Monographs to be evaluated against the text "Related substances in dosage form monographs"

2018

A list of all monographs included in *The International Pharmacopoeia* before the publication of the guidance note: " *Guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products* " is presented in this document. Compliance of the monographs listed hereunder shall be evaluated against the previous text " *Related substances in dosage form monographs*" unless required otherwise by the competent authority. This text can be found on the website of The International Pharmacopoeia under "*Omitted texts*".

In the event that a revision of any of the specified texts are to be published in *The International Pharmacopoeia*, the revised text will be removed from this list and compliance of the revised text will be evaluated against the " *Guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products* " guidance note.

Pharmaceutical substances monographs

Abacavir sulfate

Acacia

Acetazolamide

Acetic acid

Acetylsalicylic acid

Aciclovir

Albendazole

Alcohol

Alcuronium chloride

Alginic acid

Allopurinol

Aluminium hydroxide

Aluminium magnesium silicate

Aluminium sulfate

Amidotrizoic acid

Amikacin sulfate

Amikacin

Amiloride hydrochloride

Aminophylline

Amitriptyline hydrochloride

Amodiaquine

Amodiaquine hydrochloride

Amphotericin B

Ampicillin

Ampicillin sodium

Anaesthetic Ether

Antimony sodium tartrate

Arachis oil

Artemether

Artemisinin

Artemotil

Artenimol

Artesunate

Ascorbic acid

Atazanavir sulfate

Atropine sulfate

Azathioprine

Bacitracin

Bacitracin zinc

Barium sulfate

Beclometasone dipropionate

Bentonite

Benzalkonium chloride

Benzathine benzylpenicillin

Benznidazole

Benzocaine

Benzoic acid

Benzyl alcohol

Benzyl benzoate

Benzyl hydroxybenzoate

Benzylpenicillin potassium

Benzylpenicillin sodium

Bephenium hydroxynaphthoate

Betamethasone

Betamethasone valerate

Biperiden

Biperiden hydrochloride

Bleomycin hydrochloride

Bleomycin sulfate

Bupivacaine hydrochloride

Busulfan

Butylated hydroxyanisole

Butylated hydroxytoluene

Caffeine

Calamine

Calcium carbonate

Calcium folinate

Calcium gluconate

Calcium hydrogen phosphate

Calcium phosphate

Calcium stearate

Calcium sulfate

Capreomycin sulfate

Captopril

Carbamazepine

Carbidopa

Carbomer

Carmellose sodium

Carnauba wax

Cellacefate

Cetomacrogol 1000

Cetostearyl alcohol

Cetrimide

Cetyl alcohol

Cetyl esters wax

Charcoal, activated

Chloral hydrate

Chlorambucil

Chloramphenicol

Chloramphenicol palmitate

Chloramphenicol sodium succinate

Chlorhexidine diacetate

Chlorhexidine dihydrochloride

Chlormethine hydrochloride

Chlorobutanol

Chlorocresol

Chloroquine phosphate

Chloroquine sulfate

Chlorphenamine hydrogen maleate

Chlorpromazine hydrochloride

Chlortalidone

Chlortetracycline hydrochloride

Cimetidine

Ciprofloxacin

Ciprofloxacin hydrochloride

Cisplatin

Citric acid

Clindamycin phosphate

Clofazimine

Clomifene citrate

Cloxacillin sodium

Coal tar

Codeine monohydrate

Codeine phosphate

Colchicine

Colecalciferol

Cyanocobalamin

Cyclophosphamide

Cycloserine

Cytarabine

Dactinomycin

Dapsone

Deferoxamine mesilate

Dehydroemetine dihydrochloride

Dexamethasone

Dexamethasone acetate

Dexamethasone sodium phosphate

Dextromethorphan hydrobromide

Diazepam

Diazoxide

Dicloxacillin sodium

