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 articles 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 up to 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 576 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 or Sterile Assemblies and medical Devices
2.2.19. Amino Acid Analysis
2.3.51. 2-Ethylhexanoic Acid
2.3.52. Assay of Folic Acid
2.3.53. Ammonium
2.3.54. Assay of Alpha tocopherol
2.3.55. Fluorides
2.4.35. Bulk Density and Tapped Density of Powders
2.4.36. Completeness of Solution
2.4.37. Crystallinity
2.4.38. Specific Surface Area
2.4.39. Mass Spectroscopy
2.4.40. Ethylene Oxide and Dioxan
2.4.41. Acetic Acid in Peptides
2.4.42. Inductively Coupled Plasma - Mass Spectroscopy
2.4.43. Characterisation of Crystalline and Partially Crystalline solids by X-ray Power Diffraction
2.4.44. Flash Point
2.5.11. Polymorphism

**Monographs on drug substances, dosage forms and pharmaceutical aids**

Acamprosate Calcium
Acesulfame Potassium
Acetretin Capsules
Aciclovir Cream
Aciclovir Dispersible Tablets
Aciclovir Eye Ointment
Aciclovir Oral Suspension
Acitretin
Adefovir Dipivoxil
Adefovir Tablets
Adenosine
Adenosine Injection
Adipic Acid
Albendazole Oral Suspension
Alfacalcidol
Alfuzosin Hydrochloride
Alfuzosin Prolonged-release Tablets
Alfuzosin Tablets
Alprazolam Prolonged-release Tablets
Alprostadil
Alprostadil Injection
Aminophylline Prolonged-release Tablets
Amiodarone Intravenous Infusion
Amisulpride
Amisulpride Tablets
Amorolfine Hydrochloride
Aprotinin
Aripiprazole
Ascorbyl Palmitate
Aspirin Gastro-resistant Tablets
Atomoxetine Hydrochloride
Atracurium Besylate Injection
Atracurium Besylate
Azelaic acid
Azelastine Eye Drop
Azelastine Hydrochloride
Bambuterol Hydrochloride
Bambuterol Tablets
Benazepril Hydrochloride
Benazepril Hydrochloride Tablets
Benzoyl Peroxide Cream
Benzoyl Peroxide Gel
Betahistine Mesilate
Betamethasone Valerate Cream
Betaxolol Eye Drops
Betaxolol Hydrochloride
Bezafibrate
Bezafibrate Tablets
Bicalutamide
Bicalutamide Tablets
Bortezomib
Cabergoline
Cabergoline Tablets
Caffeine Citrate Oral Solution
Calcipotriol Anhydrous
Calcipotriol Ointment
Calcitonin (Salmon)
Calcitonin (Salmon) Injection
Calcium Dobesilate Monohydrate
Carboplatin
Carboplatin Injection
Carboxymethylcellulose Calcium
Carboxymethylcellulose Eye Drops
Carisoprodol
Carisoprodol Tablets
Cefpirome Injection
Cefpirome Sulphate
Ceftiofur Sodium
Celiprolol Hydrochloride
Celiprolol Tablets
Chloramphenicol Ear Drops
Chlorohexidine Mouthwash
Cilostazol
Cilostazol Tablets
Citicoline Sodium
Clemastine Fumarate
Clemastine Tablets
Clindamycin Injection
Clindamycin Phosphate
Clobetasol Cream
Clobetasol Ointment
Clobetasol Propionate
Clobetasone Butyrate
Clobetasone Cream
Colistimethate Injection
Colistimethate Sodium
Corn Oil
Cottonseed Oil
Crotamiton
Crotamiton Cream
Alfacyclodextrin
Betacyclodextrin
Cyclopentolate Eye Drops
Cyclopentolate Hydrochloride
Cyclosporine
Cyclosporine Capsules
Dalteparin Sodium
Dalteparin Sodium Injection
Desmopressin
Desmopressin Intranasal Solution
Diclofenac Prolonged-release Tablets
Diltiazem Injection
Dipivefrine Eye drops
Dipivefrine Hydrochloride
Dipyridamole
Dipyridamole Tablets
Divalproex Prolonged-release Tablets
Dobutamine Hydrochloride
Dobutamine Injection
Docetaxel Anhydrous
Domperidone Suspension
Dopamine Hydrochloride
Dopamine Injection
Doxapram Hydrochloride
Doxapram Injection
Drotaverine Tablets
Dutasteride
Ebastine
Eberconazole Nitrate
Entacapone
Ephedrine Nasal Drops
Epinastine Eye Drops
Epinastine Hydrochloride
Eplerenone
Eptifibatide
Eptifibatide Injection
Erlotinib Hydrochloride
Erlotinib Tablets
Esmolol Hydrochloride
Ethambutol Hydrochloride
Ethanolamine
Ethopropazine and Theophylline Tablets
Etilanol
Etilparaben
Etidronate Disodium
Etidronate Tablets
Etoricoxib
Etoricoxib Tablets
Ezetimibe
Ezetimibe Tablets
Famciclovir
Famciclovir Tablets
