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Review

Ensuring the quality of medicines in India: An update on the development, modernization, and harmonization of drug standards in the Indian Pharmacopoeia

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ABSTRACT

India has a sparkling pharmaceutical sector that holds a distinguished place by producing and supplying high-quality and affordable medicines across the globe. Ensuring the quality and safety of the marketed medicinal products is one of the most important components of the drug regulatory framework and assessment of the quality of medicines is usually achieved by referring to the public standards of the official Pharmacopoeia. In India, the Indian Pharmacopoeia (IP) is published at regular intervals to fulfill the requirements of the Drugs and Cosmetics Act, 1940 to ensure the quality of medicines being manufactured and/or marketed in India. The present article aims to provide an overview of the history of the IP, its standards-setting process, and the current status of monographs in the 9th edition of the IP 2022. Special focus is placed on the newly added and upgraded general chapters and monographs within the IP 2022. There are a total of 223 general chapters and 3152 drug monographs available under various categories in the IP 2022. This study also highlights a total of 92 new drug monograph additions and 412 monograph revisions in the IP 2022. It is anticipated that the standards laid down in the IP 2022 will play an imperative role in delivering quality medicines to patients within and outside India.

1. Introduction

India's pharmaceutical industry has established itself as the world's third-largest producer of drugs in terms of volume and fourteenth-largest in terms of value (Anonymous, 2022). Globally, India is the world's twelfth-largest exporter of pharmaceutical products, exporting almost 19 billion USD worth of high-quality and low-cost medications to more than 200 countries (Guerin et al., 2020). According to a study by the India Brand Equity Foundation, India is the largest supplier of generic drugs and it fulfills more than 50% of the total global demand for vaccines, 30% of the annual United Nations International Children's Emergency Fund (UNICEF) requirements, 40% of generics consumed in the United States of America (USA), 25% of all the medicines in the United Kingdom (UK), and 60% supplies of the anti-retroviral drugs globally (Anonymous, 2022). In India, pharmaceutical goods' import, manufacture, distribution, and sale are regulated by the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under (Drugs and Cosmetics Act, 2016) wherein the state drug regulatory bodies are granted authority to regulate the grant of license, production, marketing, and distribution of medicines while the central drug regulatory body is responsible for approving new drugs, clinical trials, listing standards for drugs, and administering the quality of imported drugs (Drugs and Cosmetics Act, 2016).

From a healthcare perspective, it is essential to ensure and regulate the quality, efficacy, and safety of pharmaceutical products within a country or region. Accordingly, the Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) as the book of official drug standards in India (Indian Pharmacopoeia, 2022). The IPC aims to promote public and animal health in India by bringing out authoritative and officially accepted standards for the quality of drugs, including active pharmaceutical ingredients (APIs), finished pharmaceutical products (FPPs), and excipients used by healthcare

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professionals, patients, and consumers. The same is accomplished through developing and publishing IP standards for medicines along with assisting in their implementation through a regulatory framework within the country. IP contains a comprehensive collection of approved procedures for analysis along with their specifications for drugs that are imported, manufactured, stocked, exhibited for sale, or distributed within India (Drugs and Cosmetics Act, 2016).

In this article, we present a brief overview of the development of monographs for their inclusion in the IP as well as the current status of monographs and general chapters in the current edition of the IP 2022.

2. History of the Pharmacopoeia in India

The inception of the IP traces back to 1833 when a committee of the East India Company's Dispensary recommended the publication of a pharmacopoeia. Accordingly, the IP 1868 was published covering drugs from the British Pharmacopoeia (BP) 1867 and indigenous drugs used in India. However, after 1885, the BP became officially recognized in India (Indian Pharmacopoeia, 2022).

After India gained independence, the IP Committee was constituted in 1948 under the Ministry of Health and Family Welfare (MoHFW), Government of India with the primary responsibility of publishing the IP. Accordingly, the first edition of IP was published in 1955 by the IP Committee followed by a supplement in 1960. This edition of IP included the Western and traditional system of drugs extensively used in India. The same approach was adopted for the second edition of the IP in 1966 and its subsequent supplement in 1975. However, due to the rapid growth of the Indian pharmaceutical sector at the time, it was decided to issue new editions of IP and its addenda at more frequent and shorter intervals for which the IP Committee was reconstituted in 1978. Consequently, the third edition of IP was published in 1985 followed by its addenda in 1989 and 1991. The inclusion of the traditional system of drugs was limited in this IP edition; nonetheless, most new drugs manufactured and/or commercialized were covered. Continuing this trajectory, the IP Committee published the fourth edition of IP 1996 followed by its addendum in 2000 along with a supplement for veterinary products and an addendum in 2002 (Indian Pharmacopoeia, 2022).

