Guidance Document

Legal Status of Indian Pharmacopoeia

Document ID	Version	Issue Date
IPC/GD/01	1.0	16th September 2021

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This Guidance Document is compiled by the Indian Pharmacopoeia Commission (IPC) after consultations with the 'Core Expert Committee' constituted by the IPC for this purpose. The information contained herein represents the current best practices in the field of pharmacopoeial sciences to demonstrate compliance with the existing regulatory requirements. The guidance provided in this document 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 document 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 Guidance Document may be adopted if found suitable and justified. Where provisions of the law exist, the law as prevailing at the relevant time shall apply.

Introduction

Indian Pharmacopoeia (IP) is the official book of standard for drugs in India under the Drugs and Cosmetics Act 1940 and Rules 1945 there under. Section 8 relating to import of drugs (into India) and Section 16 of the Act lay down as under:

8. Standards of quality. (1) For the purposes of this Chapter, the expression "standard quality" means-
(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule…",

16. Standards of quality. (1) For the purposes of this Chapter, the expression "standard quality" means-
(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, …..".

Clause 5 of the Second Schedule to the Act states as under:

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.
(b) Drugs not included in the Indian Pharmacopoeia but included in the official Pharmacopoeia of any other country.	Standards of identity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country 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 such official Pharmacopoeia for the time being in force but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of such official Pharmacopoeia and such other standards as may be prescribed.

This status is laid down in the Drugs & Cosmetics Rules 1945 under part XII standards also.

Rule 124 states as under:

R.124- Standards of drugs:

(1) Drugs included in the Indian Pharmacopoeia-

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.

(b) In case the standards for 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 for identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia.

(c) Include rule 124 (c) 124-A, 124-B, 124-C and 124-D

(2) For other drugs-

(a) The standards for identity, purity and strength shall be those as may be specified in the edition of the official pharmacopoeia, for the time being in force, of any country to which the drug claims to comply with.

(b) In case the standards for identity, purity and strength for drugs are not specified in the edition of such official pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of such official pharmacopoeia to which the drug claims to comply with.

Thus all drugs imported into the country except those intended for personal use or in small quantities for tests and analysis, are to comply with the standards set out in the IP (the current or immediate preceding edition as the case may be) and other standards apply only in cases not covered by the IP.

A drug that does not conform to the above standards is one “Not of standard quality” and activities of import, manufacture, sale and distribution of a drug ‘not of standard quality, is an offence punishable under the Drugs and Cosmetics Act 1940.

The letters IP in relation to a drug is to be used only for the purpose of informing the user or others as the case may be that the drug is of IP standards. Rule 104 of the Drugs and Cosmetics Rules 1945 lays down as:

“**R.104 Use of letters I.P. etc:** The letters ‘I.P.’ and recognised abbreviations of pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such pharmacopoeia or official compendium of drug standards recognised under the Rules.”

Labels of drugs are to conform to Rule 96 of the Drugs and Cosmetics Rules and clause (b) of sub-rule (1) of this rule stipulates as under:

R.96. Manner of Labelling: (1).……

(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:-

(i) The name of the drug:

For this purpose, the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be:-

(a) for drugs included in Schedule F or Schedule F(1), the name given therein;

(b) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P.' or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';

(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

Any drug not conforming to the above labelling requirements is a "misbranded drug" as defined and punishable under the law.

Rule 96 as stated above applies to imported drugs also as laid down in Rule 32.

R. 32 Packing and labelling of imported drugs: No drug shall be imported unless it is packed and labelled in conformity with the rules in Parts IX and X and further conforms to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F(1).

These are some of the excerpts from the Drugs & Cosmetics Act and Rules and the users are cautioned not to deviate from the legal provisions in public interest apart from own interests to avoid violations of the law inadvertently or otherwise.

Schedule N of the Drugs & Cosmetics Rules require a pharmacy to keep IP as a book of reference. The requirement is as under:

A Pharmacy shall be provided with the following minimum books necessary for making of official preparations and prescriptions:-

Schedule "V" of the Drugs and Cosmetics Rules, 1945 requires application of IP parameters to Patent and Proprietary Medicines as under:

SCHEDULE V
(See rule 124B)
STANDARDS FOR PATENT OR PROPRIETARY MEDICINES

* * * * *

2. Standards for patent or proprietary medicines, containing vitamins:

Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified below in single or in two divided daily doses, namely: -

4. General Standards for Different Categories of Patent or Proprietary Medicines:

In the case of pharmaceutical products containing several active ingredients, the selection shall be such that the ingredients do not interact with one another and do not affect the safety and therapeutic efficacy of the product. The combination shall not also lead to analytical difficulties for the purpose of assaying the content of such ingredient separately. The substances added as additives shall be innocuous, shall not affect the safety or therapeutic efficacy of the active ingredients, and shall not affect the assays and identity tests in the amount present.

Subject to the provisions of these rules, patent or proprietary medicines shall comply with the following standards, namely: -

1. Patent or proprietary medicines shall comply with the general requirements of the dosage form under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is included in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements of the dosage of such pharmacopoeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour consistency, clarity, stability, freedom from contamination with foreign matter or fungal growth, defects like chipping and capping of tablets, cracking of the coating, mottled appearance and other characteristic defects that can be perceived by visual inspection.

2. Without prejudice to the generality of the following paras, dosage forms of patent or proprietary medicines shall comply with the following requirements, namely:-

(a) *Tablets*: Medicines shall comply with requirements for tablets as laid down in the Indian Pharmacopoeia. The nature of coating shall be indicated on the label.

Permitted colours may, however, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or film coated, shall be declared on the label.

(b) *Capsules*: Medicines shall comply with the requirements for capsules as laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion or shape, discolouration and other physical defects like leakage of powder from joints, pinholes or cracks in the capsules;

(c) *Liquid oral dosage forms*: Emulsions and suspensions shall disperse uniformly on shaking. Homogeneous solutions shall contain no sediments. The volume of the product (net content) in the container shall be not less than the labelled volume. The limit for ethanol content of pharmaceutical products shall be not less than 90 per cent and not more than 110 per cent of the labelled contents.

(d) *Injections*: Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

(e) *Ointments*: Medicines shall comply with the requirements for ointments as laid down in the Indian Pharmacopoeia.

3. The content of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines shall be not less than 90 per cent and not more than 110 per cent of the labelled content; however, for enzymes and vitamins, only for lower limit of 90 per cent shall apply. In all dry formulations containing antibiotics, the limit shall be 90 to 130 per cent of the labelled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140 per cent of labelled contents.

Fiducial limits for error for microbiological assay of antibiotics may be estimated depending upon the design of assay procedure. Methods, used for assaying active ingredients shall employ the same basic principles and shall use same organisms as given in the latest edition of the Indian Pharmacopoeia or shall follow any other methods as approved by the authority competent to grant licence to manufacture.

4. All patent or proprietary medicines containing aspirin shall be subjected to “Free Salicylic Acid Test” and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.

5. Patent or proprietary medicine to be tested under the provisions of rule 121-A for pyrogen shall be tested by injecting into rabbits not less than the human dose of the medicine based on body weight of a 60 kg human being. Methodology and limits shall be based on the method recorded in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall be not greater than 5 times the human dose based on body weight of 60 kg for man.

6. In injectable patent or proprietary medicines, the test for freedom from toxicity, shall be performed as described in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall not be less than five times the human dose based on body weight of 60 kg human being.

References

1. The Indian Pharmacopoeia, 2018
2. The Drugs and Cosmetics Act, 1940.
3. The Drugs and Cosmetics Rules, 1945