



**Decisions Ph. Eur. Com.
November 2005**

***Report of the Decisions taken at the
123rd Session of the European Pharmacopoeia Commission
22nd - 24th November 2005***

Participants:

Member States: 28 delegations were present

Observer States: 4 delegations participated in the session

I. TEXTS and CRS/BRPs ADOPTED

**LIST OF TEXTS ADOPTED FOR PUBLICATION IN THE 5TH EDITION
(SUPPLEMENT 5.6) AND DATE OF IMPLEMENTATION: 01/01/2007**

34 NEW MONOGRAPHS ADOPTED

Alverine citrate (2156)

Anthrax vaccine for human use (2188)

Benzoin, sumatra (1814)

Capsicum oleoresin, refined and quantified (2336)

Capsicum tincture, standardised (2337)

Cascara dry extract, standardised (1844)

Cefepime dihydrochloride monohydrate (2126)

Cladribine (2174)

Dembrexine HCl monohydrate for Vet. Use (2169)

Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigens content) (2328)

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigens content) (2329)

Dopexamine dihydrochloride (1748)

Enalaprilate dihydrate (1749)

Feline chlamydiosis vaccine (inactivated) (2324)

Gemcitabine hydrochloride (2306)

Guaiacol (1978)

* Human haematopoietic stem cells (2323)

Human von Willebrand factor (2298)

Letrozole (2334)

Loratadine (2124)

Mandarin oil (2355)

Manganese glycerophosphate, hydrated (2163)

Milk thistle dry extract, refined and standardised (2071)

Modafinil (2307)

Mycoplasma gallisepticum vaccine (inactivated) (1942)

* Naproxen sodium (1702)

New and revised Standard Terms

* To be confirmed

Oxitropium bromide (2170)
Purple coneflower herb (1823)
Purple coneflower root (1824)
Pyrrolidone (2180)
Terazosin hydrochloride dihydrate (2021)
Tropisetron hydrochloride (2102)
Verbena herb (1854)

9 NEW GENERAL TEXTS AND GENERAL METHODS OF ANALYSIS

Apparent dissolution (2.9.43)
* Herbal drugs: determination of aflatoxin B₁ (2.8.18)
Characterisation of crystalline and partially crystalline solids by XRPD (2.9.33)
Flocculation value (Lf) of diphtheria and tetanus toxins and toxoids (2.7.27)
* Flow cytometry (2.7.24)
Gene transfer medicinal products for human use (5.14)
* Microbiological control of cellular products (2.6.27)
Particle-size analysis by laser-light diffraction (2.9.31)
* Reference standards (5.12)

18 REVISED MONOGRAPHS

Agnus castus fruit (1844)
Azithromycin (1649)
Bendroflumethiazide (0370)
Bisacodyl
Bromazepam (0879)
Diazepam (0022)
Human anti-D immunoglobulin (0557)
Human anti-D immunoglobulin for intravenous administration (1527)
Human normal immunoglobulin (0338)
Human normal immunoglobulin for intravenous administration (0918)
Human plasma (pooled and treated for virus inactivation) (1646)
Levodopa (0038)
Lorazepam (1121)
Marek's disease vaccine (live) (0589)
Methotrexate (0560)
Newcastle disease vaccine (inactivated) (0870)
Phytosterol (1911)
Prednisolone acetate (0734)

6 REVISED GENERAL TEXTS AND GENERAL METHODS

Composition of fatty acids by GC (2.4.22)
In vivo assay of poliomyelitis vaccine (inactivated) (2.7.20)
Microbiological examination of non-sterile products (test for specified micro-organisms) (2.6.13)
Microbiological examination of non-sterile products (total viable aerobic count) (2.6.12)
* Microbiological quality of pharmaceutical preparations (5.1.4)
Mycoplasmas (2.6.7)

