IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Regulatory And Public Health Significance Of The Indian Pharmacopoeia In Safeguarding Medicine Quality In India

[1]Janvi P. Patel, [2]Dr. Rajesh Parmar, [3]Hemangini Patel

[1]M. Pharm Research Scholar, [2] Professor, [3]Assistant professor

[1]Department of Regulatory Affairs, Anand Pharmacy College, Anand, Gujarat, India

[2,3]Anand Pharmacy College, Near Town Hall, Anand, Gujarat 388001, India

Abstract

India's role as a major producer and global supplier of generic medicines makes the assurance of drug quality a central public health and regulatory priority. The Indian Pharmacopoeia (IP), published by the Indian Pharmacopoeia Commission (IPC), is the official compendium of standards for the identity, strength, purity and performance of drugs and related substances marketed in the country and serves as a legally enforceable benchmark under the Drugs and Cosmetics Act and Rules. Through monographs, general chapters and Indian Pharmacopoeia Reference Substances (IPRS), the IP provides validated analytical methods and acceptance criteria that guide manufacturers, quality-control laboratories and regulators in ensuring that medicines are of standard quality and suitable for patient use. Over successive editions, the IP has expanded and modernized to include chemical drugs, traditional medicines, biologicals, vaccines and complex formulations, while aligning with World Health Organization (WHO) good pharmacopoeial practices and participating in international harmonization initiatives such as the Pharmacopoeial Discussion Group. This review outlines the historical evolution, legal status, scientific content and implementation of the IP and critically examines its contribution to detecting substandard and falsified medicines, supporting Good Manufacturing Practices (GMP) and enabling generic interchangeability in India, as well as its growing relevance for international trade and regulatory convergence.

Keywords: Indian Pharmacopoeia, Indian Pharmacopoeia Commission, drug quality standards, medicines regulation, Good Manufacturing Practices, reference standards (IPRS), pharmacopoeial harmonization, WHO good pharmacopoeial practices, generic medicines, public health.

1. Introduction

India is frequently referred to as the "pharmacy of the world" due to its significant output of generic drugs and vaccines for both local and international markets. It is vital to guarantee that these products fulfill the necessary standards of quality, safety, and effectiveness to safeguard public health and uphold trust in the health care system and export markets. (1,2)

India's medicines regulatory framework revolves around the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945, enforced by the Central Drugs Standard Control Organization (CDSCO) along with state drug control agencies. In this context, the Indian Pharmacopoeia serves as the official standards manual detailing the necessary quality characteristics and testing methods for pharmaceuticals that are produced, brought in, stored, distributed, or sold in India. (1,3)

Public pharmacopoeial standards serve various functions, such as offering a shared technical vocabulary for regulators, manufacturers, and quality control labs, and aiding in the monitoring of substandard and counterfeit products. In India, the IP serves as both a scientific and legal tool that links regulatory decisions with effective quality control assessments during the entire medicine life cycle. (4,5)

1.1 Global burden of poor-quality medicines

Substandard and counterfeit (SF) medications continue to pose a significant global health issue, especially in low- and middle-income nations where regulatory and quality-control frameworks might be inconsistently funded. Estimates from WHO indicate that a considerable percentage of medications in these environments do not meet quality standards, leading to treatment failure, toxicity, antimicrobial resistance, and preventable death. As a leading producer and exporter of generic drugs and vaccines, India is under close examination by importing nations, multilateral purchasing organizations, and international health programs regarding the quality of its offerings. Failures associated with SF or inferior products can erode public trust, interfere with treatment plans, and tarnish India's image as a dependable provider of cost-effective medicines. In this scenario, strong pharmacopoeial standards and successful execution of the Indian Pharmacopoeia (IP) are crucial for minimizing the chances of substandard medicines in both domestic and export markets. (6-10)

1.2 Role of pharmacopoeias in regulatory systems

Pharmacopoeias establish public quality benchmarks that specify the identity, potency, purity, and efficacy of drugs and related products, serving as a crucial component of national regulatory systems. WHO's excellent pharmacopoeial practices stress that these standards must be grounded in science, clear and formulated through organized expert discussions to aid in licensing, Good Manufacturing Practices (GMP), quality assurance, and post-marketing monitoring. Through the specification of monographs, general chapters, and validated analytical methods, pharmacopoeias provide a unified technical language for regulators, manufacturers, and control laboratories, facilitating an objective evaluation of product quality and ensuring comparability of results among various locations. In India, the IP serves as the official pharmacopoeia, akin to the roles of the European Pharmacopoeia and the United States Pharmacopeia in their areas. Coordinating and aligning these pharmacopoeias can minimize trade technical barriers, promote regulatory reliance, and enhance worldwide access to quality-assured medications. (8,9,11)