Dicoumarol

Didanosine

Diethylcarbamazine dihydrogen citrate

Diethyltoluamide

Digitoxin

Digoxin

Diloxanide furoate

Dilute hydrochloric acid

Diluted Isosorbide dinitrate

Dimercaprol

Dinitrogen oxide

Diphenoxylate hydrochloride

Disodium edetate

Dithranol

Dopamine hydrochloride

Doxorubicin hydrochloride

Doxycycline hyclate

Edrophonium chloride

Efavirenz

Emetine hydrochloride

Emtricitabine

Ephedrine

Ephedrine hydrochloride

Ephedrine sulfate

Epinephrine

Epinephrine hydrogen tartrate

Ergocalciferol

Ergometrine hydrogen maleate

Ergotamine tartrate

Erythromycin

Erythromycin ethylsuccinate

Erythromycin lactobionate

Erythromycin stearate

Ethambutol hydrochloride

Ethanol

Ethinylestradiol

Ethionamide

Ethosuximide

Ethyl hydroxybenzoate

Ethylcellulose

Etoposide

Ferrous fumarate

Ferrous sulfate

Fluconazole

Flucytosine

Fludrocortisone acetate

Fluorescein sodium

Fluorouracil

Fluphenazine decanoate

Fluphenazine enantate

Fluphenazine hydrochloride

Folic acid

Furosemide

Gallamine triethiodide

Gelatin

Gentamicin sulfate

Glibenclamide

Glucose

Glycerol

Glycerol 85% m/m

Glyceryl monostearate

Griseofulvin

Haloperidol

Halothane

Hard fat

Hard paraffin

Heparin calcium

Heparin sodium

Homatropine hydrobromide

Homatropine methylbromide

Hydralazine hydrochloride

Hydrochloric acid

Hydrochlorothiazide

Hydrocortisone

Hydrocortisone acetate

Hydrocortisone sodium succinate

Hydrous Benzoyl peroxide

Hydroxocobalamin

Hydroxocobalamin chloride – Hydroxocobalamin sulfate

Hydroxyethylcellulose

Hydroxypropylcellulose

Hypromellose

Ibuprofen

Idoxuridine

Imipramine hydrochloride

Indinavir sulfate

Indometacin

Insulin

Iodine

Iohexol

Iopanoic acid

Iotroxic acid

Ipecacuanha root

Isoniazid

Isoprenaline hydrochloride

Isoprenaline sulfate

Kanamycin acid sulfate

Kanamycin monosulfate

Kaolin

Ketamine hydrochloride

Ketoconazole

Lactic acid

Lactose

Lamivudine

Levamisole hydrochloride

Levodopa

Levonorgestrel

Levothyroxine sodium

Lidocaine

Lidocaine hydrochloride

Lindane

Lithium carbonate

Loperamide hydrochloride

Lopinavir

Lumefantrine

Magnesium hydroxide

Magnesium oxide

Magnesium stearate

Magnesium sulfate heptahydrate

Mannitol

Mebendazole

Medroxyprogesterone acetate

Mefloquine hydrochloride

Meglumine

Mercaptopurine

Mercuric oxycyanide

DL-Methionine

Methotrexate

Methyl hydroxybenzoate

Methylcellulose

Methyldopa

Methylrosanilinium chloride

Methyltestosterone

Methylthioninium chloride

Metoclopramide hydrochloride

Metrifonate

Metronidazole

Metronidazole benzoate

Miconazole nitrate

Microcrystalline cellulose

Morphine hydrochloride

Morphine sulfate

Naloxone hydrochloride

Nelfinavir mesilate

Neomycin sulfate

Neostigmine bromide

Neostigmine metilsulfate

Nevirapine

Niclosamide

Nicotinamide

Nicotinic acid

Nifedipine

Nifurtimox

Niridazole

Nitrazepam

Nitrofurantoin

Nonoxinol 9

Norethisterone acetate

Norethisterone

Norethisterone enantate

Noscapine

Noscapine hydrochloride

Nystatin

Oseltamivir phosphate

Oxamniquine

Oxygen

Oxytetracycline dihydrate

Oxytetracycline hydrochloride

Oxytocin

Papaverine hydrochloride

Paracetamol

Paromomycin sulfate

Penicillamine

Pentamidine isetionate

Pentamidine mesilate

Pethidine hydrochloride

Phenobarbital

Phenobarbital sodium

Phenoxymethylpenicillin

Phenoxymethylpenicillin calcium

