New Features of IP 2010

This new edition of the Indian Pharmacopoeia entitled 6th edition (Indian Pharmacopoeia 2010) is published by the Indian Pharmacopoeia Commission (IPC) in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years. It supersedes the 2007 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 2010 is presented in three volumes. Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters. Volume II contains the General Notice, 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 Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products.

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 and the drugs as well as their formulations not in use now a days 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 development of latest technology in the field. A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery. A chapter on NMR is incorporated in Appendices. The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

Format

In an effort to make the pharmacopoeia more user-friendly, design of the texts of the monographs and of the test methods are kept same. Cross-referencing has been avoided to make each monograph complete in itself thus making it convenient to the analyst.

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 inculcate on the manufacturer to ensure that the article is manufactured in accordance with the 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 date 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 monograph, 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 in the information on category of a drug, dosage and usual available strengths of dosage forms has been re-kept in this edition.

General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric 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 more 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 are upgraded by liquid chromatography method in view to have more specificity and to harmonise with other International Pharmacopoeias.

The test for pyrogens involving the use of animals has been virtually eliminated. The test for bacterial endotoxins introduced in the previous edition is now applicable to more items. The test for abnormal toxicity is now confined to certain vaccines.

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.

The trend towards controlling the microbial quality of all medicinal products has been recognized and the requirement regarding limits of bacterial contamination even of products for oral administration and topical application so that adequate controls are exercised by manufacturers by the adoption of GMPs has been continued.

The chapter on Vaccines: General requirements has been updated. Minor corrections have been made in the appendices entitled Tests on Chicken flocks free from specified pathogens for the production and quality control of vaccines and General provisions: Avian viral vaccines- Tests for extraneous agents in seed lot. The peptide mapping test for Inactivated Hepatitis B Vaccine has been deleted. Wherever appropriate, other corrections have also been incorporated and overall presentation improved.

In view of considering the microbiological quality, the whole microbiological general chapter comprising of effectiveness of antimicrobial preservatives, microbial contamination in nonsterile products and microbiological quality of raw material, dosage forms, herbs, processed herbs and herbal products have been extensively revised. For the first time in this chapter the analysis of strain *Shigella boydii* has been introduced which is possibly not available in other Pharmacopoeias. The addition of this strain *Shigella boydii* is essential as it is acute dysentry causing strain of tropical region of our country.

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. 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 veterinary products are given in separate sections in Volume III.

A list of 287 new monographs items not included in the 2007 edition of the Indian Pharmacopoeia and its addendum 2008 but added in this edition is given below:

Admissions

Monographs on drug substances, dosage forms and pharmaceutical aids

Acepromazine Maleate
Allantoin
Aluminium Magnesium Silicate
S-Amlodipine Besylate
S-Amlodipine Tablets
Liposomal Amphotericin B Injection
Anastrozole
Anastrozole Tablets
Anhydrous Lactose
Artesunate
Atazanavir Sulphate
Atazanavir Capsules
Benzoic Acid Solution
Betamethasone Dipropionate
Betamethasone Cream
Betamethasone Lotion
Betamethasone Ointment
Bifonazole
Bifonazole Cream
Bumetanide
Bumetanide Injection
Bumetanide Oral solution
Bumetanide Tablets
Butylparaben
Calcium Chloride Injection
Capecitabine
Capecitabine Tablets
Cefamandole Nafate
Cefamandole Injection
Cetrimide Cream
Cetyl Palmitate
Chlorothiazide
Chlorothiazide Oral Suspension
Chlorothiazide Tablets
Chymotrypsin
Cilastatin Sodium
Clindamycin Hydrochloride
Clindamycin Capsules