Flavoxate Hydrochloride
Flavoxate Tablets
Flucloxacillin Capsules
Flucloxacillin Oral solution
Flucloxacillin Sodium
Fludarabine Phosphate
Fludarabine Phosphate Injection
Flumazenil
Flumazenil Injection
Fluorometholone
Fluorometholone Eye Drops
Flupentixol Decanoate
Flupentixol Injection
Flurazepam Capsules
Flurazepam Hydrochloride
Flurbiprofen Eye Drops
Flurbiprofen Sodium
Flutamide Tablets
Fluticasone Cream
Fluticasone Nasal Spray
Fluticasone Ointment
Fluvastatin Capsules
Fluvastatin Sodium
Fluvoxamine Maleate
Fluvoxamine Tablets
Fosinopril Sodium
Fosinopril Sodium Tablets
Gemcitabine Hydrochloride
Gemcitabine Injection
Gemfibrozil
Gemfibrozil Capsules
Glutaraldehyde Solution
Strong Glutaraldehyde Solution
Glycerin Oral Solution
Diluted Glyceryl Trinitrate
Hydrocortisone Ointment
Hydrocortisone Acetate Cream
Hydrogenated Vegetable Oil
Hydroxychloroquine Sulphate
Hydroxychloroquine Tablets
Hydroxyethylcellulose
Hydroxypropyl Methylcellulose Phthalate
Hydroxypropyl Methylcellulose Phthalate
Hydroxyzine Hydrochloride
Hydroxyzine Oral Solution
Hydroxyzine Tablets
Imatinib Tablets
Imidurea
Invert Syrup
Iopanoic Acid
Iopanoic Acid Tablets
Irbesartan
Irbesartan and Hydrochlorothiazide Tablets
Irbesartan Tablets
Iron and Folic Acid Syrup
Iron and Folic Acid Tablets
Isopropyl Palmitate
Isopropyl Rubbing Alcohol
Isotretinoin
Ivermectin
Ivermectin Injection
Labetalol Injection
Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
Lapatinib Ditosylate
Lapatinib Tablets
Leflunomide
Leflunomide Tablets
Levodropropizine
Levofloxacin Injection
Levosalbutamol Hydrochloride
Levosalbutamol Inhalation Solution
Lithium Carbonate Prolonged-release Tablets
Lorazepam
Lorazepam Injection
Lorazepam Tablets
Meloxicam
Mesalazine
Mesalazine Prolonged-release Tablets
Metoprolol Injection
Midazolam
Midazolam Injection
Midazolam Oral Solution
Mifepristone
Mifepristone Tablets
Misoprostol Tablets
Mitomycin
Mitomycin Injection
Morphine Tablets
Moxifloxacin Eye Drops
Moxifloxacin Hydrochloride
Mupirocin
Mupirocin Ointment
Nicorandil
Nicorandil Prolonged-release Tablets
Nicorandil Tablets
Octyl Dodecanol
Ofloxacin Oral Suspension
Ornidazole Injection
Oxacillin Capsules
Oxacillin Sodium
Ozagrel Hydrochloride
Paracetamol Infusion
Paracetamol Paediatric Oral Suspension
Parecoxib Sodium
Paroxetine Hydrochloride
Paroxetine Tablets
Petrolatum
Phenylethyl Alcohol
Phenyramidol Hydrochloride
Phenyramidol Tablets
Pitavastatin Calcium
Polacrilin Potassium
Polyvinyl Acetate Phthalate
Polyvinyl Alcohol
Potassium Chloride for Injection
Prednisolone Sodium Phosphate Eye Drops
Pemetrexed Disodium
Procarbazine Hydrochloride
Progesterone
Progesterone Injection
Propyliodone
Propyliodone Injectable Oil Suspension
Pyridostigmine Bromide
Pyridostigmine Injection
Pyridostigmine Tablets
Racecadotril
Racecadotril Capsules
Racecadotril Sachet
Raloxifene Hydrochloride
Rebamipide
Reboxetine Methanesulphonate
Repaglinide
Repaglinide Tablets
Risedronate Sodium
Ritodrine Hydrochloride
Ritodrine Injection
Ritodrine Tablets
Rupatidine Fumarate
Saquinavir Capsules
Selegiline Hydrochloride
Selegiline Tablets
Sertraline Hydrochloride
Sertraline Tablets
Silver Sulphadiazine
Silver Sulphadiazine Cream
Sodium Nitroprusside
Sodium Nitroprusside Injection
Monobasic Sodium Phosphate
Sodium Valproate Gastro-resistant Tablets
Sorafenib Tablets
Sorafenib Tosylate
Soyabean Oil
Sulpiride
Sulpride Tablets
Surgical Spirit
Tenofovir Fumarate, Lamivudine and Efavirenz Tablets
Theophylline Prolonged-release Tablets
Tranexamic Acid
Tranexamic Acid Injection
Tranexamic Acid Tablets
Triclofos Oral Solution
Triclofos Sodium
Ursodeoxycholic Acid
Ursodeoxycholic Acid Tablets
Vecuronium Bromide
Vecuronium Bromide Injection
Voglibose
Voglibose Dispersible Tablets
Voglibose Tablets
Zonisamide
Zopiclone
Zopiclone Tablets
Zuclopenthixol Acetate
Zuclopenthixol Acetate Injection

