

Addendum 2024 to IP 2022

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INDIAN PHARMACOPOEIA COMMISSION

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Salient Features of IP Addendum 2024

New Additions

New General Chapters & General Monographs (N=10)

- Guidelines on the Bacterial Endotoxins Tests (2.2.33)
- Particle Size Analysis by Laser Light Diffraction (2.5.12)
- Particle Size Analysis by Dynamic Light Scattering (2.5.13.)
- Extraction and Purification Techniques of Phytoconstituents (2.6.10)
- Phytoconstituents Enrichment Process (2.6.11)
- Evaluation of Safety of Veterinary Vaccines and Immunoserum (2.7.17)
- Healthy Chicken Flocks for the Production of Inactivated Vaccines for Veterinary Use (2.7.18)
- Management of Extraneous Agents in Immunological Veterinary Medicinal Products (2.7.19)
- Substitution of *in-vivo* Method (s) by *in-vitro* Method (s) for the Quality Control of Vaccines (2.7.20)
- Premixes (Veterinary General Monograph)

New Monographs (N=75)	
Pharmaceuticals (N=51)	
<ul style="list-style-type: none"> ○ Aceclofenac and Paracetamol Tablets ○ Amlodipine and Olmesartan Medoxomil Tablets ○ Atropine Ophthalmic Solution ○ Azacitidine for Injection ○ Azilsartan Kamedoxomil ○ Azilsartan Tablets ○ Bilastine ○ Bilastine Tablets ○ Bisoprolol Tablets ○ Brivaracetam Injection ○ Brivaracetam Oral Solution ○ Cabozantinib S-malate ○ Cabozantinib Tablets ○ Cellulose Acetate ○ Copovidone ○ Dasatinib ○ Dasatinib Tablets ○ Etophylline ○ Gliclazide Prolonged-release Tablets ○ Ibuprofen Oral Suspension ○ Itraconazole Capsules ○ Itraconazole Capsules (Supra Bioavailable Formulation) ○ Lactulose Concentrate ○ Lactulose Solution ○ Lenalidomide 	<ul style="list-style-type: none"> ○ Lenalidomide Capsules ○ Lindane Lotion ○ Mefenamic Acid Suspension ○ Miltefosine ○ Miltefosine Capsule ○ Molnupiravir ○ Molnupiravir Capsules ○ Moxifloxacin Tablets ○ Nepafenac ○ Nepafenac Ophthalmic Suspension ○ Pantoprazole for Injection ○ Paracetamol and Tramadol Tablets ○ Perampanel ○ Perampanel Tablets ○ Remogliflozin Etabonate ○ Remogliflozin Tablets ○ Rifaximin ○ Rifaximin Tablets ○ Saline Nasal Solution ○ Sodium Bicarbonate Tablets ○ Sofosbuvir and Velpatasvir Tablets ○ Thalidomide ○ Thalidomide Capsules ○ Tobramycin Sulphate ○ Velpatasvir ○ Vildagliptin Prolonged-release Tablets
Phytopharmaceuticals (N=3)	
<ul style="list-style-type: none"> ○ Glycyrrhiza glabra PPI ○ Justicia adhatoda PPI 	<ul style="list-style-type: none"> ○ Zingiber officinale PPI
Biotechnology Derived Therapeutic Products (N=1)	
<ul style="list-style-type: none"> ○ Pegfilgrastim Injection 	
Veterinary Pharmaceuticals (N=20)	
<ul style="list-style-type: none"> ○ Aspirin Tablets/Boluses ○ Carboprost Tromethamine ○ Carboprost Tromethamine Injection ○ Carprofen Tablets ○ Cephapirin Benzathine ○ Cephapirin Benzathine Intramammary Infusion ○ Clopidogrel Bisulphate ○ Flunixin Meglumine Injection ○ Ketamine Hydrochloride ○ Ketamine Injection 	<ul style="list-style-type: none"> ○ Pimobendan ○ Pimobendan Capsules ○ Propofol ○ Propofol Injection ○ Quiniodochlor ○ Selamectin ○ Tilimicosin ○ Tilimicosin Phosphate ○ Tilimicosin Injection ○ Triclabendazole

Revisions and Upgradations

General Chapters & General Monographs (N=21)

- Effectiveness of Antimicrobial Preservatives (2.2.2)
- Microbial Contamination in Nonsterile Products (2.2.9)
- Test for Biological Reactivity, *In Vivo* (2.2.24)
- Design and Development of Biological Assay and its Validation (2.2.31)
- Atomic Absorption Spectrometry (2.4.2)
- Gas Chromatography (2.4.13)
- Liquid Chromatography (2.4.14)
- Solubility (2.4.26)
- Characterisation of Crystalline and Partially Crystalline Solids by X-ray Powder Diffraction (XRPD) (2.4.43)
- Dissolution Test (2.5.2)
- Friability of Uncoated Tablets (2.5.5)
- Particle Size Distribution Estimation (2.5.7)
- Optical Microscopy (2.5.8)
- Test for Absence of Non-Avian Mycoplasmas and Ureaplasmas (2.7.8)
- Test for Absence of Avian Mycoplasma in Live Viral Poultry Vaccines (2.7.9)
- Infra-red Reference Spectra (3.1)
- Thin Layer Chromatography (3.2.1)
- High Performance Liquid/ Gas/ NMR Chromatogram of Phytopharmaceuticals (3.3.1)
- General Reagents (4.2)
- Standard Solutions (4.4)
- Capsules (General Monograph)

