भारतीय भेषज संहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर - २३, राज नगर,
गाजियाबाद - २०१ ००२, उत्तर प्रदेश, भारत

सत्यमेव जयते
IPC

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector - 23, Raj Nagar
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डा. वी. कलईशेलवण
सचिव-सह-वैज्ञानिक निदेशक

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Secretary-cum-Scientific Director

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

Date: August 13, 2025

To,

1. The Drugs Controller General (India)
2. All State/UT Drug Controllers
3. CDSCO Zonal Offices
4. Directors of the Drugs Testing Laboratories
5. Government Analysts
6. IDMA/OPPI/IPA/BDMA/FOPE/FSSAI/Small Scale Industry Associations

Subject: Frequently Asked Questions (FAQs) about the Indian Pharmacopoeia (IP), IP Reference Substances (IPRS), and their compliance—reg.

The IPC frequently receives enquiries from the stakeholders on certain common subjects pertaining to the Indian Pharmacopoeia (IP) and IP Reference Substances (IPRS). Accordingly, a document on Frequently Asked Questions (FAQs) along with their answers has been compiled and is being released. IPC encourages that stakeholders should refer these FAQs as first–hand clarifications to resolve regulatory issues, if any, that may arise about the IP, IPRS, and their compliance.

All concerned are requested to bring it to the notice of all authorities under their control.

Thanking you,

Yours sincerely,

(Dr. V. Kalaiselvan)

Encl. Frequently Asked Questions (FAQs)

Frequently Asked Questions

1. What is the legal status of the Indian Pharmacopoeia (IP)?

As per provisions of the Second Schedule of the Drugs and Cosmetics Act 1940, Indian Pharmacopoeia (IP) is the official book of standards for drugs in India. IP standards are authoritative in nature and are legally enforceable in India. The IP is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India.

2. Does the IPC have any role in drug approval process?

The IPC is an autonomous institution under the Ministry of Health & Family Welfare, Government of India that is solely responsible for setting and publishing official drug standards in the IP. IPC does not have any role in the regulatory review and approval of drugs in India. As per provisions of the Drugs and Cosmetics Act 1940, Central Drugs Standards Control Organization (CDSCO) and State Licensing Authorities (SLAs) are competent to take regulatory decisions.

3. From where users can purchase the IP?

Users can purchase copy of the IP directly from the IPC and details in this regard are available on the IPC website www.ipc.gov.in.

4. What is IP Online and how to subscribe it?

IP Online is the digital version of the IP that provides user friendly access to the IP monographs and associated IP Reference Substances along with advanced search functions. Users may visit www.iponline.ipc.gov.in to subscribe the IP Online.

5. What are different types of publications issued by the IPC (e.g., edition, addendum, amendment list, notice, updates, corrigenda)? Which of these are considered official publications?

The IPC issues various types of publications to maintain and update the drug standards in the country. These include, but not limited to, the following:

- **Edition of the IP:** A comprehensive publication issued periodically by the IPC, incorporating all monographs, general chapters, and other standards approved for that cycle. It becomes official from the effective date mentioned in the printed book.
- **Addendum to the IP:** A supplement that is issued to add new monographs, general chapters or their revisions in the current edition of the IP. Addendum to the IP also becomes official from the effective date mentioned in the printed book.
- **Amendment List:** These are issued by the IPC on its website, as and when required, to add minor corrections and/or revisions in the IP text that warrant immediate implementation. Content of the amendment list is official in nature and takes effect immediately, unless otherwise stated therein.
- **Notices and Updates:** These are communications issued by the IPC from time-to-time to provide clarifications about IP standards and their compliance, or information about proposed standards to be included in the IP. Notices and updates are informative in nature and are usually not considered official text, unless explicitly stated.
- **Corrigenda:** Published to make corrections, if any, required in already issued amendment list, notices or updates.

6. How stakeholders can collaborate with the IPC to participate in standard development?

Interested stakeholders can collaborate with the IPC and participate in the standards setting process in following ways:

- **Sponsoring New Monograph Development:** Stakeholders, including the pharma manufacturers, are encouraged to share new monograph proposals to lab.ipc@gov.in for considering their inclusion in the IP. Check list of the desired documents for monograph development is available on www.ipc.gov.in.
- **Proposals for Monograph Revisions and Upgradations:** Stakeholders may also contribute in monograph modernization by sending monograph revision proposals to lab.ipc@gov.in along with the justification and supporting data.
- **Donation of Candidate Material for Establishment of IP Reference Substances:** IPC encourages collaboration with stakeholders for establishing the IP Reference Substances by way of donating the candidate material. Please reach out to IPC at lab.ipc@gov.in for further details.