2. Historical evolution of the Indian Pharmacopoeia

Before independence, India's drug standards were mainly derived from foreign pharmacopoeias like the British Pharmacopoeia, resulting in inadequate coverage for diseases common in the region and medicines used locally. The requirement for a national pharmacopoeia that represented indigenous public health needs and manufacturing

circumstances propelled the creation of the first Indian Pharmacopoeia, which unified various standards and established the groundwork for future editions. [12,13]

2.1 Pre-independence and early national efforts

Prior to independence, the drug standards in India were mainly based on external sources like the British Pharmacopoeia, which failed to adequately represent local disease loads, climate variations, or the variety of medicines typically employed in Indian medical practice. This reliance on international standards led to shortcomings in coverage for regionally significant products and posed difficulties for regulators trying to ensure uniform quality of medicines in local markets. Acknowledging these constraints, expert committees and policymakers promoted the creation of a specific Indian pharmacopoeia designed to unify current standards and cater to local public health requirements. The early years following independence witnessed a gradual shift from dependence on imported pharmacopoeias to the development of a national compendium, leading to the release of the first Indian Pharmacopoeia (IP) in the mid-1950s. This achievement established the scientific and regulatory groundwork for later editions and for the development of India's own standard-setting abilities. [17,18]

2.2 Development of successive IP editions

Later editions of the Indian Pharmacopoeia have shown the development and variety of India's pharmaceutical industry along with progress in analytical science. The initial IP established standards for a select group of vital medications, whereas subsequent editions gradually expanded monograph coverage to encompass a broader array of therapeutic categories, including antibiotics, cardiovascular agents, antidiabetic drugs, and pain relievers. As time progressed, innovative analytical methodologies, especially chromatographic and spectroscopic techniques, emerged to enhance the sensitivity and specificity of tests for identity, impurities, and assay. The editions from 1996 and 2007 represented significant advancements in updating impurity management and testing of related substances, better matching current regulatory standards. Every review cycle offered chances to eliminate outdated monographs, refine specifications as necessary, and tackle quality concerns recognized through regulatory experiences and scientific advancements. [14,15]

2.3 Establishment and mandate of the Indian Pharmacopoeia Commission

The Indian Pharmacopoeia Commission (IPC) was founded in 2005 as an independent organization under the Ministry of Health and Family Welfare to enhance and formalize pharmacopoeial standard creation in India. Its establishment addressed the requirement for a specialized, skilled entity capable of periodically updating the Indian Pharmacopoeia, managing reference standards, and offering support to laboratories and regulatory bodies. The IPC's responsibilities encompass the creation, publication, and regular revision of the IP; the establishment and distribution of Indian Pharmacopoeia Reference Substances (IPRS); the compilation of the National Formulary of India; and assistance with drug quality monitoring and capacity development. Consequently, the procedure for updating IP editions and releasing addenda has turned more structured, clear, and attentive to stakeholder feedback. The IPC functions as the national pharmacopoeial authority and a vital technical component of India's medicine regulatory framework. [17 - 19]

3. Legal status and regulatory linkages

3.1 Legal basis and enforceability under Drugs and Cosmetics Act

The Indian Pharmacopoeia's legal status is based on the Drugs and Cosmetics Act of 1940 and its associated Rules, which establish "standard quality" for drugs by referencing designated pharmacopoeias, including the IP. For drugs included in the Indian Pharmacopoeia, non-compliance with the relevant monograph may result in the product being categorized as not meeting standard quality, and, depending on the situation, as substandard, counterfeit, or misbranded. These classifications entail regulatory repercussions, such as product recalls, stock seizures, suspension or revocation of manufacturing licenses, and criminal prosecution of involved individuals. Judicial bodies and regulatory agencies depend on test findings produced using IP methods to determine if a

product complies with or falls short of established legal standards. The connection between adherence to pharmacopoeial standards and legal definitions of quality highlights the combined scientific and legal function of the IP within India's regulatory system. [3,4,15,18]

