Updated Work Programme of the European Pharmacopoeia

(November 2010)

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

2.6.16. Tests for extraneous agents in viral vaccines for human use	Update of the testing procedures needed in terms of the 3Rs principle
2.6.31. Microbiological examination of herbal medicinal products for oral use	Include validation of culture media
2.7.4. Assay of human coagulation factor VIII	Chromogenic assay
2.9.10. Ethanol content and alcoholimetric tables	Introduction of oscillating transducer density meter
3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders	Identification B and C
5.2.3. Cell substrates for the production of vaccines for human use	Update of the testing procedures needed in terms of the 3Rs principle
Acacia / Acaciae gummi (0307)	Identification: TLC/HPTLC
Acacia, spray-dried (0308)	Identification: TLC/HPTLC
Basic butylated methacrylate copolymer (1975)	Improvement of the method for monomers
Belladonna leaf / Belladonnae folium (0221)	Identification: TLC/HPTLC
Buckwheat herb / Fagopyri herba (2184)	Content of rutin
Captopril (1079)	Related substances: limit for impurity J
Cassia oil / Cinnamomi cassiae aetheroleum (1496)	Identification: TLC/HPTLC Chromatographic profile: GC method
Cetirizine dihydrochloride (1084)	Related substances: correction factors, system suitability criteria
Cetostearyl alcohol (type A), emulsifying (0801)	Identification: improvement of TLC
Cetostearyl alcohol (type B), emulsifying (0802)	Identification: improvement of TLC
Ciclosporin (0994)	Assay limits in-line with the Technical guide
Cinnamon / Cinnamomi cortex (0387)	Identification: TLC/HPTLC Chromatographic profile: GC method
Cinnamon bark oil, Ceylon / Cinnamomi zeylanici corticis aetheroleum (1501)	Identification: TLC/HPTLC Chromatographic profile: GC method
Cinnamon leaf oil, Ceylon / Cinnamomi zeylanici folii aetheroleum (1608)	Identification: TLC/HPTLC Chromatographic profile: GC method
Cinnamon tincture / Cinnamomi corticis tinctura (1819)	Identification: TLC/HPTLC Chromatographic profile: GC method
Danaparoid sodium (2090)	Anti-factor IIa activity, anti-factor Xa activity, chondroitin sulfate and dermatan sulfate (including the dermatan sulfate limit)
Dihydrostreptomycin sulfate for veterinary use (0485)	Investigate the need for widening the limits
Fennel, bitter / Foeniculi amari fructus (0824)	Limits of water content
Filgrastim concentrated solution (2206)	Definition, potency
Gentamicin sulfate (0331)	Consider a test for substances that lower blood pressure

Glycerol distearate (1428)	Identification: deletion of the TLC Assay: revision of calculations
Haemophilus type b conjugate vaccine (1219)	Sterility requirement for bulk intermediates
Heparins, low-molecular-mass (0828)	Tests for nucleotide and protein impurities, heavy metals and sodium
Human plasma (pooled and treated for virus inactivation) (1646)	Addition of a test for Activated Partial Thromboplasmin Time (APTT)
Hyoscyamus for homoeopathic preparations (2091)	Assay: LC method
Java tea / Orthosiphonis folium (1229)	Calculation formula and chromatographic conditions
Magnesium oxide, heavy (0041) Magnesium oxide, light (0040)	Bulk density of a product that does not comply with the requirements of either of the 2 monographs
Meningococcal group C conjugate vaccine (2112)	Sterility requirement for bulk intermediates
Netilmicin sulfate (1351)	Related substances: review of the limits and analytical procedure
Nicotine resinate (1792)	Water (Karl Fischer test)
Norethisterone acetate (0850)	Addition of specified impurities and an increase in the limit for impurity F
Parenteral preparations (0520)	Implants: addition of a statement on the need for testing the release of the active substances
Pneumococcal polysaccharide conjugate vaccine (adsorbed) (2150)	Sterility requirement for bulk intermediates
Rocuronium bromide (1764)	Tests for water, heavy metals and 2-propanol
Sodium cetostearyl sulfate (0847)	Identification: improvement of TLC
Tablets (0478)	Addition of a statement under Definition and addition of a Production section, both for chewable tablets
Tiapride hydrochloride (1575)	Harmonisation with current policy
Vaccines for human use (0153)	Antimicrobial preservative specification

NEW TEXTS TO BE ELABORATED

Adhatoda vasica leaf / Adhatodae vasicae folium (2738)

Chionanthus virginicus ad praeparationes homoeopathicas (2739)

Datura stramonium ad praeparationes homoeopathicas (2734)

Dienogest (2732)

Escitalopram oxalate (2733)

Highly pathogenic chicken influenza vaccine (inactivated) (2749)

Lachesis mutus ad praeparationes homoeopathicas (2502)

Magnolia flower / Magnoliae flos (2742)

Picrorhiza kurroa rhizome and root / Picrorhizae kurroae rhizoma et radix (2744)

Podophyllotoxin (2750)

Sodium selenite, anhydrous (2740)

Sulfadimethoxine (2741)

Sulfadimethoxine sodium (2745)

Withania somnifera root / Withaniae somniferae radix (2746)

Zolmitriptan (2737)