Monographs (N=220)

Chemicals (N=158)

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| <ul style="list-style-type: none">○ Abacavir Sulphate○ Alprazolam○ Alprazolam Prolonged-release Tablets○ Amiodarone Hydrochloride○ Amiodarone Intravenous Infusion○ Amiodarone Tablets○ Artesunate Injection○ Atenolol○ Atenolol Tablets○ Benzyl Alcohol○ Bromhexine Tablets○ Buprenorphine Hydrochloride○ Buprenorphine Injection○ Carboxymethylcellulose Eye Drops○ Cefepime Hydrochloride○ Cefepime Injection○ Cefixime Dispersible Tablets○ Chlorothiazide○ Chlorothiazide Tablets○ Chlorpropamide | <ul style="list-style-type: none">○ Metronidazole Gel○ Metronidazole Tablets○ Mexiletine Hydrochloride○ Mianserin Tablets○ Miconazole Nitrate○ Montelukast and Levocetirizine Tablets○ Morphine Sulphate○ Mustine Hydrochloride○ Neomycin Sulphate○ Neomycin Eye Drops○ Neomycin Eye Ointment○ Neostigmine Bromide○ Neostigmine Tablets○ Nortriptyline Hydrochloride○ Nystatin○ Ofloxacin○ Ofloxacin Tablets○ Oleic Acid○ Olmesartan Medoxomil○ Olmesartan Medoxomil Tablets |
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- Chlorpropamide Tablets
- Chlorthalidone
- Cilostazol
- Clindamycin Hydrochloride
- Clindamycin Capsules
- Clopidogrel Bisulphate
- Codeine Phosphate
- Colchicine and Probenecid Tablets
- Crospovidone
- Cyclobenzaprine Hydrochloride
- Cyclobenzaprine Tablets
- Dexamethasone Tablets
- Dexamethasone Sodium Phosphate
- Dextrose
- Doxycycline Hydrochloride
- Doxycycline Capsules
- Doxycycline Dispersible Tablets
- Drotaverine Tablets
- Dutasteride Capsules
- Dydrogesterone
- Dydrogesterone Tablets
- Erythromycin Gastro-resistant Tablets
- Esomeprazole Gastro-resistant Tablets
- Ethanol
- Ethyl Paraben
- Fasudil Hydrochloride
- Fluphenazine Decanoate Injection
- Flurazepam Capsules
- Flurbiprofen
- Flurbiprofen Tablets
- Flutamide
- Fosinopril Sodium Tablets
- Frovatriptan Succinate
- Fusidic Acid
- Gemcitabine Injection
- Glibenclamide Tablets
- Glibenclamide and Metformin Tablets
- Hydroxypropylmethylcellulose
- Imipenem and Cilastatin Injection
- Anhydrous Lactose
- Lactulose
- Leflunomide
- Levamisole Tablets
- Losartan Potassium
- Losartan Tablets
- Liquid Maltitol
- Mefenamic Acid Capsules
- Mercaptopurine

- Olmesartan Medoxomil and Hydrochlorothiazide Tablets
- Ondansetron Hydrochloride
- Ondansetron Injection
- Ondansetron Oral Solution
- Ondansetron Tablets
- Pantoprazole Sodium
- Pantoprazole Gastro-resistant Tablets
- Pioglitazone Hydrochloride
- Pioglitazone Tablets
- Poloxamers
- Polymyxin B Sulphate
- Prednisolone Tablets
- Pregabalin
- Primaquine Phosphate
- Primaquine Tablets
- Propylparaben
- Pyrimethamine and Sulphadoxine Tablets
- Quiniodochlor
- Rabeprazole Sodium
- Rabeprazole Gastro-resistant Tablets
- Repaglinide Tablets
- Repaglinide and Metformin Tablets
- Reserpine Tablets
- Ribavirin
- Salbutamol Syrup
- Saquinavir Capsules
- Secnidazole
- Sitagliptin Tablets
- Sodium Benzoate
- Sodium Fusidate
- Sodium Lactate Injection
- Sodium Nitroprusside Injection
- Sodium Valproate Gastro-resistant Tablets
- Spironolactone
- Spironolactone Tablets
- Stearyl Alcohol
- Sucrose
- Teicoplanin Injection
- Telmisartan
- Telmisartan Tablets
- Terbutaline Sulphate
- Terbutaline Inhalation
- Terbutaline Injection
- Terbutaline Tablets
- Tinidazole Tablets
- Trandolapril Tablets
- Tranilast
- Trimethoprim and Sulphamethoxazole Oral