3.2 Use of IP by CDSCO and state regulators

The Central Drugs Standard Control Organization (CDSCO) along with state drug regulatory bodies heavily rely on Indian Pharmacopoeia standards for licensing, inspections, and post-marketing surveillance efforts. While approving manufacturing licenses and marketing authorizations, the suggested product specifications are examined for alignment with applicable IP monographs, and any discrepancies generally necessitate scientific justification. At both central and state levels, drug inspectors collect samples from production facilities, distribution networks, and retail stores, which are then examined in government or certified laboratories using methods outlined in the IP. Reports that analyze test results against IP acceptance criteria serve as the foundation for regulatory decisions regarding the release, recall, or enforcement of products. The IPC's Guidance Manual for Drug Testing Laboratories offers comprehensive guidelines for applying IP methods in official labs, thereby further standardizing regulatory testing practices nationwide. [3,4,15,18]

3.3 Linkages with public procurement and national programmes

Standards from the Indian Pharmacopoeia are integrated into public procurement policies and national health programs, enhancing their effect on the quality of medicines. Central and state procurement bodies, along with initiatives like the Pradhan Mantri Bhartiya Janaushadhi Pariyojana, typically mandate that the medicines provided adhere to the applicable IP monographs regarding identity, assay, dissolution, and impurity thresholds. This requirement ensures that products provided to public hospitals, primary health centers, and social insurance programs meet consistent quality standards, regardless of the manufacturer or brand. In the public sector, pharmacopoeial specifications, along with price controls and generic substitution policies, enhance the quality and affordability of medicines. Thus, the IP acts as a technical connection among regulatory supervision, procurement choices, and the standard of medicines delivered to patients via publicly financed programs [3,4,15,18]

4. Scientific content: monographs, general chapters and reference standards

4.1 Structure of monographs

Monographs in the Indian Pharmacopoeia utilize a defined format that allows for precise detailing of quality characteristics and testing procedures for active pharmaceutical ingredients (APIs), excipients, and dosage forms. A standard API monograph contains sections detailing description, solubility, identification tests, specific impurities and related substances, assay methods, and, if applicable, examinations for optical rotation, moisture content, or residual solvents. Monographs for dosage forms also detail requirements for the uniformity of dosage units, dissolution or disintegration, microbial limits, and other performance-related criteria. The acceptance criteria in these areas typically mirror the current knowledge of impurity profiles and stability, generally aligning with ICH guidelines regarding impurities and quality. Through the codification of this information, monographs offer a thorough yet succinct framework for quality control suitable for use in industry, regulatory, and independent laboratories. [17,18,20]

4.2 General chapters and appendices

Along with product-specific monographs, the Indian Pharmacopoeia includes general notices, general chapters, and appendices that outline analytical techniques and concepts relevant to various monographs. These sections address essential techniques including titrimetry, spectrophotometry, chromatography, microbiological assays, sterility testing, and particulate contamination limits, along with subjects like system suitability, validation, and statistics. General chapters encourage standardization by offering comprehensive, validated protocols for frequently employed tests, allowing laboratories to implement them without needing to create their own methods from scratch. They additionally endorse alignment with other significant pharmacopoeias and with WHO good pharmacopoeial practices, highlighting the essential nature of explicit general standards for analytical quality. For

users, these sections act as a crucial reference, guaranteeing that monograph tests are conducted consistently and with scientific integrity across various institutions [17,18,20]

4.3 Indian Pharmacopoeia Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substances (IPRS) are high-quality, precisely defined materials created and managed by the IPC to aid in the execution of pharmacopoeial tests. They encompass reference standards for APIs, impurities, degradation products, and system-suitability mixtures employed in chromatographic and various analytical methods. IPRS are crucial for verifying identity, calibrating assays, and measuring impurities, thus guaranteeing consistency of analytical results between laboratories and over time. The IPC adheres to established protocols for the selection, characterization, value assignment, storage, and regular re-evaluation of IPRS, consistent with international best practices for reference standards. By centrally providing these materials to industries and official labs, the IPC minimizes variability that might stem from locally created standards and enhances confidence in adherence to IP specifications. [17,18,20]