New Drugs Substances Monographs
Agomelatine
Arbidol Hydrochloride
Arterolane Maleate
Asenapine Maleate
Atosiban Acetate
Azelnidipine
Azacitidine
Biapenam
Brinzolamide
Choline Fenofibrate
Dapoxetine Hydrochloride
Dexlansoprazole
Dienogest
Eletriptan Hydrobromide
Eslicarbazepine
Fasoterodine Fumarate
Fasudil Hydrochloride
Fenspiride Hydrochloride
Fingolimod Hydrochloride
Fomepizole
Frovatriptan Succinate
Galanthamine Hydrobromide
Ibudilast
Ilaprazole
Iloperidone
Levo Bupivacaine Hydrochloride
Lubiprostone
Moexipril Hydrochloride
Naproxinod
Ramelteon
Rilpivirine
Roflumilast
Rufinamide
Safinamide Methane Sulphonate
Seratrodast
Tapentadol Hydrochloride
Tauroursodeoxycholic Acid
Tofluprost
Tolvaptan
Tranilast
Trimethobenzamide Hydrochloride
Udenafil
Ulipristal Acetate

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

**Radiopharmaceutical Monographs**
Radiopharmaceuticals
Fluorodeoxyglucose ($^{18}$F) Injection
Iobenguane ($^{131}$I) Injection for Diagnostic use ($^{131}$I-MIBG_diagnostic)
Iobenguane ($^{131}$I) Injection for Therapeutic use ($^{131}$I-MIBG_Therapeutic)
Samarium ($^{153}$Sm) Ethylene DiamineTetramethylenePhosphonate complex (EDTMP) Injection
Sodium Fluoride ($^{18}$F) Injection
Sodium Iodide ($^{131}$I) Capsule for diagnostic use
Sodium Iodide ($^{131}$I) Capsules for therapeutic use
Sodium Iodide ($^{131}$I) Solution
Sodium Pertechnetate (99mTc) Injection (non-fission)
Sodium Pertechnetate (99mTc) Injection (fission)
Sodium Phosphate (32P) Injection
Technetium (99mTc) Bicisate Complex Injection (Technetium (99mTc) ECD Injection)
Technetium (99mTc) Gluceptate Injection (99mTc_GHA_INJECTION)
Technetium (99mTc) Methrofenin complex Injection
Technetium (99mTc) Methylene Diphosphonate (MDP) complex Injection
Technetium (99mTc) Pentetate complex Injection (DTPA)
Technetium (99mTc) Sestamibi complex Injection (99mTc_MIBI_INJECTION)
Technetium (99mTc) Succimer Injection (Technetium [99mTc-(III)] DMSA Injection)
99mTc_EC_Injection

