

Introduction

The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) 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 and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years. It supersedes the IP 2010 edition but any monograph of the earlier edition that does not figure in this edition continues to be official as stipulated in the Second Schedule of the Drugs and Cosmetics Act, 1940.

Presentation

The Indian Pharmacopoeia 2014 is presented in four volumes. Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction and the General Chapters. Volume II contains the General Notices, General Monographs on dosage forms, Monographs on drug substances, dosage forms and pharmaceutical aids (A to M). Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z) followed by and distinguished by colour codes, Monographs on Vaccines and Immunosera for human use, Herbs and herbal products, Blood and blood-related products, Biotechnology products and Radiopharmaceutical preparations, Volume IV contains Veterinary monographs and Index.

The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations currently not used are omitted from this edition. The number of monographs of Excipients, Anticancer drugs, Herbal products and Antiretroviral drugs have been increased in this edition. Monographs of Vaccines and Immunosera are also upgraded in view of the latest development of the technology in the field. Many chapters have been revised in the Appendices. The monographs on Water for Injections in Bulk and Purified Water are also upgraded to harmonise with prevailing international requirements.

Format

In an effort to make the pharmacopoeia more user-friendly, the design of the texts of the monographs and test methods are kept same. Cross-referencing has been avoided to make

each monograph complete in itself, thus making it convenient to the user.

Basis of Pharmacopoeial Requirements

As in the past, this compendium provides a publicly available statement concerning the quality of a product that can be expected and demonstrated at any time throughout the accepted shelf-life of the article. The standards laid down represent the minimum with which the article must comply and it is for the manufacturer to ensure that the article is manufactured in accordance with Good Manufacturing Practices (GMPs). It is essential that sufficiently stringent limits are applied at the time of release of a batch of a drug substance or drug product so that the pharmacopoeial standards are met until its expiry when stored under the storage conditions specified.

It must be noted that a valid interpretation of any requirement of the Pharmacopoeia should be done in the context of the monograph as a whole, the relevant general monographs, where appropriate, the specified tests and methods of analysis including any reference to the relevant General Notices. Familiarity with the General Notices will facilitate the correct application of the requirements.

Changes

Keeping in view the essential requirement under the Drugs and Cosmetics Act, 1940 and Rules thereunder, the information on the category of a drug, dosage and usual available strengths of dosage forms has been kept in this edition.

General chemical tests for identification of an article have been almost eliminated and the more specific infrared, ultraviolet spectrophotometric 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 the specificity in assays and in particular, in assessing the nature and extent of impurities in drug substances and drug products. Most of the existing assays and related substances tests have been upgraded to liquid chromatography method in view to have the specificity and to harmonise with other International Pharmacopoeias to the extent necessary.

In most of the parenteral preparation and other monographs, the test of pyrogens involving the use of animals has been almost eliminated and replaced with Bacterial Endotoxin test. In some blood and blood related monographs, the Bacterial Endotoxin test has been incorporated. The test for *Shigella* has been added along with *Salmonella* in the Microbial

Contamination test of several monographs. Several new monographs on antibiotics have been added where the Assay is by microbiological methods.

More essential oils monographs, crude herbal drugs and extracts have been incorporated and also some existing monographs have been revised under the section Herbs and Herbal Products in volume III.

For the first time, 19 monographs on radiopharmaceutical preparations along with a chapter on Radiopharmaceuticals have been added in Volume III, of this edition.

A separate volume for veterinary monographs as Volume IV of this edition of Indian Pharmacopoeia has been designed to provide comprehensive information to those concerned with the quality control of veterinary medicines. For the first time, a general chapter on cell cultures for the production of veterinary vaccines and other general monographs has been incorporated. Several monographs on chemicals along with a number of monographs on veterinary vaccines, diagnostic, immunosera and surgical materials have been given place in this volume. Many monographs just on the basis of usual strength and doses have been mentioned in this volume while complete monographs are mentioned in other volumes of IP.

The monograph on *Salmonella pullorum* antigen to *Salmonella pullorum* coloured antigen has been fully revised and the monograph of *Brucella abortus* coloured antigen has been omitted. The inactivation test has been added in many monographs. Any necessary corrections have been incorporated in this edition.

General Chapters

Volume I is devoted mainly to test methods that are applicable to all the articles of the pharmacopoeia and general information pertaining to the quality requirements of medicinal substances. It also includes reference data such as reference spectra, typical chromatograms etc. The test methods reflect the sophistication of analytical methodology and instrumentation.