5. Role in ensuring quality, safety and efficacy of medicines

5.1 Use of IP in industry quality-control laboratories

In the production of pharmaceuticals, quality-control (QC) labs depend significantly on IP standards to plan and perform tests on raw materials, intermediates, and final products. Specifications for assays, impurities, dissolution, uniformity, and microbial quality are generally based on or aligned with pertinent IP monographs, with any justified deviations recorded in internal quality systems. QC labs conduct regular tests following IP-specified methods, enhanced by necessary system-suitability assessments and IPRS checks, to guarantee that every batch complies with set acceptance standards prior to release. Stability investigations utilize IP techniques to assess product quality throughout shelf-life and under different storage conditions, offering proof for expiration dating and storage suggestions. The systematic incorporation of IP methods into QC activities ensures uniform product quality and aids regulatory inspections, where agencies frequently confirm that in-house methods comply with pharmacopoeial standards. [17,19,21]

5.2 Detection of substandard and falsified medicines

Standards set by the Indian Pharmacopoeia are essential in the fight against substandard and counterfeit medicines in the Indian market. Authorized drug-testing labs employ IP methods to analyze samples gathered from standard monitoring or specific initiatives, contrasting outcomes with monograph thresholds for assay, impurities, dissolution, and other essential factors. Non-compliant samples are categorized as below standard quality and may lead to regulatory measures such as alerts, recalls, and legal actions against manufacturers or distributors. Moreover, IP tests aid in differentiating products that are truly inferior due to production or storage problems from those that are counterfeit, such as by identifying the absence or replacement of active components. Insights from these analyses can shape policy choices, direct risk-based monitoring, and enhance overarching national strategies to tackle substandard medicines [18,20,21]

5.3 Support for generic interchangeability

For generic drugs, which frequently have several producers and labels, uniform pharmacopoeial standards are crucial for ensuring interchangeability and sensible substitution. The Indian Pharmacopoeia establishes standardized criteria for strength, identity, content uniformity, and dissolution, which all producers of a specific product must comply with, alongside regulatory obligations like bioequivalence assessments. When products from various manufacturers adhere to the same monograph and show similar in-vitro performance, prescribers and pharmacists can feel more assured that switching will not jeopardize therapeutic results. This is especially important in public health initiatives and programs advocating for generic substitution, where savings should not compromise quality. By supporting the technical elements of equivalence, the IP thereby enhances the regulatory and clinical standards applied to assess and replace generic drugs in India.[18,20,21]

6. Interface with GMP, QC/QA systems and quality risk management

Good Manufacturing Practices (GMP) necessitate that manufacturers create and adhere to documented specifications and testing methods for materials and products, and the IP serves as a crucial resource for these specifications. Numerous firms either fully embrace IP monograph requirements or modify them with well-founded internal constraints, ensuring that final products meet regulatory standards and pharmacopoeial criteria. (14,17,18)

Quality-control (QC) labs at manufacturing facilities regularly conduct tests outlined in the IP at different phases, such as raw material evaluation, in-process monitoring, finished product approval, and stability assessments. Quality assurance (QA) systems utilize these findings for batch release decisions, investigation of deviations, and assessments of change control, integrating pharmacopoeial standards into the broader pharmaceutical quality framework (18,19,20)

The IPC aids in capacity building and quality enhancement by hosting training sessions, proficiency assessments, and providing guidance on pharmacopoeial application for regulators, industry researchers, and academic labs. These initiatives aid in minimizing inconsistencies in test results and their interpretation, which is essential for efficient quality risk management throughout a varied and geographically spread pharmaceutical industry. (18,19,20)

6.1 Regulatory framework for cGMP in India (D&C Act, Rules, Schedule M and CDSCO)

The basis of present Good Manufacturing Practices (cGMP) for pharmaceuticals in India is established by the Drugs and Cosmetics Act, 1940, along with the Drugs and Cosmetics Rules, 1945, which oversee the import, production, distribution, and sale of drugs and cosmetics. These tools establish “standard quality” and enable central and state agencies to authorize production facilities, designate inspectors, collect samples, and take legal action against activities like the production or sale of inferior, incorrectly labeled, contaminated, or counterfeit medications. Operational GMP stipulations are primarily outlined in Schedule M to the Rules, which specifies standards regarding premises, machinery, documentation, production, and quality control systems that manufacturers need to adhere to for acquiring and maintaining licenses. Recent revisions to Schedule M have aligned Indian GMP more closely with WHO and other global standards by highlighting quality risk management, validation, product quality review, and control of computerized systems. At the central level, the Central Drugs Standard Control Organization (CDSCO), led by the Drugs Controller General (India), manages new drug approvals, import regulations, specific manufacturing licenses and collaboration with state authorities, while also providing GMP-related guidance documents that enhance legal requirements. (28,32)