In 2005, MoHFW established the IPC as an autonomous institute to publish IP at regular intervals and to develop reference standards (Indian Pharmacopoeia, 2022). Thereafter, IPC first published the IP addendum 2005 which featured many monographs on anti-retroviral pharmaceuticals and herbal plants commonly used in traditional Indian medicines which were not covered by other pharmacopoeias. Thereafter, in 2007 IPC published the fifth edition of IP encompassing 271 new drug monographs focused on pharmaceuticals recommended in National Health Programmes (NHPs) and the National List of Essential Medicines (NLEM). This was followed by the publication of IP addendum 2008. The sixth edition of IP was published in 2010 and its addendum in 2012 featuring monographs on therapeutic categories such as antiretroviral, anticancer, antituberculosis, herbal drugs, human vaccines, and biotechnology-derived drugs. The seventh edition of IP was published in 2014 and its addenda in 2015 and 2016. The seventh edition witnessed the inclusion of a general chapter on radiopharmaceutical preparations and its 19 monographs for the first time, of which 16 were injectable, 02 were capsules and 01 was a solution for oral use (Teotia et al., 2013). The eighth edition of the IP was published in 2018 and was supplemented by subsequent publications of IP addenda 2019 and 2021. The current official ninth edition of the IP was published in 2022, which became effective from 1st December 2022. Fig. 1 provides a concise historical overview of the publication of IP editions.

3. Monograph development process: Role of expert working groups (EWGs)

The inclusion of monographs in the IP is based on specific criteria with priority given to drugs listed in NHPs and NLEM along with other clinically relevant drugs with significant market share. The development of monographs commences by drafting them based on validated analytical procedures and specifications approved by the regulatory authority and donated by the manufacturers to IPC (Anonymous, 2021; Rastogi et al., 2022). The drafted monographs undergo review by specialized EWGs having members from regulatory authorities, pharmaceutical industry, drug control laboratories, health authorities, and research organizations. Currently, a total of 23 EWGs comprising of more than 160 representatives are involved in developing and revising monographs under various drug categories. Members of the EWGs are required to uphold strict confidentiality regarding all the material, knowledge, information, and data generated and/or exchanged during