Codeine Phosphate Tablets
Cyproterone Acetate
Cyproterone Tablets
Daunorubicin Hydrochloride
Daunorubicin Injection
Dexchlorpheniramine Maleate
Dexchlorpheniramine Oral Solution
Dexchlorpheniramine Tablets
Dextropropoxyphene Hydrochloride
Dextropropoxyphene Capsules
Dextropropoxyphene Napsilate
Diacerein
Diacerein Capsules
Diazoxide
Diazoxide Tablets
Dicloxacillin Sodium
Dicloxacillin Capsules
Dicloxacillin Oral Suspension
Diethanolamine
Dihydroergocristine Mesylate
Dihydroergotamine Mesylate
Dimethicone
Disopyramide
Disopyramide Capsules
Disopyramide Phosphate Capsules
Disopyramide Phosphate Sustained-release Capsules
Divalproex Sustained-release Tablets
Docetaxel Trihydrate
Docetaxel Injection
Domperidone
Doxofylline
Doxofylline Tablets
Enoxaparin Sodium
Enoxaparin Injection
Escitalopram Oxalate
Escitalopram Tablets
Estradiol and Norethisterone Tablets
Etodolac
Etodolac Capsules
Etodolac Tablets
Famotidine
Famotidine Tablets
Felodipine
Felodipine Sustained-release Tablets
Fenbendazole
Fenofibrate
Fentanyl
Fentanyl Citrate
Fentanyl Injection
Finasteride
Finasteride Tablets
Fluconazole
Fluconazole Capsules
Fluconazole Tablets
Flucytosine
Flucytosine Capsules
Flucytosine Oral Suspension
Flucytosine Tablets
Fluorescein Injection
Flutamide
Flutamide Capsules
Fumaric Acid
Gefitinib
Gefitinib Tablets
Gemifloxacin Mesylate
Gemifloxacin Tablets
Gliclazide
Gliclazide Tablets
Glimepiride
Glimepiride Tablets
Homatropine Methylbromide
Homatropine Methylbromide Tablets
Hyoscyamine Sulphate
Hyoscyamine Injection
Hyoscyamine Oral Solution
Hyoscyamine Tablets
Ibuprofen Cream
Ibuprofen Gel
Imatinib Mesylate
Imatinib Capsules
Indapamide Tablets
Isobutane
Isopropyl Myristate
Lactulose
Lamotrigine Sustained-release Tablets
Lansoprazole
Lansoprazole Sustained-release Capsules
Lecithin
Levosalbutamol Sulphate
Linezolid
Linezolid Tablets
Losartan Potassium and Amlodipine Tablets
Losartan Potassium and Hydrochlorothiazide Tablets
Maleic Acid
Malic Acid
Maltitol
Liquid Maltitol
Maltodextrin
Mefloquine Hydrochloride
Meloxicam Oral Suspension
Menthol and Benzoin Inhalation
Metformin Hydrochloride Sustained-release Tablets
Methadone Linctus
Metronidazole Sterile Suspension
Miconazole
Microcrystalline Cellulose and Carboxymethylcellulose Sodium
Misoprostol
Mometasone Furoate
Mometasone Aqueous Nasal Spray
Mometasone Cream
Mometasone Ointment
Montelukast Sodium
Montelukast Tablets
Mycophenolate Mofetil
Mycophenolate Mofetil Capsules
Myristic Acid
Naloxone Hydrochloride
Naloxone Injection
Naltrexone Hydrochloride
Naltrexone Tablets
Naproxen
Naproxen Oral Suspension
Naproxen Suppositories
Naproxen Sustained-release Tablets
Naproxen Tablets
Neotame

