

EUROPEAN PHARMACOPOEIA COMMISSION

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Strasbourg, March 2013

GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPEE)

Summary of Decisions taken at the 145th Session

Résumé des Décisions prises lors de la 145^e Session

Strasbourg 19-20 mars 2013

Strasbourg, 19-20 March 2013

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EDQM address: 7 allée Kastner, CS 30026, FR-67081 Strasbourg (France)

**EUROPEAN PHARMACOPOEIA COMMISSION
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 145th Session
19-20 March 2013**

**Résumé des décisions de la 145^e Session
19-20 March 2013**

Deadline for confirmation / Date de confirmation : 19 April 2013

Item	I. ADOPTED TEXTS	Subject to Confirmation
	I.1 Monographs and chapters/Monographies et chapitres	
	I.1.1 Minor revisions / Révisions mineures	
19.3.1	Abacavir sulfate / Abacavir (sulfate d') (2589)	
30.3.1	Acarbose/Acarbose (2089)	
28.3.1	Avian viral vaccines: tests for extraneous agents in seed lots /Vaccins viraux aviaires : recherche des agents étrangers dans les lots de semenc (2.6.24)	
18.3.1	Carbimazole / Carbimazole (0884)	
15.3.3	Cefazolin sodium / Céfazoline sodique (0988)	
19.3.2.	Flecainide acetate / Flécaïnide (acétate de) (1324)	
19.3.3	Fluticasone propionate / Fluticasone (propionate de) (1750)	
19.3.4	Ioxaglic acid / Ioxaglique (acide) (2009)	
24.3.1	Ivy leaf / Lierre (feuille de) (2148)	
19.3.5	Lamotrigine / Lamotrigine (1756)	
19.3.6	Metamizole sodium monohydrate / Métamizole sodique monohydraté (1346)	
15.3.2	Oxytetracycline hydrochloride / Oxytétracycline (chlorhydrate d') (0198)	
39.3.1	Pea starch/Amidon de pois (2403)	
17.3.1	Propyphenazone / Propyphénazone (0636)	
19.3.7	Quinapril hydrochloride / Quinapril (chlorhydrate de) (1763)	
15.3.1	Sulfadimidine / Sulfadimidine (0295)	
18.3.2	Tribenoside / Tribénoside (1740)	
	I.1.2 Revisions / Révisions	
24.2.2	Black cohosh / Actée à grappes (2069)	
11.3	Cellulose acetate / Cellulose (acétate de) (887)	
11.2	Cellulose acetate phthalate / Cellulose (acétate phtalate de) (314)	
25.2.1	Cetostearyl alcohol (type A), emulsifying / Cétostéarylique (alcool émulsifiant (type A) (0801)	

I.1.2 Revisions / Révisions		
25.2.2	Cetostearyl alcohol (type B), emulsifying / Cétostéarylique (alcool émulsifiant (type B) (0802)	
11.6	Citric acid monohydrate / Citrique (acide) monohydraté (456)	
11.7	Citric acid, anhydrous / Citrique (acide) anhydre (455)	
19.2.1	Clemastine fumarate / Clémastine (fumarate de) (1190)	
18.2.1	Dexamethasone sodium phosphate / Dexaméthasone (phosphate sodique de) (0549)	
13.2.2	Enoxaparin sodium / Énoxaparine sodique (1097)	
11.4	Ethanol (96 per cent) / Éthanol à 96 pour cent (1317)	
11.5	Ethanol, anhydrous / Éthanol anhydre (1318)	
55.2.1	Foreign matter / Éléments étrangers (2.8.2.)	
47.2.1	Gelatin/Gélatine (0330)	
24.2.1	Goldenrod / Solidage (1892)	
19.2.2	Ketotifen hydrogen fumarate / Kétotifène (hydrogénofumarate de) (1592)	
82.2.1	Magnolia officinalis bark / Magnolia officinalis (écorce de) (2567)	
55.2.2	Mother tinctures for homoeopathic preparations / Teintures mères pour préparations homéopathiques (2029)	
11.1	Pharmacopoeial harmonisation / Harmonisation des pharmacopées (5.8.)	
18.2.2	Prednicarbate / Prednicarbate (1467)	
19.2.3	Salmeterol xinafoate / Salmétérol (xinafoate de) (1765)	
25.2.3	Sodium cetostearyl sulfate / Cétostéaryle (sulfate de) sodique (0847)	
13.2.1	Somatostatin / Somatostatine (949)	
11.8	Substances for pharmaceutical use / Substances pour usage pharmaceutique (2034)	
19.2.4	Sulpiride / Sulpiride (1045)	
17.2.1	Tiapride hydrochloride / Tiapride (chlorhydrate de) (1575)	
18.2.3	Warfarin sodium / Warfarine sodique (0698)	
18.2.4	Warfarin sodium clathrate / Warfarine sodique clathrate (0699)	
17.2.2	Xylazine hydrochloride for veterinary use / Xylazine (chlorhydrate de) pour usage vétérinaire (1481)	
I.1.3 New texts for adoption / Nouveaux textes pour adoption		
21.1.1	2,4-Dichlorobenzyl alcohol / 2,4-Dichlorobenzilylique (alcool) (2410)	
82.1.1	Amomum fruit / Amomum (fruit d') (2554)	

