# Introduction

#### Introduction

The eighth edition of the Indian Pharmacopoeia (IP 2018) is published by the Indian Pharmacopoeia Commission (IPC) in accordance with a designed plan by the Scientific Body of IPC, in fulfilment of the requirements of the Drugs and Cosmetics Act 1940 and 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 2014 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 2018 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 Derived Therapeutic products, Allergen products and Radiopharmaceutical preparations, Volume IV contains Veterinary monographs and Index.

The scope of the Indian Pharmacopoeia has been extended to include products of biotechnology, 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 and included in National List of Essential Medicines are added and the drugs as well as their formulations currently not used are omitted from this edition. The number of monographs of Drugs substances, Dosage forms, Excipients, Vaccines and Immunosera for Human use, Herbs and Herbal Products, Blood and Blood related products and Biotechnology Derived Therapeutic products have been increased in this edition. Monographs of Vaccines and Immunosera for Human use are also upgraded in view of the latest development of the technology in the field. Many general chapters such as Tablets, Capsules, Volumetric Glassware and Maintenance, Identification, Preservation and Disposal of Microorganism have been revised. The monographs on General Chapters such as Disintegration, Dissolution are also upgraded to harmonise with prevailing international requirements. Some chapters such as Dimension of Hard Cellulose Capsule Shells, Hard Gelatin Capsule Shells, Taste and Odour, Granules, Approximate pH of Solutions, Monocyte activation test, Microbiological assay of vitamin B<sub>12</sub> activity, Microbiological assay of calcium pantothenate, Test for biological reactivity, *in vivo* as well as *in vitro*, Botanical Extract and Viral safety evaluation of biotechnology products derived from cell lines of Human or Animal origin are newly included as per the technological 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.

## **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 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 Indian 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, and available usual strengths of dosage forms has been kept in this edition.

General chemical tests for identification of an article have been almost eliminated and 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.

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The use of chromatographic methods has been greatly extended to cope up 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. The up-gradation in this edition covers all the amendments and errata released after publication of Addendum 2016 to IP-2014.

In most of the parenteral preparation and other monographs, the test for 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 Biological Reactivity, *in vivo*. Test for Biological reactivity, *in vitro* Microbiological Assay of Vitamin B<sub>12</sub> activity and Microbiological Assay of Calcium Pantothenate has been added.

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.

Three monographs on radiopharmaceutical preparations, 10 monographs on Blood and Blood related products, 06 monographs on Biotechnology Derived Therapeutic products, 02 new monograph on Vaccines and Immunosera for Human use and 15 monographs on Herbs and Herbal products 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. 14 new veterinary monographs have been added in this volume. 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 strengths and doses have been mentioned in this volume while complete monographs are mentioned in other volumes of IP.

The monograph on Brucella Melitensis (Strain Rev.1) Vaccine, Live; Canine Adenovirus Vaccine, Inactivated; Canine adenovirus vaccine, Live; Canine Contagious Hepatitis Vaccine, Live; Old Adjuvant Vaccine Against Pasturellosis in sheep and Goats & Rinderpest Vaccine, Live have been omitted. 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 in general are 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 10 new chapters have been introduced based on current technologies used by the stakeholders and harmonized with other international pharmacopoieas; like Dimensions of Hard Cellulose Capsule Shells, Monocyte Activation Test, Granules and Odour and Taste 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 Chapter on Maintenance, identification, preservation and disposal of micro-organisms has been revised and a general chapter on Viral safety evaluation of biotechnology products derived from cell lines of Human or Animal origin has been included for the first time.

In the Herbs and Herbal products section, general chapter on Botanical Extract has been revised.

#### **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 special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology derived therapeutic products and radiopharmaceuticals preparations are given in separate sections in Volume III. Special emphasis has been given to veterinary monographs adding new ones and updating the existing monographs in volume IV.