Analytical methods are, in general, in harmony with those adopted internationally for monitoring the quality of drugs. The steps taken for harmonization have been initiated by the need to cope with the increasing demand for drugs manufactured in the country to meet globally accepted standards.

Accordingly we have introduced 19 new chapters based on current technologies used by the stakeholders and harmonized with other international pharmacopoeias; like mass spectroscopy, inductively coupled mass spectroscopy and polymorphism etc.

The trend towards controlling the microbial quality of all medicinal products has been recognized and the requirement regarding limits of microbial contamination, even of products

for oral administration and topical application, so that adequate controls are exercised by the manufacturers by the adoption of GMPs has been continued.

General chapters on Bacterial Endotoxins, Microbial contamination of non-sterile products, Microbiological quality of pharmaceutical preparations, Microbiological assay of antibiotics and Sterility has been extensively revised. The general chapters of Microbial contamination of non sterile products and Microbiological quality of pharmaceutical preparations have been merged together. For the first time, a general chapter on Maintenance, identification, preservation and disposal of microorganisms has been added. The two general chapters on (i) Transfusion and infusion assemblies and similar medical devices and (ii) Amino acid analysis have been also included first time. The general monographs on Purified Water and Water for Injections in bulk have been fully revised and a comprehensive note on Drinking Water has been incorporated in the general chapter of Water for pharmaceutical use.

In the Herbs and herbal products section, the chapter on DNA based authentication techniques of herbal drugs and determination of flash point of essential oils has been incorporated.

The chapter on biotechnology derived therapeutic products has been fully revised. Special emphasis has been given on monoclonal antibodies antisera.

Monographs

The General Monographs for dosage forms of active pharmaceutical ingredients (APIs) are grouped together at the beginning of Volume II. They are followed by the monographs for the APIs, pharmaceutical aids and individual dosage forms, all in alphabetical order upto Volume III. Monographs for other articles of a special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and radiopharmaceuticals preparations are given in separate sections in Volume III. Special emphasis has been given to veterinary monographs adding and updating in volume IV.

A list of 577 new monographs not included in the 2010 edition of the Indian Pharmacopoeia and its addendum 2012 but added in this edition is given below:

