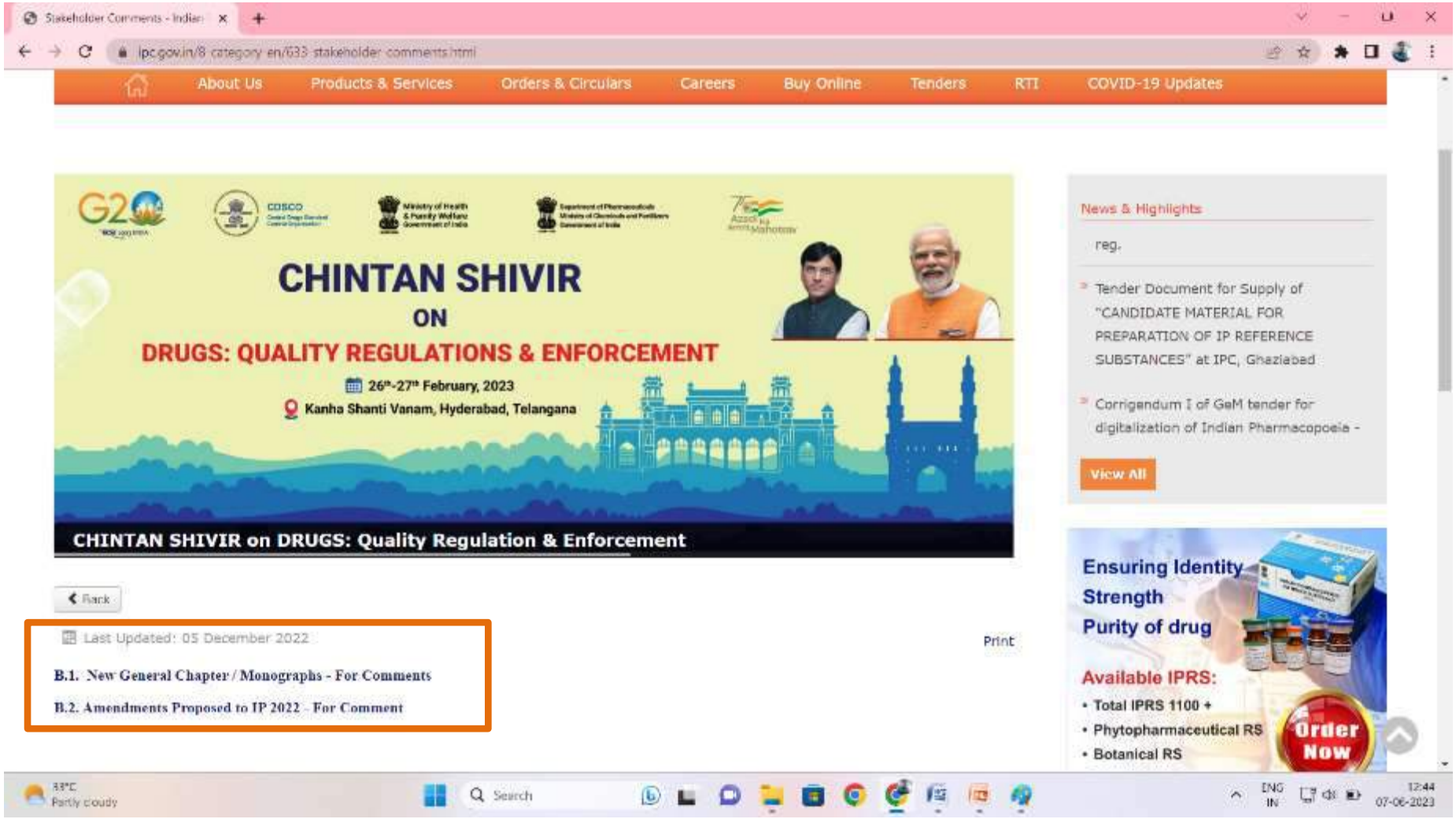
President Droupadi Murmu held restricted talks and delegation-level talks with Surinam President Chandrikapersad Santokhi on Monday. Three MoUs in Health and Agriculture sectors were signed between India and the Republic of Suriname in Paramaribo. These MoUs include a Joint Work Plan for Cooperation in the Field of Agriculture and Allied Sectors for the period of 2023-2027; an MoU between the Indian Pharmacopoeia Commission and the Health Ministry of Suriname for recognition of the Indian Pharmacopoeial standards; and an MoU between Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health of Suriname on cooperation in the field of Medical products regulations.

On a three-day visit to Suriname, as President Droupadi Murmu arrived at the Presidential Palace, she was received by the President of the Republic of Suriname, Chandrikapersad Santokhi. The National Anthems of both India and Suriname were played upon her arrival. The first lady of Suriname, Mellisa Santokhi-Seenacherry, was also present at the occasion.

Accessing IPC Website



Pharmacopoeia Text for Comments



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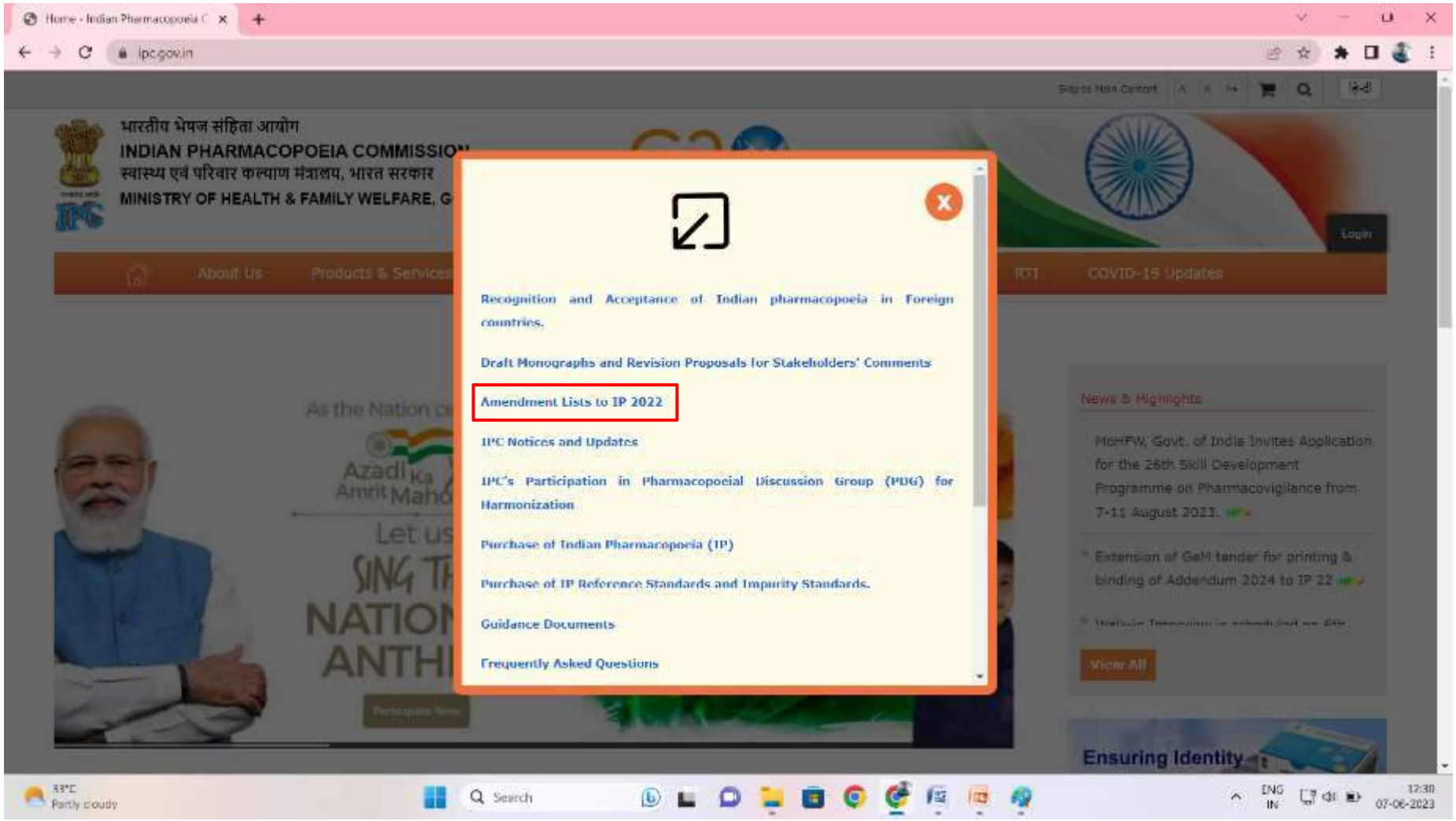

