

EUROPEAN PHARMACOPOEIA COMMISSION

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(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 154th Session of the Commission

Résumé des Décisions prises lors de la 154^e Session de la Commission

Strasbourg, 15-16 mars 2016

Strasbourg, 15-16 March 2016

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**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPÉE**

**Summary of Decisions of the 154th Session
15-16 March 2016**

**Résumé des décisions de la 154^e Session
15-16 mars 2016**

Deadline for confirmation / Date de confirmation: 15 April 2016

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
13.3.1	Assay of heparin / Titrage de l'héparine (2.7.5.)	
19.3.1	Estradiol hemihydrate / Estradiol hémihydraté (0821)	
48.3.1	Homoeopathic preparations / Préparations homéopathiques (1038)	
31.3.1	Montelukast sodium / Montélukast sodique (2583)	
70.2.2	Names of herbal drugs used in traditional Chinese medicine / Noms des drogues végétales utilisées en médecine traditionnelle chinoise (5.22.)	
11.6	Pharmacopoeial harmonisation (5.8.) / Harmonisation des pharmacopées (5.8.)	
31.3.2	Sitagliptin phosphate monohydrate / Sitagliptine (phosphate de) monohydraté (2778)	
60.3.1	Specific surface area by air permeability/Surface spécifique par perméabilité à l'air (20914)	
56.3.1	Teriparatide / Tériparatide (2829)	
	I.1.2 Revisions / Révisions	
19.2.1	Alfuzosin hydrochloride / Alfuzosine (chlorhydrate d') (1287)	
70.2.1	Angelica sinensis root / Angelica sinensis (racine d') (2558)	
19.2.2	Atenolol / Aténolol (0703)	
15.2.1	Bacitracin / Bacitracine (0465)	
15.2.2	Bacitracin zinc / Bacitracine-zinc (0466)	
19.2.3	Bromhexine hydrochloride / Bromhexine (chlorhydrate de) (0706)	
45.2.3	Caprylocaproyl macroglycerides / Macrogolglycérides caprylocapriques (1184)	
15.2.3	Chloramphenicol / Chloramphénicol (0071)	
22.2.2	Dicycloverine hydrochloride/dicycloverine (chlorhydrate de) (1197)	
20.2.1	Etoposide / Étoposide (0823)	
48.2.1	Homoeopathic pillules, impregnated / Granules homéopathiques	

	imprégnés (2079)	
	I.1.2 Revisions / Révisions	
45.2.4	Lauroyl macroglycerides / Macroglycérides lauriques (1231)	
45.2.5	Linoleoyl macroglycerides / Macroglycérides linoléiques (1232)	
11.4	Melting point - capillary method (2.2.14.) / Point de fusion - méthode au tube capillaire (2.2.14.)	
45.2.6	Oleoyl macroglycerides / Macroglycérides oléiques (1249)	
15.2.4	Phenoxymethylpenicillin / Phénoxy méthylpénicilline (0148)	
15.2.5	Phenoxymethylpenicillin potassium / Phénoxy méthylpénicilline potassique (0149)	FR
22.2.1	Pholcodine/Pholcodine (0522)	
28.2.2	Poliomyelitis vaccine (oral) / Vaccin poliomyélitique oral (0215)	
70.2.1	Salvia miltiorrhiza root and rhizome / Salvia miltiorrhiza (racine et rhizome de) (2663)	
26.2.1	Sesame oil, refined / Sésame (huile de) raffinée (0433)	
45.2.14	Sodium starch glycolate (type A) / Carboxyméthylamidon sodique (type A) (0983)	
45.2.15	Sodium starch glycolate (type B) / Carboxyméthylamidon sodique (type B) (0984)	
45.2.13	Sorbitan laurate / Sorbitan (laurate de) (1040)	
45.2.12	Sorbitan oleate / Sorbitan (oléate de) (1041)	
45.2.11	Sorbitan palmitate / Sorbitan (palmitate de) (1042)	
45.2.10	Sorbitan sesquioleate / Sorbitan (sesquioléate de) (1916)	
45.2.9	Sorbitan stearate / Sorbitan (stéarate de) (1043)	
45.2.8	Sorbitan trioleate / Sorbitan (trioléate de) (1044)	
45.2.7	Stearoyl macroglycerides / Macroglycérides stéariques (1268)	
11.2	Substances for pharmaceutical use / Substances pour usage pharmaceutique (2034)	
23.2.1	Uniformity of dosage units (2.9.40.) / Uniformité des préparations unidoses (2.9.40.)	
25.4.2	Valerian root / Valériane (racine de) (0453)	
25.4.1	Valerian root, cut / Valériane (racine de) divisée (2526)	
20.2.2	Vecuronium bromide / Vécuronium (bromure de) (1769)	
73.2.1	Water for injections / Eau pour préparations injectables (0169)	

