

Press Release IP-2018

The latest Edition of Indian Pharmacopoeia, IP-2018 has been released on 29th September, 2017 by Sh. C.K. Mishra, Secretary Health & Family Welfare, Govt. of India in the presence of senior officers of Ministry of Health & Family Welfare and the IP Commission.

The IP is an authoritative and legally enforceable book of standard of drugs manufactured/marketed in India. It is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India in fulfillment of the requirements of the Drugs and Cosmetics Act, 1940 and the Rules there under. It intends to help in the licensing of manufacturing, inspection and distribution of medicines.

Publication of IP on regular basis is an important mandate of IPC aimed at improvement of health of the people through ensuring the quality, safety and efficacy of medicines. The Commission has been receiving significant advisory and directions from regulatory and valuable inputs from industrial houses, academic institutions, national laboratories, individual scientists and others.

IP-2018 has been brought out in 4 Volumes incorporating 220 new monographs (Chemical Monographs (170), Herbal Monographs (15), Blood and Blood related products (10), Vaccines and Immunoserum for Human use monographs (02), Radiopharmaceutical monographs (03), Biotechnology Derived Therapeutic Products (06), Veterinary monographs (14)), 366 revised monographs and 7 omissions.

Salient Features of IP-2018

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

- General Chemical tests & Thin Layer Chromatography (TLC) for identification of an article have been almost eliminated and more specific infrared, ultraviolet spectrophotometer and HPLC 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 the existing Assays and Related Substances Test methods are upgraded by liquid chromatographic in view to harmonize with other International Pharmacopoeia.

- Pyrogen test have been replaced by Bacterial Endotoxin test (BET) in parenteral preparations and other monographs.
- For ease of access to make Pharmacopoeia more user friendly, Index has been incorporated in Volume-I along with that already existing in Volume-IV of IP.
- 53 New Fixed Dose Combination (FDC's) combination monographs have been included, out of which 25 FDC monographs are not available in any Pharmacopoeia.
- General Chapters on Volumetric Glassware, Conductivity, Dissolution test, Disintegration test, Dimensions of Hard Gelatin Capsule Shells etc. have been revised.
- For Controlling the Microbial quality of all the medicinal product general chapter on Maintenance, Identification, Preservation and Disposal of Microorganism have been revised.

Specific Features of IP-2018:

(i) 170 Chemical Monographs

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| 1. Abiraterone Acetate Tablets | 17. Bosentan Monohydrate |
| 2. Aluminium, Magnesium and Simethicone Chewable Tablets | 18. Bosentan Tablets |
| 3. Aluminium, Magnesium and Simethicone Oral Suspension | 19. Calcium and Vitamin D ₃ Tablets |
| 4. Ambrisentan | 20. Captopril and Hydrochlorothiazide Tablets |
| 5. Ambrisentan Tablets | 21. Carmustine |
| 6. Amiloride and Hydrochlorothiazide Tablets | 22. Carmustine Injection |
| 7. Amlodipine and Benazepril Hydrochloride Capsules | 23. Cefdinir |
| 8. Aprepitant | 24. Cefdinir Oral Suspension |
| 9. Aprepitant Capsules | 25. Cefixime Dispersible Tablets |
| 10. Armodafinil | 26. Cefuroxime Axetil and Potassium Clavulanate Tablets |
| 11. Artesunate Injection | 27. Cholecalciferol Concentrate (Powder Form) |
| 12. Atenolol and Chlorthalidone Tablets | 28. Cilnidipine |
| 13. Atorvastatin and Fenofibrate Tablets | 29. Cilnidipine Tablets |
| 14. Azelnidipine Tablets | 30. Cinacalcet Hydrochloride |
| 15. Bisoprolol Fumarate | 31. Clindamycin Palmitate Hydrochloride |
| 16. Bisoprolol Fumarate and Hydrochlorothiazide Tablets | 32. Clindamycin Palmitate Hydrochloride Oral Suspension |
| | 33. Clonidine Hydrochloride and Chlorthalidone Tablets |

