Decisions Ph. Eur. Com.
June 2004

Report of the 119th session
of the European Pharmacopoeia Commission
16-17th June 2004

Participants:
Member States: 28 delegations were present
Observer States: 5 delegations participated in the session

Decisions:
The European Pharmacopoeia Commission, meeting for its 119th session elected Prof. De Jong as the First Vice-chair and Mrs Köszegi-Szalai as the Second Vice-chair of the Commission.

I. TEXTS and CRS/BRPs ADOPTED
LIST OF TEXTS ADOPTED FOR PUBLICATION IN THE 5TH EDITION (SUPPLEMENT 5.2) AND DATE OF IMPLEMENTATION: 1/07/2005

23 NEW MONOGRAPHS ADOPTED
Monoclonal antibodies for human use (2031)
Atracurium besilate (1970)
Barium chloride dihydrate for homoeopathic preparations (2142)
Benzoe, Siam (2158)
Calcium iodide tetrahydrate for homoeopathic preparations (2144)
Carboprost trometamol (1712)
Chondroitin sulphate sodium (2064)
Cinchona liquid extract, standardised (1818)
Copper acetate monohydrate for homoeopathic preparation (2146)
Didanosine (2200)
Narrow-leaved coneflower root (1821)
Pale coneflower root (1822)
Buckwheat herb (2184)
Felypressin (1634)
Red mercuric sulphide for homoeopathic preparations (2145)
Methanol (1989)
Mycophenolate mofetil (1700)
Sodium iodide (131I) capsules for therapeutic use (2116)
Pimobendan (2179)
Repaglinide (2135)
Salmeterol xinafoate (1765)
Torasemide, anhydrous (2132)
Trospium chloride (1798)

1 NEW GENERAL TEXTS AND GENERAL METHODS OF ANALYSIS
2.9.40 Uniformity of dosage units

33 REVISED MONOGRAPHS

Human albumin solution (0255)
Ear preparations (0652)
Capsules (0016)
Sodium starch glycolate (Type A) (0983)
Sodium starch glycolate (Type B) (0984)
Chlordiazepoxide hydrochloride (0474)
Chlordiazepoxide (0656)
Cocoyl caprylocaprate (1411)
Tablets (0478)
Diethylene glycol monopalmitostearate (1415)
Patches, transdermal (1011)
Fluorescein sodium (1213)
Granules (0499)
Hedera helix for homoeopathic preparations (2092)
Hexamidine diisetionate (1436)
Hyoscyamus for homoeopathic preparations (2091)
Chewing gums, medicated (1239)
Metacresol (2077)
Methadone hydrochloride (0408)
Morphine hydrochloride (0097)
Morphine sulphate (1244)
Naproxen (0731)
Eye preparations (1163)
Parenteral preparations (0520)
Herbal drugs for homoeopathic preparations (2045)
Human plasma for fractionation (0853)
Intraruminal devices (1228)
Liquid preparations for oral use (0672)
Powders for cutaneous application (1166)
Powders, oral (1165)
Rectal preparations (1145)
Goldenrod (1892)
Vaginal preparations (1164)

5 REVISED GENERAL TEXTS AND GENERAL METHODS

2.2.25 Absorption spectrophotometry, ultraviolet and visible
2.2.27 Thin-layer chromatography
2.5.1 Acid value
2.9.7 Friability of uncoated tablets
2.9.25 Dissolution test for medicated chewing gums

30 NEW CRSs/BRPs ADOPTED

Betahistine dihydrochloride CRS 1, Chondroitin sulphate sodium CRS Batch 1, Clioquinol CRS 1, Closantel for system suitability CRS 1, Closantel sodium dihydrate CRS 1, Dodecyl gallate CRS 1, Famotidine impurity D CRS 1, Felypressin CRS Batch 3, Granisetron impurity E CRS 1, Salicylic acid impurity B (4-Hydroxyisophthalic acid) CRS 1, Iopamidol impurity H CRS 1, Lysine acetate CRS 1, Methyl nicotinate CRS 1, Naftidrofuryl reference spectrum, Naltrexone hydrochloride CRS 1, Naltrexone impurity C CRS 1, Naproxen (racemic) CRS 1, Octyl gallate CRS 1, Oxeladin impurity C CRS 1, Pentazocine lactate reference spectrum, Pyrantel embonate CRS 1, Pyrantel impurity A CRS 1, Ranitidine for system suitability CRS 1, Ranitidine impurity J CRS 1, Ribavirin

for system suitability CRS 1, Risperidone for system suitability CRS 1, Sulfamethoxazole impurity A CRS 1, Sulfamethoxazole impurity F CRS 1, Tiamulin for peak identification CRS 1, Tiamulin hydrogen fumarate CRS 1

30 REPLACEMENT BATCHES

Acesulfame potassium impurity B CRS 2, Acetylsalicylic acid CRS 3, Bacampicillin hydrochloride CRS 3, Betaxolol impurity A CRS 2, Butylhydroxyanisole CRS 3, Carbamazepine impurity A CRS 3, Ceftriaxone impurity A CRS 3, Gitoxin CRS 2, 3-Methoxymethyldopa CRS 3, Methyl stearate CRS 2, Metoclopramide hydrochloride CRS, Nabumetone impurity F CRS 2, Neamine CRS, Nimodipine CRS 2, Nimopidine impurity A CRS 2, Nitrendipine CRS 2, Orciprenaline sulphate CRS 2, Prednisolone acetate CRS 3, Prednisolone CRS 5, Protirelin CRS Batch 3, D-His Protirelin CRS Batch 2, rDNA Hepatitis B (Method B) BRP batch 2, Retinol acetate CRS 5, Spiramycin CRS 3, Terfenadine impurity A CRS 2, Tinidazole impurity B CRS 3, Tramadol impurity A CRS 2, Tramadol impurity E CRS 2, Zidovudine impurity A CRS 2, Zopiclone oxide CRS 2

II. EUROPEAN PHARMACOPOEIA WORK PROGRAMME

NEW MONOGRAPHS AND GENERAL CHAPTERS

Assay of anti-tumour necrosis factor (TNF) monoclonal antibodies
Cefpodoxime proxetil
Cefprozil
Ceftazidime for injection with arginine
Ceftazidime for injection with sodium carbonate
Choline bitartrate
Flucloxacillin magnesium
Fluorescein
Friability of Pellets and Granules
Ginkgo dry extract, standardised, non-refined
Hydrocodone

REVISIONS OF MONOGRAPHS AND GENERAL CHAPTERS

Air, medicinal (1238)
Amlodipine besilate (1491)
Cinchona liquid extract, standardised (1818)
Buckwheat herb (2184)
Fludeoxyglucose (^{18}F) injection (1325)
Hyoscyamus for homoeopathic preparations (2091)
Meglumine (2055)
Morphine hydrochloride (0097)
Morphine sulphate (1244)
Mycophenolate mofetil (1700)
Pentaerythrityl tetranitrate, diluted (1355)
Pentamidine Diisetionate (1137) (Production section)
Phytosterol (1911)
Sorbitol (435) (CRB)

Streptokinase bulk solution (356)
Valerian root (453)