Amendment Lists to IP 2022

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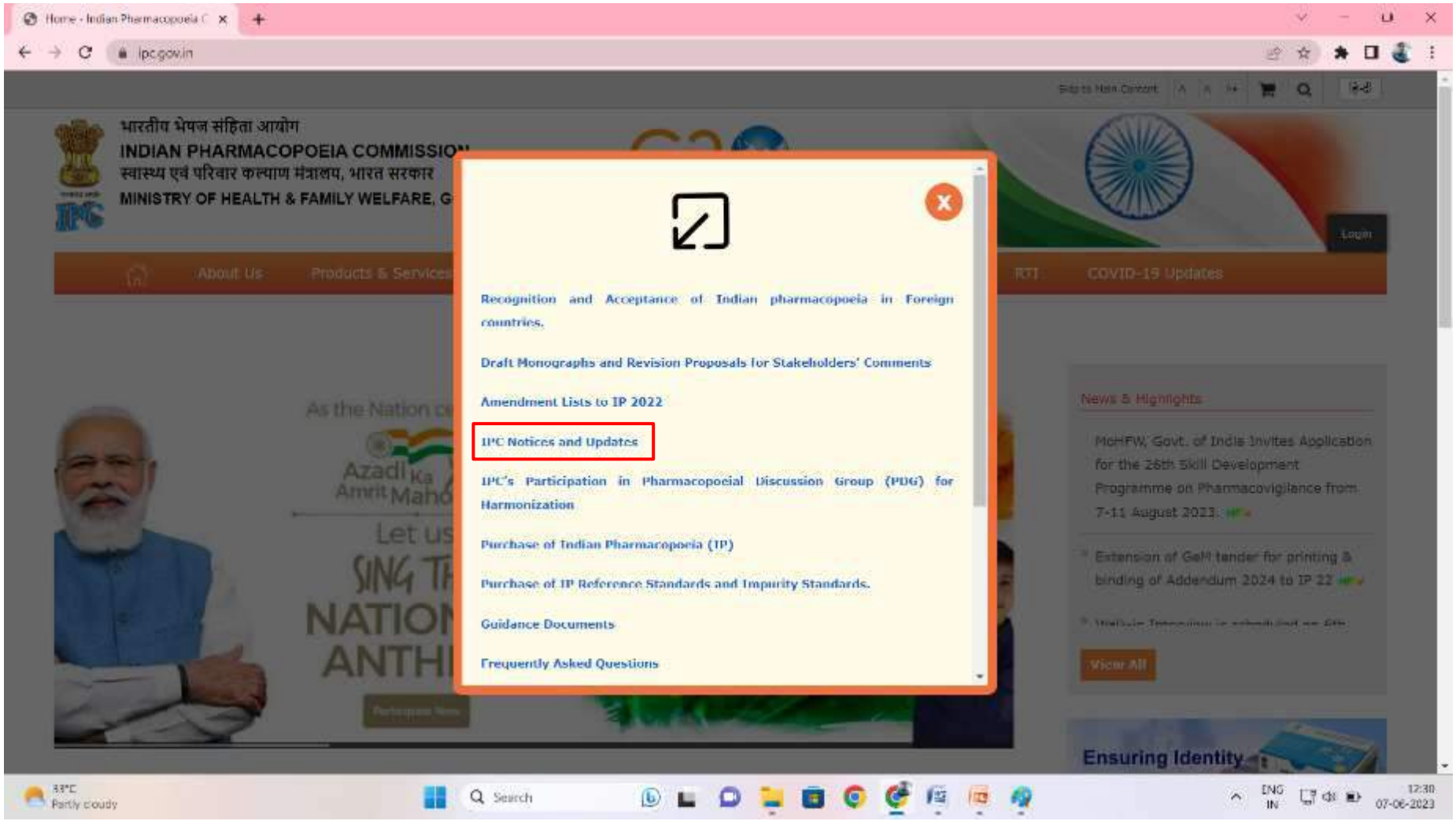
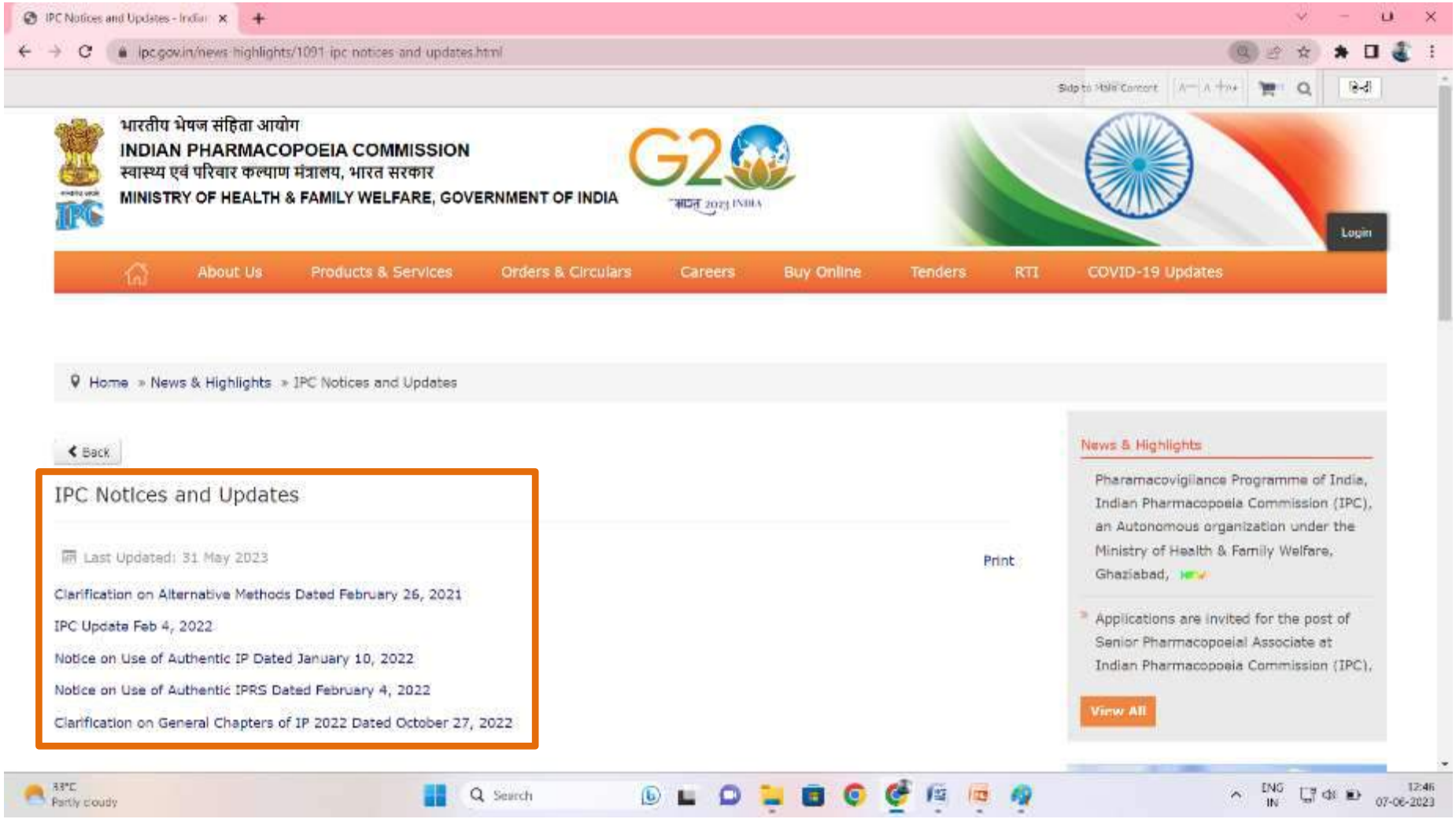


