

UPDATED WORK PROGRAMME OF THE EUROPEAN PHARMACOPOEIA

(June 2009)

The following items have recently been added to the work programme of the European Pharmacopoeia. Please note that the accumulative work programme is available in the Knowledge database (<http://www.edqm.eu/site/Databases-10.html>).

Interested parties are invited to contact the EDQM (lynn.kelso@edqm.eu) with a view to participating in the work on items of interest.

TEXTS TO BE REVISED

2.4.27. Heavy metals in herbal drugs and fatty oils	Introduction of inductively coupled plasma-atomic emission spectrometry and inductively coupled plasma-mass spectrometry
2.6.26. Test for anti-D antibodies in human immunoglobulin for intravenous administration	Technical improvements to the direct method
2.8.13. Pesticide residues	Proposal to delete the limit for inorganic bromide
2.9.41. Friability of granules and spheroids	Modified dimensions and equations
3.2.1. Glass containers for pharmaceutical use	Revision of test B: Hydrolytic resistance of glass grains
5.2.2. Chicken flocks free from specified pathogens for the production and quality control of vaccines	Routine testing of designated SPF flocks: raise the maximum weekly mortality limit of SPF chickens to 0.2 %
Betamethasone (0312)	Related substances
Birch leaf (1174)	Total ash
Bromocriptine mesilate (0596)	Related substances
Buserelin (1077)	Identification test B
Calcium folinate (0978)	Related substances
Calcium stearate (0882)	Addition of a test for thermogravimetry
Capsicum oleoresin, refined and quantified (2336)	Definition, content of total capsaicinoids
Carboplatin (1081)	Related substances
Cloxacillin sodium (0661)	Quality and incomplete expression of limits
Copovidone (0891)	Test for 2-pyrrolidone
Diclofenac potassium (1508)	Related substances
Diclofenac sodium (1002)	Related substances
Dicloxacillin sodium (0663)	Quality and incomplete expression of limits
Dobutamine hydrochloride (1200)	Related substances
Domperidone (1009)	Related substances
Doxylamine hydrogen succinate (1589)	Related substances, system suitability criterion
Econazole nitrate (0665)	Related substances
Estradiol valerate (1614)	Related substances
Estriol (1203)	Related substances
Ethyl parahydroxybenzoate sodium (2134)	Identification, related substances, assay
Fentanyl (1210)	Related substances
Fentanyl citrate (1103)	Related substances
Fish oil, rich in omega-3-acids (1912)	Test for oligomers
Flucloxacillin sodium (0668)	Quality and incomplete expression of limits
Fluoxetine hydrochloride (1104)	Replacement of toxic reagents/solvents

General Information

Flutamide (1423)	Related substances
Glyceryl trinitrate solution (1331)	Related substances
Goserelin (1636)	Identification test A
Haemofiltration and for haemodiafiltration, solutions for (0861)	Bacterial endotoxins
Haloperidol (0616)	Related substances
Hawthorn berries (1220)	Assay
Human normal immunoglobulin (0338)	Anti-A and B haemagglutinins: replacement of the indirect method by a direct method
Human normal immunoglobulin for intravenous administration (0918)	Anti-A and B haemagglutinins: replacement of the indirect method by a direct method
Human tetanus immunoglobulin (0398)	Potency: addition of 2 <i>in vitro</i> methods
Hydrochlorothiazide (0394)	Assay
Hydrocortisone (0335)	Related substances
Hydroxypropylbetadex (1804)	Related substances
Ketoprofen (0922)	Related substances
Lactose monohydrate (0187)	Microbial contamination
Mepivacaine hydrochloride (1242)	Related substances
Methylprednisolone acetate (0933)	Related substances
Miconazole nitrate (0513)	Related substances
Mitoxantrone hydrochloride (1243)	Related substances
Noscapine (0516)	Related substances
Noscapine hydrochloride (0515)	Related substances
Ofloxacin (1455)	Related substances
Omega-3-acid ethyl esters 60 (2063)	Test for oligomers
Omega-3-acid ethyl esters 90 (1250)	Test for oligomers
Omega-3-acid triglycerides (1352)	Test for oligomers
Parnaparin sodium (1252)	Definition and Identification C: potency and molecular mass distribution specifications
Phenoxymethylpenicillin (0148)	Quality and incomplete expression of limits
Phenoxymethylpenicillin potassium (0149)	Quality and incomplete expression of limits
Povidone (0685)	Test for 2-pyrrolidone
Praziquantel (0855)	Related substances
Sodium citrate (0412)	Replacement of the test for pyrogens
St. John's wort dry extract, quantified (1874)	Loss on drying/Water content
Tamoxifen citrate (1046)	Related substances
Thiopental sodium and sodium carbonate (0212)	Replacement of toxic reagents/solvents
Triglycerol diisostearate (2032)	Iodine value
Vaccines for veterinary use (0062)	Include a general statement allowing licensing authorities to apply EMEA Guideline in case of minor use, revise sterility and mycoplasma tests, add a statement on the calculation of the expiry date, add antigenic component on the label
Zolpidem tartrate (1280)	Related substances

NEW TEXTS TO BE ELABORATED

5.1.11. Test for determination of the bactericidal and yeasticidal activity