7. What process is adopted by the IPC for monograph development?

IPC has published a guidance document 'IPC/GD/02–Process for Development of Indian Pharmacopoeia Monographs' wherein the process for monograph development is elaborated. Please visit IPC website www.ipc.gov.in to view the guidance document.

8. Can manufacturers adopt a published monograph of the IP for an early implementation before it becomes effective?

IPC does not restrict an early adoption of the monograph specifications, and manufacturers may adopt published IP monograph(s) for an early implementation, before the effective date. This may be done in consultation with the competent regulatory authority and IPC does not grant any approval for an early implementation of the IP monograph(s), which remains a regulatory function.

9. Whether IP specifications shall be applicable on the batch of a drug product which is manufactured before the effective date of the IP monograph?

As per the Section 16 of the Drugs and Cosmetics Act, 1940, read with the Rule 124 of the Drugs Rules, 1945, and the Second Schedule, any drug included in the IP shall comply with the standards of identity, purity and strength as prescribed in the current edition of the IP. Accordingly, once a monograph is published in the IP, it becomes official from the effective date mentioned therein, and all marketed drug products in India shall comply with the IP specifications after the effective date.

10. Can stakeholders apply alternative analytical procedure or reagent as a substitute for the official IP method?

Alternative analytical methods or reagents, other than those published in the IP, may be applied by the manufacturers for *in-house* control purposes provided the same are proven to give results of equivalent accuracy. Such alternative methods or reagents must be validated and are subject to approval by the competent regulatory authority. However, in the event of doubt or dispute, the official IP method shall be alone authoritative and results obtained by the IP method shall be considered as conclusive. Moreover, IPC does not have any role to approve alternative methods or reagents. For further details, please refer to the 'Alternative Methods' in the General Notices of the IP and IPC's Notice dated February 26, 2021.

11. What is approach of the IP for inclusion of dissolution specifications in the prolonged-release formulations?

Please refer to IPC's Update dated February 4, 2022 on this subject (available on www.ipc.gov.in) which is self-explanatory.

12. In case if the solubility of an API does not comply with the IP specifications, will it be considered as noncompliance with the IP?

Solubility specifications mentioned in the IP are intended as information on the approximate solubility at a temperature between 15º and 30º, unless otherwise stated, and are not to be considered as official IP requirements. Please refer to the 'Solubility' in the General Notices of the IP.

13. Is compliance with the 'Description' of the IP monograph a mandatory requirement?

The statements under the description are for preliminary evaluation and shall not to be interpreted in a strict sense and are not to be regarded as official requirements. Please refer to the 'Description' in the General Notices of the IP.

14. Is it mandatory to comply with the storage conditions mentioned in the IP monographs?

The statements mentioned under the storage constitute non-mandatory advice and serve as guidance for maintaining the quality of the drug substance or drug product. Please refer to the 'Storage' in the General Notices of the IP.

15. What are usual strengths mentioned in the IP monographs? Can medicines with different strengths be manufactured in India?

The usual strengths mentioned in the individual IP monographs indicate the strength(s) of the drug products that are usually marketed in India. These are suggestive in nature and do not restrict the stakeholders to manufacture other strengths which are not mentioned in the IP. Such strengths shall be approved by the competent regulatory authority. Drug products with usual strengths, other than those mentioned in the IP, shall also comply with the requirements of IP standards.

16. What are the acceptance criteria for deviation in the relative retention time (RRT) indicated in the IP monograph?

The RRTs are given in the IP monograph for information purpose only, to aid in peak identification. There are no acceptance criteria applied to variation in RRTs.

17. How to use correction factor and relative response factor (RRF) given in the monographs?

In cases where correction factors are mentioned in the IP monographs, the same should be applied by direct multiplication with area of the corresponding peak. In cases where RRFs are mentioned, the peak area should be divided by the RRFs.

18. To what extent a chromatographic procedure be modified to meet the system suitability criteria mentioned in the IP monograph?