IPC Notices & Updates



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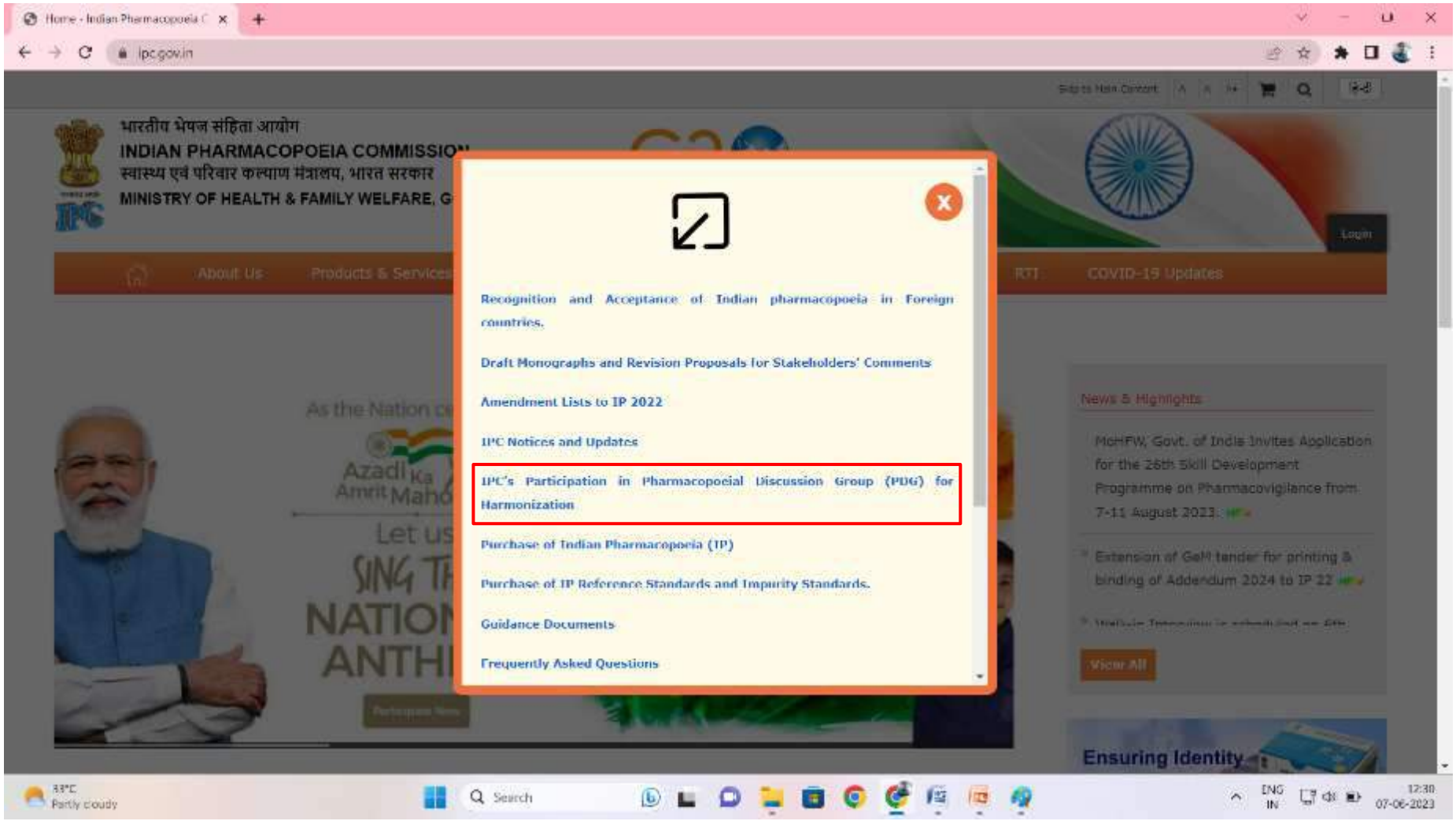

IPC's Participation in PDG

Pharmacopeial Discussion Group

ipc.gov.in/news-highlights/1057-pharmacopeial-harmonisation-group-pdg-updates.html

भारतीय भेषज संहिता आयोग
INDIAN PHARMACOPOEIA COMMISSION
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

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Pharmacopeial Discussion Group (PDG)

