

Features of IP-Addendum-2015 to IP-2014

Introduction

- IP Addendum-2015 to Indian Pharmacopoeia (IP 2014) is to be published in accordance with a designed plan by the Scientific Body of IPC, in fulfillment of the requirements of the Drugs and Cosmetics Act and the Rules thereunder.
- The Addendum-2015 to Indian Pharmacopoeia 2014 contains the Notices, Preface, Structure of the IPC, Acknowledgements, Introduction and the General Chapters. Monographs on dosage forms, Monographs on drug substances, Monographs on Vaccines and Immunoserum for human use, Herbs and herbal products, and Radiopharmaceutical preparations and Index.
- This Addendum has the same authority as the Indian Pharmacopoeia 2014.
- The General Notices, Monographs, Appendices and other contents of the Indian Pharmacopoeia that are amended by this Addendum supersede the original matter.
- This Addendum amends as well as adds new materials to the Indian Pharmacopoeia 2014.
- The General Notices and Appendices included in the Indian Pharmacopoeia 2014 apply to the contents of this Addendum as well unless specifically stated otherwise.

Changes:

- General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.
- The use of chromatographic methods has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.
- Most of existing Assays and Related substances tests are upgraded by liquid chromatographic method in view to harmonize with other international Pharmacopoeias.

General Chapters :

Keeping in view the essential requirement for harmonization of analytical methods with those adopted internationally, steps have been taken for monitoring the quality of drug.

- According we have revised general chapters on volumetric glasses, peptide mapping, sterility testing, conductivity, solubility, dissolution test, bulk density and tapped density of powders.
- For controlling the microbial quality of all the medicinal product general chapters on microbial contamination in non-sterile products and test for colony forming units have been revised.

Specific Features of Addendum-2015

- (i) 57 new Chemical monographs

- (ii) 13 new Herbal monographs
- (iii) 02 new Human Vaccines Monographs
- (iv) 10 Radiopharmaceutical Monographs
- (v) 06 Revised monographs
- (vi) 29 Revised tests
- (vii) About 20 new IR spectras

New Chemical Monographs (57):

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| 1) Aripiprazole Tablets | 27) Methylphenidate Hydrochloride |
| 2) Barium Sulphate Suspension | 28) Metolazone |
| 3) Brimonidine Eye Drops | 29) Metolazone Tablets |
| 4) Brimonidine Tartrate | 30) Mirtazapine |
| 5) Budesonide Inhalation | 31) Mirtazapine Tablets |
| 6) Budesonide Powder for Inhalation | 32) Nabumetone |
| 7) Calcium Pantothenate Tablets | 33) Nabumetone Tablets |
| 8) Citicoline Prolonged-release Tablets | 34) Rabeprazole Injection |
| 9) Citicoline Injection | 35) Raloxifene Hydrochloride Tablets |
| 10) Citicoline Sodium Tablets | 36) Sitagliptin Phosphate |
| 11) Clemastine Oral Solution | 37) Sitagliptin Tablets |
| 12) Dorzolamide Eye drops | 38) Tadalafil |
| 13) Dorzolamide Hydrochloride | 39) Tadalafil Tablets |
| 14) Ebastine Tablets | 40) Tamsulosin Prolonged-release Capsules |
| 15) Esclicarbazepine Tablets | 41) Terazosin Tablets |
| 16) Ifosfamide | 42) Tolterodine Tablets |
| 17) Ifosfamide Injection | 43) Torsemide |
| 18) Iloperidone Tablets | 44) Torsemide Tablets |
| 19) Isotretinoin Capsules | 45) Voriconazole |
| 20) Ketotifen Fumarate Tablets | 46) Voriconazole Tablets |
| 21) Lacidipine | 47) Brinzolamide Ophthalmic Suspension |
| 22) Lacidipine Tablets | 48) Ranitidine Oral Solution |
| 23) Lactulose Oral Powder | 49) Dorzolamide and Timolol Eye Drops |
| 24) Metformin Oral Solution | 50) Entacapone Tablets |
| 25) Methadone Oral Solution | 51) Tibolone |
| 26) Methylphenidate HCl Prolonged-release Tablets | 52) Tibolone Tablets |
| | 53) Sodium Nitrite |

- 54) Sodium Nitrite Injection
- 55) Netilmicin Sulphate Injection

- 56) Dutasteride Capsules
- 57) Sterile Water for Inhalation

Herbal Monographs: (13)

1. Hingu
2. Birmi
3. Shankhpushpi
4. Draksha
5. Lodhra
6. Sahajana Leaf
7. Sahajana stick
8. Ginseng
9. Ginseng Dry Extract
10. Bassant
11. Bassant Dry Extract
12. Asthisamhrta
13. Mirch

Human Vaccines Monographs: (02)

1. BCG for Immunotherapy
2. Influenza vaccine (Human, live attenuated)

Radiopharmaceuticals Monographs: (10)

1. Gallium Citrate [⁶⁷Ga] Injection
2. Strontium (⁸⁹Sr) Chloride Injection
3. Technetium (^{99m}Tc) Colloidal Rhenium Sulphide Injection
4. Technetium (^{99m}Tc) Exametazime Injection
5. Technetium (^{99m}Tc) HYNIC-TOC Injection
6. Technetium (^{99m}Tc) Macrosalb Injection
7. Technetium (^{99m}Tc) Mertiatide Injection
8. Technetium (^{99m}Tc) Tetrofosmin Complex Injection
9. Technetium (^{99m}Tc) Tetrofosmin Complex Injection
10. Urea (¹⁴C) Capsules

Purchase of Addendum-2015 to IP-2014

Addendum 2015 to IP-2014 can be procured from the office of the Secretary-cum-Scientific Director, IP Commission at IPC Campus, Raj Nagar, Sector 23, Ghaziabad – 201 002 (UP), India or from our distribution network (see website: www.ipc.gov.in).

Other Distribution Centres:

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Your participation in IP

Interested parties can participate in the following ways:

❖ **Submit draft monographs along with supporting documents.**

The Indian Pharmacopoeia encourages you to submit draft monographs. Your draft may be the starting point for an official public standard.

❖ **Propose Revisions to Existing General Chapters and Monographs**

You can propose revisions to the general chapters and monographs in the current official edition of the Indian Pharmacopoeia.