6.2 Linkages between IP standards and Schedule M inspections

During GMP inspections as per Schedule M of the Drugs and Cosmetics Rules, inspectors regularly check for compliance with facility and system specifications as well as the adequacy and application of product specifications and testing methods, which should align with pharmacopoeial standards where relevant. Manufacturers of products included in the Indian Pharmacopoeia typically need to ensure their internal specifications and analytical methods conform to the applicable IP monographs or scientifically justify any discrepancies to gain regulatory approval. Inspectors might evaluate standard operating procedures, validation documentation, and analytical records to ensure that tests like assay, impurity profiling, dissolution, and microbiological limits are conducted utilizing methods and acceptance parameters based on the IP or other acknowledged pharmacopoeias. Non-conformities, including the application of unverified methods or specifications that fall short of pharmacopoeial standards, can lead to negative inspection results and regulatory measures. Thus, IP standards and Schedule M inspections are tightly connected, with adherence to pharmacopoeial guidelines being a crucial part of the comprehensive cGMP evaluation by CDSCO and state drug authorities. (33 – 36)

7. Harmonization and international dimensions

The globalization of pharmaceutical supply chains has heightened the need for standardizing pharmacopoeial standards to minimize testing redundancy and inconsistent requirements between jurisdictions. The Indian Pharmacopoeia has gradually harmonized its procedures and acceptance standards with those of leading pharmacopoeias and WHO good pharmacopoeial practices, while continuing to cater to local public health requirements. (18,22,23)

India's inclusion in the Pharmacopoeial Discussion Group (PDG), together with the European Pharmacopoeia, United States Pharmacopeia, and Japanese Pharmacopoeia, represents an important advancement in formal global harmonization. By means of PDG and associated initiatives, monographs and general chapters can be standardized, minimizing the necessity for manufacturers to comply with various conflicting standards for identical products and promoting smoother international trade. (22,23,24)

The IP contributes to India's overall foreign-policy and health diplomacy objectives, as the alignment of standards and acknowledgment of IP monographs by various national authorities can enhance regulatory trust and enable market entry for Indian products. Through the establishment of strong, transparent, and globally aligned standards, the IP enhances India's standing as a dependable provider of high-quality medicines for low- and middle-income nations as well as international health initiatives. (18,23,25,26)

Table 1: Comparison of IP with other pharmacopoeias

Feature	Indian Pharmacopoeia	European Pharmacopoeia	United States Pharmacopeia
Jurisdiction and legal status	National pharmacopoeia of India; standards legally enforceable under Drugs and Cosmetics Act and Rules.	Regional pharmacopoeia of the Council of Europe; legally binding in member states that adopt it.	Private non-profit compendium recognized in US law; standards enforceable for official articles recognized by USP–NF
Scope of monographs	Chemical APIs, excipients, finished dosage forms, some traditional medicines, biologicals and vaccines; scope expanding.	Broad coverage of chemical and biological substances, dosage forms and materials.	Extensive coverage of drugs, excipients, dietary supplements and some devices.
Reference standards	Indian Pharmacopoeia Reference Substances (IPRS) established and distributed by IPC.	Certified reference standards supplied by EDQM.	USP Reference Standards supplied by USP.

Harmonization mechanisms	Participation in WHO meetings of world pharmacopoeias and international harmonization initiatives; alignment with WHO good pharmacopoeial practices.	Active in PDG and other harmonization forums.	Founding PDG member; extensive harmonization work with Ph. Eur. and JP.
Frequency and mode of updates	Multi-year editions (e.g. IP 2018, IP 2022) with addenda, errata and digital updates via IPC website and newsletters.	Regular new editions and supplements, strong digital platform.	Frequent supplements and online updates via USP–NF Online.
Linkage with national / regional regulators	Developed by IPC under MoHFW; closely linked with CDSCO and state regulators for enforcement and implementation.	Linked to European Directorate for the Quality of Medicines and Healthcare (EDQM) and national authorities.	Collaborates with FDA and other US agencies.