Last Updated: 28 February 2023

Print

1)PDG work plan

2)PDG welcomes Indian Pharmacopoeia Commission to pilot for global expansion

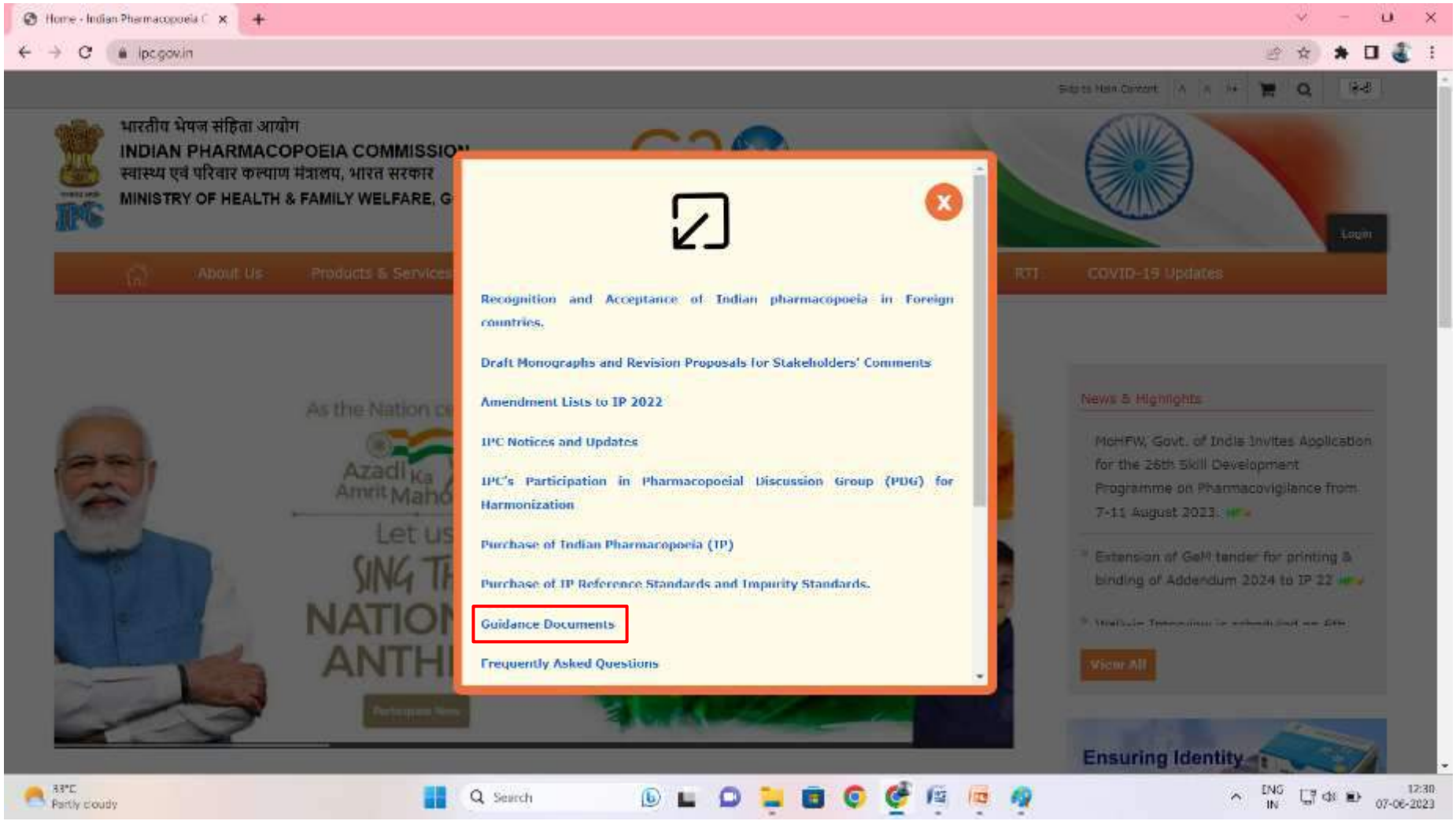
3)Press Release

News & Highlights

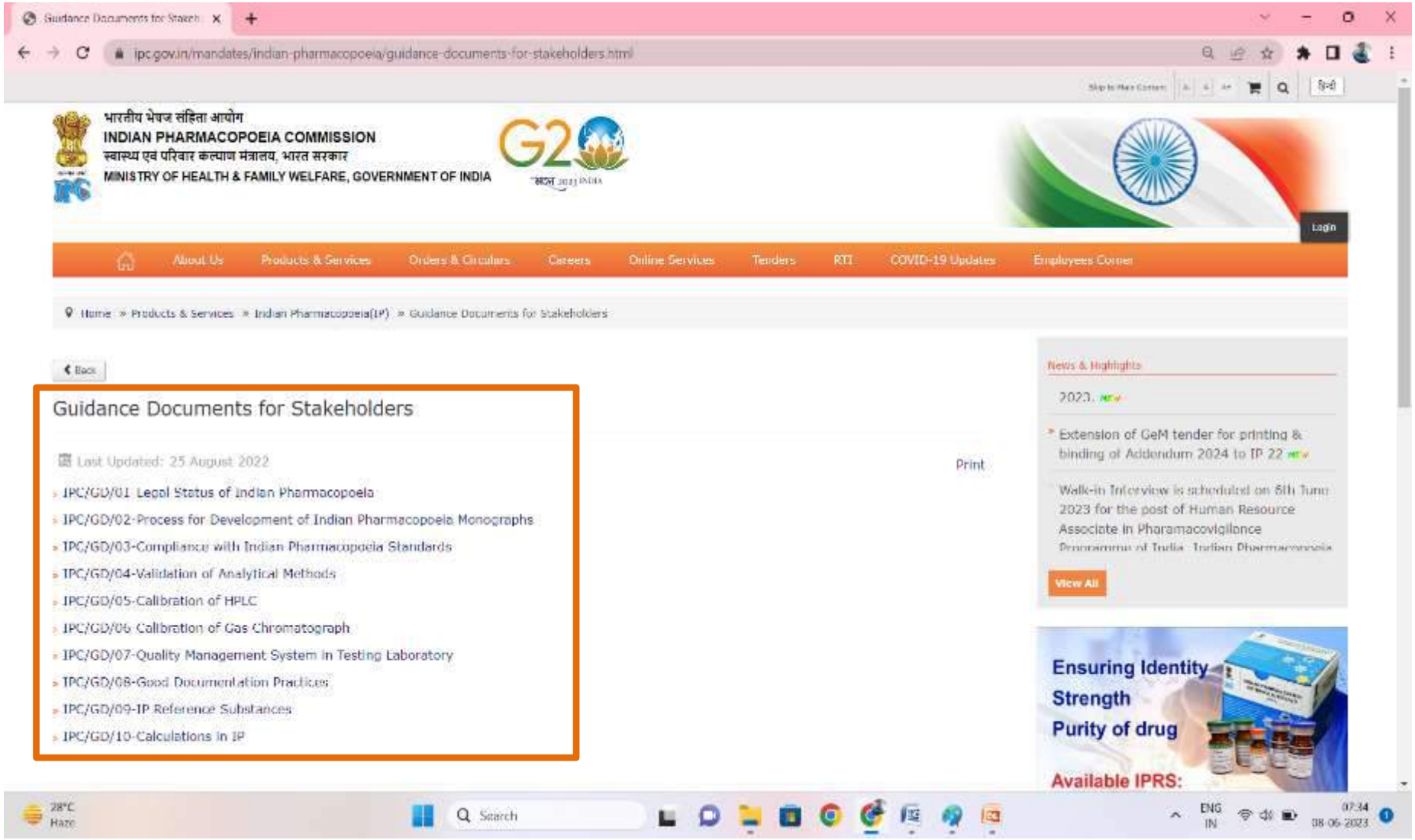
Recognition of the Indian Pharmacopoeia (IP-2022) by Republic of Suriname NEW

View All

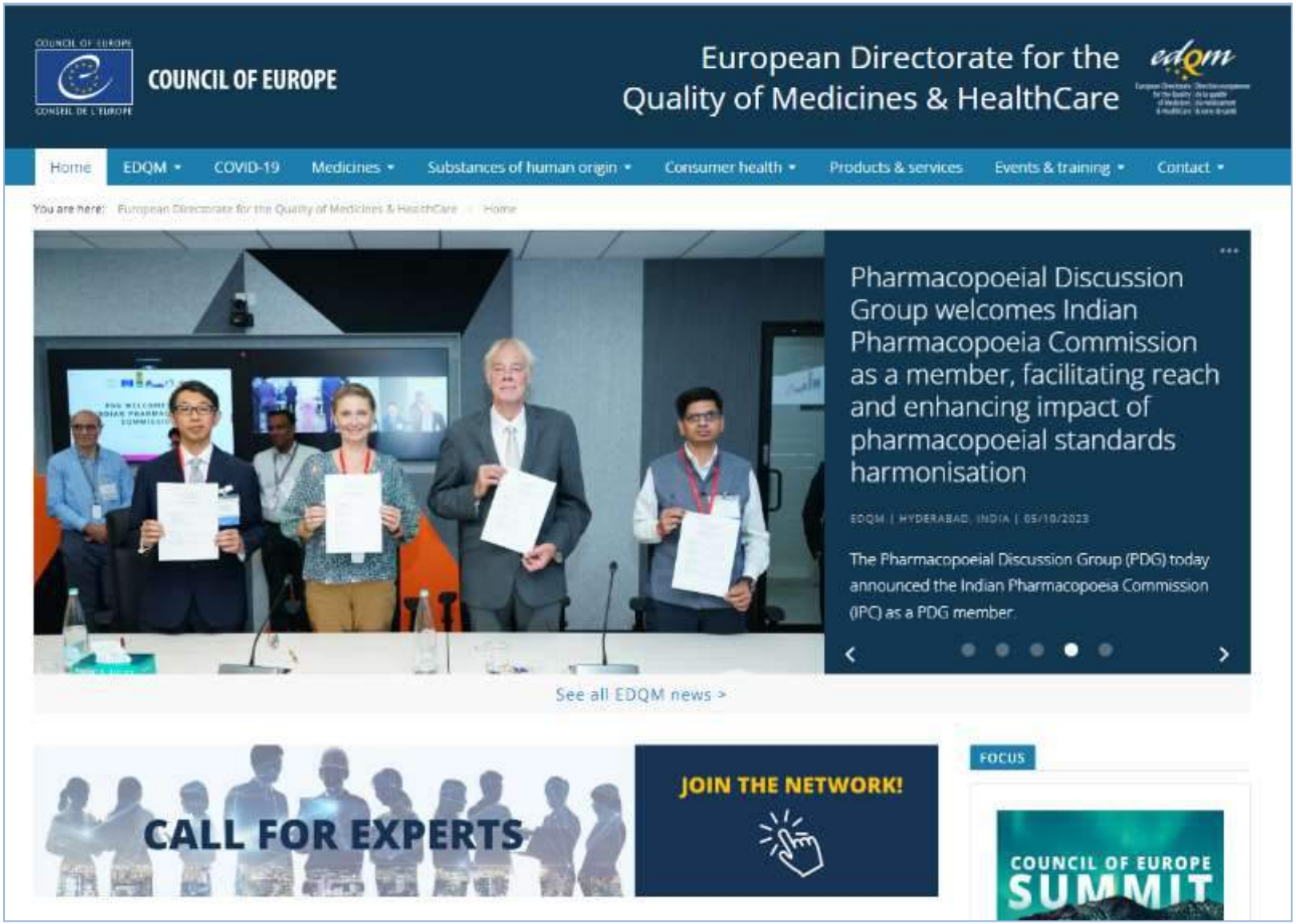
Accessing IPC Website



Guidance to Stakeholders



PDG Welcomes IPC as a Member



PDG Welcomes IPC as a Member

独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Press Release

Pharmacopoeial Discussion Group Welcomes Indian Pharmacopoeia Commission as a Member, Facilitating Reach and Impact of Pharmacopoeial Standards Harmonisation

Hyderabad, India, October 5, 2023 – The Pharmacopoeial Discussion Group (PDG) today announced the Indian Pharmacopoeia Commission (IPC) as a PDG member. IPC officially joined as a member in the PDG which was established by the European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the U.S. Pharmacopeia (USP), at the PDG's Annual Meeting on Oct. 3-4 in Hyderabad. The World Health Organization (WHO) also continues to serve as observer of the group.

"IPC is honored to be considered for membership in the PDG," said Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC. "Since becoming PDG's pilot for expansion to its membership in October 2022, IPC has participated in PDG meetings and technical discussions, and submitted implementation timelines for various PDG standards. As a PDG member, we look forward to continuing to work to advance standards convergence around the world."

"We warmly welcome IPC to PDG," said Cathie Vielle, Secretary to the European Pharmacopoeia Commission. "This is a milestone in PDG's commitment to expanding recognition of harmonised pharmacopoeial standards. Working together will further advance convergence around robust science - based quality standards across pharmacopoeias for the benefit of public health."

"For over three decades, the original PDG members – including JP, Ph. Eur., and USP – have worked to increase the reach and impact of global standards harmonisation efforts," said Yoshiro Saito, Ph.D., Deputy Director General of National Institute of Health Sciences and Chair of the JP Expert Committee. "Adding IPC marks the culmination of several years of discussions on new member participation to help increase global access to quality medicines and ensure PDG's continued success."

US Pharmacopeia
143,529 followers
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USP's work to advance global convergence around robust, science-based quality standards will get a boost through the newly expanded Pharmacopeial Discussion Group (PDG), which now includes the Indian Pharmacopoeia Commission (IPC). Founding PDG members including USP, the European Pharmacopoeia, and the Japanese Pharmacopoeia formally welcomed IPC to the group at the PDG Annual Meeting Oct. 3-4 in Hyderabad, India.

Expansion of the PDG is just the latest step in USP's and PDG's efforts to facilitate the reach and impact of quality standards harmonization. Pharmacopeial convergence helps increase global alignment on the definition of quality as well as best practices used to measure it, supporting medicines supply chain resilience and improved public health.