A list of 220 new monographs included in the 2018 edition of the Indian Pharmacopoeia, is given below:

#### **Admissions**

#### **General Chapters**

2.2.23. Test for Biological Reactivity, In Vitro

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2.2.24. Test for Biological Reactivity, In Carmustine Enalapril Maleate and Hydrochlorothiazide Tablets Carmustine Injection Escitalopram Oxalate and Clonazepam 2.2.25. Monocyte Activation Test Cefdinir **Tablets** 2.2.26. Microbiological Assay of Cefdinir Oral Suspension Esmolol Injection Calcium Pantothenate Cefixime Dispersible Tablets Etodolac Prolonged-release Tablets 2.2.27. Microbiological Assay of Vitamin Cefuroxime Axetil and Potassium B<sub>12</sub> Activity Folic Acid and Methylcobalamin Clavulanate Tablets Tablets 2.4.45. Odour and Taste Cholecalciferol Concentrate (Powder Ganciclovir 5.8.2. Dimensions of Hard Cellulose Form) Ganciclovir Injection Capsule Shells Cilnidipine Ganciclovir Oral Suspension 2.2.28. Viral Safety Evaluation of Cilnidipine Tablets Biotechnology products derived Glibenclamide and Metformin Tablets Cinacalcet Hydrochloride from cell lines of Human or Glycopyrrolate Clindamycin Palmitate Hydrochloride Animal origin Glycopyrrolate Injection Clindamycin Palmitate Hydrochloride 2.4.46. Approximate pH of Solutions Glycopyrrolate Tablets Oral Suspension Granules (General Monographs for Hydroxyurea Clonidine Hydrochloride Dosage Forms) and Chlorthalidone Tablets Hydroxyurea Capsules Monographs on drug substances, dosage **Ibuprofen and Paracetamol Tablets** Cyclobenzaprine Hydrochloride forms and pharmaceutical aids Ibuprofen and Pseudoephedrine Cyclobenzaprine Tablets Abiraterone Acetate Tablets Hydrochloride Tablets Dacarbazine Aluminium, Magnesium and Isoflurane Dacarbazine Injection Simethicone Chewable Tablets Isotretinoin Gel Daclatasvir Dihydrochloride Aluminium, Magnesium and Latanoprost Eye Drops Simethicone Oral Suspension **Dapoxetine Tablets** Latanoprost and Timolol Ophthalmic Ambrisentan S-Dapoxetine Hydrochloride Solution Ambrisentan Tablets S-Dapoxetine Tablets Letrozole Amiloride and Hydrochlorothiazide Dapsone Gel Letrozole Tablets **Tablets** Darifenacin Hydrobromide Levetiracetam Tablets Amlodipine and Benazepril Hydrochloride Capsules Darifenacin Prolonged-release Tablets Levodopa and Carbidopa Prolongedrelease Tablets Aprepitant Darunavir Ethanolate Levofloxacin Oral Solution Aprepitant Capsules **Darunavir Tablets** Lignocaine Armodafinil Diclofenac Diethylamine Lignocaine and Prilocaine Cream Artesunate Injection Diclofenac Sodium and Paracetamol Atenolol and Chlorthalidone Tablets Lignocaine Hydrochloride Topical **Tablets** Solution Atorvastatin and Fenofibrate Tablets Diclofenac Gel Lignocaine Oral Topical Solution Azelnidipine Tablets Diethylene Glycol Monoethyl Ether Lorcaserin Hydrochloride Hemihydrate Bisoprolol Fumarate Dinoprostone Lorcaserin Tablets Bisoprolol Fumarate and **Dinoprostone Oral Solution** Hydrochlorothiazide Tablets Magaldrate and Simethicone Chewable Diphenoxylate Hydrochloride and Bosentan Monohydrate **Tablets** Atropine Sulphate Tablets Bosentan Tablets Magaldrate and Simethicone Oral Dopamine Hydrochloride and Dextrose Suspension Calcium and Vitamin D3 Tablets Injection Mefenamic Acid and Dicyclomine Captopril and Hydrochlorothiazide **Dothiepin Tablets Hydrochloride Tablets Tablets** 