Admissions

General Chapters

2.2.17. DNA based Authentication techniques

2.2.18. Transfusion and Infusion Assemblies and similar Medical Devices

2.2.19. Amino Acid Analysis	Aminophylline Prolonged-release Tablets	Carisoprodol Tablets
2.3.51. 2-Ethylhexanoic Acid	Amiodarone Intravenous Infusion	Cefpirome Injection
2.3.52. Assay of Folic Acid	Amisulpride	Cefpirome Sulphate
2.3.53. Ammonium	Amisulpride Tablets	Ceftiofur Sodium
2.3.54. Assay of Alpha tocopherol	Amorolfine Hydrochloride	Celiprolol Hydrochloride
2.3.55. Fluorides	Aprotinin	Celiprolol Tablets
2.4.35. Bulk Density and Tapped Density of Powders	Aripiprazole	Chloramphenicol Ear Drops
2.4.36. Completeness of Solution	Ascorbyl Palmitate	Chlorohexidine Mouthwash
2.4.37. Crystallinity	Aspirin Gastro-resistant Tablets	Cilostazol
2.4.38. Specific Surface Area	Atomoxetine Hydrochloride	Cilostazol Tablets
2.4.39. Mass Spectroscopy	Atracurium Besylate Injection	Citicoline Sodium
2.4.40. Ethylene Oxide and Dioxan	Atracurium Besylate	Clemastine Fumarate
2.4.41. Acetic Acid in Peptides	Azelaic acid	Clemastine Tablets
2.4.42. Inductively Coupled Plasma - Mass Spectroscopy	Azelastine Eye Drop	Clindamycin Injection
2.4.43. Characterisation of Crystalline and Partially Crystalline solids by X-ray Power Diffraction	Azelastine Hydrochloride	Clindamycin Phosphate
2.4.44. Flash Point	Bambuterol Hydrochloride	Clobetasol Cream
2.5.11. Polymorphism	Bambuterol Tablets	Clobetasol Ointment
Monographs on drug substances, dosage forms and pharmaceutical aids	Benazepril Hydrochloride	Clobetasol Propionate
Acamprosate Calcium	Benazepril Hydrochloride Tablets	Clobetasone Butyrate
Acesulfame Potassium	Benzoyl Peroxide Cream	Clobetasone Cream
Acetretin Capsules	Benzoyl Peroxide Gel	Corn Oil
Aciclovir Cream	Betahistine Mesilate	Cottonseed Oil
Aciclovir Dispersible Tablets	Betamethasone Valerate Cream	Crotamiton
Aciclovir Eye Ointment	Betaxolol Eye Drops	Crotamiton Cream
Aciclovir Oral Suspension	Betaxolol Hydrochloride	Alfacyclodextrin
Acitretin	Bezafibrate	Betacyclodextrin
Adefovir Dipivoxil	Bezafibrate Tablets	Cyclopentolate Eye Drops
Adefovir Tablets	Bicalutamide	Cyclopentolate Hydrochloride
Adenosine	Bicalutamide Tablets	Cyclosporine
Adenosine Injection	Bortezomib	Cyclosporine Capsules
Adipic Acid	Cabergoline	Dalteparin Sodium
Albendazole Oral Suspension	Cabergoline Tablets	Dalteparin Sodium Injection
Alfacalcidol	Caffeine Citrate Oral Solution	Desmopressin
Alfuzosin Hydrochloride	Calcipotriol Anhydrous	Desmopressin Intranasal Solution
Alfuzosin Prolonged-release Tablets	Calcipotriol Ointment	Diclofenac Prolonged-release Tablets
Alfuzosin Tablets	Calcitonin (Salmon)	Diltiazem Injection
Alprazolam Prolonged-release Tablets	Calcitonin (Salmon) Injection	Dipivefrine Eye drops
Alprostadil	Calcium Dobesilate Monohydrate	Dipivefrine Hydrochloride
Alprostadil Injection	Carboplatin	Dipyridamole
	Carboplatin Injection	Dipyridamole Tablets
	Carboxymethylcellulose Calcium	Divalproex Prolonged-release Tablets
	Carboxymethylcellulose Eye Drops	Dobutamine Hydrochloride
	Carisoprodol	Dobutamine Injection
		Docetaxel Anhydrous

Domperidone Suspension	Flupentixol Injection	Iron and Folic Acid Tablets
Dopamine Hydrochloride	Flurazepam Capsules	Isopropyl Palmitate
Dopamine Injection	Flurazepam Hydrochloride	Isopropyl Rubbing Alcohol
Doxapram Hydrochloride	Flurbiprofen Eye Drops	Isotretinoin
Doxapram Injection	Flurbiprofen Sodium	Ivermectin
Drotaverine Tablets	Flutamide Tablets	Ivermectin Injection
Dutasteride	Fluticasone Cream	Labetalol Injection
Ebastine	Fluticasone Nasal Spray	Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
Eberconazole Nitrate	Fluticasone Ointment	Lapatinib Ditosylate
Entacapone	Fluvastatin Capsules	Lapatinib Tablets
Ephedrine Nasal Drops	Fluvastatin Sodium	Leflunomide
Epinastine Eye Drops	Fluvoxamine Maleate	Leflunomide Tablets
Epinastine Hydrochloride	Fluvoxamine Tablets	Levodropropizine
Eplerenone	Fosinopril Sodium	Levofloxacin Injection
Eptifibatide	Fosinopril Sodium Tablets	Levosaltbutamol Hydrochloride
Eptifibatide Injection	Gemcitabine Hydrochloride	Levosaltbutamol Inhalation Solution
Erlotinib Hydrochloride	Gemcitabine Injection	Lithium Carbonate Prolonged-release Tablets
Erlotinib Tablets	Gemfibrozil	Lorazepam
Esmolol Hydrochloride	Gemfibrozil Capsules	Lorazepam Injection
Ethambutol Injection	Glutaraldehyde Solution	Lorazepam Tablets
Ethanolamine	Strong Glutaraldehyde Solution	Meloxicam
Ethophylline and Theophylline Tablets	Glycerin Oral Solution	Mesalazine
Ethyl Vanillin	Diluted Glyceryl Trinitrate	Mesalazine Prolonged-release Tablets
Ethylparaben	Hydrocortisone Ointment	Metoprolol Injection
Etidronate Disodium	Hydrocortisone Acetate Cream	Midazolam
Etidronate Tablets	Hydrogenated Vegetable Oil	Midazolam Injection
Etoricoxib	Hydroxychloroquine Sulphate	Midazolam Oral Solution
Etoricoxib Tablets	Hydroxychloroquine Tablets	Mifepristone
Ezetimibe	Hydroxyethylcellulose	Mifepristone Tablets
Ezetimibe Tablets	Hydroxypropyl Methylcellulose Phthalate	Misoprostol Tablets
Famciclovir	Hydroxyzine Hydrochloride	Mitomycin
Famciclovir Tablets	Hydroxyzine Oral Solution	Mitomycin Injection
Flavoxate Hydrochloride	Hydroxyzine Tablets	Morphine Tablets
Flavoxate Tablets	Imatinib Tablets	Moxifloxacin Eye Drops
Flucloxacillin Capsules	Imidurea	Moxifloxacin Hydrochloride
Flucloxacillin Oral solution	Invert Syrup	Mupirocin
Flucloxacillin Sodium	Iopanoic Acid	Mupirocin Ointment
Fludarabine Phosphate	Iopanoic Acid Tablets	Nicorandil
Fludarabine Phosphate Injection	Irbesartan	Nicorandil Prolonged-release Tablets
Flumazenil	Irbesartan and Hydrochlorothiazide Tablets	Nicorandil Tablets
Flumazenil Injection	Irbesartan Tablets	Octyl Dodecanol
Fluorometholone	Iron and Folic Acid Syrup	
Fluorometholone Eye Drops		
Flupentixol Decanoate		