Learn more: https://ow.ly/EwVm50PTsJT

European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

#standards #supplychain

PDG Welcomes IPC as a Member

PDG Harmonization Plan: General Chapters

Pilot Phase

Tablet Friability
Optical Microscopy

Implementation
1st December 2022

Phase I

Particulate Contamination
Analytical Sieving
Laser Diffraction Measurement of Particle Size
X-Ray Powder Diffraction
Chromatography
Peptide Mapping

Implementation
December 2024

Phase II

Dissolution
Disintegration
Uniformity of Uniformity of Content/Mass
Color (Instrumental method)
Residue on Ignition
Bulk Density and Tapped Density
Conductivity
Powder Fineness
Water-solid Interaction
Amino Acid determination
Capillary Electrophoresis

Implementation
December 2026

Phase III

Tests for Specified Microorganism
Microbial Enumeration
Limits for Non-sterile Products
Bacterial Endotoxins
Extractable Volume
Sterility Test
Gas Pycnometric Density of Solids
Powder Flow
Specific Surface Area
Thermal Analysis
Isoelectric Focusing
Polyacrylamide Gel Electrophoresis

Implementation
December 2028

PDG Harmonization Plan: Excipients

Phase I

Alcohol
Dehydrated Alcohol
Benzyl Alcohol
Croscarmellose Sodium
Lactose, Anhydrous
Ethyl Paraben
Propyl Paraben

Implementation December 2024

Phase II

Calcium Disodium Edetate
Calcium Phosphate Dibasic
Calcium Phosphate Dibasic Anhydrous
Carmellose Calcium
Cellulose, Microcrystalline
Crospovidone
Ethylcellulose
Hydroxyethylcellulose
Hydroxypropylcellulose
Hydroxypropylcellulose, Low Substituted
Lactose, Monohydrate
Magnesium Stearate
Butyl Paraben

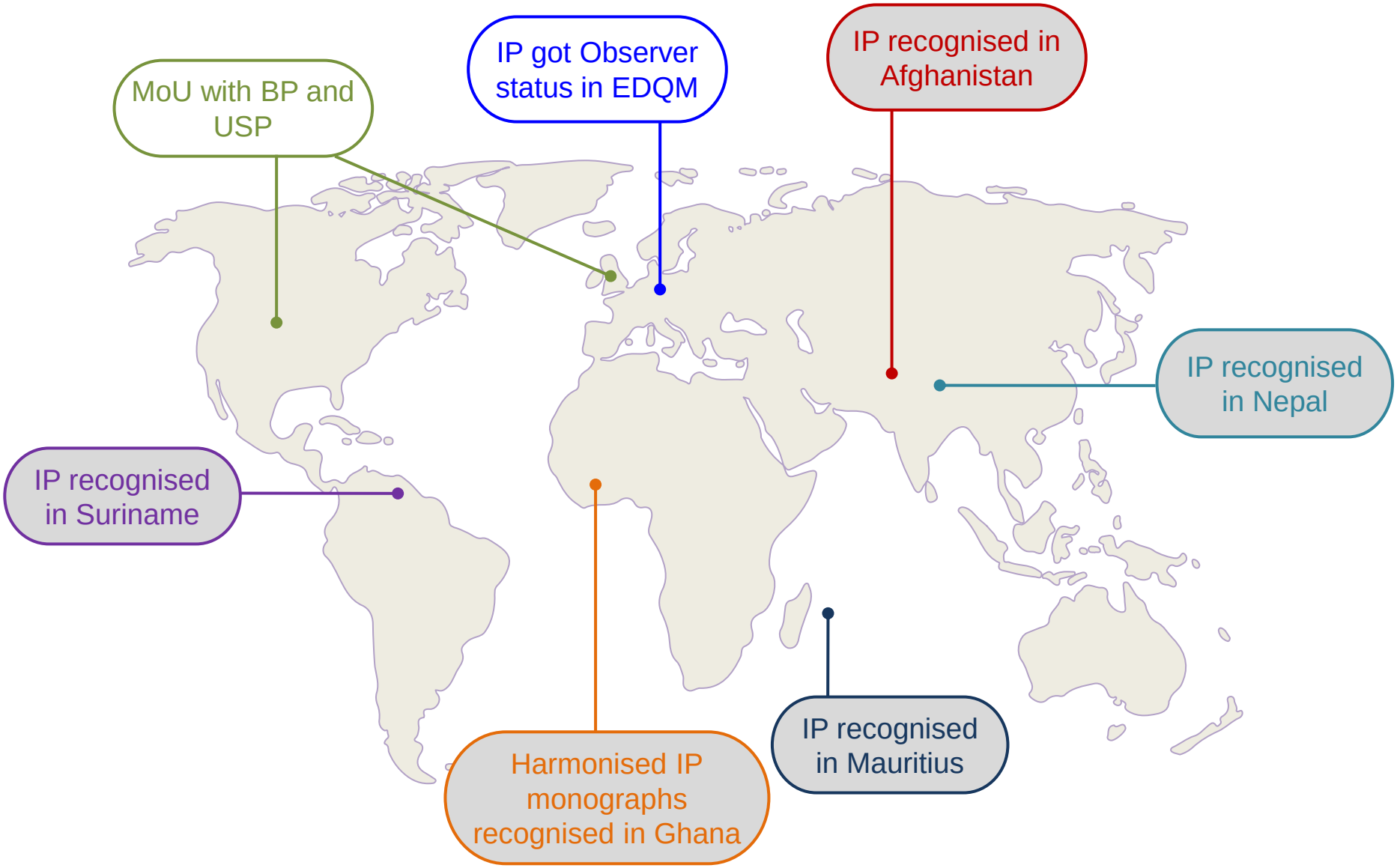
Implementation December 2026

Phase III

Cellulose, Powdered
Cellulose Acetate Phthalate
Citric Acid, Anhydrous
Citric Acid, Monohydrate
Hypromellose
Hypromellose Phthalate
Methylcellulose
Methyl Paraben
Petrolatum
White Petrolatum
Polysorbate 80
Povidone
Sodium Chloride
Sodium Starch Glycolate
Starch, Corn
Starch, Potato
Starch, Rice
Starch, Wheat
Stearic Acid
Sucrose
Talc
Carmellose
Copovidone
Gelatin
Glucose
Mannitol
Sodium Laurylsulfate
Isomalt

Implementation December 2028

Global Recognition of IP



IP Reference Standards (IPRS)

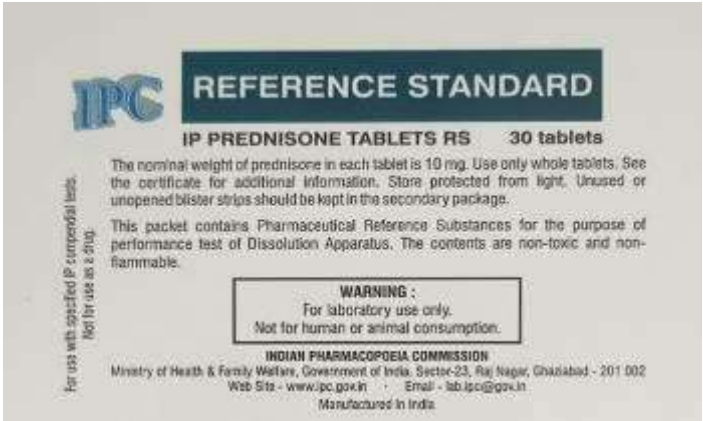
- IPRS is a primary standard that has the appropriate quality within a specified context and is accepted without requiring comparison to another standard
- IPRS are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the IP

Types of Reference Standards

IP Reference Substances

Impurity Reference Substances

Phytochemical Reference Substances



IPC

REFERENCE STANDARD

IP PREDNISONE TABLETS RS 30 tablets

The nominal weight of prednisone in each tablet is 10 mg. Use only whole tablets. See the certificate for additional information. Store protected from light. Unused or unopened blister strips should be kept in the secondary package.

This packet contains Pharmaceutical Reference Substances for the purpose of performance test of Dissolution Apparatus. The contents are non-toxic and non-flammable.

For use with specified IP compendial tests. Not for use as a drug.

WARNING :
For laboratory use only.
Not for human or animal consumption.

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India. Sector-23, Raj Nagar, Ghaziabad - 201 002
Web Site - www.ipc.gov.in · Email - lab.ipc@gov.in
Manufactured in India

Prednisone Dissolution Calibrator Tablet

Legal Status of IPRS

- IP is published by the IPC to fulfill the requirements of the Second Schedule of the Drugs and Cosmetics Act 1940 and Rules there under.
- IPRS are authoritative standards for determining the quality of medicines in India.

Drugs and Cosmetics Act, 1940

Class of drug	Standard to be complied with
1	2
[1][5. Other drugs: (*a*) Drugs included in the Indian Pharmacopoeia	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian pharmacopoeia immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be prescribed.

Second Schedule of the Drugs and Cosmetics act 1940

IP Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substances abbreviated, as IPRS in the individual monographs, are issued by the Indian Pharmacopoeia Commission (IPC) or by laboratories authorized by the IPC and assume the official status in India. Where an IPRS is referred to in an official IP monograph, it becomes a part of the official standard that is alone authoritative in case of doubt or dispute to determine compliance with the IP.

Legal Notices

In India, under the Drugs and Cosmetics Act 1940, the current edition of Indian Pharmacopoeia is a book of standards for drugs included therein and the standards as included in the Indian Pharmacopoeia would be official. Also, in several other laws of India, the Indian Pharmacopoeia is recognised as the standard book. It is expedient that enquiry be made in each

Use of IPRS in Monographs

is not more than 5 times the area of the peak in the chromatogram obtained with the reference solution (a) (0.5 per cent). Disregard any peak which is 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.01 per cent).

