Decisions Ph. Eur. Com.
November 2004

Modification Work Programme European Pharmacopoeia Commission

Participants:
Member States: 29 delegations were present
Observer States: 3 delegations participated in the session

Decisions:

Revisions	**Reason for revision:**
Alfuzosin hydrochloride (1287)	Related substances, pH, Impurities section
Allergen products (1063)	Deletion of abnormal toxicity test
Amphotericin B (1292)	Identification by LC to replace UV, test for related substances/composition by LC to replace determination tetraenes
Ascorbyl palmitate (0807)	Revise storage section
Atenolol (0703)	Related substances
Buprenorphine hydrochloride (1181)	Revise related substances test (introduce gradient) to allow the detection of an additional impurity
Buprenorphine (1180)	Revise related substances test (introduce gradient) to allow the detection of an additional impurity
Calcitonin (Salmon) (0471)	Impurities section
Cefoxitin sodium (0990)	Related substances
Carnauba wax (0597)	Saponification value
Cholecaliferol (0072)	Add related substances test by HPLC to control a precursor (currently no related subtances test)
Clindamycin hydrochloride (0582)	Expression of content in Definition
Clobetasone butyrate (1090)	Revise related substances test and limits
Clonidine hydrochloride (0477)	Revise related substances tests: replace TLC by HPLC
Dimenhydrinate (0601)	Revise related substances tests
Drop Point (2.2.17)	Description of an automated method
Enoxaparin sodium (1097)	Specification for anti-IIa activity

Erythromycin lactobionate (1098)	Related substances
Erythropoietin concentrated solution (1316)	Upper limit for sialic acid, limits for dimer, test for oxidised forms, glycan mapping, *in vitro* assay
Estradiol benzoate (0139)	Related substances, Impurities section
Fenoterol hydrobromide (0901)	Add an HPLC test for related substances
Human prothrombin complex (0554)	Revision of the definition so that potency is based on the factor II (prothrombin) content
Hydrocortisone (0335)	Revise related substances test and limits
Ibuprofen (0721)	Impurities section
Levonorgestrel (0926)	Revise related substances tests
Lincomycin hydrochloride (0583)	Expression of content in Definition
Magnesium lactate dihydrate (2160)	Add a test for related substances (LC) and a test for calcium and alkali salts
Norethisterone acetate (0850)	Related substances, Impurities section
Pethidine hydrochloride (0420)	Revise related substances test to improve sensitivity for impurity B determination
Protein determination for plasma products (2.5.33)	Inclusion of alternative methods for protein determination
RRR-alpha-Tocopherol (1256)	Contamination by benzo[a]pyrene
Serological assay of diphtheria vaccine (2.7.6)	Addition of serological assay
Serological assay of tetanus vaccine (2.7.8)	Revision of serological assay to allow assay of diphtheria and tetanus vaccines in the same groups of animals
Technetium (99mTc) etifenin injection (0585)	Physiological distribution, radiochemical purity
Technetium (99mTc) gluconate injection (1047)	Physiological distribution, radiochemical purity
Technetium (99mTc) human albumin injection (0640)	Physiological distribution, radiochemical purity
Technetium (99mTc) medronate injection (0641)	Physiological distribution, radiochemical purity
Technetium (99mTc) succimer injection (0643)	Physiological distribution, radiochemical purity
Timolol maleate (0572)	Revise related substances test and impurity section, introduce HPLC
Tributyl acetylcitrate (1770)	Related substances; limits
Trimipramine maleate (0534)	Revise related substances tests, replace TLC by HPLC, update transparency statement
Vinpocetine (2139)	Related substances

New monographs	
Calcium gluconate, anhydrous	
Cholesterol in fish oils rich in omega-3-acids	
Dextropropoxyphene base	
Galantamine hydrobromide	
Hydroxyethylstarch	
Refined castor oil	
Rifaximin	
Somatropin injection in liquid form	
Sucralose	
Tagatose	
Traditional Chinese Medicines	