* To be confirmed

59 MINOR REVISION OF MONOGRAPHS AND GENERAL CHAPTERS

Absorption spectrometry (2.2.25)
all-rac-alpha-Tocopherol (0692)
all-rac-alpha-Tocopheryl acetate (0439)
alpha-Tocopheryl Acetate Conc. (powder form) (0691)
Ascorbic acid (0253)
Ascorbyl palmitate (0807)
Assay of heparin (2.7.5)
Betacarotene (1069)
Bromocriptine mesilate (0596)
Buserelin (1077)
Calcitonin (salmon) (0471)
Calcium Ascorbate (1182)
Cetostearyl emulsifying alcohol (type A) (0801)
Cetostearyl emulsifying alcohol (type B) (0802)
Cholecalciferol concentration (oily form) (0575)
Cholecalciferol concentration (powder form) (0574)
Cholecalciferol concentration (water-dispersible form) (0598)
Cyanocobalamin (fermentation product-definition) (0547)
Diphtheria and tetanus vaccine (adsorbed) for adults and adolescents (0647)
Diphtheria vaccine (adsorbed) for adults and adolescents (0646)
DL-alpha-Tocopheryl hydrogen succinate (1258)
Fluconazole (2287)
General Notices
Glycerol mono-oleate (1430)
* Hepatitis A vaccine (inactivated, adsorbed) (1107)
* Hepatitis B vaccine (rDNA) (1056)
Human coagulation factor VIII (0275)
Human fibrinogen (0024)
Human plasma for fractionation (0853)
Hydroxocobalamin acetate (0913)
Hydroxocobalamin chloride (0914)
Hydroxocobalamin sulphate (0915)
Liquid preparations for oral use (0672)
Magnesium oxide, heavy (0041)
Magnesium oxide, light (0040)
Mannitol (0559)
Nasal preparations (0676)
Optical rotation (2.2.7)
Phytomenadione (1036)
* Poliomyelitis vaccine (inactivated) (0214)
Preparations for irrigation (1116)
* Rabies vaccine for human use prepared in cell culture (0216)
Riboflavin sodium phosphate (0786)
RRR-alpha-Tocopherol (1256)
RRR-alpha-Tocopheryl acetate (1257)
RRR-alpha-Tocopheryl hydrogen succinate (1259)
Sodium ascorbate
Sodium sulphite heptahydrate (0776)
Sodium sulphite, anhydrous (0775)

* To be confirmed

Stannous chloride dihydrate (1266)
Stearic acid (1474)
Sulphated ash (2.4.14)
Test for deliverable mass or volume of liquid and semi-solid preparations (2.9.28)
Tetanus vaccine for veterinary use (0697)
Vitamin A (0217)
Vitamin A Concentrate (oily form), synthetic (0219)
Vitamin A Concentrate (powder form), synthetic (0218)
Vitamin A Concentrate (solubil./ emulsion), synthetic (0220)
Zuclopenthixol decanoate (1707)

49 NEW CRSs/BRPs ADOPTED

Amitriptyline HCl CRS 1; Anhydrous nevirapine CRS 1; Anhydrous paroxetine HCl impurity C CRS 1; Anhydrous paroxetine HCl impurity H CRS 1; Benzyl alcohol CRS 1; Buspirone HCl CRS 1; Calcipotriol monohydrate CRS 1; Cefalotin for impurity B identification CRS 1; Cefotaxime acid CRS 1; Cefotaxime for peak identification CRS 1; Chlorogenic acid CRS 1; Danaparoid sodium CRS 1; Desogestrel CRS 1; Desogestrel for system suitability CRS 1; Dihydrotestosterone CRS 1; Dihydrotestosterone for system suitability CRS 1; Etidronate disodium CRS 1; Fluconazole CRS 1; Fluconazole for peak identification CRS 1; Fluconazole impurity B CRS 1; Fluconazole impurity C CRS 1; Gemfibrozil CRS 1; Glimepiride CRS 1; Glimepiride for system suitability CRS 1; Ivy leaf standardised tincture CRS 1; Methotrexate for peak identification CRS 1; Mycophenolate mofetil for peak identification CRS 1; Myo-Inositol CRS 1; Nevirapine for peak identification CRS 1; Oxacillin sodium monohydrate CRS 1; Oxazepam for peak identification CRS 1; Pamidronate disodium pentahydrate CRS 1; Paroxetine HCl impurity E CRS 1; Rocuronium bromide for peak identification CRS 1; Rocuronium bromide reference spectrum; Spectinomycin for system suitability CRS 1; Sulbactam for peak identification CRS 1; Sultamicillin CRS 1; Sultamicillin for peak identification CRS 1; Thioridazine for system suitability CRS 1; Trandolapril CRS 1; Trandolapril impurity C CRS 1; Trandolapril impurity D CRS 1; Valerian standardised dry extract CRS 1; Valnemulin HCl CRS 1; Valnemulin impurity E CRS 1; Vinpocetine impurity A CRS 1; Vinpocetine impurity B CRS 1; Zuclopenthixol for system suitability CRS 1.