	I.1.3 New texts for adoption / Nouveaux textes pour adoption	
30.1.2	Aripiprazole / Aripiprazole (2617)	
30.1.1	Capecitabine / Capécitabine (2762)	
82.1.3	Dioscorea rhizome / Dioscorea (rhizome de) (2473)	
25.1.1	Macrogols, high-molecular-mass / Macrogols de masse moléculaire élevée (2444)	
82.1.2	Round amomum fruit / Amomum (fruit rond d') (2555)	
22.1.1	Veterinary semi-solid preparations for oral use / Préparations vétérinaires semi-solides pour usage oral (2638)	
30.1.3	Ziprasidone mesilate trihydrate / Ziprasidone (mésilate de) trihydraté (2649)	
	<i>I-2 CRS/BRP SCR/PBR</i>	
	New substances / Nouvelles substances	
	Alfacalcidol for system suitability CRS 1	
	Alimemazine for system suitability CRS 1	
	Alimemazine hemitartrate CRS 1	
	Atovaquone CRS 1	
	Atovaquone for system suitability CRS 1	
	Chlorhexidine for system suitability CRS 1	
	Desloratadine CRS 1	
	Desloratadine for system suitability CRS 1	
	Dexamethasone for peak identification CRS 1	
	Finasteride for peak identification CRS 1	
	Flubarabine for system suitability CRS 1	
	Flutamide for system suitability CRS 1	
	Insulin glargine CRS 1	
	Insulin glargine for peak identification CRS 1	
	Isoprenaline impurity A CRS 1	
	Isoquercitroside CRS 1	
	Lactulose for peak identification CRS 1	
	Metformin impurity F CRS 1	
	Methylprednisolone for system suitability CRS 1	
	Naloxone impurity D CRS 1	
	Nitrofurantoin impurity B CRS 1	
	Norflurane Reference Spectrum	
	Oxcarbazepine CRS 1	
	Oxcarbazepine impurity mixture CRS 1	
	Pemetrexed disodium heptahydrate CRS 1	

	New substances / Nouvelles substances	
	Poly (vinyl alcohol) CRS 1	
	Poly(vinyl acetate) CRS 1	
	Propylene glycol CRS 1	
	Quillaia saponin for assay CRS 1	
	Quinapril for peak identification CRS 1	
	Risedronate impurity A CRS 1	
	Risedronate impurity E CRS 1	
	Risedronate sodium 2.5-hydrate CRS 1	
	Salvianolic acid B CRS 1	
	Tanshinone IIA CRS 1	
	Replacement batches / Lots de remplacement	
	(R)-Timolol CRS 2	
	1-nonadecanol CRS 2	
	all-rac- α -Tocopherol for peak identification CRS 2	
	Alpha-apo-oxytetracycline CRS 5	
	Atorvastatin calcium trihydrate CRS 2	
	Atropine sulfate CRS 4	
	Bisoprolol for system suitability CRS 3	
	Butylhydroxyanisole CRS 4	
	Caffeine for system suitability CRS 3	
	Cefaclor CRS 3	
	Cefuroxime axetil CRS 4	
	Cetirizine impurity A CRS 5	
	Cetyl alcohol CRS 2	
	Chenodeoxycholic acid CRS 3	
	Chlordiazepoxide impurity A CRS 2	
	Chlorphenamine impurity A CRS 4	
	Chlortalidone CRS 3	
	Cyanidin chloride CRS 2	
	Cysteine hydrochloride monohydrate CRS 2	
	Diclofenac sodium CRS 4	
	Dihydroergotamine mesilate CRS 4	
	Dithranol impurity C CRS 3	
	Dithranol impurity D CRS 4	
	Docetaxel trihydrate CRS 2	
	Ergocalciferol CRS 8	
	Etofenamate impurity G CRS 2	
	Fludarabine phosphate CRS 2	