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Memantine Hydrochloride Oxymetazoline Hydrochloride Nasal Telmisartan and Hydrochlorothiazide Solution **Tablets** Memantine Tablets Oxymetazoline Hydrochloride Terbinafine Hydrochloride Mesna Terbinafine Cream Paliperidone Metadoxine Terbinafine Tablets Pantoprazole Gastro-resistant and Metformin Hydrochloride Prolonged-Domperidone Prolonged-release Thioguanine release and Glimepiride Tablets Capsules Thioguanine Tablets Methylcobalamin Paracetamol and Caffeine Tablets Ticagrelor Methyldopa and Hydrochlorothiazide Paroxetine Hydrochloride Hemihydrate Tobramycin and Fluorometholone **Tablets** Phenylephrine Eye Drops Acetate Ophthalmic Suspension Metoprolol Succinate Prolonged-Phenylephrine Hydrochloride and **Tobramycin Inhalation Solution** release and Amlodipine Besilate Chlorpheniramine Maleate Drops **Tablets** Trimetazidine Tablets Phenylephrine Hydrochloride and **Trospium Chloride Tablets** Metoprolol Tartrate and Chlorpheniramine Maleate Syrup Hydrochlorothiazide Tablets Voriconazole Injection Phytomenadione Montelukast Granules Xylometazoline Hydrochloride and Phytomenadione Injection Sorbitol Nasal Drops Montelukast Sodium and Piperacillin and Tazobactam Injection Zolpidem Tartrate Prolonged-release Levocetirizine Hydrochloride Tablets **Tablets** Piroxicam Tablets Mycophenolate Mofetil Oral Zonisamide Capsules Suspension Pregabalin and Methylcobalamin Capsules Mycophenolate Mofetil Tablets Antibiotic Prilocaine Nadifloxacin Gentamicin Cream Procarbazine Hydrochloride Capsules Nadifloxacin Cream Gentamicin Ointment Propylene Glycol Monocaprylate Nadifloxacin Gel Radiopharmaceutical Quinapril Hydrochloride Nitroglycerin Injection Gallium (68 Ga) Chloride solution for Quinapril and Hydrochlorothiazide Norethisterone and Ethinyl Estradiol **Tablets** Radiolabelling **Tablets** Sodium Iodide (123 I) Injection (From 124 Repaglinide and Metformin Tablets Norgestimate Xe) Risedronate Sodium Tablets Norgestimate and Ethinyl Oestradiol Sodium Iodide (123 I) Solution for Ropivacaine Hydrochloride **Tablets** Radiolabelling Ropivacaine Injection Ofloxacin and Ornidazole Tablets Herbal Rosuvastatin Calcium and Ezetimibe Olanzapine and FluoxetineTablets **Tablets** Amarbel Olmesartan Medoxomil and Rosuvastatin and Fenofibrate Tablets Anise Oil Hydrochlorothiazide Tablets Sertaconazole Nitrate Belladona Dry Extract Tablets Omeprazole and Domperidone Sertaconazole Nitrate and Capsules Citronella Oil (Geraniol type) Beclomethasone Dipropionate Cream Citronella Oil (Java type) Olopatadine Hydrochloride Sodium Alendronate Trihydrate Green Coffee Bean Extract Olopatadine Ophthalmic Solution Sucralfate Horse Chestnut Dry Extract Olopatadine Tablets SucralfateTablets Juniper Oil Oxaliplatin Tamsulosin Hydrochloride Prolonged-Mandarin Oil Oxaliplatin Injection release and Dutasteride Capsules

Telmisartan and Amlodipine Tablets

Tazobactam

Oxybutynin Hydrochloride

Oxybutynin Prolonged-release Tablets

Milk Thistle

Milk Thistle Dry Extract

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Schisandra Dry Extract

Schisandra Fruit

Sweet Orange Oil

Tvak

# Vaccines and Immunosera for Human Use

Pneumococcal polysaccharide conjugate vaccine (Adsorbed)