Ondansetron Orally Disintegrating Tablets
Ondansetron Oral Solution
Pantoprazole Sodium
Pantoprazole Sustained-release Tablets
Perphenazine
Perphenazine Tablets
Phenoxyethanol
Phenylpropanolamine Hydrochloride
Phenytoin
Phenytoin Capsules
Phenytoin Oral Suspension
Pimozide
Pimozide Tablets
Piperacillin
Piperacillin Intravenous Infusion
Poloxamers
Polyoxyl 35 Castor Oil
Polyoxyl 40 Hydrogenated Castor Oil
Potassium Sorbate
Pravastatin Sodium
Pravastatin Tablets
Praziquantel
Praziquantel Tablets
Prednisolone Acetate
Pregabalin
Pregabalin Capsules
Pregelatinised Starch
Progesterone Injectable Suspension
Promazine Tablets
Propane
Propionic Acid
Propofol
Propofol Injection
Protriptyline Hydrochloride
Protriptyline Tablets
Pyrimethamine Tablets
Quiniodochlor Cream
Quiniodochlor Ointment
Quiniodochlor and Hydrocortisone Cream
Quiniodochlor and Hydrocortisone Ointment
Ramipril and Hydrochlorothiazide Tablets
Ribavirin
Ribavirin Inhalation Solution
Serratiopeptidase
Serratiopeptidase Tablets
Sildenafil Citrate
Sildenafil Tablets
Simvastatin
Simvastatin Tablets
Sorbitan Oleate
Sucralose
Sumatriptan
Sumatriptan Injection
Telmisartan
Telmisartan Tablets
Temozolomide
Temozolomide Capsules
Terazosin Hydrochloride
Thiocolchicoside
Thiocolchicoside Capsules
Ticarcillin and Clavulanic Acid Injection
Tolazamide
Tolazamide Tablets
Tolnaftate
Tolnaftate Cream
Tolnaftate Gel
Tolnaftate Topical Powder
Tolnaftate Topical Solution
Tolterodine Tartrate
Tramadol Hydrochloride
Tramadol Capsules
Trandolapril
Trandolapril Tablets
Travoprost
Travoprost Eye drops
Tributyl Citrate
Trichloromonofluoromethane
Triethyl Citrate
Trimetazidine Hydrochloride
Valproate Injection
Valproic Acid
Valproic Acid Capsules
Valproic Acid Oral Solution
Valsartan
Valsartan Tablets
Valsartan and Hydrochlorothiazide Tablets
Vancomycin Hydrochloride
Vancomycin Capsules
Vancomycin Intravenous Infusion
Vancomycin Oral Solution
Xanthan Gum
Zoledronic Acid
Zoledronic Acid Injection

Herbal Monographs

Amla Juice Powder
Arjuna Dry Extract
Ashwagandha Dry Extract
Belladonna Tincture
Bhibhitaki Aqueous Extract
Brahmi Extract
Coconut Oil
Coleus Dry Extract
Coriander Oil
Garcinia Aqueous Extract
Haridra Dry Extract
Haritaki Extract
Haritaki Aqueous Extract
Ipecac Tincture
Lavang
Methi
Neem
Sarpagandha Powder
Sarpagandha Tablets
Sunthi Extract
Tulasi Dry Extract
Vasaka Extract

Veterinary Monographs

Infectious Bursal Disease Vaccine , Live
Infectious Chicken Aneamia Vaccine, Inactivated
Infectious Chicken Aneamia Vaccine, Live
Marek's Disease Vaccine, Live
Reo Virus Vaccine, Inactivated
Reo Virus Vaccine, Live