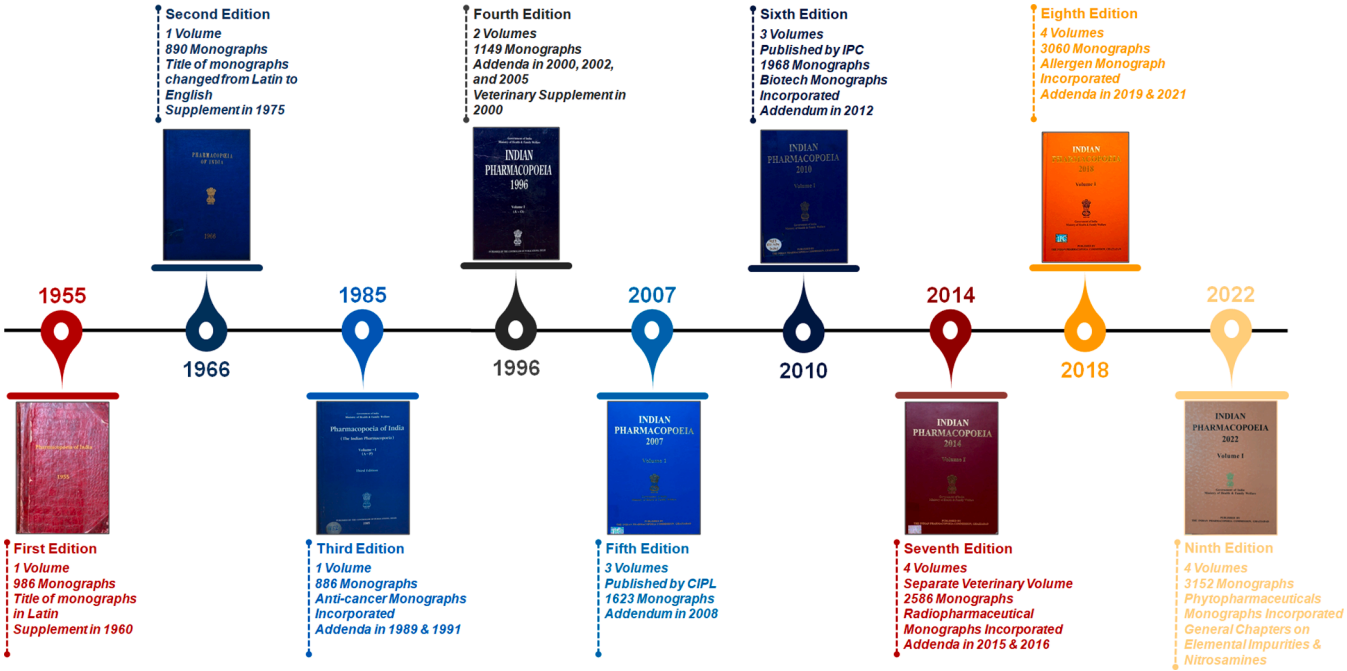

Fig. 1. History of the publication of IP editions.

monograph development process. Throughout the monograph development process, pharmaceutical manufacturers play a key role starting from sharing of approved drug specifications for the proposed monograph, providing test samples for method verification purposes, donating candidate material for reference standard development, and offering technical inputs on the draft monograph specifications before finalization.

To ensure transparency in the standards-setting process, proposals on new monographs and monograph revisions are publicized on the IPC website (https://ipc.gov.in/) besides following the conventional approach of obtaining comments through consultations. The IPC and EWGs evaluate the comments received from the stakeholders on the draft monographs to assess their suitability and acceptance. Any necessary additional revisions are made by the IPC and updated monographs are once again made accessible online on the IPC website. If no further revisions are needed, the monograph is approved and prepared for IP publication. The IPC secretariat evaluates whether the drug standards are appropriate for publishing in the IP after consulting with various EWGs and Scientific Body of the IPC. Monographs are published in the IP upon approval by the IPC and are considered official from the date mentioned in the IP. Since the publication of IP 2007, the status of drug standards in each subsequent IP edition with respect to the total number of monographs, new monograph additions, monograph revisions, and omissions is illustrated in Fig. 2.

4. Features of IP 2022

In a bid to promote the utmost standards of drugs for human and animal use, the IPC has released the ninth edition of IP, denoted as IP 2022, which is currently official in India. The publication of IP 2022 significantly improved drug standards particularly with respect to the increase in the number of drug monographs included therein and the revision of existing monographs and general chapters. Compared to the IP 2018 edition, the IP 2022 edition, reveals a 5.2% increase in the number of general chapters and a 2.9% increase in the number of monographs. These improved standards would profoundly promote the quality of medicines marketed in India. Notably, IP 2022 has also applied improved analytical methods for assessing quality attributes and promoted using *in-vitro* methods as alternatives to *in-vivo* bioassays. Furthermore, to focus on contemporary challenges, two new categories were also introduced in IP 2022 viz. 'phytopharmaceuticals' and 'vitamins, minerals, amino acids, fatty acids etc'. IP 2022 consists of four volumes with monographs classified under various categories as depicted in Fig. 3. Additionally, it provides an overview of the addition and revision status of monographs across different categories in the IP 2022. There are a total of 223 general chapters and 3152 monographs in the IP 2022. Among these monographs, 92 are newly added while 412 are older monographs which have been revised. Similarly, 12 new general chapters were added while 25 general chapters have undergone revisions. Several key improvements made within the IP 2022 standards are summarized in the following section.

4.1. General chapters additions

During the COVID-19 pandemic, the world has witnessed an urgent need for making available safe medicines to the patient at the earliest (Tian et al., 2021). However, the healthcare system faced challenges in maintaining a continuous supply of COVID-19-related drugs during the pandemic (Francis, 2020). To cope with this, the IP 2022 introduced a general chapter entitled 'Approach to Alternative Microbiological Methods' which serves as guidance for the stakeholders seeking alternatives to classical microbiological methods for early batch release of critical COVID-19 related medicines. Further, a general requirement for 'Phytopharmaceuticals', aimed at providing operational clarity on the current definition of this specific class of drugs, has been introduced in the IP 2022. IPC has also introduced a new general chapter on 'Elemental Impurities' with the intention of providing guidance to the stakeholders. This new chapter does not presently serve as a mandatory prerequisite in individual monographs. Nevertheless, stakeholders may adopt and implement this general chapter as an alternative to test on heavy metals in accordance with the provisions of IP general notices. IPC aims to progressively replace tests on heavy metals in the individual monographs to make Elemental Impurities mandatory from the next edition of the IP. Additionally, the newly added general chapter on Nitrosamine Impurities provides guidance to the stakeholders in determining the nitrosamine impurities in the marketed products. A summary of the newly added general chapters in IP 2022 is presented in Table 1.