Ofloxacin Oral Suspension	Saquinavir Capsules	Atosiban Acetate
Ornidazole Injection	Selegiline Hydrochloride	Azelnidipine
Oxacillin Capsules	Selegiline Tablets	Azacitidine
Oxacillin Sodium	Sertraline Hydrochloride	Biapenam
Ozagrel Hydrochloride	Sertraline Tablets	Brinzolamide
Paracetamol Infusion	Silver Sulphadiazine	Choline Fenofibrate
Paracetamol Paediatric Oral Suspension	Silver Sulphadiazine Cream	Dapoxetine Hydrochloride
Parecoxib Sodium	Sodium Nitopruside	Dexlansoprazole
Paroxetine Hydrochloride	Sodium Nitroprusside Injection	Dienogest
Paroxetine Tablets	Monobasic Sodium Phosphate	Eletriptan Hydrobromide
Petrolatum	Sodium Valproate Gastro-resistant Tablets	Eslicarbazepine
Phenylethyl Alcohol	Sorafenib Tablets	Fasoterodine Fumarate
Phenylramidol Hydrochloride	Sorafenib Tosylate	Fasudil Hydrochloride
Phenylramidol Tablets	Soyabean Oil	Fenspiride Hydrochloride
Pitavastatin Calcium	Sulpiride	Fingolimod Hydrochloride
Polacrillin Potassium	Sulpride Tablets	Fomepizole
Polyvinyl Acetate Phthalate	Surgical Spirit	Frovatriptan Succinate
Polyvinyl Alcohol	Tenofovir Fumarate, Lamivudine and Efavirenz Tablets	Galanthamine Hydrobromide
Potassium Chloride for Injection	Theophylline Prolonged-release Tablets	Ibudilast
Prednisolone Sodium Phosphate Eye Drops	Tranexamic Acid	Ilaprazole
Pemetrexed Disodium	Tranexamic Acid Injection	Iloperidone
Procarbazine Hydrochloride	Tranexamic Acid Tablets	Levo Bupivacaine Hydrochloride
Progesterone	Triclofos Oral Solution	Lubiprostone
Progesterone Injection	Triclofos Sodium	Moexipril Hydrochloride
Propylidone	Ursodeoxycholic Acid	Naproxinod
Propylidone Injectable Oil Suspension	Ursodeoxycholic Acid Tablets	Ramelteon
Pyridostigmine Bromide	Vecuronium Bromide	Rilpivirine
Pyridostigmine Injection	Vecuronium Bromide Injection	Roflumilast
Pyridostigmine Tablets	Voglibose	Rufinamide
Racecadotril	Voglibose Dispersible Tablets	Safinamide Methane Sulphonate
Racecadotril Capsules	Voglibose Tablets	Seratrodast
Racecadotril Sachet	Zonisamide	Tapentadol Hydrochloride
Raloxifene Hydrochloride	Zopiclone	Tauroursodeoxycholic Acid
Rebamipide	Zopiclone Tablets	Tofluprost
Reboxetine Methanesulphonate	Zuclopenthixol Acetate	Tolvaptan
Repaglinide	Zuclopenthixol Acetate Injection	Tranilast
Repaglinide Tablets		Trimethobenzamide Hydrochloride
Risendronate Sodium	New Drugs Substances Monographs	Udenafil
Ritodrine Hydrochloride	Agomelatine	Ulipristal Acetate
Ritodrine Injection	Arbidol Hydrochloride	Antibiotic Monographs
Ritodrine Tablets	Arterolane Maleate	Colistimethate Injection
Rupatidine Fumarate	Asenapine Maleate	Colistimethate Sodium
		Colistin Sulphate