Salmonella Vaccine, Inactivated
Sterile Diluent for Live Vaccines

Monographs upgraded

Monographs on drug substances, dosage forms and pharmaceutical aids

Acarbose
Aciclovir
Adrenaline Injection
Alprazolam
Alprazolam Tablets
Aminophylline
Aminophylline Injection
Aminophylline Tablets
Amitriptyline Hydrochloride
Amodiaquine Tablets
Arginine
Arteether
Artemether
Artemesinin
Atorvastatin Calcium
Azithromycin
Azithromycin Oral Suspension
Azithromycin Tablets
Bacitracin
Bacitracin Zinc
Benzyl alcohol
Bromhexine Hydrochloride
Bromhexine Tablets
Bromocriptine Mesylate
Bromocriptine Capsules
Bromocriptine Tablets
Bisacodyl
Bisacodyl Tablets
Buprenorphine Hydrochloride
Benzhexol Hydrochloride
Calcium Gluconate Tablets
Calcium Levulinate
Calcium Stearate
Captopril
Citric Acid
Citric Acid Monohydrate
Cellulose Acetate Phthalate
Clofazimine Capsules
Carbimazole
Carvedilol Tablets
Cefadroxil
Crospovidone
Cefuroxime Injection
Cefaclor Oral suspension
Cefadroxil Capsules
Cefotaxime Sodium
Cefazolin Sodium
Cefixime
Cinnarizine
Cefaperazone Sodium
Cefazolin Injection
Cimetidine Tablets
Cephalexin
Cetostearyl Alcohol
Cetyl Alcohol
Carbimazole Tablets
Cefadroxil Tablets
Chlordiazepoxide
Cisplatin
Clopidogrel Bisulphate
Clopidogrel Tablets
Clotrimazole Cream
Cresol with Soap Solution
Cytarabine
Danazol
Danazol Capsules
Desferrioxamine Mesylate
Desferrioxamine Injection
Dexamethasone Sodium phosphate
Dextromethorphan Hydrobromide
Dibutyl Phthalate
Dicyclomine Injection
Digoxin
Disodium Edetate
Diphenhydramine Hydrochloride
Erythromycin Estolate
Esomeprazole Magnesium Trihydrate
Esomeprazole Tablets
Ethambutol Hydrochloride
Ferrous Gluconate
Ferrous Sulphate
Dried Ferrous Sulphate
Fexofenadine Hydrochloride
Fluocinolone Acetonide
Fluorescein Injection
Folic Acid
Frusemide
Frusemide Injection
Frusemide Tablets
Gallamine Triethiodide
Gallamine Injection
Gentamycin Sulphate
Glibenclamide
Glibenclamide Tablets
Guaiphenesin
Heparin Sodium
Heparin Injection
Ibuprofen
Ibuprofen Tablets
Imipenem
Imipenem and Cilastatin Injection
Isoxsuprine Hydrochloride
Ketamine Hydrochloride
Ketamine Injection
Ketonazole
Ketonazole Tablets
Ketoprofen
Ketoprofen Capsules
Lactose
Levamisole Tablets
Levocitrizine Hydrochloride
Levocetirizine Tablets
Levofloxacin Tablets
Magnesium Stearate
Magnesium Trisilicate
Mannitol
Mannitol Injection
Mebendazole
Mebendazole Tablets
Megestrol Acetate
Mercaptopurine
Methotrexate Injection
Methylergometrine Tablets
Metronidazole
Metronidazole Tablets
Metronidazole Injection
Morphine Sulphate

Mosapride Citrate Dihydrate
Naphazoline Nitrate
Nebivolol Hydrochloride
Nebivolol Tablets
Nefedipine Sustained- release Tablets
Niclosamide
Niclosamide Tablets
Nitrazepam
Nitrazepam Tablets
Nitrofurazone
Norethisterone
Noscapine
Nystatin
Ofloxacin
Olanzapine
Omeprazole
Ondansetron Tablets
Oxytocin
Oxytocin Injection
Oxytocin Nasal Solution
Phenobarbitone
Phenobarbitone Sodium
Paracetamol
Paracetamol Tablets
Diluted Pentaerythritol Tetranitrate
Pentamidine Isethionate
Pentamidine Injection
Pethidine Hydrochloride
Pethidine Injection
Phenolphthalein
Phenylbutazone
Piracetam
Piroxicam
Polysorbate 20
Polysorbate 80
Potassium Iodide
Povidone
Prednisolone
Propranolol Hydrochloride
Propranolol Injection
Propranolol Tablets
Pseudoephedrine Hydrochloride
Pyrantel Pamoate
Quetiapine Fumarate
Quinine Dihydrochloride Injection
Rabeprazole Tablets
Riboflavine Sodium Phosphate
Ritonavir Tablets
Salbutamol
Salbutamol Sulphate
Salbutamol Injection
Salmeterol and Fluticasone Propionate Powder for Inhalation
Secnidazole
Sodium Alginate
Sorbitol
Soritol Solution (70 per cent) (Crystallizing)
Soritol Solution (70 per cent) (Non-crystallizing)
Spironolactone
Spironolactone Tablets
Sodium Fusidate
Sodium Fusidate Capsules
Sodium Propylparaben
Sodium Methylparaben
Methylparaben
Propylparaben
Stearyl Alcohol
Sucrose
Sulphacetamide Sodium
Sulphacetamide Eye drops
Talc
Terbutaline Tablets
Theophylline
Theophylline Tablets
Thiamine Hydrochloride
Thiamine Nitrate
Tenofovir and Emtricitabine Tablets
Terbutaline Sulphate
Thiotepa
Topiramate Tablets
Verapamil Hydrochloride
Verapamil Tablets
Vessopressin Injection
Vincristine Sulphate
Vincristine Injection
Xylometazoline Hydrochloride
Warfarin Sodium
Warfarin Sodium Clatharate
Zidovudine Tablets

