

***Report of the 134th Session
of the European Pharmacopoeia Commission
30 June to 1 July 2009***

Participants:

Member States: 30 delegations were present

Observer States: 5 delegations participated in the session

I. TEXTS AND REFERENCE STANDARDS ADOPTED

**LIST OF TEXTS ADOPTED FOR PUBLICATION IN THE 6TH EDITION (VOLUME 6.8)
AND DATE OF IMPLEMENTATION: 01/07/2010**

8 NEW MONOGRAPHS ADOPTED

Argon (2407)

Fosinopril sodium / Fosinopril sodique (1751)

Galantamine hydrobromide / Galantamine (bromhydrate de) (2366)

Iodixanol / Iodixanol (2215)

Pramipexole dihydrochloride monohydrate / Pramipexole (dichlorhydrate de) monohydraté (2416)

Tiotropium bromide monohydrate/Tiotropium (bromure de) monohydrate (2420)

Trehalose dihydrate / Tréhalose dihydraté (2297)

Valerian root, cut / Valériane (racine de) divisée (2526)

1 NEW GENERAL TEXTS AND GENERAL METHODS OF ANALYSIS

Recommendations on dissolution testing / Recommandations relatives à l'essai de dissolution (5.17.1.)

30 REVISED MONOGRAPHS

Aniseed / Anis (fruit d') (262)

Arachis oil, hydrogenated / Arachide (huile d') hydrogénée (1171)

Azathioprine (369)

Calcium stearate / Calcium (stéarate de) (882)

Cyproterone acetate / Cyprotérone (acétate de) (1094)

Ethyl parahydroxybenzoate (900)

Eucalyptus oil / Eucalyptus (huile essentielle d') (390)

Filgrastim concentrated solution / Filgrastim (solution concentrée de) (2206)

Herbal drug preparations / Préparations à base de drogues végétales (1434)

Herbal drugs / Drogues végétales (1433)

Josamycin / Josamycine (1983)

Lavender oil / Lavande (huile essentielle de) (1338)

Magnesium stearate / Magnésium (stéarate de) (229)

Magnesium trisilicate / Magnésium (trisilicate de) (403)

Meglumine / Méglumine (2055)

Methylene chloride / Méthylène (chlorure de) (932)

Methylparahydroxybenzoate (409)

Omeprazole / Oméprazole (942)
Oregano / Origan (1880)
Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037)
Propyl parahydroxybenzoate (431)
Salbutamol sulfate (687)
Sodium methyl parahydroxybenzoate / Méthyle (parahydroxybenzoate de) sodique (1262)
Sodium stearyl fumarate / Stéaryle (fumarate de) sodique (1567)
Soya-bean oil, hydrogenated / Soja (huile de) hydrogénée (1265)
Stearic acid / Stéarique (acide) (1474)
Trolamine / Trolamine (1577)
Valerian root / Valériane (racine de) (453)
Vibriosis (cold-water) vaccine (inactivated) for salmonids / Vaccin inactivé de la vibriose des eaux froides pour salmonidés (1580)
Vibriosis vaccine (inactivated) for salmonids / Vaccin inactivé de la vibriose pour salmonidés (1581)

5 REVISED GENERAL TEXTS AND GENERAL METHODS

Bulk density and tapped density of powders / Masse volumique vrac et masse volumique après tassement (2.9.34.)
*General notices / Prescriptions générales (1.)
Heavy metals / Métaux lourds (2.4.8.)
Nucleic acid amplification techniques / Techniques d'amplification des acides nucléiques (20621)
Total cholesterol in oils rich in omega-3 acids / Cholestérol total dans les huiles riches en acides oméga-3 (20432)
* subject to confirmation

58 MINOR REVISION OF MONOGRAPHS AND GENERAL TEXTS

Acitretin (1385)
Asparagine monohydrate / Asparagine monohydratée (2086)
Atropine / Atropine (2056)
Betahistine mesilate / Bétahistine (mésilate de) (1071)
Betaxolol hydrochloride / Bétaxolol (chlorhydrate de) (1072)
Bezafibrate / Bézafibrate (1394)
Cefradine / Céfradine (814)
Cetirizine dihydrochloride / Cétirizine (dichlorhydrate de) (1084)
Chicken flocks free from specified pathogens for the production and quality control of vaccines / Elevages de poulets exempts de microorganismes pathogènes spécifiés pour la production et le contrôle de qualité des vaccins (5.2.2)
Ciclopirox / Ciclopirox (407)
Ciclopirox olamine / Ciclopirox olamine (1302)
Clazuril for veterinary use / Clazuril pour usage vétérinaire (1714)
Composition of fatty acids in oils rich in omega-3 acids / Composition en acides gras des huiles riches en acides oméga-3 (20429)
Crotamiton / Crotamiton (1194)
Dextromethorphan hydrobromide / Dextrométhorphan (bromhydrate de) (0020)
Diltiazem hydrochloride / Diltiazem (chlorhydrate de) (1004)
Dobutamine hydrochloride / Dobutamine (chlorhydrate de) (1200)
Econazole / Éconazole (2049)
Econazole nitrate / Éconazole (nitrate d') (665)
Enalapril maleate / Énalapril (maléate d') (1420)
Enilconazole for veterinary use / Énilconazole pour usage vétérinaire (1720)
Flumequine / Fluméquine (1517)
Folic acid (67)
Foscarnet sodium hexahydrate / Foscarnet sodique hexahydraté (1520)
Fumitory / Fumeterre (1869)
Glass containers for pharmaceutical use / Récipients de verre pour usage pharmaceutique (3.2.1.)
Iceland moss / Lichen d'Islande (1439)
Kaolin, heavy / Kaolin lourd (503)

