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 Immunosera 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- Pyrogen test have been replaced by Bacterial Endotoxin test (BET) in parenteral preparations and other monographs.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

<table>
<thead>
<tr>
<th>No.</th>
<th>Chemical Name</th>
<th>No.</th>
<th>Chemical Name</th>
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<td>Abiraterone Acetate Tablets</td>
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<td>Bosentan Monohydrate</td>
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<td>Aprepitant Capsules</td>
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<td>Cefuroxime Axetil and Potassium Clavulanate Tablets</td>
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<td>11</td>
<td>Artesunate Injection</td>
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<td>Atenolol and Chlorthalidone Tablets</td>
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<td>Cinidipine</td>
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<td>Atorvastatin and Fenofibrate Tablets</td>
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<td>Cinidipine Tablets</td>
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<td>15</td>
<td>Bisoprolol Fumarate</td>
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<td>Clindamycin Palmitate</td>
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<td>Bisoprolol Fumarate and Hydrochlorothiazide Tablets</td>
<td>32</td>
<td>Clindamycin Palmitate</td>
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<td>33</td>
<td>Clonidine Hydrochloride</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>and Chlorthalidone Tablets</td>
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34. Cyclobenzaprine Hydrochloride
35. Cyclobenzaprine Tablets
36. Dacarbazine
37. Dacarbazine Injection
38. Daclatasvir Hydrochloride
39. Dapoxetine Tablets
40. S-Dapoxetine Hydrochloride
41. S-Dapoxetine Tablets
42. Dapsone Gel
43. Darifenacin Hydrobromide
44. Darifenacin Prolonged-release Tablets
45. Darunavir Ethanolate
46. Darunavir Tablets
47. Diclofenac Diethylamine
48. Diclofenac Sodium and Paracetamol Tablets
49. Diclofenac Gel
50. Diethylene Glycol Monoethyl Ether
51. Dinoprostone
52. Dinoprostone Oral Solution
53. Diphenoxylate Hydrochloride and Atropine Sulphate Tablets
54. Dopamine Hydrochloride and Dextrose Injection
55. Dothiepin Tablets
56. Enalapril Maleate and Hydrochlorothiazide Tablets
57. Escitalopram Oxalate and Clonazepam Tablets
58. Esmolol Injection
59. Etodolac Prolonged-release Tablets
60. Folic Acid and Methylcobalamin Tablets
61. Ganciclovir
62. Ganciclovir Injection
63. Ganciclovir Oral Suspension
64. Glibenclamide and Metformin Tablets
65. Glycopyrrolate
66. Glycopyrrolate Injection
67. Glycopyrrolate Tablets
68. Hydroxyurea
69. Hydroxyurea Capsules
70. Ibuprofen and Paracetamol Tablets
71. Ibuprofen and Pseudoephedrine Hydrochloride Tablets
72. Isoflurane
73. Isotretinoin Gel
74. Latanoprost Eye Drops
75. Latanoprost and Timolol Ophthalmic Solution
76. Letrozole
77. Letrozole Tablets
78. Levetiracetam Tablets
79. Levodopa and Carbidopa Prolonged-release Tablets
80. Levofloxacin Oral Solution
81. Lignocaine
82. Lignocaine and Prilocaine Cream
83. Lignocaine Hydrochloride Topical Solution
84. Lignocaine Oral Topical Solution
85. Lorcaserin Hydrochloride Hemihydrate
86. Lorcaserin Tablets
87. Magaldrate and Simethicone Chewable Tablets
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| 97. | Metoprolol Succinate Prolonged-release and Amlodipine Besilate Tablets |
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| 99. | Montelukast Granules |
| 100. | Montelukast Sodium and Levoctirizine Hydrochloride Tablets |