50 REPLACEMENT BATCHES

4-Epitetracycline HCl CRS 6; 4-Epixytetracycline CRS 6; Adenine CRS 2; Alfacalcidol CRS 4; Allopurinol impurity A CRS 2; Allopurinol impurity C CRS 2; Allopurinol impurity D CRS 3; Amiodarone HCl CRS 3; Betadex CRS 4; Betamethasone sodium phosphate CRS 3; Bifonazole impurity B CRS 2; Calcium pantothenate CRS 3; Carbamazepine impurity A CRS 4; Ceftazidime impurity A CRS 2; Clomifene citrate CRS 2; Codeine impurity A CRS 3; Dalteparin sodium CRS 2; Ergocalciferol CRS 6; Erythromycin C CRS 4; Estrone CRS 3; Fenofibrate impurity A CRS 3; Flucloxacillin sodium CRS 6; Flumequine impurity B CRS 2; Flunarizine diHCl CRS 3; Formoterol fumarate dihydrate CRS 2; Galactose CRS 2; Glycerol monostearate 40-55 CRS 2; Glycine CRS 3; Human immunoglobulin (molecular size) BRP 1; Human Immunoglobulin BRP 3; Human Insulin CRS 3; Hydrocortisone acetate CRS 8; Hydrocortisone CRS 8; Itraconazole CRS 2; Ketofusidic acid CRS 3; Ketoprofen CRS 2; Levocarnitine CRS 2; Oxaliplatin impurity C CRS 2; Pheniramine maleate CRS 2; Piracetam CRS 2; Piroxicam for system suitability CRS 3; Prednisolone sodium phosphate CRS 4; Propofol CRS 3; Riboflavin CRS 3; Sodium cromoglicate CRS 2; Spectinomycin HCl CRS 2; Sulfapyrazone impurity A CRS 3; Sumatriptan impurity A CRS 2; Terbutaline impurity C CRS 3; Zolpidem impurity A CRS 3.

II. EUROPEAN PHARMACOPOEIA WORK PROGRAMME

6 NEW MONOGRAPHS AND GENERAL CHAPTERS

Cholesterol (high-purity)
Cod-liver oil, farmed
Microcrystalline wax
Synthetic paraffin
Trimagnesium citrate 14-hydrate
Trimagnesium citrate 9-hydrate

33 REVISIONS OF MONOGRAPHS AND GENERAL CHAPTERS

Agnus castus fruit (2147)
Anti-A and Anti-B haemagglutinins (2.6.20)
Cefazolin sodium (0988)
Clove oil (1091)
Cocaine hydrochloride (0073)
Colistin sulphate (0320)
Devil's claw root (1095)
Ethyl parahydroxybenzoate sodium (2134)
Extracts (765)
Folic acid (0067)
Glucagon, human (1635)
Gonadorelin acetate (0827)
Human anti-D immunoglobulin (0557)
Human anti-D immunoglobulin for intravenous administration (1527)
Levothyroxine sodium (0401)
Liquid preparations for cutaneous application (0927)
Semi-solid preparations for cutaneous application (0132)
Measurement of consistency by penetrometry (2.9.9)
Melissa leaf (1447)
Minocycline hydrochloride (1030)
Nicotinamide (0047)
NMR spectroscopy (2.2.33)
Nomegestrol acetate (1551)
Phytomenadione (1036)
Protamine hydrochloride
Roselle (1623)
Statistical analysis of results of biological assays and tests (5.3)
Stearic acid (1474)
Thiamine hydrochloride (0303)
Thiamine nitrate (0531)
Vaginal preparations (1164)
Rectal preparations (1145)
Willow bark (1583)

**4 DELETIONS OF MONOGRAPHS AND GENERAL CHAPTERS FROM THE
WORK PROGRAMME**

Anistreplase

Dornase alfa rDNA

* Hydrocodone (2349)

Imiglucerase

**1 DELETION OF MONOGRAPHS AND GENERAL CHAPTERS FROM THE REVISIONS
PROGRAMME**

Urokinase (0695)