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| 34. | Cyclobenzaprine Hydrochloride | 64. | Glibenclamide and Metformin
Tablets |
| 35. | Cyclobenzaprine Tablets | 65. | Glycopyrrolate |
| 36. | Dacarbazine | 66. | Glycopyrrolate Injection |
| 37. | Dacarbazine Injection | 67. | Glycopyrrolate Tablets |
| 38. | Daclatasvir Hydrochloride | 68. | Hydroxyurea |
| 39. | Dapoxetine Tablets | 69. | Hydroxyurea Capsules |
| 40. | <i>S</i> -Dapoxetine Hydrochloride | 70. | Ibuprofen and Paracetamol Tablets |
| 41. | <i>S</i> -Dapoxetine Tablets | 71. | Ibuprofen and Pseudoephedrine
Hydrochloride Tablets |
| 42. | Dapsone Gel | 72. | Isoflurane |
| 43. | Darifenacin Hydrobromide | 73. | Isotretinoin Gel |
| 44. | Darifenacin Prolonged-release
Tablets | 74. | Latanoprost Eye Drops |
| 45. | Darunavir Ethanolate | 75. | Latanoprost and Timolol
Ophthalmic Solution |
| 46. | Darunavir Tablets | 76. | Letrozole |
| 47. | Diclofenac Diethylamine | 77. | Letrozole Tablets |
| 48. | Diclofenac Sodium and
Paracetamol Tablets | 78. | Levetiracetam Tablets |
| 49. | Diclofenac Gel | 79. | Levodopa and Carbidopa
Prolonged-release Tablets |
| 50. | Diethylene Glycol Monoethyl
Ether | 80. | Levofloxacin Oral Solution |
| 51. | Dinoprostone | 81. | Lignocaine |
| 52. | Dinoprostone Oral Solution | 82. | Lignocaine and Prilocaine Cream |
| 53. | Diphenoxylate Hydrochloride and
Atropine Sulphate Tablets | 83. | Lignocaine Hydrochloride Topical
Solution |
| 54. | Dopamine Hydrochloride and
Dextrose Injection | 84. | Lignocaine Oral Topical Solution |
| 55. | Dothiepin Tablets | 85. | Lorcaserin Hydrochloride Hemihy-
drate |
| 56. | Enalapril Maleate and
Hydrochlorothiazide Tablets | 86. | Lorcaserin Tablets |
| 57. | Escitalopram Oxalate and
Clonazepam Tablets | 87. | Magaldrate and Simethicone
Chewable Tablets |
| 58. | Esmolol Injection | 88. | Magaldrate and Simethicone Oral
Suspension |
| 59. | Etodolac Prolonged-release
Tablets | 89. | Mefenamic Acid and Dicyclomine
Hydrochloride Tablets |
| 60. | Folic Acid and Methylcobalamin
Tablets | 90. | Memantine Hydrochloride |
| 61. | Ganciclovir | 91. | Memantine Tablets |
| 62. | Ganciclovir Injection | 92. | Mesna |
| 63. | Ganciclovir Oral Suspension | 93. | Metadoxine |

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| 94. | Metformin Hydrochloride Prolonged-release and Glimepiride Tablets | 120. | Oxybutynin Prolonged-release Tablets |
| 95. | Methylcobalamin | 121. | Oxymetazoline Hydrochloride Nasal Solution |
| 96. | Methyldopa and Hydrochlorothiazide Tablets | 122. | Oxymetazoline Hydrochloride |
| 97. | Metoprolol Succinate Prolonged-release and Amlodipine Besilate Tablets | 123. | Paliperidone |
| 98. | Metoprolol Tartrate and Hydrochlorothiazide Tablets | 124. | Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules |
| 99. | Montelukast Granules | 125. | Paracetamol and Caffeine Tablets |
| 100. | Montelukast Sodium and Levocetirizine Hydrochloride Tablets | 126. | Paroxetine Hydrochloride Hemihydrate |
| 101. | Mycophenolate Mofetil Oral Suspension | 127. | Phenylephrine Eye Drops |
| 102. | Mycophenolate Mofetil Tablets | 128. | Phenylephrine Hydrochloride and Chlorpheniramine Maleate Drops |
| 103. | Nadifloxacin | 129. | Phenylephrine Hydrochloride and Chlorpheniramine Maleate Syrup |
| 104. | Nadifloxacin Cream | 130. | Phytomenadione |
| 105. | Nadifloxacin Gel | 131. | Phytomenadione Injection |
| 106. | Nitroglycerin Injection | 132. | Piperacillin and Tazobactam Injection |
| 107. | Norethisterone and Ethinyl Estradiol Tablets | 133. | Piroxicam Tablets |
| 108. | Norgestimate | 134. | Pregabalin and Methylcobalamin Capsules |
| 109. | Norgestimate and Ethinyl Oestradiol Tablets | 135. | Prilocaine |
| 110. | Ofloxacin and Ornidazole Tablets | 136. | Procarbazine Hydrochloride Capsules |
| 111. | Olanzapine and Fluoxetine Tablets | 137. | Propylene Glycol Monocaprylate |
| 112. | Olmesartan Medoxomil and Hydrochlorothiazide Tablets | 138. | Quinapril Hydrochloride |
| 113. | Omeprazole and Domperidone Capsules | 139. | Quinapril and Hydrochlorothiazide Tablets |
| 114. | Olopatadine Hydrochloride | 140. | Repaglinide and Metformin Tablets |
| 115. | Olopatadine Ophthalmic Solution | 141. | Risedronate Sodium Tablets |
| 116. | Olopatadine Tablets | 142. | Ropivacaine Hydrochloride |
| 117. | Oxaliplatin | 143. | Ropivacaine Injection |
| 118. | Oxaliplatin Injection | 144. | Rosuvastatin Calcium and Ezetimibe Tablets |
| 119. | Oxybutynin Hydrochloride | | |