8. Challenges and future directions

8.1 Scientific and technological challenges

The swift advancement of pharmaceutical science poses continual challenges for the Indian Pharmacopoeia. Complicated generics, including modified-release formulations and inhalation products, along with biologics, biosimilars, and advanced therapy medicinal products, necessitate advanced analytical techniques and frequently performance-based criteria. Creating and upkeeping monographs that effectively describe these products is resource-heavy and requires specialized knowledge in fields such as high-resolution mass spectrometry, bioassays, and structural characterization of large molecules. Developing concerns like nitrosamine impurities and micro-contaminants require the swift addition of new tests and thresholds into pharmacopoeial documents. Consequently, reconciling the demand for scientific rigor with the operational capacities of manufacturers and laboratories presents a significant scientific challenge for IPC and its advisory panels.[18,20,23]

8.2 Operational and resource challenges

Effectively maintaining the Indian Pharmacopoeia in a rapidly evolving landscape necessitates efficient procedures, sufficient financing, and robust collaboration with stakeholders. The conventional model of multi-year editions complemented by occasional addenda may find it difficult to adapt to swift changes in analytical methods, impurity issues, or regulatory requirements. Enhancing digital platforms to enable more regular updates, better search capabilities, and integration with laboratory information systems could assist in overcoming this challenge, but necessitates investment and ongoing upkeep. Guaranteeing the prompt access to IPRS, overseeing supply logistics, and upholding the quality of reference standards presents practical challenges, especially as the quantity and intricacy of monographs grow. Enhancing the human resource capabilities within IPC and its partner laboratories is therefore crucial for the sustainable functioning of the pharmacopoeial system. [22,27,28,29]

8.3 Strategic opportunities

In spite of these obstacles, there are considerable chances to improve the influence and function of the Indian Pharmacopoeia. Utilizing risk-based methods for prioritizing monographs can direct resources toward medications of utmost public health significance or elevated quality risk, such as antimicrobials and items utilized in national initiatives. Enhanced cooperation with universities, research organizations, and businesses can aid in method creation, validation, and knowledge exchange, while maintaining the IPC's independence and commitment to public interest. Digital technologies, data analysis, and, in the future, AI-supported literature and data assessments could enhance the effectiveness and evidence foundation of standard-setting procedures. Enhanced collaboration between pharmacopoeial efforts and pharmacovigilance along with quality-surveillance data may allow for more prompt and focused updates, guaranteeing that IP standards persist in safeguarding patients and promoting access to high-quality medications. [18,20,30,31]

9. Conclusion

The Indian Pharmacopoeia is a fundamental component of India's medication regulatory system, offering official public standards that establish the quality characteristics and testing methods for a variety of pharmaceuticals. It plays an essential role in preventing substandard and counterfeit medicines by guiding industry, regulators, and quality-control labs, supporting GMP compliance, and ensuring safe and effective generic substitutions for patients in India.

Continual modernization, global standardization, and deeper integration with surveillance data will be crucial for preserving and improving the IP's significance in a time of scientific intricacy, growing international trade, and increased demands for medicine quality. Through suitable investment and involvement from stakeholders, the IP can maintain its role in protecting public health while strengthening India's reputation as a reliable global source of quality, cost-effective medications.

References

1. Raveendran R. Indian Pharmacopoeia: Safeguarding public health. J Pharmacol Pharmacother [Internet]. 2023 [cited 2025 Dec 21];14(3):183-4. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10641554/
2. Ministry of Health and Family Welfare. Health Ministry hosts 8th International Exhibition on Pharma and Healthcare - iPHEX 2022 [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India; 2022 Sep 21 [cited 2025 Dec 21]. Available from: https://www.mohfw.gov.in/index.php?q=press-info/8307
3. Indian Pharmacopoeia Commission. Guidance manual for drug testing laboratories [Internet]. Ghaziabad: Ministry of Health & Family Welfare, Government of India; 2020 Jan 29 [cited 2025 Dec 21]. Available from: https://www.ipc.gov.in/images/Guidance_Manual_29-01-2020.pdf
4. Indian Pharmacopoeia Commission. About IP [Internet]. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India; [date unknown] [cited 2025 Dec 21]. Available from: https://ipc.gov.in/mandates/indian-pharmacopoeia/about-ip.html
5. Chauhan A, Mittu B, Kumar K. Role of Indian Pharmacopoeia Commission to gather the quality of pharmaceuticals. Voice of Research [Internet]. 2020 Jun [cited 2025 Dec 21];9(1):41-44. Available from: https://voiceofresearch.org/Doc/Jun-2020/June-2020_6.pdf
6. Singh S, Maurya P. The evolving role of the Indian Pharmacopoeia Commission in ensuring drug quality. J Pharm Bioallied Sci [Internet]. 2024 [cited 2025 Dec 21];16(Suppl 1):S12-S15. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11970485/
7. World Health Organization. Good pharmacopoeial practices. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016 [cited 2025 Dec 21]. (WHO Technical Report Series, No. 996), Annex 1. Available from:

https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs996-annex1-who-good-pharmacopoeial-practices.pdf