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method A (20 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Water (2.3.43). 4.0 to 6.0 per cent, determined on 0.4 g.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 25 mg of the substance under examination in 25.0 ml of the mobile phase. Dilute 5.0 ml of the solution to 100.0 ml with the same solvent.

Reference solution. A 0.005 per cent w/v solution of *secnidazole IPRS* in mobile phase.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 35 volumes of *methanol* and 65 volumes of 0.14 per cent w/v solution of *potassium dihydrogen phosphate*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 318 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_7H_{13}N_3O_3$.

Storage. Store protected from light and moisture.

Secnidazole Tablets

Secnidazole Tablets contain not less than 95.0 per cent and not more than 110.0 per cent of the stated amount of secnidazole, $C_7H_{13}N_3O_3$.

Usual strengths. 1 g; 2 g.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Medium. 900 ml of *0.1 M hydrochloric acid.*

Speed and time. 100 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter promptly through a membrane filter disc having an average pore diameter not greater than 1.0 µm, rejecting the first 1 ml of the filtrate. Dilute the filtrate, if necessary, with the same solvent. Measure the absorbance of the resulting solution at the maximum at about 277 nm (2.4.7). Calculate the content of $C_7H_{13}N_3O_3$ in the medium from the absorbance obtained from a solution of known concentration of *secnidazole IPRS* in the same medium.

Q: Not less than 80 per cent of the stated amount of $C_7H_{13}N_3O_3$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Weigh a quantity of powdered tablets containing 50 mg of Secnidazole, disperse in 100 ml of mobile phase and filter.

Reference solution (a). A 0.05 per cent w/v solution of *secnidazole IPRS* in the mobile phase.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with mobile phase.

Chromatographic system as described under Assay.

Inject reference solution (a). The test is not valid unless the tailing factor is not more than 2.0 and the column efficiency in not less than 2000 theoretical plates.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the peak in the chromatogram obtained with reference solution (b) (1.0 per cent) and the sum of areas of all the secondary peaks is not more than 2.0 times the area of the peak in the chromatogram obtained with the reference solution (b) (2.0 per cent).

Water (2.3.43). Not more than 6.5 per cent, determined on 0.5 g.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powdered tablet containing 50 mg of Secnidazole, disperse in 100.0 ml of mobile phase and filter. Dilute 5.0 ml of the filtrate to 50.0 ml with mobile phase.

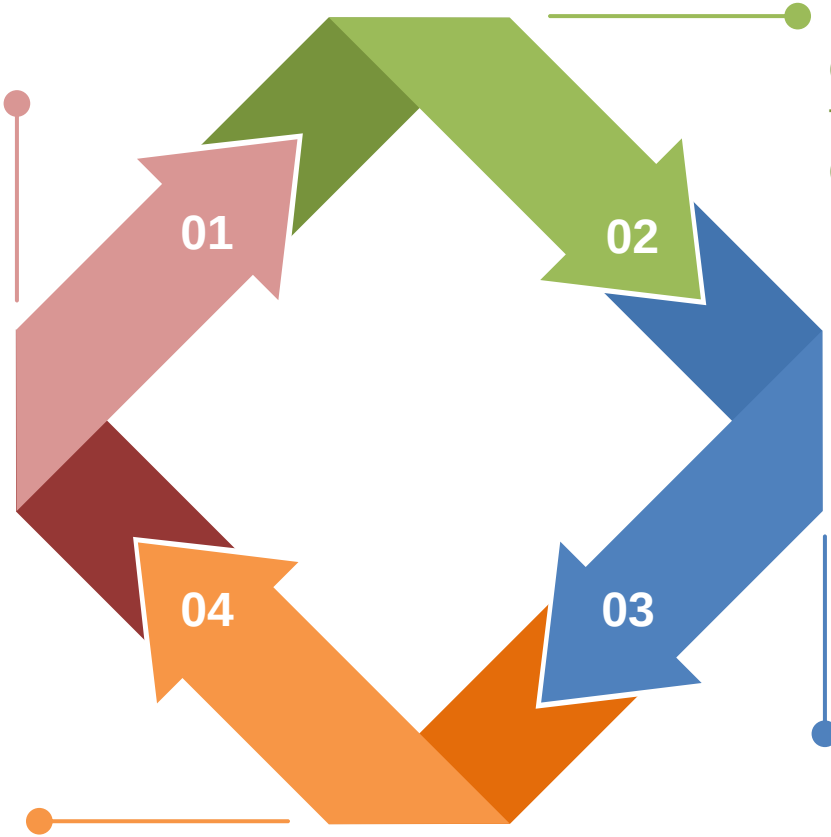
Reference solution. A 0.005 per cent w/v solution of *secnidazole IPRS* in mobile phase.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm packed with octadecylsilane chemically bonded to porous silica

IP Reference Standards & Impurity Standards

- IPRS developed through collaborative approach
- Reference material producer per ISO 17034
- PT provider per ISO 17043

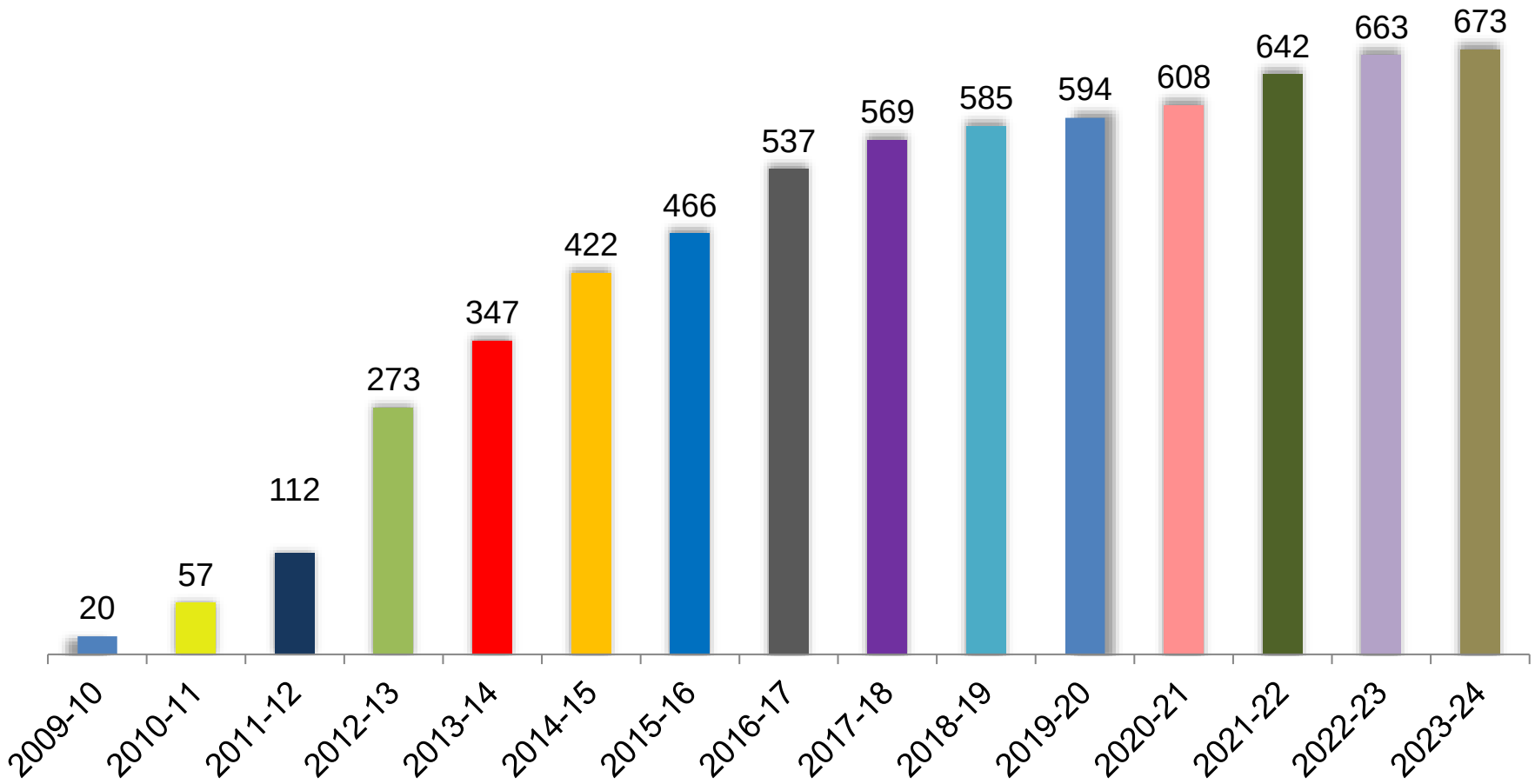


IPRS are authoritative in case of doubt or dispute to determine compliance with the IP