Scorpion Venom Antiserum

# **Biotechnology Derived Therapeutic Products**

Follicle Stimulating Hormone Concentrated Solution

Follicle Stimulating Hormone Injection

Follicle Stimulating Hormone

Interferon β-1a Injection

Teriparatide

Teriparatide injection

#### **Blood and Blood Related Products**

Anti-D (IgM) monoclonal blood grouping reagent

Blood Grouping Reagent Anti-Fy<sup>a</sup>, Anti-Fy<sup>b</sup>

Blood Grouping Reagent Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup>

Blood Grouping Reagent Anti-K, Anti-k

Blood Grouping Reagent Anti-M, Anti-N

# Blood Grouping Reagents Anti Pi

Blood Grouping Reagents Anti-Le<sup>a</sup>, Anti-Le<sup>b</sup>

Blood Grouping Reagents Anti-S, Anti-s

Blood Grouping Lectins Anti-H Blood Grouping Lectins Anti-A<sub>1</sub>

#### Veterinary Non-biological

Albendazole Veterinary Oral Powder

Amoxycillin Tablets

Amprolium Oral Powder

Buparvaquone

Buparvaquone Injection

Cefuroxime Intramammary Infusion

Cephalexin Intrauterine Powder for Suspension

Cephalexin Veterinary Oral Powder

**Enrofloxacin Injection** 

Marbofloxacin Injection

myo-Inositol

Oxytetracycline Hydrochloride Injection

Sodium Acid Phosphate Injection

Trimethoprim and Sulphamethoxazole Injection

## **Up-gradation**

# **General Chapters upgraded:**

2.1.6. Volumetric Glassware

2.2.3. Bacterial Endotoxins

2.2.15. Host Cell Proteins and Host Cell DNA

2.2.20. Maintenance, Identification, Preservation and Disposal of Microorganisms

2.3.9. Aluminium in Adsorbed Vaccines

2.3.30. Nitrogen

2.4.9. Conductivity

2.5.1. Disintegration Test

2.5.2. Dissolution Test

5.8.1. Dimensions of Hard Gelatin Capsule Shells

Vaccines: General Requirements

Veterinary Diagnostics Veterinary Immunosera

Veterinary Vaccines: General

Requirements

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

Abiraterone Acetate

Acepromazine Maleate

Acepromezine Injection

Aciclovir

Adrenaline

Adrenaline Tartrate

Adsorbed Diphtheria, Tetanus,

Pertussis and Inactivated Poliomyelitis Vaccine

Adsorbed Diphtheria, Tetanus, Pertussis, Inactivated Poliomyelitis Vaccine and *Haemophilus influenzae* Type b Conjugate Vaccine

Adsorbed Diphtheria, Tetanus, Pertussis and (Acellular Component) Poliomyelitis (Inactivated) Vaccine.

Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and *Haemophilus influenzae* Type b Conjugate Vaccine

Allopurinol Tablets

Aluminium Hydroxide Gel

Amoxycillin Capsules

Amoxycillin Dispersible Tablets

Amoxycillin Injection

Amoxycillin Oral Suspension

Amoxycillin Sodium

Amoxycillin Trihydrate

Ampicillin Capsules

**Ampicillin Injection** 

Ampicillin Oral Suspension

Ampicillin Sodium

Ampicillin Trihydrate

Ampicillin Veterinary Oral Powder

Amprolium Hydrochloride

Anthrax Spore Vaccine, Live

Anti-D (Rho) Immunoglobulin

Arjuna Dry Extract

Atracurium Besylate Injection

Avian Infectious Bronchitis Vaccine, Inactivated

Avian Infectious Bronchitis Vaccine,

Avian Infectious Laryngotracheitis Vaccine, Live

Avian Mycoplasma Antigen

Azathioprine Tablets

Bacillus Calmette-Guerin Vaccine (Freeze-Dried)