Phenoxymethylpenicillin potassium

Phenylmercuric nitrate

Phenytoin

Phenytoin sodium

Physostigmine salicylate

Phytomenadione

Pilocarpine hydrochloride

Pilocarpine nitrate

Piperazine adipate

Piperazine citrate

Podophyllum resin

Polysorbates 20, 60, 80

Potassium chloride

Potassium citrate

Potassium iodide

Povidone

Praziquantel

Prednisolone

Prednisolone acetate

Prednisolone sodium phosphate

Primaquine diphosphate

Probenecid

Procainamide hydrochloride

Procaine benzylpenicillin

Procaine hydrochloride

Procarbazine hydrochloride

Progesterone

Proguanil hydrochloride

Promethazine hydrochloride

2-Propanol

Propranolol hydrochloride

Propylene glycol

Propyliodone

Propyl hydroxybenzoate

Propylthiouracil

Protamine sulfate

Purified water

Pyrantel embonate

Pyrazinamide

Pyridostigmine bromide

Pyridoxine hydrochloride

Pyrimethamine

Quinidine sulfate

Quinine bisulfate

Quinine dihydrochloride

Quinine hydrochloride

Quinine sulfate

Reserpine

Retinol concentrate, oily form

Riboflavin

Rifampicin

Ritonavir

Saccharin sodium

Salbutamol

Salbutamol sulfate

Salicylic acid

Saquinavir mesilate

Saquinavir

Selenium disulfide

Senna fruit

Senna leaf

Silver nitrate

Sodium amidotrizoate

Sodium calcium edetate

Sodium chloride

Sodium citrate

Sodium cromoglicate

Sodium fluoride

Sodium hydrogen carbonate

Sodium hydroxide

Sodium nitrite

Sodium nitroprusside

Sodium salicylate

Sodium stibogluconate

Sodium sulfate

Sodium sulfate, anhydrous

Sodium thiosulfate

Sodium valproate

Spectinomycin hydrochloride

Spironolactone

Starches

Stavudine

Sterile water for injections

Streptomycin sulfate

Sulfacetamide

Sulfacetamide sodium

Sulfadiazine silver

Sulfadimidine

Sulfadimidine sodium

Sulfadoxine

Sulfamethoxazole

Sulfamethoxypyridazine

Sulfasalazine

Suramin sodium

Suxamethonium chloride

Talc

Tamoxifen citrate

Tenofovir disoproxil fumarate

Testosterone enantate

Testosterone propionate

Tetracaine hydrochloride

Tetracycline hydrochloride

Thiamine hydrobromide

Thiamine hydrochloride

Thiamine mononitrate

Thioacetazone

Thiopental sodium

Tiabendazole

Timolol maleate

Tolbutamide

Trihexyphenidyl hydrochloride

Trimethadione

Trimethoprim

Tropicamide

Tubocurarine chloride

Verapamil hydrochloride

Vinblastine sulfate

Vincristine sulfate

Warfarin sodium

Water for injections

White, soft paraffin; Yellow soft paraffin

Wool fat

Zidovudine

Zinc acetate

Zinc gluconate

Zinc oxide

Zinc sulfate

Dosage form monographs

Abacavir oral solution

Abacavir tablets

Acetylsalicylic acid tablets

Aciclovir for injection

Aciclovir tablets

Albendazole chewable tablets

Allopurinol tablets

Amikacin for injection

Amodiaquine tablets

Amoxicillin oral suspension

Amphotericin B for injection

Ampicillin capsules

Ampicillin sodium for injection

Artemether and lumefantrine oral suspension

Artemether and lumefantrine tablets

Artemether capsules

Artemether injection

Artemether tablets

Artemotil injection

Artenimol tablets

Artesunate for injection

Artesunate tablets

Atazanavir capsules

Atropine sulfate tablets

Benzylpenicillin potassium for injection

Capreomycin for injection

Carbamazepine tablets

Chewable mebendazole tablets

Chloroquine phosphate tablets

Chloroquine sulfate oral solution

Chloroquine sulfate tablets

Chlorphenamine hydrogen maleate tablets