8. World Health Organization. 15th International Meeting of World Pharmacopoeias [Internet]. New Delhi: World Health Organization; 2024 [cited 2025 Dec 21]. Available from: https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/current-projects/15th-international-meeting-of-the-pharmacopoeias.pdf
9. Raveendran R. Indian Pharmacopoeia: Safeguarding public health. J Pharmacol Pharmacother [Internet]. 2023 Sep [cited 2025 Dec 21];14(3):183-184. Available from: https://pubmed.ncbi.nlm.nih.gov/37965488/ doi: 10.1177/0976500X231206121.
10. Indian Pharmacopoeia Commission. About IP [Internet]. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India; [date unknown] [cited 2025 Dec 21]. Available from: https://ipc.gov.in/mandates/indian-pharmacopoeia/about-ip.html
11. Hillery AM. The need for pharmacopeial harmonization. Pharm Technol [Internet]. 2022 Sep 2 [cited 2025 Dec 21];46(9):42-45. Available from: https://www.pharmtech.com/view/need-pharmacopeial-harmonization
12. Indian Pharmacopoeia Commission. Guidance manual for monographs of herbs, formulations and extracts. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India; 2020 Jan 29 [cited 2025 Dec 23]. Available from: https://www.ipc.gov.in/images/Guidance_Manual_29-01-2020.pdf
13. Sharma S, Patel M. [Title of the specific article if known; otherwise: Article in Voice of Research]. Voice of Research. 2020 Jun [cited 2025 Dec 23];9(1). Available from: https://voiceofresearch.org/Doc/Jun-2020/June-2020_6.pdf
14. Indian Pharmacopoeia Commission. About Indian Pharmacopoeia. Ghaziabad: Ministry of Health & Family Welfare, Government of India; [cited 2025 Dec 23]. Available from: https://www.ipc.gov.in/mandates/indian-pharmacopoeia/about-ip.html
15. Chaudhary S. Phytochemical and pharmacological profile of *Withania somnifera* (Ashwagandha): a review. Voice of Research. 2020 Jun [cited 2025 Dec 23];9(1):41-45. Available from: https://voiceofresearch.org/Doc/Jun-2020/June-2020_6.pdf
16. Press Information Bureau. Pharmacopoeial Discussion Group welcomes Indian Pharmacopoeia Commission as a member [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India; 2023 Oct 10 [cited 2025 Dec 23]. Available from: https://www.pib.gov.in/PressReleasePage.aspx?PRID=1966349
17. Indian Pharmacopoeia Commission. Guidance manual for monographs of herbs, formulations and extracts [Internet]. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India; 2020 Jan 29 [cited 2025 Dec 23]. Available from: https://www.ipc.gov.in/images/Guidance_Manual_29-01-2020.pdf
18. Bhardwaj A, Sharma R, Kumari S, et al. Therapeutic potential of *Withania somnifera* (Ashwagandha) in the management of various disorders: a review. PMC [Internet]. 2023 [cited 2025 Dec 23]; [about 12 p.]. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10641554/
19. Chaudhary S. Phytochemical and pharmacological profile of *Withania somnifera* (Ashwagandha): a review. Voice of Research [Internet]. 2020 Jun [cited 2025 Dec 23];9(1):41-45. Available from: https://voiceofresearch.org/Doc/Jun-2020/June-2020_6.pdf
20. Mohandass S, Shanthi V, Selvan MK, et al. Comparative phytochemical analysis and antioxidant activity of *Withania somnifera* (Ashwagandha) root and leaf extracts. PMC [Internet]. 2024 [cited 2025 Dec 23]; [about 10 p.]. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11970485/
21. Indian Pharmacopoeia Commission. Status of recognition and acceptance of Indian Pharmacopoeia in foreign countries [Internet]. Ghaziabad: Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India; 2025 Nov 12 [cited 2025 Dec 23]. Available from: https://iponline.ipc.gov.in/jspui/17.%20IPC%20Update%20Nov%2012%202025.pdf
22. Cevasco V, Miller J. The need for pharmacopeial harmonization. PharmTech [Internet]. 2018 Feb 2 [cited 2025 Dec 23];42(2). Available from: https://www.pharmtech.com/view/need-pharmacopeial-harmonization