Bacitracin

Bacitracin Zinc

Bambuterol Hydrochloride

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**Bambuterol Tablets** Cetrimide Cream Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Batamethasone Cream Cetrimide Emulsifying Ointment Haemophilus influenzae Type b BCG Immunotherapy Chlorthalidone Conjugate Vaccine (Adsorbed) Bendamustine Injection Cholecalciferol Dipyridamole Benzathine Penicillin Cholera Vaccine (Inactivated, Oral) Disopyramide Phosphate Capsules Benzathine Penicillin Injection Clarithromycin Tablets Disopyramide Phosphate Prolonged-Benzhexol Tablets release Capsules Classical Swine Fever Vaccine, Live Benzyl Alcohol Divalproex Prolonged-release Tablets Clobazam Tablets Benzyl Benzoate Divalproex Sodium Clobetasone Cream Betamethasone Valerate Cream Docetaxel Anhydrous Clomifene Citrate Bhibhitaki Doxofylline Clotrimazole Cream Bifonazole Cream Doxorubicin Injection Clotrimazole Pessaries **Duloxetine Gastro-resistant Tablets** Biphasic Insulin Lispro Injection Clonidine Tablets Egg Drop Syndrome'76 (Adenovirus) Blackquarter Vaccine Closantel Sodium Dihydrate Vaccine, Inactivated Brimonidine Tartrate Eye Drops Enrofloxacin Crospovidone Brucella Abortus (Strain 19 Vaccine) Enterotoxaemia Vaccine, Inactivated Vaccine, Live Crotaminton Ergotamine Injection **Bumetamide Injection** Cyclosporine Esmolol Hydrochloride Butylparaben Daruharidra Roots Ethacrynic Acid Calcitonin (Salmon) Injection Decoquinate Ethanolamine Calcium Folinate (Leucovorin Ca) Desferrioxamine Injection Etoposide Calcium Magnesium Borogluconate Dexamethasone Sodium Phosphate Fibrin Sealant Kit filgrastin Injection Dexamethasone Tablets concentrated solution Calcium Stearate Dexlansoprazole Fenspiride Hydrochloride Canine Adenovirus Vaccine, Live Diazoxide Finasteride Canine Coronavirus Vaccine, Finasteride Tablets Diclazuril Inactivated Foot and Mouth Disease Vaccine. Dichlorophen Tablets Canine Distemper Vaccine, Live Inactivated Canine Infectious Contagious Diclofenac Prolonged-release Tablets Flucloxacillin Oral Solution Hepatitis Vaccine, Inactivated Dicloxacillin Sodium Fortified Benzathine Penicillin Injection Canine Parainfluenza Virus Vaccine, Diloxanide Furoate Folic Acid Live Diluted Pentaerythritol Tetranitrate Fortified Procaine Penicillin Injection Canine Parvovirus Vaccine, Inactivated Dimethicone Fosinopril Sodium Canine Parvovirus Vaccine, Live Dinitolamide Fowl Cholera Vaccine, Inactivated Caprofen Diphtheria Vaccine (Absorbed) Fowl Pox Vaccine, Live Carboxymethylcellulose Sodium Diphtheria, Tetanus and Pertussis Fructose Injection Carnauba Wax Vaccine (Adsorbed) Frusemide Tablets Cefoperazone Injection Diphtheria, Tetanus, Pertussis (Whole Furazolidone Cefoperazone Sodium Cell) and Haemophilus influenzae Gabapentin Capsules Cefoperazone Sodium Intramammary Type b Conjugate Vaccine Gemcitabine Hydrochloride Suspension (Adsorbed) Cefotaxime Sodium Injection Ginkgo Dry Extract

Diphtheria, Tetanus, Pertussis (Whole

(Adsorbed)