Colistin Tablets
 Gramicidin
 Natamycin
 Natamycin Ophthalmic Suspension
 Netilmicin Sulphate
 Sisomicin Sulphate
 Sisomicin Sulphate Injection
 Teicoplanin
 Tyrothricin

Radiopharmaceutical Monographs

Radiopharmaceuticals
 (¹³¹I) Meta-Iodobenzyl Guanidine Injection for Diagnostic Use
 (¹³¹I) Meta-Iodobenzyl Guanidine Injection for Therapeutic Use
 Fluorodeoxyglucose (¹⁸F) Injection
 Samarium (¹⁵³Sm) Ethylene Diamine Tetramethylene Phosphonate (EDTMP) Injection
 Sodium Fluoride (¹⁸F) Injection
 Sodium Iodide (¹³¹I) Capsules for Diagnostic Use
 Sodium Iodide (¹³¹I) Capsules for Therapeutic Use
 Sodium Iodide (¹³¹I) Solution
 Sodium Pertechnetate (^{99m}Tc) Injection (Fission)
 Sodium Pertechnetate (^{99m}Tc) Injection (Non-fission)
 Sodium Phosphate (³²P) Injection
 Technetium (^{99m}Tc) DMSA Injection
 Technetium (^{99m}Tc) DTPA Injection
 Technetium (^{99m}Tc) EC Injection
 Technetium (^{99m}Tc) ECD Injection
 Technetium (^{99m}Tc) Glucoheptonate Injection
 Technetium (^{99m}Tc) Mebrofenin Injection
 Technetium (^{99m}Tc) Medronate Complex Injection
 Technetium (^{99m}Tc) MIBI Injection

Herbal Monographs

Amaltas
 Bala

Basil Oil
 Bakuci
 Belladonna Soft Extract
 Black Pepper Oil
 Caraway Oil
 Cardamom Oil
 Clove Bud Oil
 Clove Leaf Oil
 Clove Stem Oil
 Cumin Oil
 Dill Seed Oil
 Ergot
 Ivy Leaf
 Ivy Leaf Dry Extract
 Kaunch
 Lavender Oil
 Lemon Grass Oil
 Lemon Oil
 Lime Oil
 Mentha Arvensis Oil
 Nagakesar
 Nutmeg Oil
 Prepared Ergot
 Rosemarry Oil
 Thyme Oil
 Valerian Dry Extract
 Valerian Root
 Vidanga
 Vijaysara

Human Vaccines

Cholera Vaccine (Inactivated, Oral)
 Diphtheria Vaccine (Adsorbed) for Adults and Adolescents
 Group A Meningococcal Conjugate Vaccine
 Meningococcal Polysaccharide A and C Vaccine
 Rotavirus Vaccine (Live Attenuated, Oral)

Insulin Products

Biphasic Insulin Aspart Injection
 Biphasic Insulin Lispro Injection
 Insulin Aspart

Insulin Aspart Injection
 Insulin Lispro
 Insulin Lispro Injection
Biotechnology Products
 Erythropoietin for Injection
 Erythropoietin Injection
 Filgrastim Injection
 Interferon Alfa-2a Injection
 Interferon Alfa-2b Injection
 Interferon Beta-1a Concentrated Solution

Recombinat Streptokinase Injection

Veterinary Non-biological Monographs

Activated Charcoal
 Adrenaline Tartrate
 Albendazole Oral Suspension
 Amitraz Pour-on
 Amoxicillin Oral Powder
 Amoxicillin Injection
 Ampicillin Injection
 Ampicillin Sodium
 Ampicillin Trihydrate
 Benzocaine
 Benzyl Benzoate Application
 Benzylpenicillin Injection
 Benzylpenicillin Potassium
 Benzylpenicillin Sodium
 Betamethasone Injection
 Betamethasone Sodium Phosphate
 Buserelin
 Buserelin Injection
 Calcium Levulinate Injection
 Carprofen
 Cefoperazone Injection
 Cefoperazone Sodium Intramammary Suspension
 Cefpodoxime Oral Suspension
 Cefpodoxime Tablets
 Cefprozime for Injection
 Cefprozime Sodium
 Ceftriaxone Injection
 Chloramphenicol
 Chloramphenicol Sodium Succinate
 Chlorpheniramine Injection