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| 102. | Mycophenolate Mofetil Tablets |
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| 104. | Nadifloxacin Cream |
| 105. | Nadifloxacin Gel |
| 106. | Nitroglycerin Injection |
| 107. | Norethisterone and Ethinyl Estradiol Tablets |
| 108. | Norgestimate |
| 109. | Norgestimate and Ethinyl Oestradiol Tablets |
| 110. | Ofloxacin and Ornidazole Tablets |
| 111. | Olanzapine and Fluoxetine Tablets |
| 112. | Olmesartan Medoxomil and Hydrochlorothiazide Tablets |
| 113. | Omeprazole and Domperidone Capsules |
| 114. | Olopatadine Hydrochloride |
| 115. | Olopatadine Ophthalmic Solution |
| 116. | Olopatadine Tablets |
| 117. | Oxaliplatin |
| 118. | Oxaliplatin Injection |
| 119. | Oxybutynin Hydrochloride |
| 120. | Oxybutynin Prolonged-release Tablets |
| 121. | Oxymetazoline Hydrochloride Nasal Solution |
| 122. | Oxymetazoline Hydrochloride |
| 123. | Paliperidone |
| 124. | Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules |
| 125. | Paracetamol and Caffeine Tablets |
| 126. | Paroxetine Hydrochloride Hemihydrate |
| 127. | Phenylephrine Eye Drops |
| 128. | Phenylephrine Hydrochloride and Chlorpheniramine Maleate Drops |
| 129. | Phenylephrine Hydrochloride and Chlorpheniramine Maleate Syrup |
| 130. | Phytomenadione |
| 131. | Phytomenadione Injection |
| 132. | Piperacillin and Tazobactam Injection |
| 133. | Piroxicam Tablets |
| 134. | Pregabalin and Methylcobalamin Capsules |
| 135. | Prilocaine |
| 136. | Procainamide Hydrochloride Capsules |
| 137. | Propylene Glycol Monocaprylate |
| 138. | Quinapril Hydrochloride |
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| 140. | Repaglinide and Metformin Tablets |
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| 143. | Ropivacaine Injection |
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145. Rosuvastatin and Fenofibrate Tablets
146. Sertaconazole Nitrate
147. Sertaconazole Nitrate and Beclomethasone Dipropionate Cream
148. Sodium Alendronate Trihydrate
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150. Tamsulosin Hydrochloride Prolonged-release and Dutasteride Capsules
151. Tazobactam
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157. Thioguanine
158. Thioguanine Tablets
159. Ticagrelor
160. Tobramycin and Fluorometholone Acetate Ophthalmic Suspension
161. Tobramycin Inhalation Solution
162. Trimetazidine Tablets
163. Trospium Chloride Tablets
164. Voriconazole Injection
165. Xylometazoline Hydrochloride and Sorbitol Nasal Drops
166. Zolpidem Tartrate Prolonged-release Tablets
167. Zonisamide Capsules
168. Gentamicin Cream
169. Gentamicin Ointment
170. (ii) 15 Herbal Monographs

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

(iii) 10 Monographs on Blood and Blood related products

1. Anti-D (IgM) monoclonal blood grouping reagent
2. Blood Grouping Reagent Anti-Fya, Anti-Fyb
4. Blood Grouping Reagent Anti-K, Anti-k
5. Blood Grouping Reagent Anti-M, Anti-N
6. Blood Grouping Reagents Anti-P1
8. Blood Grouping Reagents Anti-S, Anti-s

(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 Immunosera for Human use**
1. Pneumococcal polysaccharide conjugate vaccine (Adsorbed)
2. Scorpion Venom Antiserum

(vi) **3 Monographs of Radiopharmaceutical**
1. Gallium ($^{68}$ Ga) Chloride solution for Radiolabelling
2. Sodium Iodide ($^{123}$ I) Injection (From $^{124}$ Xe)
3. Sodium Iodide ($^{123}$ I) Solution for Radiolabelling

(vii) **14 Monographs of Veterinary Non-biological**
1. Albendazole Veterinary Oral Powder
2. Amoxycillin 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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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.