

## EUROPEAN PHARMACOPOEIA COMMISSION

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# BILINGUE

Strasbourg, April 2014

GROUP COM

(EUROPEAN PHARMACOPOEIA COMMISSION / COMMISSION EUROPEENNE DE PHARMACOPÉE)

### Summary of Decisions taken at the 148th Session

Résumé des Décisions prises lors de la 148<sup>e</sup> Session

Strasbourg, 25-26 mars 2014  
Strasbourg, 25-26 March 2014

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**EUROPEAN PHARMACOPOEIA COMMISSION  
COMMISSION EUROPEENNE DE PHARMACOPEE**

**Summary of Decisions of the 148<sup>th</sup> Session  
25-26 March 2014**

**Résumé des décisions de la 148<sup>e</sup> Session  
25-26 mars 2014**

**Deadline for confirmation / Date de confirmation: 28 April 2014**

<b>Item</b>	<b>I. ADOPTED TEXTS</b>	<b>Subject to Confirmation</b>
	<b>I.1 Monographs and chapters/Monographies et chapitres</b>	
	<b>I.1.1 Minor revisions / Révisions mineures</b>	
21.3.2	Alprostadil / Alprostadil (1488)	
16.3.1	Ammonium bromide / Ammonium (bromure d') (1389)	
29.3.1	Brucellosis vaccine (live) (Brucella melitensis Rev. 1 strain) for veterinary use / Vaccin vivant de la brucellose (Brucella melitensis souche Rev. 1) pour usage vétérinaire (0793)	
18.3.1	Carisoprodol / Carisoprodol (1689)	
26.3.2	Cetostearyl isononanoate / Cétostéaryle (isononanoate de) (1085)	
19.3.1	Ciprofloxacin / Ciprofloxacine (1089)	
19.3.2	Ciprofloxacin hydrochloride / Ciprofloxacine (chlorhydrate de) (0888)	
26.3.1	Cocoyl caprylocaprate / Cocoyle (caprylocaprate de) (1411)	
19.3.3	Drospirenone / Drospirénone (2404)	
26.3.3	Ethylene oxide and dioxan / Oxyde d'éthylène et dioxane (20425)	
18.3.2	Hydralazine hydrochloride / Hydralazine (chlorhydrate d') (0829)	
31.3.1	Lamivudine / Lamivudine (2217)	
19.3.5	Levamisole for veterinary use / Lévamisole pour usage vétérinaire (1728)	
19.3.4	Levamisole hydrochloride / Lévamisole (chlorhydrate de) (0726)	
18.3.3	Marbofloxacin for veterinary use / Marbofloxacine pour usage vétérinaire (2233)	
21.3.1	Oxaliplatin / Oxaliplatine (2017)	
11.2	Pharmacopoeial harmonisation / Harmonisation des pharmacopées (5.8.)	
16.3.2	Potassium bromide / Potassium (bromure de) (0184)	
11.3	Rice starch / Amidon de riz (0349)	
16.3.3	Sodium bromide / Sodium (bromure de) (0190)	
11.4	Sodium chloride / Sodium (chlorure de) (0193)	
16.3.4	Sodium citrate / Sodium (citrate de) (0412)	

	<b>I.1.1 Minor revisions / Révisions mineures</b>	
39.3.1	Sorbitol liquid (crystallising) / Sorbitol liquide (cristallisable) (0436)	
39.3.3	Sorbitol liquid (non-crystallising) / Sorbitol liquide (non cristallisable) (0437)	
11.5	Stearic acid / Stéarique (acide) (1474)	
	<b>I.1.2 Revisions / Révisions</b>	
26.2.1	Arachis oil, refined / Arachide (huile d') raffinée (0263)	
29.2.1	Avian live virus vaccines: tests for extraneous agents in batches of finished product / Vaccins viraux vivants aviaires : recherche des agents étrangers dans les lots de produit final (20625)	
18.2.1	Carbidopa / Carbidopa (0755)	
39.2.1	Carrageenan / Carraghénanes (2138)	
19.2.1	Chlorhexidine dihydrochloride / Chlorhexidine (dichlorhydrate de) (0659)	
15.2.1	Colistin sulfate / Colistine (sulfate de) (0320)	
15.2.2	Demeclocycline hydrochloride / Déméclocycline (chlorhydrate de) (0176)	
20.2.1	Detomidine hydrochloride for veterinary use / Détomidine (chlorhydrate de) pour usage vétérinaire (1414)	
15.2.4	Doxycycline hyclate / Doxycycline (hyclate de) (0272)	
15.2.3	Doxycycline monohydrate / Doxycycline monohydratée (0820)	
19.2.2	Fluocinolone acetonide / Fluocinolone (acétonide de) (0494)	
13.2.1	Follitropin / Follitropine (2285) <sup>1</sup>	
13.2.2	Follitropin concentrated solution / Follitropine (solution concentrée de) (2286) <sup>1</sup>	
23.2.2	Glass containers for pharmaceutical use / Récipients de verre pour usage pharmaceutique (3.2.1.)	
43.2.1	Haemodialysis, solutions for / Solutions pour hémodialyse (0128)	
20.2.2	Lisinopril dihydrate / Lisinopril dihydraté (1120)	
30.2.2	Materials based on non-plasticised poly(vinyl chloride) for containers for non-injectable, aqueous solutions / Matériaux à base de poly(chlorure de vinyle) non plastifié pour conditionnement des solutions aqueuses non injectables (30110)	
30.2.4	Materials based on non-plasticised poly(vinyl chloride) for containers for dry dosage forms for oral administration / Matériaux à base de poly(chlorure de vinyle) non plastifié pour conditionnement de formes pharmaceutiques sèches pour administration par voie orale (30111)	