- 673 IPRS & 545 Impurity standards available from IPC (www.ipc.gov.in)
- 3rd highest number among global pharmacopoeias

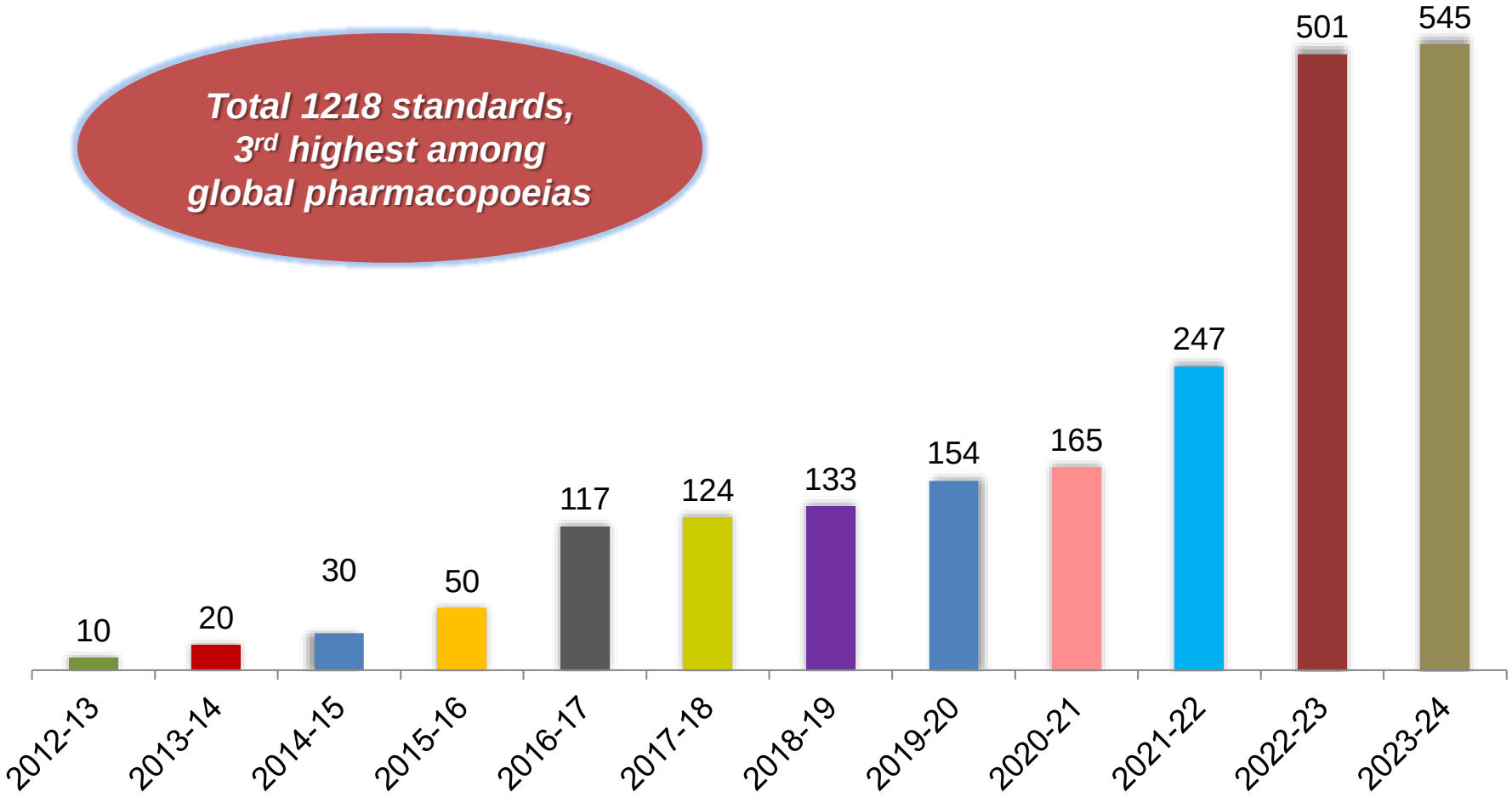
- Vaccine NRS available from CDL, Kasauli
- Reference Microbial Cultures available from IMTech, Chandigarh

Development of IPRS



Development of Impurity Standards

Total 1218 standards, 3rd highest among global pharmacopoeias



Certificate of IPRS

COAs of IPRS and Impurity RS are now available online at official website of IPC (www. ipc.gov.in) and can be downloaded by using CAT no. written on the purchased vial as password.

IPC/CHEM/STP/002/09/FMT/05

INDIAN PHARMACOPOEIA COMMISSION

(MINISTRY OF HEALTH AND FAMILY WELFARE, GOVT. OF INDIA)
SECTOR-23, RAJ NAGAR, GHAZIABAD-201002
Tel No: 0120-2783392, 2783400, 2783401; Fax: 2783111
Mail: lab.ipc@gov.in, Web: www.ipc.gov.in

CERTIFICATE OF ANALYSIS

Hydrochlorothiazide

6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide1,1-dioxide.

Structure:

IDENTIFICATION

Lot No.: IPRSH005	**Catalogue Number**: H-001
Unit Quantity: 200 mg	**Chemical Formula**: $C_7H_8ClN_3O_4S_2$
Molecular Weight: 297.7	**Assigned Value (Purity)** : 0.997 mg per mg on as is basis
Validity Date*	
Storage: Store between 2°C to 8°C, protected from light and moisture	

Intended Use

IPRS/CRM is intended for use in pharmaceutical testing, R&D, Validation or Quality Control of Analytical Methods with specified quantity. This Material cannot be used as "Drug" or household.

Instruction for handling and use

Allow the sealed container to equilibrate at ambient/room temperature before opening for use. Do not dry, use "As on basis". Once the container has been opened, Stability of content, value can not be guaranteed. It is for immediate use.

Safety Information

Refer to the material safety data sheet

(Dr. Ajay Prakash)
Principal Scientific Officer
Approving Officer

Indian Pharmacopoeia Commission is NABL ISO/IEC 17025:2017, ISO/IEC 17043:2010, ISO/IEC 17034:2016 and Accredited and WHO pre-qualified Laboratory

Page 1 of 2

Certificate of Impurity Standards

IPC/CHEM/STP/002/09/FMT/05

INDIAN PHARMACOPOEIA COMMISSION

(MINISTRY OF HEALTH AND FAMILY WELFARE, GOVT. OF INDIA)
SECTOR-23, RAJ NAGAR, GHAZIABAD-201002
Tel No: 0120-2783392, 2783400, 2783401, Fax: 2783411
Mail: lab.ipc@gov.in, Web: www.ipc.gov.in

CERTIFICATE OF ANALYSIS

Pregabalin Impurity c

α-Hydroxy-Benzeneacetic Acid; (RS)-2-Hydroxy-2-phenylacetic Acid; (RS)-Mandelic Acid; (2RS)-2-Hydroxy-2-phenylacetic Acid

IDENTIFICATION

Lot No.: IMPM030	**Catalogue Number**: IPRS/IMP-275
Unit Quantity: 20 mg	**Chemical Formula**: $C_8H_{15}NO$
Molecular Weight: 141.21	**Purity**: For Qualitative Use Only
Validity Date*	
Storage: Store between 2°C to 8°C, protected from light and moisture	

Instruction for Use

Allow the closed container to equilibrate at ambient temperature before opening and use. Use "on as is basis". Once the container has been opened, stability of the content cannot be guaranteed. It is for immediate use.

(Dr. Anuj Prakash)
Senior Scientific Officer
Approving Officer

Indian Pharmacopoeia Commission is NABL ISO/IEC 17025:2005 Accredited and WHO pre-qualified Laboratory

Page 1of 2

IPC/CHEM/STP/002/09/FMT/05

Any other Additional Information

1. IPRS is produced & certified under responsibilities of IPC according to regulatory authorities for quality control of medicine in India, having legal acceptance for IP standards. (this statement can be change/alter or added with gazette notification reference also)
2. The result listed refers only to the tested sample(s) and applicable parameter(s). Endorsement of products is neither inferred nor implied.
3. IPRS are not intended for administration to human or animal or medical device.

*The lot is valid until it is present in IPRS list on the website (www.ipc.gov.in)

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Page 2 of 2

IPC Collaborations

Observer in Ph. Eur.