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| 145. Rosuvastatin
and Fenofibrate Tablets | 156. Terbinafine Cream |
| 146. Sertaconazole Nitrate | 157. Terbinafine Tablets |
| 147. Sertaconazole Nitrate and
Beclomethasone Dipropionate
Cream | 158. Thioguanine |
| 148. Sodium Alendronate Trihydrate | 159. Thioguanine Tablets |
| 149. Sucralfate | 160. Ticagrelor |
| 150. Sucralfate Tablets | 161. Tobramycin and Fluorometholone
Acetate Ophthalmic Suspension |
| 151. Tamsulosin Hydrochloride
Prolonged-release and Dutasteride
Capsules | 162. Tobramycin Inhalation Solution |
| 152. Tazobactam | 163. Trimetazidine Tablets |
| 153. Telmisartan and Amlodipine
Tablets | 164. Tropicium Chloride Tablets |
| 154. Telmisartan and
Hydrochlorothiazide Tablets | 165. Voriconazole Injection |
| 155. Terbinafine Hydrochloride | 166. Xylometazoline Hydrochloride and
Sorbitol Nasal Drops |
| | 167. Zolpidem Tartrate Prolonged-
release Tablets |
| | 168. Zonisamide Capsules |
| | 169. Gentamicin Cream |
| | 170. Gentamicin Ointment |

(ii) 15 Herbal Monographs

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| 1. Amarbel | 9. Mandarin Oil |
| 2. Anise Oil | 10. Milk Thistle |
| 3. Belladonna Dry Extract Tablets | 11. Milk Thistle Dry Extract |
| 4. Citronella Oil (Geraniol type) | 12. Schisandra Dry Extract |
| 5. Citronella Oil (Java type) | 13. Schisandra Fruit |
| 6. Green Coffee Bean Extract | 14. Sweet Orange Oil |
| 7. Horse Chestnut Dry Extract | 15. Tvak |
| 8. Juniper Oil | |

(iii) 10 Monographs on Blood and Blood related products

1. Anti-D (IgM) monoclonal blood grouping reagent
2. Blood Grouping Reagent Anti-Fy^a, Anti-Fy^b
3. Blood Grouping Reagent Anti-Jk^a, Anti-Jk^b
4. Blood Grouping Reagent Anti-K, Anti-k
5. Blood Grouping Reagent Anti-M, Anti-N
6. Blood Grouping Reagents Anti P₁
7. Blood Grouping Reagents Anti-Le^a, Anti-Le^b

8. Blood Grouping Reagents Anti-S, Anti-s
9. Blood Grouping Lectins Anti-H
10. Blood Grouping Lectins Anti-A₁

(iv) 6 Monographs on Biotechnology Derived Therapeutic products

1. Follicle Stimulating Hormone Concentrated Solution
2. Follicle Stimulating Hormone Injection
3. Follicle Stimulating Hormone
4. Interferon b-1a Injection
5. Teriparatide
6. Teriparatide injection

(v) 2 Monographs on Vaccines and Immoserum for Human use

1. Pneumococcal polysaccharide conjugate vaccine (Adsorbed)
2. Scorpion Venom Antiserum

(vi) 3 Monographs of Radiopharmaceutical

1. Gallium (⁶⁸Ga) Chloride solution for Radiolabelling
2. Sodium Iodide (¹²³I) Injection (From ¹²⁴Xe)
3. Sodium Iodide (¹²³I) Solution for Radiolabelling

(vii) 14 Monographs of Veterinary Non-biological

1. Albendazole Veterinary Oral Powder
2. Amoxicillin Tablets
3. Amprolium Oral Powder
4. Buparvaquone
5. Buparvaquone Injection
6. Cefuroxime Intramammary Infusion
7. Cephalexin Intrauterine Powder for Suspension
8. Cephalexin Veterinary Oral Powder
9. Enrofloxacin Injection
10. Marbofloxacin Injection
11. myo-Inositol
12. Oxytetracycline Hydrochloride Injection
13. Sodium Acid Phosphate Injection
14. Trimethoprim and Sulphamethoxazole Injection

Besides this index is also added to Volume-I of IP-2018, however volume IV of IP-2018 contains Veterinary monographs and index separately.

Purchase of IP-2018

IP-2018 can be procured from the office of the
Secretary-cum-Scientific Director
IP Commission at IPC Campus,
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Or from our distribution network (see website. www.ipc.gov.in)

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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 Revision of existing General Chapters and monographs.**

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