Cell) and Hepatitis B (rDNA) Vaccine

Cetirizine Hydrochloride

Cefpodoxime Tablets

Ginkgo Tablets

Glibenclamide Tablets

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Gliclazide Insulin Glargine Methylprednisolone Gliclazide Tablets Insulin Glargine Injection Metolazone Tablets Glucosamine Sulphate Sodium Ivermectin Injection Metoprolol Succinate Chloride Ivermectin Oral Paste Metoprolol Succinate Prolongedrelease Tablets Goat Pox Vaccine, Live Ivermectin Pour on Guggulipid Metoprolol Tartrate Japanese Encephalitis Live Vaccine Metronidazole Benzoate Oral (Human) Guggulipid Tablets Suspension Japanese Encephalitis Vaccine Guggul Resin Metronidazole Injection (Human) Haemorrhagic Septicaemia Vaccine, Mometasone Cream Japanese Encephalitis Vaccine Inactivated Inactivated (Adsorbed, Human) Mometasone Ointment Heparin Injection Ketorolac Tromethamine Moxidectin Heparin Sodium Labetalol Injection Myristic Acid Hepatitis A (Inactivated) and Hepatitis Lactic Acid B (rDNA) Vaccine (Adsorbed) Nifedipine Prologed-release Tablets Latanoprost Human Albumin Nitroxynil Injection Levamisole Injection Human Normal Immunoglobulin Ofloxacin Levetiracetam Human Normal Immunoglobulin for Ofloxacin Oral Suspension Intravenous use Levocetirizine Tablets Ofloxacin Tablets Human Plasma Protein Fraction Levodropropizine Olmesartan Medoxomil Hydrochlorothiazide Levofloxacin Infusion Ondansetron Hydrochloride Levofloxacin Injection Hydrochlorothiazide Tablets Ondansetron Orally Desintegrating Hydroxychloroquine Tablets Levonorgestrel and Ethinyloestradiol **Tablets Tablets** Oral Rehydration Salts Hydroxypropylmethyl Cellulose Levosalbutamol Sulphate Orphenadrine Citrate Hyoscine Butylbromide Liquid Maltitol Orphenadrine Hydrochloride Hyoscine Butylbromide Injection Marek's Disease Vaccine, Live Oxytetracycline Hydrochloride Hyoscine Butylbromide Tablets Measles and Rubella Vaccine (Live) Injection Hyoscine Hydrobromide Measles Vaccine (Live) OxytetracyclineDihydrate Injection Hyoscyamine Sulphate Measles, Mumps and Rubella Vaccine Oxytocin **Ifosfamide Injection** (Live) Oxytocin Injection Imipenem Mebendazole Paracetamol Infusion Inactivated Hepatitis A Vaccine Mebendazole Tablets Paroxetine Hydrochloride (Adsorbed) Medroxyprogesterone Injection Pegfilgrastim Inactivated Hepatitis B Vaccine Menotropin for Injection Pemetrexed Injection Inactivated Influenza Vaccine (Split Meropenem Penicillamine Tablets Virion) Mesalazine Pentobarbitone Sodium Inactivated Influenza Vaccine (Surface Mesalazine Prolonged-release Tablets Antigen) Pertussis Vaccine. Metformin Hydrochloride Inactivated Influenza Vaccine (Whole Peste Des Petits Ruminants Vaccine, Virion) Metformin Tablets Live Isoprenaline Methi **Pethidine Injection** Isoprenaline Injection Methocarbamol Phenindione Isopropyl Palmitate Phenindione Tablets Methotrexate **Isosorbide Dinitrate Tablets** Phenoxyethanol Methotrexate Tablets

Methoxamine Hydrochloride

Methyldopa

Phenylepherine Hydrochloride

Pimozide

Isoxsuprine Hydrochloride

Isoxsuprine Injection

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Piperacillin
Piperazine Citrate

Poliomyelitis Vaccine (Inactivated) Poliomyelitis Vaccine, Live (Oral)

