

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
Diethylcarbazine 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
Propylidone
Propyl hydroxybenzoate
Propylthiouracil
Protamine sulfate
Purified water
Pyrantel embonate
Pyrazinamide
Pyridostigmine bromide
Pyridoxine hydrochloride
Primethamine
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