

Updated Work Programme of the European Pharmacopoeia

(March 2011)

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 (www.edqm.eu/site/Databases-10.html).

Interested parties are invited to contact the EDQM via the EDQM HelpDesk (www.edqm.eu/hd) with a view to participating in the work on items of interest.

TEXTS TO BE REVISED

5.1.6. Alternative methods for control of microbiological quality	Addition of validation examples
5.1.8. Microbiological quality of herbal medicinal products for oral use	Acceptance criteria for extracts intended to be incorporated into herbal medicinal products for oral use
Arnica flower (1391)	TLC identification Assay method
Arnica tincture (1809)	TLC identification Assay method
Belladonna leaf dry extract, standardised (1294)	Microbiological acceptance criteria for extracts intended to be incorporated into herbal medicinal products for oral use
Carrageenan (2138)	IR identification Test for heavy metals
Chamomile flower, roman (0380)	Replacement of microscopic description of plant parts by description of powder
Diethylene glycol palmitostearate (1415)	Analytical improvement
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (1934)	D-antigen
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2329)	D-antigen
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)	D-antigen
Eleutherococcus (1419)	Calculation formula
Ethylene glycol monopalmitostearate (1421)	Analytical improvement
Filgrastim concentrated solution (2206)	Identifications B, D and E Tests for impurities with molecular masses higher than that of filgrastim, test for related proteins Assay: protein
Finasteride (1615)	Update of impurity limits
Foot-and-mouth disease (ruminants) vaccine (inactivated) (0063)	VICH harmonisation, immunogenicity, definition, target species
Frangula bark dry extract, standardised (1214)	Microbiological acceptance criteria for extracts intended to be incorporated into herbal medicinal products for oral use
Glycerol monolinoleate (1429)	Analytical improvement
Glycerol mono-oleate (1430)	Analytical improvement
Glycerol monostearate 40-55 (0495)	Analytical improvement

Human normal immunoglobulin for intravenous administration (0918)	Modification of the Production section
Hydrochlorothiazide (0394)	Update of the test for related substances
Java tea (1229)	Sinensetin content
Lamotrigine (1756)	Update of the test for related substances
Levonorgestrel (0926)	Addition of new impurities
Lovastatin (1538)	Limit of specified impurity F
Magnesium aspartate dihydrate (1445)	Optical rotation test limits
Matricaria oil (1836)	TLC identification
Nimodipine (1245)	Update of the test for related substances
Peritoneal dialysis, solutions for (0862)	Tightening of limits for bacterial endotoxins and aluminium Investigation of potential replacement of the pyrogens test by monocyte-activation test
Prednicarbate (1467)	Update of the impurity limits
Propylene glycol dicaprylocaprate (2122)	Analytical improvement
Propylene glycol dilaurate (2087)	Analytical improvement
Propylene glycol monolaurate (1915)	Analytical improvement
Propylene glycol monopalmitostearate (1469)	Analytical improvement
Protamine sulfate (0569)	Definition, identification, tests and assay, to cover the use of protamine as an excipient in insulin preparations
Rabies vaccine for human use prepared in cell cultures (0216)	Assay, glycoprotein content, test for residual infectious virus, test for residual host cell DNA, test for pyrogens
Senna leaf dry extract, standardised (1261)	Microbiological acceptance criteria for extracts intended to be incorporated into herbal medicinal products for oral use
Triglycerides, medium-chain (0868)	Analytical improvement
Turpentine oil, Pinus pinaster type (1627)	Introduction of additional plant species
Veterinary liquid preparations for cutaneous application (1808)	Revision of the Definition section
Wool alcohols (0593)	Melting point, water absorption capacity

NEW TEXTS TO BE ELABORATED

General chapter on multivariate data analysis

Iron sucrose concentrated solution (2753)

Serratulae coronatae herba (2754)