Monographs on Vaccines for Human Use

Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents
Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)
Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed)
Hepatitis B Vaccine (rDNA)
Measles, Mumps and Rubella Vaccine (Live)
Tetanus Vaccine (Adsorbed)

Monographs on Vaccines for Veterinary Use

Avian Infectious Bronchitis Vaccine, Inactivated
Avian Infectious Bronchitis Vaccine, Live
Avian Spirochaetosis Vaccine
Egg Drop Syndrome'76 (Adenovirus) Vaccine, Inactivated
Foot-and-Mouth Disease Vaccine, Inactivated
Fowl Cholera Vaccine, Inactivated
Fowl Pox Vaccine, Live
Inclusion Body Hepatitis (IBH) Vaccine, Inactivated
Infectious Avian Encephalomyelitis Vaccine, Live
Infectious Bursal Disease Vaccine, Inactivated
Infectious Coryza Vaccine
Peste Des Petits Ruminants Vaccine, Live
Ranikhet Disease Vaccine, Inactivated
Ranikhet Disease Vaccine, Live (Lentogenic Strain)
Ranikhet Disease Vaccine, Live (Mesogenic Strain)

Monographs on Veterinary Diagnostics

Avian Mycoplasma Antigen
Salmonella Pullorum Antigen

Changed Titles of Monographs

From 'Leptospira Veterinary Vaccine, Inactivated' to ' Canine Leptospirosis Vaccine, Inactivated'

From 'Avian Pleuropneumonia Live Antigen' to ' Avian Mycoplasma Antigen'

From 'Salmonella Pullorum Coloured Antigen' to 'Salmonella Pullorum Antigen'

Omissions

Adenine

Aluminium Sulphate

Analgin

Analgin Tablets

Butylated Hydroxyanisole

Caramel

Cyclopropane

Deslanoside

Deslanoside Injection

Dibutyl Phthalate

Emetine Hydrochloride

Emetine Injection

Ephedrine

Erythromycin Estolate

Erythromycin Estolate Tablets

Fusidic Acid Oral Solution

2- Deoxy- D- Glucose

Protamine Zinc Insulin Injection

Lanatoside C

Lanatoside C Tablets

Laryngotracheitis Vaccine, Live

Menadione

Methdilazine Hydrochloride

Methdilazine Tablets

Oxyphenbutazone

Oxyphenbutazone Tablets

Phenindamine Tartrate

Phenindamine Tablets

Phenylbutazone

Phenylbutazone Tablets

Propantheline Bromide

Propantheline Tablets

Sodium Aurothiomalate

Sodium Aurothiomalate Injection

Sodium Cromoglycate

Sodium Cromoglycate Powder for Inhalation

Sodium Fusidate Capsules

Prepared Storax

Sulphadimethoxine

Sulphadimethoxine Tablets

Sulphadimidine

Sulphadimidine Sodium

Sulphadimidine Injection

Sulphadimidine Tablets

Sulphafurazole

Sulphafurazole Tablets

Sulphalene

Sulphaphenazole

Sulphaphenazole Tablets

Sulphobromophthalein Sodium

Sulphobromophthalein Sodium Injection