Participation in IMWP & Pharmacopoeia Alert

Pharmacopoeial Collaboration

Academic Trainings

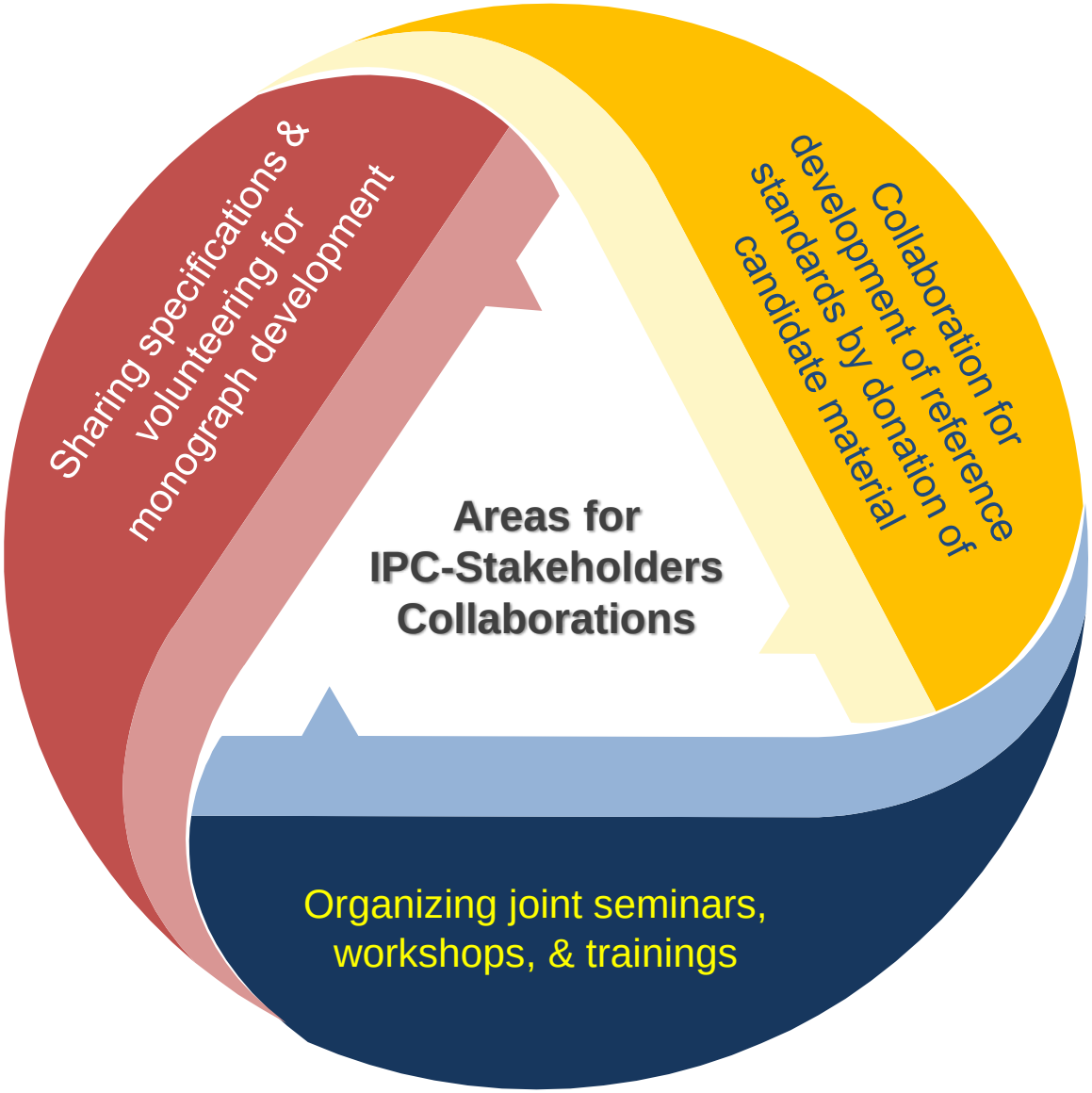
Pharmacopoeial Collaboration

DNA Barcoding & rDNA Ref. Std.

Development of Phytopharmaceuticals Monographs

Impurities Development

Collaboration Opportunities

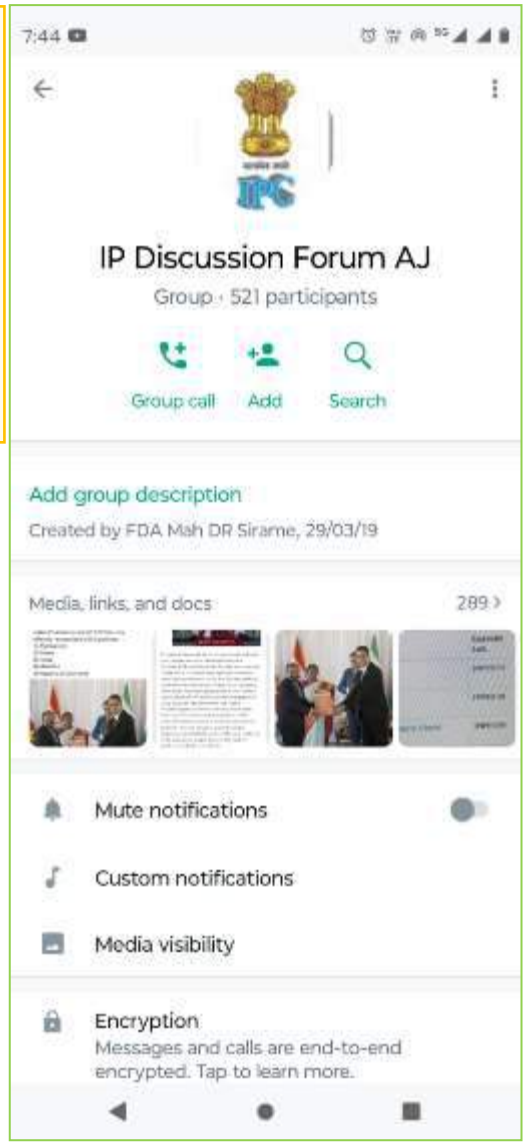


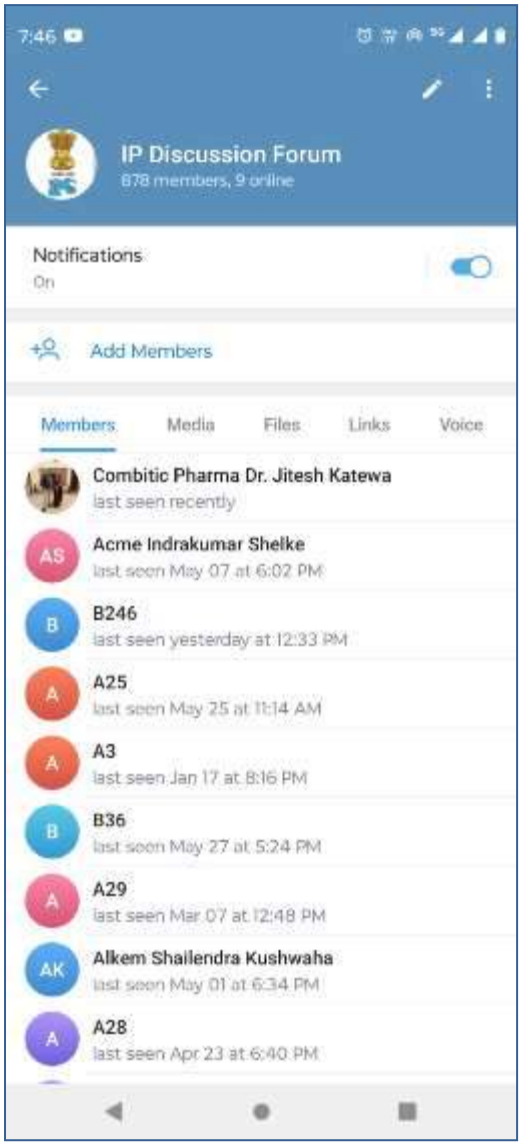
Get Connected with IPC

For general queries: Email: lab.ipc@gov.in

For purchase of IP and IPC publications: E-mail: publication-ipc@gov.in

For purchase of IPRS and Impurity standards:- E-mail: sales-ipc@gov.in





Acknowledgements

स्वास्थ्य एवं परिवार कल्याण मंत्रालय
MINISTRY OF HEALTH AND FAMILY WELFARE

CDSCO

NATIONAL INSTITUTE OF BIOLOGICALS

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BDR | Emcure | Lilly | Zydus Cadila | Dr.Reddy's

gsk GlaxoSmithKline | SERUM INSTITUTE OF INDIA PVT. LTD. | Abbott | Mylan | NOVARTIS PHARMACEUTICALS

HETERO | SANOFI | Alembic Touching Lives over 100 years | ipca A dose of life | INTAS INTAS PHARMACEUTICALS

MICRO LABS LIMITED | NEON | LUPIN | ALKEM | Glenmark A new way for a new world

….. and others

INDIAN PHARMACOPOEIA (IP)

IP REFERENCE STANDARDS (IPRS) & IMPURITIES

NATIONAL FORMULARY OF INDIA (NFI)

NATIONAL COORDINATION CENTRE-PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

Thank You

USE OF IP AND IPRS IS LEGAL OBLIGATION FOR 'IP' PRODUCTS