

*Report of the 140th Session
of the European Pharmacopoeia Commission
28-29 June 2011*

Participants:

Member States: 28 delegations were present

Observer States: 2 delegations participated in the session

I. TEXTS AND REFERENCE STANDARDS ADOPTED

**LIST OF TEXTS ADOPTED FOR PUBLICATION IN THE 7TH EDITION
(SUPPLEMENT 7.5) AND DATE OF IMPLEMENTATION: 01/07/2012**

13 NEW MONOGRAPHS ADOPTED

Aluminium monostearate / Aluminium (monostéarate de) (1663)

Angelica sinensis root / Angelica sinensis (racine d') (2558)

Atractylodes lancea rhizome / Atractylodes lancea (rhizome d') (2559)

Atractylodes largehead rhizome / Atractylodes macrocephala (rhizome d') (2560)

Black cohosh / Actée à grappes (2069)

Celecoxib / Célécoxib (2591)

Docetaxel anhydrous / Docétaxel anhydre (2593)

Drynaria rhizome / Drynaria (rhizome de) (2563)

Duloxetine hydrochloride / Duloxétine (chlorhydrate de) (2594)

Melphalan (1698)

Niaouli oil, cineole type / Niaouli type cinéole (huile essentielle de) (2468)

Poria / Poria (2475)

Sodium iodohippurate dihydrate for radiopharmaceutical preparations / Sodium (iodohippurate de) dihydraté pour préparations radiopharmaceutiques (2352)

NEW GENERAL TEXTS AND GENERAL METHODS OF ANALYSIS

53 REVISED MONOGRAPHS

Amantadine hydrochloride / Amantadine (chlorhydrate d') (463)

Amidotrizoic acid dihydrate / Amidotrizoïque (acide) dihydraté (873)

Amikacin / Amikacine (1289)

Amikacin sulfate / Amikacine (sulfate d') (1290)

Ammonium bromide / Ammonium (bromure d') (1389)

Apomorphine hydrochloride / Apomorphine (chlorhydrate d') (136)

Ash leaf / Frêne (feuille de) (1600)

Carbimazole/Carbimazol (0884)

Chlorpromazine hydrochloride / Chlorpromazine (chlorhydrate de) (475)

Chlortetracycline hydrochloride / Chlortétracycline (chlorhydrate de) (173)

Cod-liver oil (type A) / Foie de morue (huile de) (type A) (1192)

Cod-liver oil (type B) / Foie de morue (huile de) (type B) (1193)

Cod-liver oil, farmed / Foie de morue d'élevage (huile de) (2398)

Coriander / Coriandre (1304)

Dexamethasone sodium phosphate/Dexaméthasone (phosphate sodique de) (0549)

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé) (1931)

Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) (1932)

Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) (1933)

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactiv) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et polio (1934)

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactiv) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyélitique (inactivé) (2329)

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2067)

Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivate) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2065)

Diphtheria, tetanus, pertussis, poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux, poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2066)

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

Greater celandine / Chélidoine (1861)

Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219)

Human normal immunoglobulin for intravenous administration / Immunoglobuline humaine normale pour administration par voie intraveineuse (918)*

Hydrocortisone acetate/Hydrocortisone (acétate d') (0334)

Magaldrate (1539)

Melilot / Mélilot (2120)

Metamizole sodium / Métamizole sodique (1346)

Nitrendipine/Nitrendipine (1246)

Nizatidine (1453)

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

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

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

Peppermint oil / Menthe poivrée (huile essentielle de) (405)

Pertussis vaccine (acellular, component, adsorbed) / Vaccin coquelucheux (adsorbé, multicomposé, acellulaire) (1356)

Pertussis vaccine (acellular, co-purified, adsorbed) / Vaccin coquelucheux (adsorbé, copurifié, acellulaire) (1595)

Pipemidic acid trihydrate / Pipémidique (acide) trihydraté (1743)

Piroxicam (944)

Potassium bromide / Potassium (bromure de) (184)

Potassium chloride / Potassium (chlorure de) (185)

Propyphenazone / Propyphénazone (636)

Salmon oil, farmed / Saumon d'élevage (huile de) (1910)

Saw palmetto fruit / Sabal (fruit de) (1848)

Sodium bromide / Sodium (bromure de) (190)

Sulfadiazine (294)

Thiopental sodium and sodium carbonate / Thiopental et carbonate sodiques (212)

Titanium dioxide / Titane (dioxyde de) (150)

Triamcinolone acetonide/Triamcinolone (acétonide de) (0533)

Verbena herb / Verveine officinale (1854)

Yellow fever vaccine (live) / Vaccin vivant de la fièvre jaune (537)

4 REVISED GENERAL TEXTS AND GENERAL METHODS

Assay of pertussis vaccine (acellular) (2.7.16.) / Titration de l'activité du vaccin coquelucheux acellulaire (2.7.16.)

Ethanol content and alcoholimetric tables / Teneur en éthanol et tableaux alcoométriques (20910)

General notices / Prescriptions générales (1.)