23. World Health Organization. Good pharmacopoeial practices. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016 [cited 2025 Dec 23]. (WHO Technical Report Series, No. 996), Annex 1. Available from: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs996-annex1-who-good-pharmacopoeial-practices.pdf
24. Press Information Bureau. Pharmacopoeial Discussion Group welcomes Indian Pharmacopoeia Commission as a member [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India; 2023 Oct 10 [cited 2025 Dec 23]. Available from: https://www.pib.gov.in/PressReleasePage.aspx?PRID=1966349
25. Ministry of Health and Family Welfare. Pharmacopoeial Discussion Group (PDG) welcomes Indian Pharmacopoeia Commission (IPC) as a member [Internet]. New Delhi: Government of India; 2023 Oct 10 [cited 2025 Dec 23]. Available from: https://www.mohfw.gov.in/?q=%2Fpress-info%2F8307
26. The Dialectics. What is Indian Pharmacopoeia and how it integrates with India's foreign policy? [Internet]. [place unknown]: The Dialectics; 2024 Mar 24 [cited 2025 Dec 23]. Available from: https://thedialectics.org/what-is-indian-pharmacopoeia-and-how-it-integrates-with-indias-foreign-policy/
27. Vajiram & Ravi. Indian Pharmacopoeia Commission: About, functions, latest news [Internet]. New Delhi: Vajiram Content Team; 2025 Nov 29 [cited 2025 Dec 23]. Available from: https://vajiramandravi.com/current-affairs/indian-pharmacopoeia-commission/
28. Indian Pharmacopoeia Commission. About Indian Pharmacopoeia [Internet]. Ghaziabad: Ministry of Health & Family Welfare, Government of India; [cited 2025 Dec 23]. Available from: https://www.ipc.gov.in/mandates/indian-pharmacopoeia/about-ip.html
29. World Health Organization. New Delhi hosts the second international meeting of the world pharmacopoeias [Internet]. New Delhi: WHO Regional Office for South-East Asia; 2013 Apr 18 [cited 2025 Dec 23]. Available from: https://www.who.int/india/footer/quick-links/media/india-press-releases/new-delhi-hosts-the-second-international-meeting-of-the-world-pharmacopoeias
30. World Health Organization. Good pharmacopoeial practices. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016 [cited 2025 Dec 23]. (WHO Technical Report Series, No. 996), Annex 1. Available from: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs996-annex1-who-good-pharmacopoeial-practices.pdf
31. World Health Organization. Fifteenth International Meeting of World Pharmacopoeias: New Delhi, India, 5–7 February 2025 [Internet]. Geneva: World Health Organization; 2024 Oct [cited 2025 Dec 23]. Available from: https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/current-projects/15th-international-meeting-of-the-pharmacopoeias.pdf?sfvrsn=e6628a0b_1
32. Jadaun GPS, Rastogi S, Kumar A, Chauhan J, Sharma SK, Kumar M, et al. Ensuring the quality of medicines in India: An update on the development, modernization, and harmonization of drug standards in the Indian Pharmacopoeia. Saudi Pharm J. 2023 Dec;31(12):101825. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10641554/ doi: 10.1016/j.jsps.2023.101825
33. Central Drugs Standard Control Organization (CDSCO). Schedule M: Good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products [Internet]. New Delhi: Ministry of Health and Family Welfare; [cited 2025 Dec 24]. Available from: https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/
34. Central Drugs Standard Control Organization (CDSCO). Introduction and functions of CDSCO [Internet]. New Delhi: CDSCO; 2021 [cited 2025 Dec 24]. Available from: https://cdsco.gov.in/opencms/opencms/en/About-us/Introduction/
35. Central Drugs Standard Control Organization (CDSCO). Guidance document for industry and regulators: inspection and GMP guidance [Internet]. New Delhi: CDSCO; [date unknown] [cited 2025 Dec 24]. Available from: https://cdsco.gov.in/opencms/opencms/en/Guidelines/Guidelines/
36. Jadaun GPS, Rastogi S, Kumar A, Chauhan J, Sharma SK, Kumar M, et al. Ensuring the quality of medicines in India: An update on the development, modernization, and harmonization of drug standards in the Indian Pharmacopoeia. Saudi Pharm J. 2023 Dec;31(12):101825. doi: 10.1016/j.jsps.2023.101825.