Changes in chromatographic conditions can be made in accordance with the guidance provided under 'Adjustment to Chromatographic Conditions' of the IP general chapters on Gas Chromatography {2.4.13} and Liquid Chromatography {2.4.14}. As long as changes made are within the permissible limits, further validation of the method is not required. However, any change made outside the permissible limits, would warrant revalidation of the method.

19. Where can users find the information about the HPLC columns used during the development of IP methods?

In cases where the make of the HPLC column is not mentioned in the IP monographs, users can write to lab.ipc@gov.in and get desired information.

20. What impurity limits are prescribed in the IP? Is it mandatory to follow the impurity limits specified in the IP general chapter {5.5} for the new drugs?

In order to clarify impurity limits in the IP monographs and general chapter {5.5}, IPC has issued a Notice No. T.11015/01/2023-AR&D dated May 30, 2025 (available on www.ipc.gov.in) which is self-explanatory.

21. What is the legal status of the IP Reference Substances (IPRS)?

IPRS are issued by the IPC or laboratories authorized by the IPC. Once referred in the IP monograph, IPRS becomes part of the official standard and assumes status of the official reference standard that is alone authoritative in case of doubt or dispute to establish quality of drug in compliance with the IP.

22. Where can I purchase IPRS and impurity standards?

IPRS and impurity standards can be directly purchased from the IPC or laboratories authorized by the IPC. One can find the list of available IPRS and impurity standards at www.onlinestore.ipc.gov.in and can place their orders. The IPC has not authorized any vendors/distributors for the sale and distribution of IP standards.

In addition, IPC has authorized Central Drugs Laboratory, Kasauli 173204, Himachal Pradesh (www.cdlkasauli.gov.in) for supplying reference standards of human vaccines and immunosera. Similarly, IPC has also authorized Microbial Type Culture Collection (MTCC) at CSIR-Institute of Microbial Technology (IMTech), Sector 39A, Chandigarh 160036 (www.imtech.res.in) for supplying reference microbial cultures.

23. What is the validity of current lot of the IPRS?

The current lot of the IPRS or impurity standard is valid till the lot is present in the list of IPRS and impurity standards available at www.onlinestore.ipc.gov.in.

24. Does IPC provide guidance on use of non-IP reference material?

The IPC does not provide guidance on the use of non-IP reference materials in place of an IP standard. Users are advised to consult with the competent regulatory authority for guidance on the use of a non-IP reference material.

25. Does IPC provide any guideline for qualification of in-house standards?

IPC has published a guidance document 'IPC/GD/09—IP Reference Substances' wherein the procedure for preparation of working standards is elaborated. Please visit IPC website www.ipc.gov.in to view the guidance document.

26. What is 'as-is' basis mentioned on IPRS label?

The purity of IPRS is assigned on 'as-is' basis which indicates that there is no need to dry or desiccate the IPRS before use.

27. Where can I find the certificate or MSDS of IPRS or impurity standard?

The certificates or MSDS of the IPRS or impurity standards can be downloaded from www.onlinestore.ipc.gov.in.

28. Are IPRS suitable for use as drugs or for diagnostic purposes?

IPRS are intended for use in tests and assay, as specified in the official IP monographs. They are not intended for use in humans or animals as drugs, medical devices, or for diagnostic purposes.

29. What happens if a new IPRS that is specified in the IP monograph is not listed in the IPC catalogue?

If any IPRS or impurity standard is not listed in the IPC catalogue, other equivalent pharmacopoeial reference standard may be used after establishing its suitability for intended purpose. For further details, please refer to the IP general chapter on Reference Substances {5.9}.

30. What happens in case of a biotech product for which neither IPRS is listed in the IPC catalogue nor any other pharmacopoeial or International Standard is available?

In case of Biotechnology Derived Therapeutic Products, if IPRS are not available, any other equivalent pharmacopoeial standards or International Standards may be used after establishing their suitability for intended purpose. However, if no such reference standards are available, an internal reference standard may be established as per the CDSCO guidelines "Current Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India". This may be done in consultation with the competent regulatory authority and IPC does not have any role in this regulatory function.

31. Can IPRS be used in non-pharmacopoeial methods?

IPRS are primarily intended for the procedures mentioned in the IP monographs. However, if needed, IPRS may be used in non-pharmacopoeial methods also. It shall be the responsibility of the user to establish suitability of the IPRS intended for non-pharmacopoeial methods.

32. What is the HSN code for IPRS?

The HSN code of IPRS is 29242990.