	I.1.2 New texts adopted / Nouveaux textes adoptés	
70.1.1	Andrographis herb / Andrographidis herba (2712)	
70.1.2	Chinese goldthread rhizome / Coptidis (rhizome de) (2715)	UK
70.1.4	Dioscorea nipponica rhizome / Dioscorea nipponica (rhizome de) (2890)	
31.1.1	Gadodiamide / Gadodiamide (2225)	
46.1.1	Host Cell Protein Assays / Essai des protéines issues de la cellule hôte (2.6.34)	
70.1.3	Lycopus herb / Lycopus herb (2723)	
	<i>I-2 CRS/BRP SCR/PBR</i>	
	New substances / Nouvelles substances	
76.3	Hepatitis A virus RNA for NAT testing BRP batch 1	
	3-trimethylsilyl-1-propanesulfonic acid sodium salt CRS 1	
	Alverine impurity C CRS 1	
	Amorolfine for system suitability CRS 1	
	Amorolfine HCl CRS 1	
	Apigenin 7-glucoside CRS 1	
	Buserelin for NMR identification CRS 1	
	Cisatracurium besilate CRS 1	
	Costunolide CRS 1	
	Entecavir for system suitability CRS 1	
	Entecavir impurity F CRS 1	
	Entecavir monohydrate CRS 1	
	Ergocalciferol for system suitability CRS 1	
	Escitalopram for system suitability CRS 1	
	Escitalopram oxalate CRS 1	
	Gadobutrol for peak identification CRS 1	
	Gadobutrol monohydrate CRS 1	
	Gefitinib CRS 1	
	Gefitinib for system suitability CRS 1	
	Methacrylic acid - methyl methacrylate copolymer (1:1) CRS 1	
	Methacrylic acid - methyl methacrylate copolymer (1:2) CRS 1	
	Mycophenolate sodium CRS 1	

	New substances / Nouvelles substances	
	Pregabalin CRS 1	
	Pregabalin impurity A CRS 1	
	Pregabalin impurity B CRS 1	
	Pregabalin impurity D CRS 1	
	Schisandrin CRS 1	
	Sitagliptin containing impurity A CRS 1	
	Sitagliptin phosphate monohydrate CRS 1	
	Thiocolchicoside hydrate CRS 1	
	Zopiclone impurity B CRS 1	
	Replacement Batches / Lots de remplacement	
	Aciclovir for peak identification 2 CRS 4	
	Almagate CRS 2	
	Amikacin for system suitability CRS 3	
	Amlodipine for peak identification CRS 3	
	Amlodipine impurity B CRS 3	
	Arbutin CRS 2	
	Atorvastatin calcium trihydrate CRS 3	
	Atorvastatin impurity B CRS 3	
	Atorvastatin impurity D CRS 3	
	Atorvastatin impurity E CRS 3	
	Busulfan CRS 2	
	Candesartan cilexetil for peak identification CRS 2	
	Cephaeline hydrochloride CRS 4	
	Dermatan sulfate and over-sulfated chondroitin sulfate CRS 3	
	Diclofenac for system suitability CRS 2	
	Digitoxin CRS 4	
	Diltiazem impurity F CRS 2	
	Docosahexaenoic acid ethyl ester CRS 5	
	Doxycycline for system suitability CRS 3	
	Ergocalciferol CRS 9	
	Etodolac CRS 2	
	Fluconazole impurity C CRS 3	
	Fluphenazine decanoate CRS 3	
	Fluphenazine enantate CRS 3	

	Replacement Batches / Lots de remplacement	
	Fluticasone propionate CRS 4	
	Foscarnet sodium hexahydrate CRS 2	
	Galactose CRS 3	
	Histamine dihydrochloride CRS 3	
	Hydrocortisone acetate FPI CRS 2	
	Imatinib impurity F CRS 3	
	Josamycin propionate CRS 3	
	Ketorolac trometamol CRS 2	
	Losartan potassium CRS 2	
	Mesalazine for system suitability CRS 4	
	Montelukast racemate CRS 3	
	Morphine hydrochloride trihydrate CRS 3	
	Nimesulide impurity D CRS 5	
	Orphenadrine for peak identification CRS 2	
	Oseltamivir impurity C CRS 2	
	Oxaliplatin impurity B CRS 10	
	Paroxetine hydrochloride hemihydrate CRS 3	
	Pethidine impurity A CRS 2	
	Phenobarbital CRS 5	
	Poloxamer 124 CRS 2	
	Poloxamer 188 CRS 2	
	Poloxamer 338 CRS 2	
	Procaine benzylpenicillin CRS 4	
	Racecadotril impurity A CRS 3	
	Ribavirin CRS 3	
	Rosuvastatin calcium CRS 2	
	Terbutaline impurity C CRS 4	
	Trolamine impurity B CRS 3	
	Ubidecarenone CRS 3	
	II. GENERAL TEXTS APPROVED / TEXTES GÉNÉRAUX APPROUVÉS	
64.3	Code of Practice for the work of the European Pharmacopoeia / Règles de Déontologie relatives aux travaux de la Pharmacopée Européenne	
8.2	Terms of Reference and Profile for Experts	