Chlorpromazine Hydrochloride	Levofloxacin Hemihydrate	Testosterone Propionate
Chlorpromazine Injection	Light Kaolin	Testosterone Propionate Injection
Cholecalciferol	Light Magnesium Carbonate	Thiabendazole
Chorionic Gonadotropin	Lignocaine Hydrochloride	Tinidazole Tablets
Ciprofloxacin Injection	Lignocaine Injection	Tocopheryl Acetate
Ciprofloxacin Tablets	Lincomycin Hydrochloride	Trimethoprim
Cloprostenol Injection	Magnesium Sulphate	Xylazine Hydrochloride
Cloprostenol Sodium	Marbofloxacin	Zinc Oxide Cream
Closantel Sodium Dihydrate	Meloxicam Injection	Veterinary Biological Monographs
Cloxacillin Injection	Mepyramine Injection	Bluetongue Vaccine Inactivated
Cloxacillin Sodium	Mepyramine Maleate	Brucella Abortus (Strain 19 Vaccine) Live
Cynocobalamin	Methyl Ergometrine Injection	Brucella Melitensis (Strain Rev. 1) Vaccine, Live,
Cynocobalamin Injection	Methylprednisolone Acetate	Canine Adenovirus Vaccine, Inactivated
Decoquinat	Methylprednisolone Acetate Injection	Canine Adenovirus Vaccine, Live
Decoquinat Premix	Monosulfiram	Haemorrhagic Septicaemia Vaccine-Alum Treated
Deltamethrin	Morphine Injection	Laryngotracheitis Vaccine, Live (Avian Infectious Laryngotracheitis Vaccine, Live)
Deltamethrin Pour-on	Morphine Sulphate	Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats
Dexamethasone Injection	Moxidectin	Veterinary Diagnostic Monograph
Dexamethasone Sodium Phosphate	Moxidectin Injection	Avian Tuberculin Purified Protein Derivative (PPD)
Diazepam	Neomycin Sulphate	Veterinary Immoserum Monographs
Diazepam Injection	Niclosamide	Clostridium Novyi Alpha Antitoxin
Diclazuril	Oestradiol Benzoate	Clostridium Perfringens Antitoxins
Dicloxacillin Sodium	Oestradiol Injection	Clostridium Perfringens Beta Antitoxin
Diethylcabamazine Citrate	Ornidazole	Clostridium Perfringens Epsilon Antitoxin
Diethylcabamazine Tablets	Oxytetracycline Hydrochloride	Clostridium Tetani Antitoxin
Docetaxel Injection	Oxytetracycline Hydrochloride Injection	Veterinary Surgical Monographs
Enrofloxacin	Oxytetracycline Injection	Sterile Braided Silk Suture in Distributor
Febantel	Paclitaxel Injection	Sterile Catgut in Distributor
Febendazole Granules	Pentobarbitone Sodium	Sterile Linen Thread in Distributor
Febendazole Oral Paste	Promethazine Hydrochloride	Sterile Non-absorbable Strands in Distributor
Febendazole Oral Powder	Promethazine Injection	Sterile Poly (ethylene terephthalate) Suture in Distributor
Febendazole Oral Suspension	Pyridoxine Hydrochloride	
Ferrous Fumerate Tablets	Sodium Dihydrogen Phosphate Dihydrate	
Flunixin Meglumine	Sodium Thiosulphate	
Frusamide Injection	Streptomycin Sulphate	
Furazolidone	Sulphadiazine and Trimethoprim Tablets (Co-trimazine Tablets)	
Gentamicin Injection	Sulphadimidine	
Iron Dextran Injection	Sulphadimidine Injection	
Isoflupredone Acetate	Sulphadimidine Sodium	
Isoflupredone Acetate Injectable Suspension	Sulphadimidine Tablets	
Ivermectin Oral Paste	Sulphadiazine	
Ivermectin Pour-on		
Levamisole Hydrochloride		

