Indian Pharmacopoeia Commission

Government of India
(Ministry of Health & Family Welfare)
Sector-23, Raj Nagar, Ghaziabad-201 002

DEVELOPMENT OF IP MONOGRAPHS

1.0 DRAFTING A MONOGRAPH FOR INDIAN PHARMACOPOEIA

1.1 Identification of Drugs/Formulations for inclusion in IP

Candidate drugs are identified for inclusion in Indian Pharmacopoeia as official monographs and approved by the Clinical Medicine and Pharmacology Committee of the Scientific Body of Indian Pharmacopoeia Commission. The said committee will decide the criteria for inclusion of any monograph in the Indian Pharmacopoeia. Following general criteria will be adopted for the purpose of including a drug monograph/formulation monograph in Indian Pharmacopoeia.

Inclusion Criteria

- Drugs used in National Health Programs of India.
- Drugs listed in Essential Medicines List.
- Drugs approved by CDSCO (Generics not less than 3).
- Fixed Dose Combinations approved by CDSCO and recommended by the IPC Experts.
- Drugs considered appropriate by the Indian Pharmacopoeia Commission.

Exclusion Criteria

- Drugs banned in India.
- Obsolete Drugs.
- Drugs considered appropriate by Indian Pharmacopoeia Commission.

1.2 Availability of drug monographs and redrafting in IP format

The initial draft monographs and test methods will be provided by the manufacturers. Manufacturers are requested to provide the draft monograph in IP format alongwith analytical profile validation data and appropriate sample quality of reference and test material of Active Pharmaceutical Ingredient (APIs)/Formulations for monograph development. IPC will approach for the purpose through its Secretariat or through authorised persons from Scientific Body or from its Expert Committee. The monographs are redrafted in IP format as per the guidelines provided by the committee for formatting IP monographs.

1.3 Verification of Monographs

Analytical data are verified/validated by three different laboratories and consensus is arrived for their inclusion in Indian Pharmacopoeia. The three laboratories selected will be preferably NABL accredited. Simultaneously the monographs are verified in IPC laboratory also. The results will be tabulated by the analysts and tolerance values will be decided by the Committee constituted for this purpose. The different versions

of draft monographs will be identified by version number. This will help to track the progress of the monograph. The versions may be called as Initial Draft, Draft Post Ring Testing, Draft for Public Display, Pre-Final, Final etc.

2.0 COMMENTS ON MONOGRAPHS

2.1 Offering comments on monographs

Comments on draft monographs are invited from the stakeholders in the following ways:

— Conventionally by post } through Manufacturing Association
— Electronically (by e-mail) }
— By displaying the draft monographs on the website of Indian Pharmacopoeia Commission (www.ipc.gov.in) at least for one month. The comments (technical and others) are to be submitted with justification in the attached format through website or through e-mail.

2.2. Reviewing of Monographs

The comments are reviewed by the Subject Expert Committee of the Scientific Body of IPC. The IPC staff coordinates in all these activities. General corrections are taken care of by IPC staff and those need expert opinion were send to the expert for the purpose. Those need further revision are assessed.

3.0 PREPARATION OF MANUSCRIPT

3.1 Editing of Monographs in Manuscript

Revised monographs are thoroughly scrutinised at the following levels sequentially.

3.1.1 *Technical Editing*: It is done by the Subject Experts as well as by the Heads of the Departments and their staff at Indian Pharmacopoeia Commission's Secretariat within a month's time.

3.1.2 *Grammatical Editing:* Grammatical editing and format is checked by the specific team hired for this purpose within one month's time for the main edition of Pharmacopoeia and 10 days time for the Addendum.

3.1.3 *Editing by the Scientific Body of IPC*: Scrutiny of the manuscript by the members of the Scientific Body within 15 days time.

3.2 Production of Final Manuscript

Two sets of the final manuscript (hard copy) as well as electronic copy are prepared and authenticated by the Member Secretary and Chairman, Scientific Body of the Indian Pharmacopoeia Commission before sending to Press.

4.0 PRINTING OF INDIAN PHARMACOPOEIA

4.1 Handing over the Manuscript to Printer

One set of authenticated manuscript is retained in Publication Division of the Commission (collaborative test data will be kept in the safe custody in the laboratory) and one set is handed over to the Press for printing in a time bound manner. The printing time allowed to the publisher will depend on the number of sets of Pharmacopoeia to be printed. Printing time will be assured by the Printer.

4.2 Proof Reading of Printed Matter

Final printing of Pharmacopoeia is accomplished after thorough checking of galley proof in a manner so that it is free from errors, i.e., proper reproduction of structures of compounds, good reproductions of any figures, chromatograms, TLC profiles, IR spectrum, etc is ensured by the Press.

4.3 Final Version

A final version of the Pharmacopoeia after proof reading is handed over to the press with a copy retained at IPC. Soft copy of final version is kept with Secretary-cum-Scientific Director who will be the custodian of the same.

5.0 PUBLICATION OF ADDENDUM TO IP

Feed back from stakeholders in the specified format after publication of Pharmacopoeia is examined by the scientific staff and experts and published as Amendment list/Errata/Addendum to Pharmacopoeia. Addendum to Indian Pharmacopoeia are published on alternate yearly interval and main Pharmacopoeia every two years.