4.2. Monograph additions

To further strengthen the IP standards, a total of 92 new drug monographs were included in the IP 2022. Among the included monographs, 60 monographs are under the category of 'pharmaceuticals', 21 under 'Vitamins, Minerals, Amino acids, Fatty Acids, etc.', 3 under 'Biotechnology Derived Therapeutic Products', 4 under 'Vaccines and Immunosera for Human Use', 2 under 'Blood and Blood-Related Products', and 2 under 'Herbs and Herbal Products'. The inclusion of these new monographs prioritizes drugs included in NHPs, NLEM, and those clinically relevant in the present scenario in India. The current IP edition includes additional APIs and FPPs for antiretroviral and anticancer drugs along with other commonly used fixed-dose combinations and drugs used for COVID-19 therapy. Among the new additions, some of the

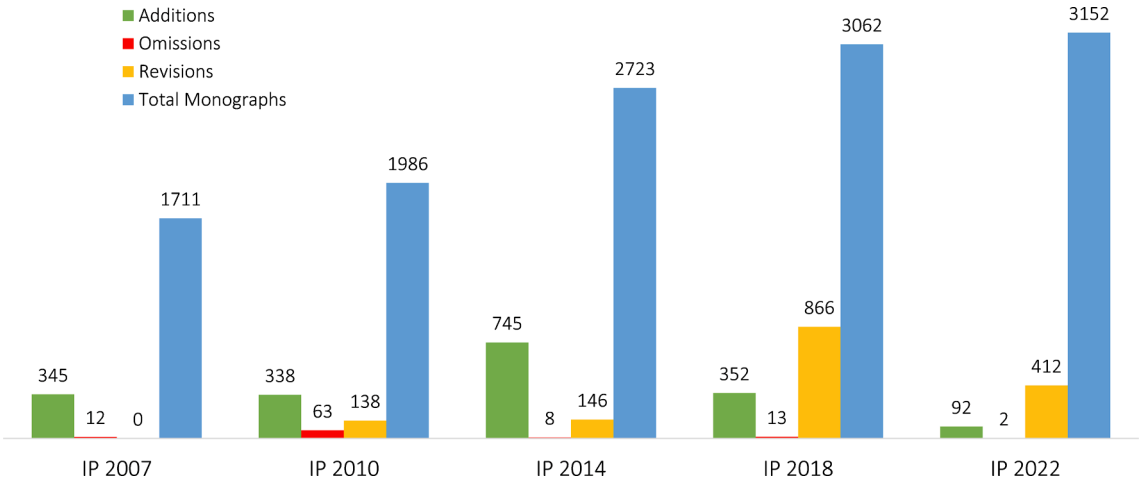

Fig. 2. Monograph status in IP editions since 2007.

