

# Addendum 2021 to Indian Pharmacopoeia 2018

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## Effective Date

**1<sup>ST</sup> OCTOBER 2021**

## Salient Features

- ▶ New Monographs: 66
- ▶ APIs: 21
- ▶ Dosage Forms (Chemicals): 38
- ▶ Herbs & Herbal Products: 05
- ▶ Blood & Blood Related Products: 02
- ▶ General Chapters: 04

## New Monograph Additions

### Chemicals

1. Amlodipine and Atenolol Tablets
2. Amlodipine and Lisinopril Tablets
3. Amlodipine and Nebivolol Tablets
4. Artemether and Lumefantrine Tablets
5. Aspirin Gastro-resistant and Atorvastatin capsules
6. Aspirin Gastro-resistant and Rosuvastatin Capsules
7. Atazanavir and Ritonavir Tablets
8. Buprenorphine and Naloxone sublingual tablets
9. Candesartan Celexitel and Hydrochlorthiazide Tablets
10. Cyclosporine Eye drops
11. Cyclosporine Injection
12. Deferasirox
13. Deferasirox Tablets
14. Disopyramide Phosphate
15. Dolutegravir Sodium
16. Dolutegravir Tablets
17. Dolutegravir, Lamivudine and Tenofovir Disoproxil fumarate Tablets
18. Eplerenone Tablets
19. Etizolam
20. Etizolam Tablets
21. Favipiravir
22. Favipiravir Tablets
23. Ferrous Ascorbate
24. Ferrous Ascorbate and Folic Acid Suspension
25. Ferrous ascorbate and Folic Acid Tablets
26. Flunarizine Dihydrochloride
27. Flunarizine Tablets
28. Itopride Hydrochloride
29. Itopride Tablets
30. Ivermectin Tablets
31. Luliconazole
32. Luliconazole Cream
33. Luliconazole Lotion
34. Lumefantrine
35. Pamidronate Disodium
36. Pamidronate Disodium Injection
37. Prasugrel Hydrochloride
38. Prasugrel Tablets
39. Quetiapine Prolonged-release Tablets
40. Rabeprazole Gastro-resistant and Itopride Prolonged-release Capsules
41. Raltegravir Potassium
42. Raltegravir Tablets
43. Remdesivir
44. Remdesivir Injection
45. Rivastigmine Tartrate
46. Rivastigmine Capsules
47. Temozolomide Injection
48. Tenofovir Alafenamide Fumarate
49. Tenofovir Alafenamide Fumarate Tablets
50. Tenoxicam
51. Tenoxicam tablets
52. Ticagrelor Tablets
53. Ticarcillin Monosodium
54. Tigecycline
55. Tigecycline Injection
56. Vildagliptin
57. Vildagliptin Tablets
58. Zuclopenthixol Decanoate
59. Zuclopenthixol Decanoate Injection

### Herbs and Herbal Products Monographs

1. Bael
2. Chulai
3. Patha
4. Powdered Senna Leaf
5. Upakunchika

### Blood and Blood Related Products

1. Anti-D Blend (IgM + IgG) Monoclonal Reagent
2. Anti-D (IgG) Monoclonal Reagent

### New General Chapters

- 2.6.6. Evaluation of Herbs and Processed herbs
- 2.6.7. Microscopic Evaluation of Herbs and Processed herbs.
- 2.6.8. Determination of Aflatoxin in herbal drugs
- 2.6.9. Pesticide Residue

## Monograph Revisions

### Chemicals

1. Glycerin
2. Hydroxychloroquine Sulphate
3. Isopropyl Alcohol
4. Quetiapine Fumarate
5. Quetiapine Tablets
6. Sumatriptan Injection

### Blood and Blood Related Products

1. Anti Human Globulin Serum

### Allergen Products

1. Allergen Products

## Monograph Up-gradations

### General Notices

1. Residual Solvents

### General Chapters

- 2.3.13. Heavy Metals
- 2.3.43. Water
- 2.3.46. Assay of Insulins
- 2.4.26. Solubility
- 2.7.1. Composition of Polysaccharide Vaccines
- 4.1. Buffer Solutions
- 5.9. Reference Substances (IPRS)
- 6.3. Closures for Containers