	III. ITEMS DEFERRED – SCHEDULED FOR A FUTURE SESSION/ SUJETS REPORTES – A INSCRIRE A UNE PROCHAINE SESSION	
	IV. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	IV.1 Approved by the Commission	
77.1	Acetone / Acétone (0872) -> Group 10D	
11.5.3	Allergen products / Produits allergènes (1063) -> ALG WP	
11.5.1	Anthrax vaccine for human use (adsorbed, prepared from culture filtrates) / Vaccin de la fièvre charbonneuse pour usage humain (adsorbé, préparé à partir de (2188) -> Group 15	
24.4.1	Bilberry fruit, fresh / Myrtille (fruit frais de) (1602) -> Group 13A	
77.1	Carbomers (1299) -> Group 13H	
13.4.1	Chondroitin sulfate sodium / Chondroïtine (sulfate sodique de) (2064) - -> Group 6	
41.4.1	Chromatographic separation techniques / Techniques de séparation chromatographique (2.2.46) -> CST WP	
15.4.1	Colistimethate sodium / Colistiméthate sodique (0319) -> Group 7 and BET WP	
77.1	Determination of ochratoxin A in herbal drugs / Dosage de l'ochratoxine A dans les drogues végétales (2.8.22) -> Group 13B	
28.4.1	Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et conjugué de l'haemophilus type b, adsorbé (1932) -> Group 15	
28.4.1	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) -> Group 15	
28.4.1	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)/ Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2065) -> Group 15	
28.4.1	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) -> Group 15	
77.1	Ethanol 96 per cent (1317) -> Group 10D	
77.1	Ethanol anhydrous (1318) -> Group 10D	

	IV.1 Approved by the Commission	
14.4.1	Fibrin sealant kit / Colle-fibrine (nécessaire de) (0903) -> Group 6B	
41.4.1	Gas chromatography / Chromatographie en phase gazeuse (2.2.28.) -> CST WP	
17.4.1	Gas detector tubes / Tubes détecteurs de gaz (2.1.6.) -> Group 9G	
28.4.1	Haemophilus type b conjugate vaccine / Vaccin conjugué de l'haemophilus type b (1219) -> Group 15	
44.4.1	Herbal drug extracts / Extraits de drogues végétales (0765) -> EXT WP	
11.5.2	Immunosera for human use, animal / Immunosérums d'origine animale pour usage humain (0084) -> Group 15	
77.1	Isopropyl alcohol (0970) -> Group 10D	
26.4.2	Methacrylic acid - ethyl acrylate copolymer (1:1) / Copolymère d'acide méthacrylique et d'acrylate d'éthyle (1:1) (1128) -> Group 13H	
77.1	Methanol (1989) -> Group 10D	
44.4.1	Monographs on herbal drug extracts (information chapter) / Monographies d'extraits de drogues végétales (chapitre informatif) (5.23.) -> EXT WP	
26.4.1	Nickel in hydrogenated vegetable oils / Nickel dans les huiles végétales hydrogénées (2.4.31.) -> Group 13H	
53.4.1	Optical rotation (2.2.7.) / Pouvoir rotatoire (2.2.7.) -> MG WP	
53.4.2	Osmolality (2.2.35.) / Osmolalité (2.2.35.) -> MG WP	
45.2.1	Polyoxypropylene stearyl ether (2602) / Polyoxypropylène stearyl ether -> FRC WP	
11.5.4	Sterile plastic containers for human blood and blood components (3.2.3.) / Récipients stériles en matière plastique pour le sang humain et les produits du (30203) -> Group 16	
24.4.2	Sweet orange oil / Orange douce (huile essentielle d') (1811) -> Group 13A	
	IV.2 Rejected by the Commission	
54.4.1	Methyl, ethyl and isopropyl methanesulfonate in active substances / Méthanesulfonate de méthyle, d'éthyle et d'isopropyle dans les substances active (2.5.38.)	
	IV.3 Deferred to the next Session	
64.3.2	Code of Practice – request for revision	
	IV.4 Confirmed by the Commission	