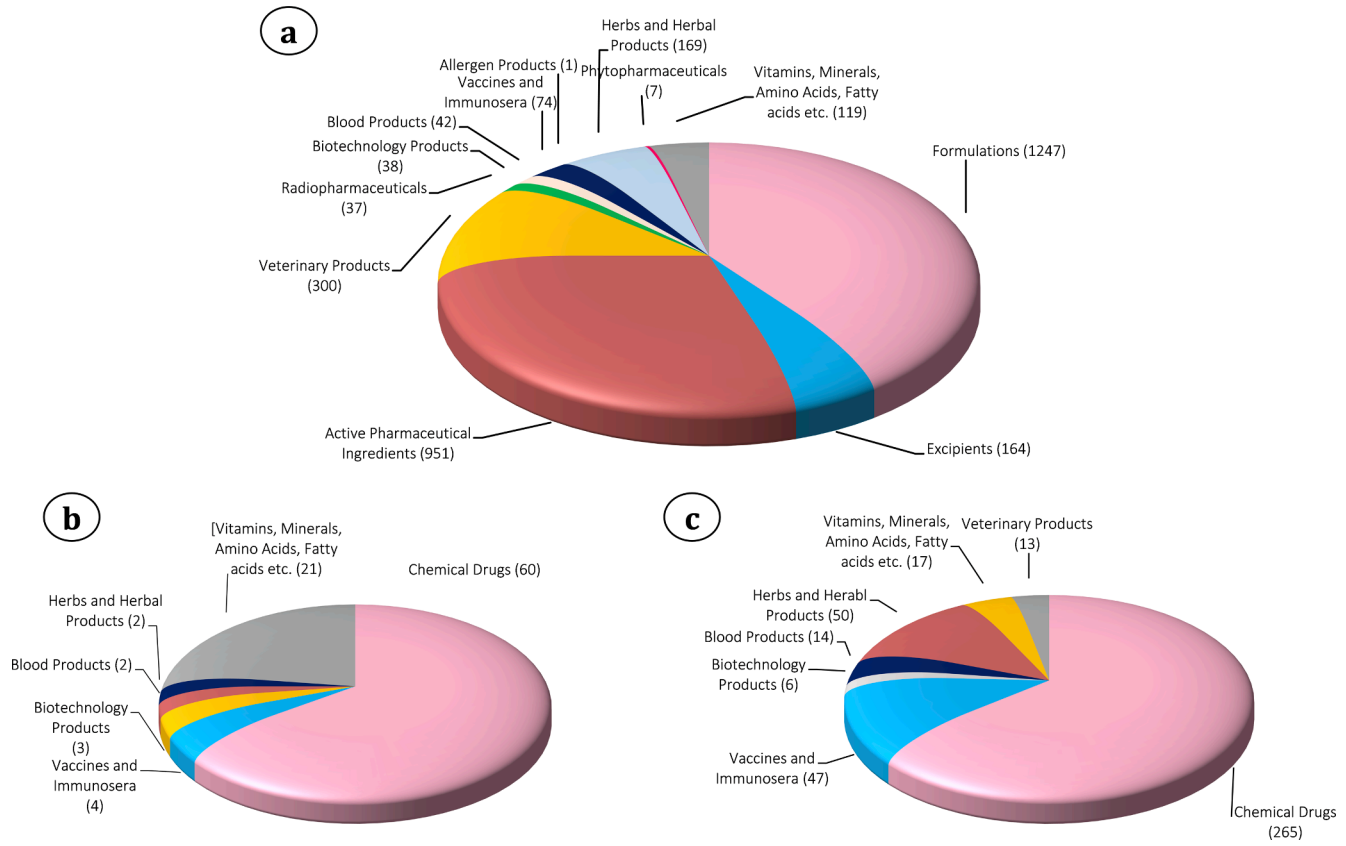

Fig. 3. Status of monographs in IP 2022. a. Category-wise distribution of IP monographs; b. Newly added monographs; c. Revised monographs.

Table 1
Newly added general chapters in the Indian Pharmacopoeia, 2022.

S. No.	General Chapters
1.	Microbiological Examination of *Burkholderia cepacia* Complex in Non-Sterile Products (2.2.29)
2.	Approach to Alternative Microbiological Methods (2.2.30)
3.	Design and Development of Biological Assay and its Validation (2.2.31)
4.	Subvisible Particulate Matter in Therapeutic Protein Injections (2.2.32)
5.	Assay of Calcium Pantothenate (2.3.56)
6.	Raman Spectrometry (2.4.47)
7.	(i) Uniformity of Dosage Units (2.5.4)
8.	Test for absence of *Mycobacteria* (2.7.14)
9.	Protocol for determination of the PRP content of Haemophilus Type b Conjugate Vaccine by HPAECPAD (2.7.15)
10.	Adjuvants for Vaccines (2.7.16)
11.	Elemental Impurities (5.10)
12.	Nitrosamine Impurities (5.11)

Numbers in the parenthesis indicates the newly added general chapter number.

important drug monograph inclusions are presented in Table 2.

Amidst the COVID-19 pandemic, several pharmaceutical products have been granted emergency approvals in India for treating and managing COVID-19. The IPC has prioritized setting standards for such drugs. For instance, the IPC has developed monographs on APIs and FPPs of Remdesivir and Favipiravir in collaboration with the pharmaceutical industries and were subsequently included in the IP Addendum 2021 (Rastogi et al., 2022). Additionally, two new monographs viz. 2-Deoxy-D-Glucose and 2-Deoxy-D-Glucose Sachet belonging to the COVID-19-related drugs (Sahu and Kumar, 2021) have been introduced in the IP 2022. These monographs provide generic specifications that help in assessing the quality of all the marketed products in India. Furthermore, several monographs under various therapeutic categories such as herbs and herbal products, blood grouping reagents, biotech-derived therapeutic products, and human vaccines have also been included in IP 2022. Notably, a general monograph on "Monoclonal Therapeutic Antibodies" has also been included in this edition of the IP. It has been designed to take care of quality attributes common to product classes/sub-classes including physicochemical tests and bioassays applicable to a wide range of monoclonal antibodies. Along with this, IP has also introduced individual monographs for monoclonal antibodies viz. Rituximab drug substance and Rituximab injection. These monograph additions aim to ensure the consistent quality of these products throughout their shelf life.