Sterile Polyamide 6 Suture in Distributor

Sterile Polyamide 6/6 Suture in Distributor

Upgradation

General Chapters upgraded:

2.2.3. Bacterial Endotoxins

2.2.9. Microbial Contamination in Non Sterile Products (5.9. Microbiological Quality of Pharmaceutical Preparations merged)

2.2.11. Sterility

2.3.31. Nitrite Titration

2.3.34. Oxygen Flask Method

2.3.38. Assay of Steroids

2.3.48 Thiomersal

2.4.9. Conductivity

2.4.17. Thin-Layer Chromatography

2.4.23. Osmolality

2.4.25. Titrimetry

2.4.27. Refractive Index

2.4.28. Viscosity

2.4.29. Weight Per Milliliter and Relative Density (Specific Gravity)

2.4.31. Thermal Analysis

2.4.34. Nuclear Magnetic Resonance Spectrometry

2.5.7. Particle Size Distribution Estimation

2.5.8. Optical Microscopy: Particle Size by Microscopy

2.8.11. A. Determination of ABO Blood Group of Blood donors

5.4. Residual solvents

Monographs on drug substances, dosage forms and pharmaceutical aids given below have been upgraded:

Amikacin

Amikacin Injection

Amikacin Sulphate

Amiodarone Hydrochloride

Amiodarone Tablets

Ampicillin Trihydrate

Anti-A Blood grouping Serum

Anti-B Blood grouping Serum

Aspirin

Azithromycin

Azithromycin Tablets

Belladonna Dry Extract

Biotechnology Derived Therapeutic Products

Blackquarter Vaccine

Bupivacaine Hydrochloride

Bupivacaine Injection

Butylparaben

Caffeine

Cefuroxime Axetil

Chloroquine Phosphate

Chloroquine Phosphate tablets

Cholecalciferol Tablets

Clarithromycin

Clofazimine

Clofazimine Capsules

Clonidine Hydrochloride

Clotrimazole

Cloxacillin Sodium

Codeine Phosphate

Colchicine Tablets

Coriander Oil

Cyclizine Hydrochloride

Cyclophosphamide Injection

Diazepam

Digoxin

Diphenhydramine Hydrochloride

Diphtheria and Tetanus Vaccine (Adsorbed)

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)

Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenza type B Conjugate Vaccine (Adsorbed)

Dithranol

Docetaxel Injection

Donepezil Tablets

Doxepin Hydrochloride

Econazole Nitrate

Erythropoietin Concentrated Solution

Etoposide

Eucalyptus Oil

Fibrin Sealant Kit

Filgrastim Concentrated Solution

Finasteride Tablets

Fluphenazine Decanoate

Fluphenazine Decanoate Injection

Fluphenazine Hydrochloride

Fumaric Acid

Haemorrhagic Septicaemia Vaccine

Haloperidol

Hepatitis B Vaccine (rDNA)

Homatropine Hydrobromide

Human Albumin

Dried Human Anti-Haemophilic fraction (Freeze dried Human Coagulation factor VIII)

Human Normal Immunoglobulin

Human Normal Immunoglobulin for Intravenous Use

Human Plasma Protein Fraction

Human Coagulation Factor IX

Hydrochlorothiazide

Hydrochlorothiazide Tablets

Hyoscine Butylbromide

Hyoscine Hydrobromide

Hyoscine Hydrobromide Injection

Hyoscine Hydrobromide Tablets

Interferon Alfa-2 Concentrated solution

Ipratropium Bromide

Isoprenaline Hydrochloride

Isoprenaline Injection

Lamivudine

Lamivudine, Nevirapine and Stavudine Dispersible Tablets

Lamivudine and Zidovudine Tablets

Lamotrigine Prolonged-release Tablets

Levamisole Hydrochloride

Levodopa

Levofloxacin Hemihydrate

Levonorgestrel Tablets

Lignocaine and Adrenaline Injection

Measles, Mumps and Rubella Vaccine (Live)