Procaine Hydrochloride

Progesterone
Promazine Tablets
Promethazine Syrup
Quinine Sulphate
Rabeprazole Injection
Rabies Vaccine, Human
Ranitidine Injection
Ranitidine Oral Solution
Ritodrine Injection

Ritonavir Ronidazole

Ronidazole Veterinary Oral Powder

Rotavirus Vaccine (Live Attenuated, Oral)

Roxithromycin

Rubella Vaccine (Live) Saccharin Sodium

Salmonella Pullorum Coloured Antigen

Salmonella Vaccine, Inactivated

Somatropin

Somatropin Concentrated Solution

Somatropin for Injection Senna Dry Extract Senna Leaf

Senna Pods Senna Tablets

Sheep Pox Vaccine, Live Attenuated

Sildenafil Citrate Sitagliptin Phosphate Sodium Acetate Sodium Phosphate Sodium Valproate Sorbitan Oleate

Spectinomycin Hydrochloride Spectinomycin Injection

Spiramycin

Sterile Diluent for live Vaccine

Sulphamethoxazole and Trimethoprim

Bolus Tacrolimus Tacrolimus Capsules

Tamsulosin Hydrochloride Prolongedrelease Capsules

Teicoplanin

Tetanus Veterinary Vaccine
Theileriosis Vaccine, Live
Theophylline Injection
Thiopentone Injection
Thiopentone Sodium

Thymol

Tick-borne Encephalitis Vaccine (Inactivated).

Tolazamide Tablets

Triamcinolone Acetonide Injection

Triamcinolone Tablets
Triethyl Citrate

Tribasic Calcium Phosphate

Triflupromazine Hydrochloride Injection

Trospium Chloride

Tylosin

Tylosin Injection Tylosin Tablets

Typhoid (Strain Ty 21a) Vaccine, Live (Oral)

Typhoid Vaccine (Freeze Dried)

Typhoid Vaccine

Typhoid Vi Conjugate Vaccine

Typhus Vaccine Valproic Acid

Vancomycin Hydrochloride for

Intravenous Infusion
Vancomycin Hydrochloride
Varicella Vaccine, Live
Vecuronium Bromide
Vinblastin Sulphate

Water for Injections in Bulk

Zidovudine

Zinc Oxide and Salicylic Acid Paste

Zolmitriptan Nasal Spray Zolmitriptan Tablets

# **Changed Titles**

#### **Changed Titles of General Chapters**

From '5.8 Dimension of Hard Gelatin Capsule Shells' to '5.8 Dimension of Capsule Shells' Changed Titles of Monographs

From Benzoyl Peroxide to Hydrous Benzoyl Peroxide

From Fasterodine Fumarate to Fesoterodine Fumarate

From Gugulipid Tablets to Gugglipid Tablets

From 'Gugulipid' to 'Guggulipid' From 'Labetalol' to 'Labetalol Injection' From 'Sulphadimidine Tablets' to 'Sulphadimidine Bolus Tablets'

# Monographs shifted from Chemical to Biotechnology Derived Therapeutic Products

Calcitonin (Salmon)

Calcitonin (Salmon) Injection

Human Insulin Insulin Injection Insulin Aspart

**Insulin Aspart Injection** 

Insulin Lispro

Insulin Lispro Injection

Biphasic Insulin Aspart Injection Biphasic Insulin Lispro Injection Biphasic Isophane Insulin Injection

Isophane Insulin Injection

Insulin Glargine

Insulin Glargine Injection

#### **Omissions**

General Monographs (Veterinary)

Dip Concentrate

Premixes

Veterinary Aerosols

Teat Dips Teat Sprays Udder Washes

Brucella Melitensis (Strain Rev. 1)

Vaccine, Live

Canine Adenovirus Vaccine, Inactivated Canine Adenovirus Vaccine, Live Canine Contagious Hepatitis Vaccine,

Live

Old Adjuvant Vaccine Against Pasturellosis in Sheep and Goats

Rinderpest Vaccine, Live

Sterile Diluent for Live Vaccines