### General Monograph

1. Lotions
2. Tablets

### Chemical Monographs

1. Allopurinol
2. Alprostadil
3. Aluminium, Magnesium and Simethicone Chewable Tablets
4. Aluminium, Magnesium and Simethicone Oral Suspension
5. Amiodarone Intravenous Infusion
6. Arteether
7. Artesunate
8. Baclofen
9. Benzyl Alcohol
10. Bisacodyl Gastro-resistant Tablets
11. Brinzolamide
12. Bronopol
13. Bupivacaine Injection
14. Butyl paraben
15. Calcium Gluconate
16. Calcium Gluconate Injection
17. Candesartan Cilexetil Tablets
18. Carbimazole Tablets
19. Carboplatin
20. Cefpodoxime Tablets
21. Cetirizine Hydrochloride
22. Cetirizine Tablets
23. Chloroquine Phosphate
24. Chloroquine Phosphate Injection
25. Chloroquine Phosphate Suspension
26. Chloroquine Phosphate Tablets
27. Chloroquine Sulphate
28. Chloroquine Sulphate Injection
29. Chloroquine Sulphate Tablets
30. Chloroquine Syrup
31. Chlorothiazide
32. Cholecalciferol Injection
33. Cholecalciferol Tablets
34. Ciclesonide Inhalation
35. Cinacalcet Hydrochloride
36. Citicoline Injection
37. Citicoline Prolonged-release Tablets
38. Citicoline Tablets
39. Clarithromycin
40. Clindamycin Capsules

41. Clindamycin Phosphate
42. Clonazepam
43. Clotrimazole Lotion
44. Colistimethate Sodium
45. Cyclophosphamide Injection
46. Diazepam Injection
47. Diltiazem Hydrochloride
48. Diltiazem Injection
49. Diltiazem Tablets
50. Dimethicone
51. Docetaxel Injection
52. Emtricitabine
53. Enoxaparin Injection
54. Erythromycin Stearate
55. Ethanol
56. Ethanol (95 Per Cent)
57. Ethionamide
58. Ethionamide Tablets
59. Dried Ferrous Sulphate
60. Finasteride
61. Fluphenazine Decanoate Injection
62. Fluticasone Propionate Inhalation
63. Fluvastatin Capsules
64. Folic Acid and Methylcobalamin Tablets
65. Gabapentin Capsules
66. Gabapentin Tablets
67. Glibenclamide and Metformin Tablets
68. Granisetron Hydrochloride
69. Granisetron Injection
70. Hydrochlorothiazide Tablets
71. Hyoscine Butylbromide
72. Hyoscine Butylbromide Injection
73. Insulin Zinc Suspension
74. Insulin Zinc Suspension (Amorphous)
75. Insulin Zinc Suspension (Crystalline)
76. Ipratropium Bromide
77. Irbesartan and Hydrochlorothiazide Tablets
78. Isopropyl Rubbing Alcohol
79. Kanamycin Injection
80. Labetalol Hydrochloride
81. Lamivudine and Zidovudine Tablets
82. Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
83. Letrozole Tablets
84. Levetiracetam Oral Solution
85. Levocarnitine
86. Levocetirizine Hydrochloride
87. Levocetirizine Tablets
88. Lignocaine Hydrochloride Topical Solution
89. Lithium Carbonate
90. Malic Acid
91. Methadone Injection
92. Methotrexate Tablets
93. Metoprolol Succinate
94. Misoprostol Tablets
95. Modafinil Tablets
96. Montelukast Sodium and Levocetirizine Hydrochloride Tablets
97. Multiple Electrolytes and Dextrose Injection Type I
98. Multiple Electrolytes and Dextrose Injection Type III
99. Niclosamide Tablets
100. Nimodipine
101. Nortriptyline Tablets
102. Nystatin
103. Olanzapine Tablets
104. Ondansetron Orally Disintegrating Tablets
105. Ormeloxifene Hydrochloride
106. Ormeloxifene Hydrochloride Tablets
107. Oxaliplatin Injection
108. D-Panthenol
109. Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules
110. Pentoxifylline
111. Perindopril Erbumine Tablets
112. Phenobarbitone Injection
113. Phentolamine Injection
114. Phenytoin Oral Suspension
115. Piperacillin and Tazobactam Injection
116. Pirfenidone
117. Polyvinyl Alcohol
118. Prednisolone Tablets
119. Procainamide Injection
120. Promethazine Injection
121. Propofol
122. Propranolol Injection
123. Propylene Glycol
124. Pyrazinamide
125. Quinapril and Hydrochlorothiazide Tablets
126. Rabeprazole Injection
127. Raloxifene Hydrochloride
128. Raloxifene Hydrochloride Tablets
129. Ranitidine Oral Solution
130. Ranitidine Tablets
131. Ritodrine Hydrochloride
132. Ritodrine Injection
133. Ropinirole Prolonged-release Tablets
134. Ropinirole Tablets
135. Serratiopeptidase Tablets
136. Sodium Alendronate Tablets
137. Colloidal Silicon Dioxide
138. Sodium Chloride
139. Sodium Citrate Irrigation Solution
140. Monobasic Sodium Phosphate
141. Sodium Propylparaben
142. Sodium Valproate Gastro-resistant Tablets
143. Solifenacin Succinate Tablets
144. Sorafenib Tosylate
145. Sorafenib Tablets
146. Stearic Acid
147. Streptomycin Sulphate
148. Sulbactam Sodium
149. Sulfasalazine Gastro-resistant Tablets
150. Talc
151. Tamsulosin Hydrochloride