4.3. Monograph revisions

Monograph revision and modernization are important for keeping the drug standards up-to-date so as to meet the current regulatory requirements. IPC usually initiates such proposals based on the stakeholder's feedback on official monographs. Such efforts towards the monograph revisions gradually lead to monograph harmonization among the different pharmacopoeias and the establishment of uniform drug standards. This also alleviates the burden on the users who would otherwise need to perform analytical procedures using different specifications, thus paving the way for the globalization of the drug market (Narula et al., 2014; Rastogi et al., 2022).

To further upgrade the drug standards of the IP, monograph revisions were initiated with respect to the modernization of analytical procedures by including stability-indicating methods, the addition of test specifications on dissolution and related substances, and the revision of test limits. For instance, IP 2022 has witnessed the revised monographs updated with methods and specifications of UV test and benzene for isopropyl alcohol and isopropyl rubbing alcohol (Rastogi et al., 2022). Furthermore, a gas chromatography-based test for related substances was introduced in the monograph on isopropyl rubbing alcohol to detect possible impurities in the hand sanitizers. These tests are critical to

Table 2
New monograph additions in the Indian Pharmacopoeia, 2022.

Category of Drugs	Monograph Additions
Analgesic (01)	Dextropropoxyphene Hydrochloride and Paracetamol Tablets
Anticancer (07)	Amifostine API, Amifostine for Injection, Bosutinib API, Bosutinib Tablets, Lenvatinib API, Lenvatinib Capsules, Mesna Tablets
Antibacterial (04)	Azithromycin Eye Drops, Ceftriaxone and Sulbactam for Injection, Polymyxin B Sulphate, Polymyxin B Sulphate Injection
Antidepressant (02)	Trazodone API, Trazodone Tablets
Antidiabetic (06)	Epalrestat API, Epalrestat Injection, Repaglinide and Voglibose Tablets, Glipizide and Metformin Tablets, Vildagliptin and Metformin Tablets, Teneligliptin and Metformin Hydrochloride Prolonged-Release Tablets
Antiepileptic (02)	Brivaracetam API, Brivaracetam Tablets
Antifibrinolytic (01)	Aprotinin Injection
Antifungal (01)	Itraconazole API
Antihistaminic (01)	Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Prolonged-Release Tablets
Antihypertension (01)	Amlodipine and Valsartan Tablets
Anti-inflammatory (02)	Apremilast API, Apremilast Tablets
Antipsychotic (01)	Risperidone Syrup
Antirheumatic (02)	Tofacitinib API, Tofacitinib Tablets
Antithrombotic (01)	Prasugrel and Aspirin Gastro-resistant Capsules
Antiviral/ Antiretroviral (09)	Ribavirin Capsules, Sofosbuvir API, Sofosbuvir and Daclatasvir Tablets, Sofosbuvir Tablets, Valacyclovir Hydrochloride API, Valacyclovir Tablets, Valganciclovir Hydrochloride API, Valganciclovir Tablets, Zanamivir API
Diuretic (01)	Triamterene and Hydrochlorothiazide Tablets
Excipient/ Pharmaceutical Aid (03)	Ethylacetate API, Sodium Starch Glycolate (Type B), Sugar Sphere
Non-depolarizing Neuromuscular Blocker (02)	Rocuronium Bromide, Rocuronium Injection
Non-steroidal Anti-inflammatory Drug (NSAID) (02)	Diclofenac Potassium API, Diclofenac Potassium Tablets
Local Anesthetic (01)	Oxetacaine
Oral Contraceptive (05)	Desogestrel API, Desogestrel and Ethinylestradiol Tablets, Ethynodiol Diacetate, Ethynodiol Diacetate and Ethinyloestradiol Tablets, Estradiol Hemihydrate
Plasma Substitute (03)	Dextran 1, Dextran 40, Dextran 70
COVID-19 Drugs (02)	2-Deoxy-D-Glucose, 2-Deoxy-D-Glucose Sachet
Vitamins, Minerals, Amino Acids, Fatty Acids etc. (21)	Oil-Soluble Vitamins Capsules, Oil-Soluble Vitamins Oral Solution, Oil-Soluble Vitamins Tablets, Water-Soluble Vitamins Capsules, Water-Soluble Vitamins Tablets, Alpha Lipoic Acid, Biotin, Calcium Citrate Malate, Chromium Picolinate, Copper Gluconate, Glutamic Acid, Inositol, Lutein, Lysine Hydrochloride, Phenylalanine, Selenomethionine, Selenious Acid, Threonine, Tryptophan, Valine, Zinc Citrate
Herbs and Herbal Products (02)	Chitrak, Siris
Vaccines and Immunosera (04)	Diphtheria, Tetanus, Acellular Pertussis, Hepatitis B, Inactivated Poliomyelitis and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, Meningococcal Group A, C, W135 and Y Conjugate Vaccine, Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B, Inactivated Poliomyelitis and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, Bivalent Poliomyelitis Vaccine Type 1 and 3 Live (Oral)
Blood and Blood Related Products (02)	Anti-D Blend (IgM + IgG) Monoclonal Reagents, Anti-D (IgG) Monoclonal Reagents
Biotechnology Derived Therapeutic Products (03)	Rituximab, Rituximab Injection, Teriparatide Concentrated Solution