**Herbal Monographs**

Amaltas
Bala
Basil Oil
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
Rosemary 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**
Biotechnology Derived Therapeutic Products
Interferon Alfa-2a Injection
Recombinant Streptokinase Injection
Filgrastim Injection
Erythropoietin for Injection
Erythropoietin Injection
Interferon Beta 1a Concentrated Solution

**Veterinary Non-biological Monographs**
Activated Charcoal
Adrenaline Tartrate
Albendazole Oral Suspension
Amitraz Pour-on
Amoxicillin Oral Powder
Amoxicillin Injection
Amoxicillin Injection
Amoxicillin Sodium
Amoxicillin 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
Ceftizoxime for Injection
Ceftizoxime Sodium
Ceftriaxone Injection
Chloramphenicol
Chloramphenicol Sodium Succinate
Chlorpheniramine Injection
Chlorpromazine Hydrochloride
Chlorpromazine Injection
Cholecalciferol
Chorionic Gonadotropin
Ciprofloxacin Injection
Ciprofloxacin Tablets
Cloprostenol Injection
Cloprostenol Sodium
Closantel Sodium Dihydrate
Cloxacillin Injection
Cloxacillin Sodium
Cynocobalamin
Cynocobalamin Injection
Decoquinate
Decoquinate Premix
Deltamethrin
Deltamethrin Pour-on
Dexamethasone Injection
Dexamethasone Sodium Phosphate
Diazepam
Diazepam Injection
Diclazuril
Dicloxacillin Sodium
Diethylcabamazine Citrate
Diethylcabamazine Tablets
Docetaxel Injection
Enrofloxacin
Febantel
Febendazole Granules
Fenbendazole Oral Paste
Fenbendazole Oral Powder
Fenbendazole Oral Suspension
Ferrous Fumerate Tablets
Flunixin Megglumine
Frusemide Injection
Furazolidone
Gentamicin Injection
Iron Dextran Injection
Isoflupredone Acetate
Isoflupredone Acetate Injectable Suspension
Ivermectin Oral Paste
Ivermectin Pour-on
Levamisole Hydrochloride
Levofoxacin Hemihydrate
Light Kaolin
Light Magnesium Carbonate
Lignocaine Hydrochloride
Lignocaine Injection
Lincomycin Hydrochloride
Magnesium Sulphate
Marbofloxacin
Meloxicam Injection
Mepyramine Injection
Mepyramine Maleate
Methyl Ergometrine Injection
Methylprednisolone Acetate
Methylprednisolone Acetate Injection
Monosulphiram
Morphine Injection
Morphine Sulphate
Moxidectin
Moxidectin Injection
Neomycin Sulphate
Nicolsamide
Oestradiol Benzoate
Oestradiol Injection
Ornidazole
Oxytetracycline Hydrochloride
Oxytetracycline Hydrochloride Injection
Oxytetracycline Injection
Paclitaxel Injection
Pentobarbitone Sodium
Promethazine Hydrochloride
Promethazine Injection
Pyridoxine Hydrochloride
Sodium Dihydrogen Phosphate Dihydrate
Sodium Thiosulphate
Streptomycin Sulphate
Sulphadiazene and Trimethoprim Tablets (Co-trimazine Tablets)
Sulphadimidine
Sulphadimidine Injection
Sulphadimidine Sodium
Sulphadimidine Tablets
Sulphadiazine
Testosterone Propionate
Testosterone Propionate Injection
Thiabendazole
Tinidazole Tablets
Tocopheryl Acetate
Trimethoprim
Xylazine Hydrochloride
Zinc Oxide Cream

**Veterinary Biological Monographs**
- Bluetongue Vaccine Inactivated
- Brucella Abortus (Strain 19 Vaccine) Live
- Brucella Melitensis (Strain Rev.1) Vaccine, Live
- Canine Adenovirus Vaccine, Inactivated
- Canine Adenovirus Vaccine, Live
- Haemorrhagic Septicaemia Vaccine- Alum Treated
- Laryngotracheitis Vaccine, Live (Avian Infectious Laryngotracheitis Vaccine, Live)
- Old Adjuvant Vaccine against Pasteurellosis in Sheep and Goats