Test for methanol and 2-propanol / Recherche du méthanol et du 2-propanol (20911)

15 MINOR REVISION OF MONOGRAPHS AND GENERAL TEXTS

Acetylsalicylic acid / Acétylsalicylique (acide) (309)

Ciclosporin / Ciclosporine (994)

Dandelion herb with root / Pissenlit (partie aérienne et racine de) (1851)

Diphtheria, tetanus and pertussis (whole cell) vaccine (adsorbed) / Vaccin diphtérique, tétanique et coquelucheux (à cellules entières), adsorbé (445)

Diphtheria, tetanus, pertussis (whole cell) and poliomyelitis (inactivated) vaccine / Vaccin diphtérique, tétanique, coquelucheux (à cellules entières) et poliomyélite (2061)

Docetaxel trihydrate / Docétaxel trihydraté (2449)

Etofenamate / Étofénamate (1513)

Fluorescein / Fluorescéine (2348)

Fluphenazine dihydrochloride / Fluphénazine (dichlorhydrate de) (904)

Fosinopril sodium / Fosinopril sodique (1751)

Gentamicin sulfate / Gentamicine (sulfate de) (331)

Magnesium aspartate dihydrate / Magnésium (aspartate de) dihydraté (1445)

Midazolam/Midazolam (936)

Piretanide / Pirétanide (1556)

Torasemide, anhydrous / Torasémide anhydre (2132)

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 PHARMACOPOEIA WORK PROGRAMME

ADDITIONS TO THE WORK PROGRAMME

The European Pharmacopoeia invites contributions to the following items of the work programme:

Abbreviated Impactor Measurement and Efficient data Analysis

Amorolfine hydrochloride

Benzydamine HCl

Brimonidine tartrate

Bupivacaine free base

Caprylocaproyl macrogolglycerides / Macrogolyglycérides caprylocarpiques (1184)

Cisatracurium besilate

Coptidis rhizoma / Huang Lian

Diphtheria, Tetanus, Pertussis (acellular) reduced antigen(s) vaccine

Eplerenone

Exemestane

Ezetimibe

Forsythiae fructus / Lao qiao

Gamma cyclodextrin

Glycerol distearate / Glycérol (distéarate de) (1428)

Glycerol mono-oleate / Glycérol (mono-oléate de) (1430)
 Glycerol monostearate 40-55 / Glycérol (monostéarate de) 40-55 (495)
 Haemofiltration and Haemodiafiltration, concentrated solutions
 Ibandronate sodium
 Latanoprost
 Lauroyl macroglycerides / Macrogolyglycérides lauriques (1231)
 Leonuri herba / Yi Mu Cao
 Linoleoyl macroglycerides / Macrogolyglycérides linoléiques (1232)
 Live attenuated intranasal influenza vaccine
 Macrogol 20 Glycerol monostearate / Macrogol 20 glycérol (monostéarate de) (2044)
 Macroglycerol hydroxystearate / Macrogolyglycérides (hydroxystéarate de) (1083)
 Macroglycerol ricinoleate / Macrogolyglycérides (ricinoléate de) (1082)
 Memantine
 Mivacurium chloride
 Nebivolol
 Nicardipine hydrochloride
 Oleoyl macroglycerides / Macrogolyglycérides oléiques (1249)
 Poloxamers / Poloxamères (1464)
 Rabeprazole
 Sorbitan laurate / Sorbitan (laurate de) (1040)
 Sorbitan oleate / Sorbitan (oléate de) (1041)
 Sorbitan palmitate / Sorbitan (palmitate de) (1042)
 Sorbitan sesquioleate / Sorbitan (sesquioléate de) (1916)
 Sorbitan stearate / Sorbitan (stéarate de) de) (1043)
 Sorbitan trioleate / Sorbitan (trioléate de) (1044)
 Stearoyl macroglycerides / Macrogolyglycérides stéariques (1268)
 Temozolomide
 Tolterodine
 Water for dilution Haemofiltration and Haemodiafiltration, concentrated solutions

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

13 REVISIONS OF MONOGRAPHS AND GENERAL CHAPTERS

Avian viral vaccines: tests for extraneous agents in seed lots/Vaccins viraux aviaires : recherche des agents étrangers dans les lots de semence (20624)
 Calcium hydrogen phosphate, anhydrous / Calcium (hydrogénophosphate de) anhydre (981)
 Dexamethasone sodium phosphate/Dexaméthasone (phosphate sodique de) (549)
 Essential oils / Huiles essentielles (2098)
 Glucosamine hydrochloride / Glucosamine (chlorhydrate de) (2446)
 Glucosamine sulfate sodium chloride / Glucosamine (sulfate de) - chlorure de (2447)
 Human alpha-1-proteinase inhibitor / Inhibiteur d'alpha-1-protéinase humain (2387)
 Hydralazine hydrochloride / Hydralazine (chlorhydrate d') (829)
 Indian frankincense / Encens indien (2310)
 Java tea / Orthosiphon (1229)
 Methylthioninium chloride / Méthylthioninium (chlorure de) (1132)
 Oxygen / Oxygène (417)
 Thiopental sodium and sodium carbonate / Thiopental et carbonate sodiques (212)

14 DELETIONS FROM THE WORK PROGRAMME

Chlorothiazide (0385)
 Dienestrol (0483)
 Emetine hydrochloride heptahydrate (0080)

Etofylline (0492)
Hexobarbital (0183)
Histamine phosphate (0144)
Iotalamic acid (0751)
Methaqualone (0510)
Methylatropine bromide (0511)
Methylatropine nitrate (0512)
Physostigmine sulphate (0684)
Succinylsulfathiazole (0357)
Sulfisomidine (0639)
Tubocurarine chloride (0305)

2 DELETIONS OF MONOGRAPHS AND GENERAL CHAPTERS FROM THE EUROPEAN PHARMACOPOEIA

Necrotic enteritis vaccine (inactivated) for pigs (2681)
Uniformity of dosage units for allergen products

* subject to confirmation