Numbers in the parenthesis indicates the number of new monographs introduced in the Indian Pharmacopoiea.

assess the quality of marketed hand sanitizer products which may contain several impurities (FDA, 2020).

Additionally, dissolution specifications were also introduced in 59 drug monographs of IP 2022 which were missing in the previous edition of the IP. Compliance with the dissolution specifications would ensure that the active ingredient will dissolve in an aqueous medium within a reasonable time limit, thus ensuring the quality of marketed products. Moreover, 53 monographs were revised by updating the assay methodology with high-performance liquid chromatography or gas chromatography. Regarding tests for related substances, 11 monographs were strengthened by introducing new tests while 29 monographs were upgraded by revising the existing tests. Furthermore, 52 monographs in IP 2022 underwent complete revision to harmonize with global standards.

Apart from monograph revisions, a total of 119 monographs that were earlier present in the chemical drugs category were shifted to a new category 'vitamins, minerals, amino acids, and fatty acids'. Additionally, 07 monographs of herbs and herbal products were shifted to phytopharmaceuticals. The criteria for an herbal to be considered a phytopharmaceutical include qualitative and quantitative characterization of an herbal drug/extract/purified fraction with at least four bioactive/analytical marker compounds, with at least one biomarker being mandatory (Indian Pharmacopoeia, 2022).

Further, considering the fact that viral vaccines manufactured through cell culture technology are prone to mycoplasma contamination (Chandler et al., 2011), the requirement for the absence of mycoplasma was included in sixteen vaccine monographs of the IP 2022 in harmonization with the World Health Organization (WHO) guidance (WHO, 2013). This inclusion will help in enhancing the quality and safety of viral vaccines produced using cell culture-based technology.

4.4. Adoption of 3Rs principles

IPC has also embraced the principles of the 3Rs (Reduction, Refinement, Replacement) in the IP 2022 edition by eliminating animal tests such as the Abnormal Toxicity Test (ATT) at final lot for biologicals by replacing the *in-vivo* bioassays with *in-vitro* assay methods, minimizing the number of animals used where elimination of the animal test is not possible, and/or refining the tests that results minimal suffering to the animals (Rastogi et al., 2015). The pyrogen test specified in the IP limits the risk of a febrile reaction following the parenteral administration of drugs. The test measures the rise in body temperature following intravenous administration of products using rabbits. To implement the 3Rs in IP, pyrogen testing using rabbits has been replaced by the bacterial endotoxin test in all human vaccine monographs of the IP 2022.

Similarly, the ATT is conducted to detect the presence of any extraneous toxic contaminants in sterile pharmaceutical preparations. Based on the WHO recommendations, the ATT requirement can be relaxed if manufacturers establish batch consistency and characterize each batch with a sufficient set of test methods approved by the National Regulatory Authority (Rastogi et al., 2015). Taking this into consideration, the ATT test has been removed in thirty-three monographs of human vaccines thereby reducing the use of laboratory animals during batch-release testing. Once the batch consistency is established, manufacturers can omit this test for routine lot release of human vaccines.