**Veterinary Diagnostic Monograph**
- Avian Tuberculin Purified Protein Derivative (PPD)

**Veterinary Immunosera Monographs**
- Clostridium Novyi Alpha Antitoxins
- Clostridium Perfringens Antitoxins
- Clostridium Perfringens Beta Antitoxins
- Clostridium Perfringens Epsilon Antitoxins
- Clostridium Tetani Antitoxins

**Veterinary Surgical Monographs**
- Sterile Braided Silk Suture in Distributor
- Sterile Catgut in Distributor
- Sterile Linen Thread in Distributor
- Sterile Non-absorbable Strands in Distributor
- Sterile Poly (ethylene terephthalate) Suture in Distributor
- Sterile Polyamide 6 Suture in Distributor
- Sterile Polyamide 6/6 Suture in Distributor

**Upgradation**

**General Chapters upgraded:**
- 2.2.3. Bacterial Endotoxin test
- 2.2.9. Microbial Contamination in Non Sterile Products
- 2.2.11. Sterility
- 2.3.31. Nitrite Titration
- 2.3.34. Oxygen Flask Method
- 2.3.38. Assay of Steroids
- 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
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
- Aspirin
- Azithromycin
- Azithromycin Tablets
- Biotechnology Derived Therapeutic Products
- 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
- Cyclizine Hydrochloride
- Cyclophosphamide Injection
- Diazepam
- Digoxin
- Diphenhydramine Hydrochloride
- Dithranol
- Docetaxel Injection
- Donepezil Tablets
- Doxepin Hydrochloride
- Econazole Nitrate
- Etoposide
Finasteride Tablets
Fluphenazine Decanoate
Fluphenazine Decanoate Injection
Fluphenazine Hydrochloride
Fumaric Acid
Haloperidol
Homatropine Hydrobromide
Hydrochlorothiazide
Hydrochlorothiazide Tablets
Hyoscine Butylbromide
Hyoscine Hydrobromide
Hyoscine Hydrobromide Injection
Hyoscine Hydrobromide Tablets
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
Mepyramine Maleate
Methadone Hydrochloride
Methotrexate
Methotrexate Injection
Methotrexate Tablets
Methylergometrine Maleate
Methylparaben
Mexiletine Hydrochloride
Mianserin Hydrochloride
Montelukast Sodium
Nicotinic Acid
Nitrazepam
Nortriptyline Hydrochloride
Ondansetron Oral Solution
Ondansteron Tablets
Orphenadrine Citrate
Orphenadrine Hydrochloride
Perphenazine
Phenobarbitone
Phentolamine Injection
Phentolamine Mesylate
Phenylephrine Hydrochloride
Phenytoin
Phenytoin Sodium
Pholcodine
Pilocarpine Nitrate
Pregabalin
Primaquine Tablets
Propylparaben
Pyridoxine Hydrochloride
Ramipril and Hydrochlorothiazide Tablets
Ranitidine Hydrochloride
Ribavirin
Salbutamol Syrup
Salicylic Acid
Salmeterol Xinafoate
S-amlodipine Besylate
Sodium Methylparaben
Sodium Propylparaben
Sodium Stibogluconate
Terbutaline Tablets
Thiotepa Injection
Thyroxine Tablets
Timolol Maleate
Tolbutamide
Tolnaftate
Travoprost Eye Drops
Triamterene
Trimethoprim
Tropicamide
Verapamil Injection
Vinorelbine Injection
Erythropoietin Concentrated Solution
Filgrastism Concentrated Solution
Interferon Alfa-2 Concentrated solution
Recombinant Streptokinase Bulk Solution
Diphtheria Vaccine (Adsorbed) for Adults and Adolescents
Group A Meningococcal Conjugate Vaccine
Haemorrhagic Septicaemia Vaccine
Blackquarter Vaccine
Water for Injections in Bulk
Purified Water

**Changed Titles**

**Changed Titles of General Chapters**

From ‘2.4.25.Potentiometric Titration’ to ‘2.4.25.Titrmetry’
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**

5.9. Microbiological Quality of Pharmaceutical Preparations

Chloral hydrate

Brucella Abortus Coloured Antigen

* Liposomal Amphotericin B Injection

Concentrated Glycryl Trinitrate Solution

* To be upgraded.