	Replacement batches / Lots de remplacement	
	Fluphenazine dihydrochloride CRS 2	
	Hydroxypropylbetadex CRS 2	
	Ifosfamide impurity B CRS 2	
	Insulin glargine CRS 2	
	Ketotifen impurity G CRS 4	
	Lansoprazole for peak identification CRS 2	
	Lincomycin for SST CRS 2	
	Metamizole impurity E CRS 2	
	Montelukast for peak identification CRS 2	
	Montelukast racemate CRS 2	
	Montelukast sodium CRS 2	
	Neomycin sulfate for microbiological assay CRS 4	
	Olsalazine sodium CRS 2	
	Oxybutynin impurity A CRS 4	
	Penbutolol impurity A CRS 2	
	Piracetam CRS 4	
	Quercetin dihydrate CRS 2	
	Racecadotril impurity A CRS 2	
	Riboflavin CRS 4	
	Rutoside trihydrate CRS 3	
	Salbutamol impurity J CRS 2	
	Salbutamol sulfate CRS 3	
	Sertraline for peak identification CRS 3	
	Somatostatin CRS 6	
	Spironolactone CRS 4	
	Tamsulosin racemate CRS 2	
	Testosterone CRS 3	
	Thiamazole impurity C CRS 2	
	Tiamulin for peak ID CRS 2	
	Tramazoline impurity A CRS 2	
	Tribenoside CRS 2	
	Tropicamide CRS 2	
	Tylosin CRS 2	
	Valsartan for system suitability CRS 2	
	Vindesine sulfate CRS 3	

	II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTES – A INSCRIRE A LA PROCHAINE SESSION	
27.4.2	Terminology used in monographs on biological products / Terminologie utilisée dans les monographies sur les produits biologiques (5.2.1) + Vaccines for human use / Vaccins pour usage humain (0153): for further consideration by Group 15, GTP, MAB	
Item	III. REQUESTS FOR REVISION / DEMANDES DE REVISION	
	III.1 Approved by the Commission	
24.4.1	Agnus castus fruit / Gattilier (fruit de) (2147) = Group 13B	
82.4.1	Astragalus mongholicus root / Astragalus mongholicus (racine d') (2435) = TCM Working Party	
23.4.1	Cascara dry extract, standardised / Cascara (extrait sec titré de) (1844) = Group 13A	
15.4.4	Cefoxitin sodium / Céfoxitine sodique (0990) = Group 7	
76.1	Code of Practice = ROP Working Party	
25.4.1	Composition of fatty acids in oils rich in omega-3 acids / Composition en acides gras des huiles riches en acides oméga-3 (2.4.29.) = Group 13H	
20.4.1	Ethanol (96 per cent) / Éthanol à 96 pour cent (1317) = Group 10D	
20.4.1	Ethanol, anhydrous / Éthanol anhydre (1318) = Group 10D	
15.4.1	Flucloxacillin magnesium octahydrate / Flucloxacilline magnésique octahydratée (2346) = Group 7	
76.1	Guide for Work = ROP Working Party	
32.4.1	Guidelines for using the test for bacterial endotoxins / Recommandations pour la réalisation de l'essai des endotoxines bactériennes (5.1.10) = BET and MAT Working Parties	
18.4.1	Iodixanol / Iodixanol (2215) = Group 10B	
18.4.1	Iohexol / Iohexol (1114) = Group 10B	
21.4.1	Levothyroxine sodium / Lévothyroxine sodique (0401) = Group 11	
23.4.2	Liquorice ethanolic liquid extract, standardised / Réglisse (extrait fluide éthanolique titré de) (1536) = Group 13A	
25.4.2	Macrogol stearate / Macrogol (stéarate de) (1234) = Group 13H	
25.4.3	Macrogolglycerol hydroxystearate / Macrogolglycérol (hydroxystéarate de) (1083) = Group 13H	
25.4.5	Methacrylic acid - methyl methacrylate copolymer (1:1) / Copolymère d'acide méthacrylique et de méthacrylate de méthyle (1:1) (1127) = Group 13H	
55.4.1	Mother tinctures for homoeopathic preparations / Teintures mères pour préparations homéopathiques (2029) = HOM Working Party	

	III.1 Approved by the Commission	
24.4.2	Myrrh / Myrrhe (1349) = Group 13B	
25.4.4	Omega-3-acid triglycerides / Oméga-3 (triglycérides d'acides) (1352) = Group 13H	
22.4.1	Parenteral preparations / Préparations parentérales (520) = Group 12	
74.4.1	Pesticide residues / Résidus de pesticides (2.8.13.)	
17.4.1	Phenytoin sodium / Phénytoïne sodique (0521) = Group 10A	
76.1	Rules of Procedure = ROP Working Party	
15.4.3	Sultamicillin / Sultamicilline (2211) = Group 7	
27.4.1	Vaccines for human use / Vaccins à usage humain (0153) = Group 15	
22.1.1	Veterinary semi-solid preparations for oral use / Préparations vétérinaires semi-solides pour usage oral (2638) = Group 12	
	III.2 Referred to Group for further consideration	
63.4.1	Microbiological quality of non-sterile pharmaceutical preparations and substance / Qualité microbiologique des préparations pharmaceutiques et des substances pour (50104): more data needed to evaluate this request -> referred to HOM/HMM	
63.4.2	Microbiological quality of herbal medicinal products for oral use and extracts / Qualité microbiologique des médicaments à base de plantes pour usage oral et des extraits (50108): more data needed to evaluate this request -> referred to HOM/HMM	
	III.3 Rejected by the Commission	
57.4.1	Aluminium hydroxide, hydrated, for adsorption / Aluminium (hydroxyde d') hydraté pour adsorption (1664): request for revision of this monograph not approved; request will be considered via revision of the monograph on Vaccines for human use (see under III.1 item 27.3.1)	
	IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)	
	Gefitinib (Group P4)	
	Isopropyl isostearate (Group 13H)	