5. Discussion

Pharmacopoeia constitutes a legally binding collection of public standards that serve to assess medicines' identity, strength, purity, and safety that can be expected and demonstrated at any time throughout their shelf-life (Rastogi et al., 2022). The standards outlined in pharmacopoeia represent the minimum requirements that a drug must comply with throughout its shelf life. Individual drug monographs, along with the referred general chapter(s), general requirements, if any, and the reference standard(s) mentioned in the monograph constitute an

official drug standard used for assessing the quality of the drug (Indian Pharmacopoeia, 2022). The availability of a public standard is expected to foster the development and marketing of a larger number of generic products which, in turn, enhances the accessibility of high-quality drugs at more affordable prices (Rastogi et al., 2022).

The development of IP standards and their revision for modernization is a continuous process that follows the principles of Good Pharmacopoeia Practices (GPhP) during the entire cycle of the standards-setting process that remains transparent for all stakeholders (WHO, 2016). The IPC engages with various EWGs and other stakeholders through expert meetings, workshops, and seminars to develop and revise IP standards. During these consultations, IPC ensures timely responses to the stakeholder's queries and comments, instilling confidence in the process of IP monograph development. GPhP principles are carefully considered during monograph development, specifically avoiding specifications that could restrict market access by favouring certain manufacturers and excluding others (WHO, 2016). This is achieved by setting drug specifications so that they can determine the quality attributes of all the marketed products and are irrespective of brand. The IPC also ensures the confidentiality of the drug specification donors and their data, safeguarding against sharing such information with competitors in the market. In general, widely used analytical methods are given preference for inclusion in the monograph to develop user-friendly drug standards. Furthermore, the IP allows manufacturers to employ alternative analytical methods to test their products provided the results obtained by alternative methods are demonstrated to be equivalent to those obtained with the official methods (Indian Pharmacopoeia, 2022).

In addition, towards a process for harmonization with global pharmacopoeias, IPC was selected as a pilot participant for 1 year to Pharmacopoeial Discussion Group (PDG) in September 2022. The IPC recognizes the utility of working with other pharmacopoeial bodies to develop harmonized monographs and general chapters. The objective of PDG is to reduce manufacturers' burden of having to perform analytical procedures in different ways, using different acceptance criteria, in order to satisfy pharmacopoeial requirements that vary across regions. Work on harmonization is carried out by a well-defined process in the PDG, in which the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia are associated (Kameyama et al., 2019). Harmonization of general chapters is carried out with an aim to arrive at interchangeable methods or requirements so that demonstration of compliance using a general chapter from one of the 3 pharmacopoeias implies that the same result would be obtained using the general chapter of either of the other pharmacopoeias. The harmonization of monographs is carried out, with the aim to arrive at identical requirements for all quality attributes of a product.

Over the past few decades, IPC has consistently fulfilled its mission concerning setting quality standards for pharmaceutical products by bringing out IP editions and their addenda at regular intervals. Each new edition not only incorporates a greater number of monographs but also updates existing monograph standards by adopting the latest available analytical methods and expanding the number of relevant tests within each monograph. The stakeholders extensively rely on the standards prescribed in the IP to assess the quality of drug products in commerce and imported pharmaceuticals in India. The availability of public IP standards also aids in monitoring counterfeit and substandard products while promoting the development of generic medicines. It is anticipated that the IP 2022 will play a significant role in enhancing the quality of medicines thus promoting public health in India and fostering the growth of the country's pharmaceutical sector while making affordable medicines available to the public. Moving forward, IPC will continue to increase the number of official drug monographs and revise the existing ones within the IP to promote the availability of safe and efficacious pharmaceutical products in the Indian market. Further, stakeholders can procure the desired edition of IP or its Addendum through the official website of IPC (https://ipc.gov.in).

Author contribution

The authors confirm their contribution to the manuscript as follows:

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Data curation: Shruti Rastogi, Amit Kumar, Jaishiv Chauhan, Mukesh Kumar;

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Manuscript review and editing: Gaurav Pratap Singh Jadaun, Pawan Kumar Saini, Ritu Tiwari, Rajeev Singh Raghuvanshi;

Supervision: Gaurav Pratap Singh Jadaun, Rajeev Singh Raghuvanshi.

All authors reviewed the associated data and approved the final version of the manuscript.

Declaration of Competing Interest

The authors declare no conflict of interest. The views expressed in this article are the personal views of the authors. They shall not be understood or quoted as being made on behalf of or reflecting the position of the Indian Pharmacopoeia.

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