Ketoprofen / Kétoprofène (922)
Ketotifen hydrogen fumarate / Kétotifène (hydrogénofumarate de) (1592)
Lomustine (928)
Lovastatin (1538)
Magnesium pidolate / Magnésium (pidolate de) (1619)
Maprotiline hydrochloride / Maprotiline (chlorhydrate de) (1237)
Marshmallow leaf / Guimauve (feuille de) (1856)
Marshmallow root / Guimauve (racine de) (1126)
Microbiological examination of non-sterile products: microbial enumeration tests / Contrôle microbiologique des produits non stériles : essais de dénombrement microbiologique (20612)
Mupirocin calcium (1451)
Nabumetone / Nabumétone (1350)
Orphenadrine citrate / Orphénadrine (citrate de) (1759)
Orphenadrine hydrochloride / Orphénadrine (chlorhydrate de) (1760)
Oxybutynin hydrochloride / Oxybutynine (chlorhydrate d') (1354)
Potassium clavulanate (1140)
Potassium clavulanate, diluted (1653)
Prochlorperazine Maleate / Prochlorpérazine (Maléate de) (244)
Rabies vaccine (inactivated) for veterinary use / Vaccin rabique inactivé pour usage vétérinaire (451)
Soya-bean oil, refined / Soja (huile de) raffinée (1473)
Sterility / Stérilité (2.6.1)
Theophylline-ethylenediamine anhydrous (300)
Theophylline-ethylenediamine hydrate (301)
Tormentil / Tormentille (1478)
Tri-n-butyl phosphate / Tri-n-butyle (phosphate de) (1682)
Valerian dry aqueous extract / Valériane (extrait aqueux sec de) (2400)
Valerian tincture / Valériane (teinture de) (1899)
Willow bark / Saule (écorce de) (1583)
Xylazine hydrochloride for veterinary use / Xylazine (chlorhydrate de) pour usage vétérinaire (1481)
Yarrow / Achillée millefeuille (1382)
Zinc acexamate / Zinc (acéxamate de) (1279)

NEW REFERENCE STANDARDS ADOPTED/ REPLACEMENT BATCHES ADOPTED

A list of new reference standards and new batches with the date of release is now available in the Reference Standards database. Click on the database button and then choose 'News'.

The database is available online, click on the following link: <http://www.edqm.eu/en/Databases-10.html>.

II. EUROPEAN PHARMAPOEIA WORK PROGRAMME

ADDITIONS TO THE WORK PROGRAMME

The European Pharmacopoeia invites contributions to the following items of the work programme:
Test for determination of the bactericidal and yeasticidal activity

*(Please note that the accumulative work programme is available in the Knowledge Database:
<http://www.edqm.eu/site/Databases-10.html>)*

67 REVISIONS OF MONOGRAPHS AND GENERAL CHAPTERS

Birch leaf / Bouleau (feuille de) (1174) (limits on total ash)
Buserelin / Busérelina (1077) (identification test B)
Calcium stearate / Calcium (stéarate de) (882) (addition of a test for thermogravimetry)
Capsicum oleoresin, refined and quantified / Piment de Cayenne (oléorésine raffinée et quantifiée de) (2336) (definition, content of total capsaicinoids)
Chicken flocks free from specified pathogens for the production and quality control of vaccines / Elevages de poulets exempts de microorganismes pathogènes spécifiés pour la production et le contrôle de qualité des vaccins (5.2.2) (routine testing of designated SPF flocks: raise the maximum weekly mortality of SPF chickens to 0.2%)

Cloxacillin sodium / Cloxacilline sodique (661) (quality and incomplete expression of limits)

Copovidone (891) (revision of test for 2-pyrrolidone)

Dicloxacillin sodium (663) (quality and incomplete expression of limits)

Doxylamine hydrogen succinate / Doxylamine (hydrogénosuccinate de) (1589) (related substances, system suitability criterion)

Ethyl parahydroxybenzoate sodium / Éthyle (parahydroxybenzoate d') sodique (2134) (identification, related substances, assay)

Fish oil, rich in omega-3-acids / Poisson (huile de) riche en acides oméga-3 (1912) (test for oligomers)