152. Tazobactam Sodium
153. Telmisartan and Amlodipine Tablets
154. Temozolomide
155. Teneligliptin Hydrobromide Hydrate
156. Teneligliptin Tablets
157. Terazosin Tablets
158. Thiamine Hydrochloride
159. Thiamine Injection
160. Thiamine Tablets
161. Thiamine Mononitrate
162. Thiocolchicoside
163. Thyroxine Sodium
164. Thyroxine Tablets
165. Ticagrelor
166. Timolol Eye Drops
167. Timolol Tablets
168. Titanium Dioxide
169. Tizanidine Tablets

170. Tobramycin Inhalation Solution
171. Torsemide Tablets
172. Tranexamic Acid
173. Tranexamic Acid Injection
174. Tranexamic Acid Tablets
175. Trimethobenzamide Hydrochloride
176. Vancomycin Intravenous Infusion
177. Venlafaxine Prolonged-release Capsules
178. Venlafaxine Prolonged-release Tablets
179. Venlafaxine Tablets
180. Vinorelbine Injection
181. Voriconazole Injection
182. Sterile Water for Injections
183. Zidovudine, Lamivudine and Nevirapine Tablets
184. Zinc Oxide Cream
185. Zopiclone Tablets

### Vaccines and Immunosera for Human Use

1. Adsorbed Pertussis Vaccine (Acellular Component)
2. Diphtheria and Tetanus Vaccine (Adsorbed)
3. Diphtheria and Tetanus Vaccine
4. (Adsorbed) for Adults and Adolescents
5. Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)
6. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)
7. Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed)
8. Diphtheria, Tetanus, Pertussis (Whole Cell) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)
9. Diphtheria Vaccine (Adsorbed)
10. Diphtheria Vaccine (Adsorbed) for Adults and Adolescents
11. Haemophilus influenzae Type b Conjugate Vaccine
12. Inactivated Hepatitis A Vaccine (Adsorbed)
13. Inactivated Hepatitis B Vaccine
14. Inactivated Influenza Vaccine (Split Virion)
15. Inactivated Influenza Vaccine (Surface Antigen)
16. Inactivated Influenza Vaccine (Whole Virion)
17. Influenza Vaccine (Human, Live Attenuated)
18. Japanese Encephalitis Vaccine (Human)
19. Japanese Encephalitis Live Vaccine (Human)
20. Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human)
21. Measles and Rubella Vaccine (Live)
22. Measles Vaccine (Live)
23. Measles, Mumps and Rubella Vaccine (Live)
24. Group A Meningococcal Conjugate Vaccine
25. Meningococcal Polysaccharide Vaccine
26. Mumps Vaccine (Live)
27. Plague Vaccine
28. Poliomyelitis Vaccine, Live (Oral)
29. Rabies Vaccine, Human
30. Rotavirus Vaccine (Live attenuated, Oral)
31. Rubella Vaccine (Live)
32. Tetanus Vaccine (Adsorbed)
33. Tick-borne Encephalitis Vaccine (Inactivated)
34. Typhoid Polysaccharide Vaccine
35. Typhoid Paratyphoid A Vaccine
36. Typhoid Vi Conjugate Vaccine
37. Typhus Vaccine
38. Varicella Vaccine, Live
39. Yellow Fever Vaccine

### Herbs and Herbal Products

1. Castor Oil
2. Ginkgo Dry Extract

3. Henna Dry Powder

### Blood and Blood Related Products

1. Anti-A Blood Grouping Serum
2. Anti-B Blood Grouping Serum
3. Anti-AB Blood Grouping Reagent

4. Anti-D (IgM) Monoclonal Blood Grouping Reagent

### Biotechnology Derived Therapeutic Products

1. Filgrastim Concentrated Solution

2. Follicle Stimulating Hormone

3. Concentrated Solution

4. Pegfilgrastim

### **Radiopharmaceutical Preparations**

1. Sodium Chromate (<sup>15</sup>Cr) Injection

### **Veterinary Monographs**

1. Amprolium Oral Powder

2. Cloprostenol Injection

3. Furazolidone Premix

4. Moxidectin

5. Tylosin Injection