Mepyramine Maleate

Methadone Hydrochloride	Shatavari
Methotrexate	Sodium Methylparaben
Methotrexate Injection	Sodium Propylparaben
Methotrexate Tablets	Sodium Stibogluconate
Methylergometrine Maleate	Terbutaline Tablets
Methylparaben	Tetanus Vaccine (Adsorbed)
Mexiletine Hydrochloride	Thiotepa Injection
Mianserin Hydrochloride	Thyroxine Tablets
Montelukast Sodium	Timolol Maleate
Nicotinic Acid	Tolbutamide
Nitrazepam	Tolnaftate
Nortriptyline Hydrochloride	Travoprost Eye Drops
Ondansetron Oral Solution	Triamterene
Ondansteron Tablets	Trimethoprim
Orphenadrine Citrate	Tropicamide
Orphenadrine Hydrochloride	Verapamil Injection
Peppermint Oil	Vinorelbine Injection
Perphenazine	Water for Injections in Bulk
Phenobarbitone	
Phentolamine Injection	
Phentolamine Mesylate	
Phenylephrine Hydrochloride	
Phenytoin	
Phenytoin Sodium	
Pholcodine	
Pilocarpine Nitrate	
Pneumococcal Polysaccharide Vaccine (Liquid/ Adsorbed)	
Poliomyelitis Vaccine (Inactivated)	
Pregabalin	
Primaquine Tablets	
Propylparaben	
Purified Water	
Pyridoxine Hydrochloride	
Ramipril and Hydrochlorothiazide Tablets	
Ranitidine Hydrochloride	
Recombinant Streptokinase Bulk Solution	
Ribavirin	
Salbutamol Syrup	
Salicylic Acid	
Salmeterol Xinafoate	
S-amlodipine Besylate	

Changed Titles

Changed Titles of General Chapters

From '2.4.25.Potentiometric Titration' to '2.4.25.Titrimetry'
From '2.4.29.Weight Per Millilitre and Relative Density' to '2.4.29.Weight Per Millilitre and Relative Density (Specific Gravity)'
From '2.4.31. Differential Scanning Calorimetry (DSC)' to '2.4.31. Thermal Analysis'
From '2.4.34. Nuclear Magnetic Resonance' to '2.4.34. Nuclear Magnetic Resonance Spectrometry'
From '2.5.7. Powder Fineness' to '2.5.7.Particle Size Distribution Estimation'
From '2.5.8. Particle Size by Microscopy' to '2.5.8.Optical Microscopy: Particle Size by Microscopy'
From '5.10. Reference Substances (IPRS)' to '5.9. Reference Substances (IPRS)'

Changed Titles of Monographs

From 'Bisacodyl Tablets' to 'Bisacodyl Gastro-resistant Tablets'
From 'Carbamazepine Extended-release Tablets' to 'Carbamazepine Prolonged-release Tablets'
From 'Cefaclor Sustained-release Tablets' to 'Cefaclor Prolonged-release Tablets'
From 'Diclofenac Tablets' to 'Diclofenac Gastro-resistant Tablets'
From 'Didanosine Capsules' to 'Didanosine Gastro-resistant Capsules'
From 'Divalproex Tablets' to 'Divalproex Gastro-resistant Tablets'
From 'Disopyramide Phosphate Sustained-release Capsules' to 'Disopyramide Phosphate Prolonged-release Capsules'
From 'Erythromycin Tablets' to 'Erythromycin Gastro-resistant Tablets'
From 'Esomeprazole Tablets' to 'Esomeprazole Gastro-resistant Tablets'
From 'Felodipine Sustained-release Tablets' to 'Felodipine Prolonged-release Tablets'
From 'Lansoprazole Tablets' to 'Lansoprazole Gastro-resistant Tablets'
From 'Lamotrigine Sustained-release Tablets' to 'Lamotrigine Prolonged-release Tablets'
From 'Metformin Hydrochloride Sustained-release Tablets' to 'Metformin Hydrochloride Prolonged-release Tablets'
From 'Naproxen Sustained-release Tablets' to 'Naproxen Prolonged-release Tablets'
From 'Nifedipine Sustained-release Tablets' to 'Nifedipine Prolonged-release Tablets'
From 'Omeprazole Tablets' to 'Omeprazole Gastro-resistant Tablets'

From 'Pantoprazole Tablets' to 'Pantoprazole Gastro-resistant Tablets'

From 'Rabeprazole Tablets' to 'Rabeprazole Gastro-resistant Tablets'

From 'Valproate Injection' to 'Sodium Valproate Injection'

From 'Salmonella pullorum Antigen' to 'Salmonella pullorum coloured Antigen'

Omissions

Chloral hydrate

Brucella Abortus Coloured Antigen

* Liposomal Amphotericin B Injection

Concentrated Glyceryl Trinitrate Solution

* To be upgraded.