Flucloxacillin sodium (668) (quality and incomplete expression of limits)

Fluoxetine hydrochloride / Fluoxétine (chlorhydrate de) (1104) (replacement of toxic reagents/solvents)

Friability of granules and spheroids / Friabilité des granulés et des sphéroïdes (2.9.41.) (modified dimensions and equations)

Glass containers for pharmaceutical use / Récipients de verre pour usage pharmaceutique (3.2.1.) (revision of test B hydrolytic resistance of glass grains)

Goserelin / Goséréline (1636) (identification test A)

Haemofiltration and for haemodiafiltration, solutions for / Solutions pour hémofiltration et pour hémodiafiltration (861) (review the limits for bacterial endotoxins)

Hawthorn berries / Aubépine (baie d') (1220); (assay)

Heavy metals in herbal drugs and fatty oils / Métaux lourds dans les drogues végétales et dans les huiles grasses (2.4.27.) (introduction of ICP-atomic emission spectrometry and ICP-mass spectrometry)

Human normal immunoglobulin / Immunoglobuline humaine normale (338) (anti-A and B haemagglutinins replacement of the indirect method by a direct method)

Human normal immunoglobulin / Immunoglobuline humaine normale (918) (anti-A and B haemagglutinins: replacement of the indirect method by a direct method)

Human tetanus immunoglobulin / Immunoglobuline humaine tétanique (398) (addition of two in vitro methods for the potency assay)

Hydrochlorothiazide (394); (assay)

Hydrocortisone (335) (limits section for related substances test)

Hydroxypropylbetadex / Hydroxypropylbétadex (1804) (related substances)

Lactose monohydrate / Lactose monohydraté (187) (microbial contamination)

Methylprednisolone acetate / Méthylprednisolone (acétate de) (933) (related substances test)

Noscapine (516) (related substances test)

Noscapine hydrochloride (515) (related substances test)

Omega-3-acid ethyl esters 60 / Oméga-3 (esters éthyliques 60 d'acides) (2063) (test for oligomers)

Omega-3-acid ethyl esters 90 / Oméga-3 (esters éthyliques 90 d'acides) (1250) (test for oligomers)

Omega-3-acid triglycerides / Oméga-3 (triglycérides d'acides) (1352) (test for oligomers)

Parnaparin sodium / Parnaparine sodique (1252) (definition and Identification C: potency and molecular mass distribution specifications)

Pesticide residues / Résidus de pesticides (20813) (proposal to delete the limit for inorganic bromide)

Phenoxymethylpenicillin (148) (quality and incomplete expression of limits)

Phenoxymethylpenicillin potassium (149) (quality and incomplete expression of limits)

Povidone (685) (revision of test for 2-pyrrolidone)

Sodium citrate / Sodium (citrate de) (412) (replacement of the test for pyrogens)

St. John's wort dry extract, quantified / Millepertuis (extrait sec quantifié de) (1874) (loss on drying/Water content)

Test for anti-D antibodies in human immunoglobulin for intravenous administration / Recherche des anticorps anti-D dans l'immunoglobuline humaine pour administration (20626) (technical improvements of the direct method)

Thiopental sodium and sodium carbonate / Thiopental et carbonate sodiques (212) (replacement of toxic reagents/solvents)

Triglycerol diisostearate / Triglycérol (diisostéarate de) (2032) (revision of the limits of Iodine value)

Vaccines for veterinary use / Vaccins pour usage vétérinaire (0062) (include a general statement allowing licensing authorities to apply EMEA Guideline in case of minor use, revise sterility and mycoplasma tests, add a statement on the calculation of the expiry date, add antigenic component on the label)

Betamethasone (312); (related substances)

Bromocriptine mesilate / Bromocriptine (mésilate de) (596); (related substances)

Calcium folinate (978); (related substances)

Carboplatin (1081); (related substances)

Diclofenac potassium (1508); (related substances)

Diclofenac sodium (1002); (related substances);
Dobutamine hydrochloride (1200); (related substances)
Domperidone (1009); (related substances)
Econazole nitrate (665); (related substances)
Estradiol valerate; (related substances)
Estriol (1203); (related substances)
Fentanyl (1210); (related substances)
Fentanyl citrate (1103); (related substances)
Flutamide (1423); (related substances)
Glyceryl trinitrate solution (1331); (related substances)
Haloperidol (616); (related substances)
Ketoprofen (922); (related substances)
Mepivacaine hydrochloride (1242); (related substances)
Miconazole nitrate (513); (related substances)
Mitoxantrone hydrochloride (1243); (related substances)
Ofloxacin (1455); (related substances)
Praziquantel (855); (related substances)
Tamoxifen citrate (1046); (related substances)
Zolpidem tartrate (1280); (related substances)

DELETION OF MONOGRAPHS AND GENERAL CHAPTERS

None

DELETION OF MONOGRAPHS AND GENERAL CHAPTERS FROM THE EUROPEAN PHARMACOPOEIA

None