23.5.1	Eye preparations / Préparations ophtalmiques (1163) -> Group 12	FR
8.4	V ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
8.4	68Ga-PSMA (3044) – Group 14	
8.4	Cannabis flos (3028) – Group 13B	
8.4	Ceftiofur hydrochloride for veterinary use (3031) – Group 7	
8.4	Daptomycin API (3034) – Group P4	
8.4	Daptomycin powder for injection or infusion (3033) – Group P4	
8.4	Dronedaron hydrochloride (3039) – Group P4	
8.4	Dronedaron tablets (3038) – Group P4	
8.4	Ginger oil (3045) – Group 13A	
8.4	Olanzapine pamoate monohydrate API (3047) – Group P4	
8.4	Palonosetron hydrochloride (3041) – Group 10C	
8.4	Pemetrexed disodium hemiheptahydrate (3046) – Group 10D	
8.4	Prasugrel hydrochloride (3040) – Group P4	
8.4	PSMA-11 (3042) – PRP Working Party	
8.4	PSMA-617 (3043) – PRP Working Party	
8.4	Tapentadol hydrochloride (3035) – Group P4	
8.4	Teriflunomide (3036) – Group P4	
8.4	Teriflunomide tablets (3037) – Group P4	
	VI. DELETIONS FROM THE WORK PROGRAMME / RETRAIT DU PROGRAMME DE TRAVAIL (New items or requests for revision)	
8.4	Sodium hyaluronate (1472)	
	VII. SUPPRESSIONS FROM THE PH. EUR. / SUPPRESSIONS DE LA PH. EUR.	
	VII.1 Approved by the Commission	
8.4	Melting point – instrumental method / Point de fusion – méthode instrumentale (2.2.60)	
8.4	Phytomenadione / Phytoménadione (1036)	
	VII.2 Rejected by the Commission	
8.4	Camphor, racemic / Camphre racémique (0655)	
8.4	Water, highly purified / Eau hautement purifiée (1927)	

	VII.1 PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
6.6 11.1	General policy : Policy for hydrates / Politique générale sur les hydrates (80001)	
8.1	Election of the Chair of the Commission -> Dr Tobias Godschan elected	
8.3	Nominations (see annex 1)	
11.1	Introduction or modification of the degree of hydration in monograph titles / Introduction ou modification du degré d'hydratation dans les titres des monographies (80001)	
11.3	Implementation of ICH Guideline Q3D on Elemental Impurities -> approach approved	
	VIII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	Dates for 2016 - 21-22 June 2016 - 22-23 November 2016	

154th Session Nominations – Item 8.3

GROUPS OF EXPERTS**Group12**

Turkey	Dr Filiz KOC	NPA – Specialist visual inspection
United Kingdom	Mr Gary NICHOLS	Industry – <u>Specialist</u> (Characterisation of particulate matter in solid and liquid dosage forms by microscopic techniques)
United Kingdom	Prof. Stephen WICKS	University

Group P4

Luxembourg	Mr Claude MARSON	OMCL
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WORKING PARTIES**Gelatin (GEL)**

France	Mrs Sylvie AUDOLY	Industry
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Paediatric formulary (PaedF)

Bulgaria	Prof. Milen DIMITROV	Hospital
Portugal	Mrs Paula Martinho	NPA

Standard Terms (ST)

Estonia	Ms Marje ZERNANT (replacing Ms P. KUSLAP)	Licensing authority
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Substitute**Group 15**

Austria	Dr Petra FALB (replacing Ms H.Schindl)	Substitute, February 2016
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Group 16

Switzerland	Dr Horst KOLLER (replacing Dr J.Thürk)	Substitute, March 2016
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ROP WP

United Kingdom	Mr James POUND (replacing Dr S Atkinson)	Substitute, February 2016
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MAB WP

Spain	Dr ORTIZ-ROSALES (replacing Dr A Portela)	Substitute, March 2016
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CTP WP

Spain	Dr S LOPEZ (replacing Dr S Ruiz)	Substitute, February 2016
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Ad-Hoc**General Methods of Analysis (MG)**

Germany	Prof. Waltraud KESSLER	University – ad hoc Specialist (Revision of the UV Chapter)
United Kingdom	Prof. Matthew ALMOND	University – ad hoc Specialist UV Chapter
United Kingdom	Mr James COWIE	Industry – ad hoc Specialist Loss on Drying
France	Mr Hervé RIBIERE	OMCL – ad hoc Specialist UV Chapter

Monoclonal Antibodies (MAB)

Switzerland	Dr Kowid HO	Industry – ad hoc Specialist (general chapters and general monographs)
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