	V DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)	
8.1	Edotreotide for radiopharmaceutical preparations (2544)	
8.1	Glutamic acid hydrochloride (2794)	
8.1	Hyoscine methylnitrate (2801)	
8.1	Kryptofix for radiopharmaceutical preparations (2548)	
21.4.1	Mitoxantrone hydrochloride (1243)	
8.1	Papaverine sulphate (2795)	
26.5.1	Parenteral preparations (520) : deleted from work programme of group 14 but kept on work programme of group 12	
15.5.1	Products of fermentation / Produits de fermentation (1468)	
8.1	Tin(II)chloride for labeling (2553)	
21.4.1	Vinblastine sulphate (748)	
21.4.1	Vincristine sulphate (749)	
Agenda Item No.	VI. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE	
6.2.2	Menotropin (follow-up 144th Session): not re-instated on the work programme	
7.1	Election of the Chair / Election du Président: Dr JL Robert, Luxembourg	
7.2	Terms of Reference and Profile for Experts for Sutures Working Party (SUT): approved	
7.2	Terms of Reference and Profile for Experts for all Groups of Experts and Working Parties	All delegations
7.3	Nominations to Groups of Experts and Working Parties: approved (see Annex I)	
77.5.1	Guidance document concerning Second Identification Testing	
79.2	Introduction of combination packs to the Standard Terms database	
	VII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION	
	- 18-19 June 2013 - 26-27 November 2013	

145th Session Nominations
MARCH 2013
ITEM 7.3

GROUPS OF EXPERTS

Group 7

Austria	Dr GRILL (Specialist: analytics of beta-lactams) (replacing Dr Binder)
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Group 9G

The Netherlands	Dr HARTIGH
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Group 10A

Spain	Ms GONZALEZ VAZQUEZ (replacing Dr Dannert Alsasua)
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Group 10B

Czech Republic	Dr DRASAROVA (replacing Dr Dolezalova)
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Group 10D

Spain	Ms DIAZ BARCO (replacing Dr Moreno)
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Group 13A

The Netherlands	Dr VAN DER NAT (replacing Dr van der Sluis)
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Group 13B

The Netherlands	Dr VAN DER NAT (replacing Dr van der Sluis)
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Group 15

Belgium	Dr PRONCE (Specialist quality control and quality assurance of pharmaceutical, biopharmaceutical (vaccines and blood-derived products) and radiopharmaceutical products)
Germany	Dr KRAEMER (Specialist: rabies vaccines) (replacing Dr Pittertschatscher)
Croatia	Dr CACIC (replacing Ms Mandusic Nazor)

Group 15V

Czech Republic	Dr SMITALOVA (Specialist: diseases of swine, molecular biology methods)
Germany	Dr LEMKE (ad-hoc Specialist in the field of Bluetongue vaccines)
Germany	Dr MOTITSCHKE (ad-hoc Specialist: exclusion or elimination of adventitious agents)

Group 16

United Kingdom	Dr ALLEN
Turkey	Dr BESKAN (Specialist: plastic materials, plastic containers, closure and medical devices)
Switzerland	Dr HAUK

Group P4

Switzerland	Dr GIRARD (replacing Dr Nick)
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Chair of the Second Identification Test Working Party (SIT)

Germany	Dr GUMZ
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Chair of the Statistics Working Party (STA)

Switzerland	Dr GERMANSDEFER (if not Chair then Member)
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Chair of the Vitamins Working Party (VIT)

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WORKING PARTIES

Carbohydrates Working Party (CRB)

Spain	Mrs MAS ESCOSA
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Modern Microbiological Methods (MMM)

United Kingdom	Mr MARCO
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P4BIO

Germany	Dr ENGELBERGS (Specialist : Bioactivity of MAB's) (replacing Dr Roos)
Finland	Dr VESTERINEN

Precursors for Radiopharmaceutical Preparations Working Party (PRP)

Poland	Dr MIKOLAJCZAK
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Second Identification Test Working Party (SIT)

Croatia	Ms JAKSIC
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