

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

Ondansetron Orally Disintegrating Tablets	Ribavirin	Valsartan Tablets
Ondansetron Oral Solution	Ribavirin Inhalation Solution	Valsartan and Hydrochlorothiazide Tablets
Pantoprazole Sodium	Serratopeptidase	Vancomycin Hydrochloride
Pantoprazole Sustained-release Tablets	Serratopeptidase Tablets	Vancomycin Capsules
Perphenazine	Sildenafil Citrate	Vancomycin Intravenous Infusion
Perphenazine Tablets	Sildenafil Tablets	Vancomycin Oral Solution
Phenoxyethanol	Simvastatin	Xanthan Gum
Phenylpropanolamine Hydrochloride	Simvastatin Tablets	Zoledronic Acid
Phenytoin	Sorbitan Oleate	Zoledronic Acid Injection
Phenytoin Capsules	Sucralose	
Phenytoin Oral Suspension	Sumatriptan	Herbal Monographs
Pimozide	Sumatriptan Injection	Amla Juice Powder
Pimozide Tablets	Telmisartan	Arjuna Dry Extract
Piperacillin	Telmisartan Tablets	Ashwagandha Dry Extract
Piperacillin Intravenous Infusion	Temozolomide	Belladonna Tincture
Poloxamers	Temozolomide Capsules	Bhibhitaki Aqueous Extract
Polyoxyl 35 Castor Oil	Terazosin Hydrochloride	Brahmi Extract
Polyoxyl 40 Hydrogenated Castor Oil	Thiocolchicoside	Coconut Oil
Potassium Sorbate	Thiocolchicoside Capsules	Coleus Dry Extract
Pravastatin Sodium	Ticarcillin and Clavulanic Acid Injection	Coriander Oil
Pravastatin Tablets	Tolazamide	Garcinia Aqueous Extract
Praziquantel	Tolazamide Tablets	Haridra Dry Extract
Praziquantel Tablets	Tolnaftate	Haritaki Extract
Prednisolone Acetate	Tolnaftate Cream	Haritaki Aqueous Extract
Pregabalin	Tolnaftate Gel	Ipecac Tincture
Pregabalin Capsules	Tolnaftate Topical Powder	Lavang
Pregelatinised Starch	Tolnaftate Topical Solution	Methi
Progesterone Injectable Suspension	Tolterodine Tartrate	Neem
Promazine Tablets	Tramadol Hydrochloride	Sarpagandha Powder
Propane	Tramadol Capsules	Sarpagandha Tablets
Propionic Acid	Trandolapril	Sunthi Extract
Propofol	Trandolapril Tablets	Tulasi Dry Extract
Propofol Injection	Travoprost	Vasaka Extract
Protriptyline Hydrochloride	Travoprost Eye drops	
Protriptyline Tablets	Tributyl Citrate	Veterinary Monographs
Pyrimethamine Tablets	Trichloromonofluoromethane	Infectious Bursal Disease Vaccine , Live
Quiniodochlor Cream	Triethyl Citrate	Infectious Chicken Aneamia Vaccine, Inactivated
Quiniodochlor Ointment	Trimetazidine Hydrochloride	Infectious Chicken Aneamia Vaccine, Live
Quiniodochlor and Hydrocortisone Cream	Valproate Injection	Marek's Disease Vaccine, Live
Quiniodochlor and Hydrocortisone Ointment	Valproic Acid	Reo Virus Vaccine, Inactivated
Ramipril and Hydrochlorothiazide Tablets	Valproic Acid Capsules	Reo Virus Vaccine, Live
	Valproic Acid Oral Solution	
	Valsartan	

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
Crosopovidone
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
Levocitizine 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	Rabeprazole Tablets	Monographs on Vaccines for Human Use
Naphazoline Nitrate	Riboflavine Sodium Phosphate	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents
Nebivolol Hydrochloride	Ritonavir Tablets	Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)
Nebivolol Tablets	Salbutamol	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed)
Nefedipine Sustained- release Tablets	Salbutamol Sulphate	Hepatitis B Vaccine (rDNA)
Niclosamide	Salbutamol Injection	Measles, Mumps and Rubella Vaccine (Live)
Niclosamide Tablets	Salmeterol and Fluticasone Propionate Powder for Inhalation	Tetanus Vaccine (Adsorbed)
Nitrazepam	Secnidazole	Monographs on Vaccines for Veterinary Use
Nitrazepam Tablets	Sodium Alginate	Avian Infectious Bronchitis Vaccine, Inactivated
Nitrofurazone	Sorbitol	Avian Infectious Bronchitis Vaccine, Live
Norethisterone	Soritol Solution (70 per cent) (Crystallizing)	Avian Spirochaetosis Vaccine
Noscapine	Soritol Solution (70 per cent) (Non-crystallizing)	Egg Drop Syndrome '76 (Adenovirus) Vaccine, Inactivated
Nystatin	Spiroinolactone	Foot-and-Mouth Disease Vaccine, Inactivated
Ofloxacin	Spiroinolactone Tablets	Fowl Cholera Vaccine, Inactivated
Olanzapine	Sodium Fusidate	Fowl Pox Vaccine, Live
Omeprazole	Sodium Fusidate Capsules	Inclusion Body Hepatitis (IBH) Vaccine, Inactivated
Ondansetron Tablets	Sodium Propylparaben	Infectious Avian Encephalomyelitis Vaccine, Live
Oxytocin	Sodium Methylparaben	Infectious Bursal Disease Vaccine, Inactivated
Oxytocin Injection	Methylparaben	Infectious Coryza Vaccine
Oxytocin Nasal Solution	Propylparaben	Peste Des Petits Ruminants Vaccine, Live
Phenobarbitone	Stearyl Alcohol	Ranikhet Disease Vaccine, Inactivated
Phenobarbitone Sodium	Sucrose	Ranikhet Disease Vaccine, Live (Lentogenic Strain)
Paracetamol	Sulphacetamide Sodium	Ranikhet Disease Vaccine, Live (Mesogenic Strain)
Paracetamol Tablets	Sulphacetamide Eye drops	Monographs on Veterinary Diagnostics
Diluted Pentaerythritol Tetranitrate	Talc	Avian Mycoplasma Antigen
Pentamidine Isethionate	Terbutaline Tablets	Salmonella Pullorum Antigen
Pentamidine Injection	Theophylline	
Pethidine Hydrochloride	Theophylline Tablets	
Pethidine Injection	Thiamine Hydrochloride	
Phenolphthalein	Thiamine Nitrate	
Phenylbutazone	Tenofovir and Emtricitabine Tablets	
Piracetam	Terbutaline Sulphate	
Piroxicam	Thiotepa	
Polysorbate 20	Topiramate Tablets	
Polysorbate 80	Verapamil Hydrochloride	
Potassium Iodide	Verapamil Tablets	
Povidone	Vessopressin Injection	
Prednisolone	Vincristine Sulphate	
Propranolol Hydrochloride	Vincristine Injection	
Propranolol Injection	Xylometazoline Hydrochloride	
Propranolol Tablets	Warfarin Sodium	
Pseudoephedrine Hydrochloride	Warfarin Sodium Clathrate	
Pyrantel Pamoate	Zidovudine Tablets	
Quetiapine Fumarate		
Quinine Dihydrochloride Injection		

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