Cloxacillin sodium capsules

Cloxacillin sodium for injection

Codeine phosphate tablets

Colchicine tablets

Cycloserine capsules

Dapsone tablets

Dexamethasone phosphate injection

Dexamethasone tablets

Didanosine oral powder

Didanosine tablets

Diethylcarbamazine dihydrogen citrate tablets

Diloxanide furoate tablets

Doxycycline capsules

Doxycycline tablets

Efavirenz capsules

Efavirenz oral solution

Efavirenz tablets

Efavirenz, emtricitabine and tenofovir tablets

Emtricitabine and tenofovir tablets

Emtricitabine capsules

Ephedrine sulfate injection

Ergometrine hydrogen maleate tablets

Ergometrine injection

Erythromycin ethylsuccinate tablets

Erythromycin stearate tablets

Ethambutol hydrochloride tablets

Fluconazole capsules

Fluconazole injection

Glyceryl trinitrate tablets

Griseofulvin tablets

Ibuprofen tablets

Indinavir capsules

Indometacin tablets

Isoniazid and ethambutol hydrochloride tablets

Isoniazid tablets

Kanamycin for injection

Lamivudine oral solution

Lamivudine tablets

Levamisole tablets

Levonorgestrel and ethinylestradiol tablets

Levonorgestrel tablets

Lopinavir and ritonavir tablets

Magnesium sulfate injection

Medroxyprogesterone injection

Mefloquine tablets

Melarsoprol injection

Metronidazole injection

Metronidazole oral suspension

Metronidazole tablets

Morphine sulfate tablets

Nelfinavir mesilate oral powder

Nelfinavir mesilate tablets

Nevirapine oral suspension

Nevirapine tablets

Niclosamide tablets

Nitrofurantoin tablets

Nystatin tablets

Oral rehydration salts

Oseltamivir capsules

Oxytocin injection

Paediatric didanosine liquid for oral use

Paediatric zinc sulfate oral solution

Paediatric zinc sulfate tablets

Paracetamol oral solution

Paracetamol oral suspension

Paracetamol tablets

Pentamidine isetionate for injection

Pethidine hydrochloride tablets

Phenobarbital tablets

Phenoxymethylpenicillin potassium tablets

Phenytoin sodium tablets

Piperazine adipate tablets

Piperazine citrate tablets

Praziquantel tablets

Prednisolone phosphate injection

Prednisolone sodium succinate for injection

Prednisolone tablets

Primaquine diphosphate tablets

Probenecid tablets

Procaine benzylpenicillin for injection

Pyrantel chewable tablets

Pyrantel oral suspension

Pyrantel tablets

Pyrazinamide tablets

Quinine bisulfate tablets

Quinine dihydrochloride injection

Quinine sulfate tablets

Retinol oral solution

Rifampicin and isoniazid dispersible tablets

Rifampicin and isoniazid tablets

Rifampicin capsules

Rifampicin tablets

Rifampicin, isoniazid and ethambutol hydrochloride tablets

Rifampicin, isoniazid and pyrazinamide dispersible tablets

Rifampicin, isoniazid and pyrazinamide tablets

Rifampicin, isoniazid, pyrazinamide and ethambutol hydrochloride tablets

Ritonavir tablets

Saquinavir mesilate capsules

Saquinavir tablets

Sodium bicarbonate intravenous infusion

Stavudine capsules

Streptomycin for injection

Sulfadoxine and pyrimethamine tablets

Sulfamethoxazole and trimethoprim intravenous infusion

Sulfamethoxazole and trimethoprim oral suspension

Sulfamethoxazole and trimethoprim tablets

Tenofovir tablets

Zidovudine and lamivudine tablets

Zidovudine capsules

Zidovudine intravenous infusion

Zidovudine, lamivudine and abacavir tablets

Zidovudine, lamivudine and nevirapine tablets

Zidovudine oral solution