<ul style="list-style-type: none"> ○ Mercaptopurine Tablets ○ Meropenem ○ Meropenem Injection ○ Metformin Hydrochloride ○ Metformin Hydrochloride Prolonged-release Tablets ○ Metformin Tablets ○ Methylparaben ○ Methyl Salicylate ○ Metoprolol Succinate Prolonged-release Tablets ○ Metronidazole ○ Metronidazole Injection 	<ul style="list-style-type: none"> Suspension ○ Valganciclovir Hydrochloride ○ Valganciclovir Tablets ○ Valsartan ○ Valsartan Tablets ○ Venlafaxine Prolonged-release Capsules ○ Venlafaxine Prolonged-release Tablets ○ Venlafaxine Tablets ○ Sterile Water for Injections ○ Zinc Undecenoate Ointment ○ Zoledronic Acid ○ Zuclopenthixol Decanoate Injection
Vitamins, Minerals, Amino Acids, Fatty Acids etc. (N=22)	
<ul style="list-style-type: none"> ○ Water-Soluble Vitamins Capsules ○ Water-Soluble Vitamins Tablets ○ Ascorbic Acid ○ Ascorbic Acid Injection ○ Calcium Carbonate Tablets ○ Tribasic Calcium Phosphate ○ Cholecalciferol Tablets ○ Chromium Picolinate ○ Cyanocobalamin ○ Folic Acid ○ Folic Acid Tablets 	<ul style="list-style-type: none"> ○ Heavy Magnesium Carbonate ○ Light Magnesium Carbonate ○ Heavy Magnesium Oxide ○ Light Magnesium Oxide ○ Magnesium Sulphate ○ Methylcobalamin ○ Nicotinamide ○ D-Panthenol ○ Pyridoxine Tablets ○ Riboflavin ○ Riboflavin Sodium Phosphate
Phytopharmaceuticals (N=1)	
<ul style="list-style-type: none"> ○ Aegle marmelos PPI 	
Vaccines and Immunosera for Human Use: General Requirements (N=4)	
<ul style="list-style-type: none"> ○ Vaccines ○ Antisera 	<ul style="list-style-type: none"> ○ Measles, Mumps and Rubella Vaccine (Live) ○ Mumps Vaccine (Live)
Blood and Blood Related Products (N=6)	
<ul style="list-style-type: none"> ○ Anti- B Blood Grouping Serum ○ Anti -AB Blood Grouping Reagent ○ Antithrombin III Concentrate ○ Blood Grouping Lectins Anti-H 	<ul style="list-style-type: none"> ○ Human Albumin ○ Human Normal Immunoglobulin for Intravenous use
Biotechnology Derived Therapeutic Products (N=5)	
<ul style="list-style-type: none"> ○ Erythropoietin Concentrated Solution ○ Pegfilgrastim ○ Recombinant Streptokinase for Injection 	<ul style="list-style-type: none"> ○ Rituximab ○ Rituximab Injection
Veterinary Vaccines (N=5)	
<ul style="list-style-type: none"> ○ Blackquarter Vaccine ○ Brucellaabortus (Strain 19) Vaccine, Live ○ Canine Adenovirus Vaccine (Live) 	<ul style="list-style-type: none"> ○ Canine Leptospirosis Vaccine, Inactivated ○ HaemorrhagicSepticaemia Vaccine, Inactivated
Veterinary Pharmaceuticals (N=16)	
<ul style="list-style-type: none"> ○ Veterinary Vaccine General Requirements ○ Veterinary Liquid Preparation for Cutaneous Application 	<ul style="list-style-type: none"> ○ Deltamethrin Pour-on ○ Ivermectin ○ Ivermectin Injection

<ul style="list-style-type: none"> ○ Veterinary Oral Liquids ○ Veterinary Oral Powders ○ Veterinary Tablets and Boluses ○ Buparvaquone ○ Buparvaquone Injection ○ Cefoperazone Sodium Intramammary Suspension 	<ul style="list-style-type: none"> ○ Ivermectin Pour-on ○ Progesterone ○ Progesterone Injection ○ Rafoxanide ○ Trimethoprim and Sulphamethoxazole Injection
Change in Title (N=3)	
<ul style="list-style-type: none"> ○ Change from: Glyceryl Trinitrate Tablets Change to: Glyceryl Trinitrate Sublingual Tablets ○ Change from: Particle Size Distribution (2.5.7) Change to: Particle Size Distribution Estimation by Analytical Sieving (2.5.7) 	<ul style="list-style-type: none"> ○ Change from: Optical Microscopy: Particle Size by Microscopy (2.5.8) Change to: Optical Microscopy (2.5.8)