<sup>1</sup> Will be published in Supplement 8.3 as already adopted at the 147<sup>th</sup> Session

	<b>I.1.2 Revisions / Révisions</b>	
30.2.3	Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion / Matériaux à base de poly(chlorure de vinyle) plastifié pour récipients destinés à contenir les solutions aqueuses pour perfusion intraveineuse (30114)	
30.2.5	Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components / Matériaux à base de poly(chlorure de vinyle) plastifié pour récipients destinés à contenir le sang humain et les produits sang (3.1.1.1.) (90001)	
30.2.6	Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components (3.1.1.2.) / Matériaux à base de poly(chlorure de vinyle) plastifié pour tubulures utilisées dans les nécessaires pour transfusion de sang et des composants sanguins (3.1.1.2.) (90002)	
50.2.1	Methods of preparation of homoeopathic stocks and potentisation / Méthodes de préparation des souches homéopathiques et déconcentration (2371)	DE
23.2.1	Parenteral preparations / Préparations parentérales (0520)	
23.2.3	Plastic containers and closures for pharmaceutical use / Récipients et fermetures en matière plastique pour usage pharmaceutique (3.2.2.)	
11.1	Reference standards / Étalons de référence (5.12.)	
22.2.1	Sodium alendronate / Sodium (alendronate de) (1564) <sup>2</sup>	
26.2.2	Squalane / Squalane (1630)	
27.2.1	Technetium (99mTc) etifenin injection / Technétium (99mTc) (etifénine-), solution injectable d' (0585)	
	<b>I.1.3 New texts for adoption / Nouveaux textes pour adoption</b>	
19.1.1	Eplerenone / Éplérénone (2765)	
31.1.1	Imatinib mesilate / Imatinib (mésilate d') (2736)	
70.1.1	Lycii fructus (2612)	
56.1.1	Methyl, ethyl and isopropyl toluenesulfonate in active substances / Toluènesulfonate de méthyle, d'éthyle et d'isopropyle dans les substances active (2.5.40)	
26.1.1	Polyoxypropylene stearyl ether / Polyoxypropylène (éther stéarylique de) (2602)	
31.1.2	Rosuvastatin calcium / Rosuvastatine calcique (2631)	
20.1.1	Tizanidine hydrochloride / Tizanidine (chlorhydrate de) (2578)	
20.1.2	Tolterodine tartrate / Toltérodine (tartrate de) (2781)	
20.1.3	Zanamivir, hydrated / Zanamivir hydraté (2611)	UK

<sup>2</sup> Will be published in Supplement 8.3 as already adopted at the 147<sup>th</sup> Session

83	<b><i>I-2 CRS/BRP SCR/PBR</i></b>	
	<b>New substances / Nouvelles substances</b>	
	Follitropin CRS 1	
	High-molecular-mass macrogol CRS 1	
	Methotrexate for system suitability CRS 1	
	Neostigmine impurity A CRS 1	
	Progesterone for peak identification CRS 1	
	Progesterone for system suitability CRS 1	
	Stavudine impurity I CRS 1	
	Valaciclovir impurity S CRS 1	
	Vardenafil for system suitability CRS 1	
	Vardenafil hydrochloride CRS 1	
	Zidovudine Impurity D CRS 1	
	<b>Replacement batches / Lots de remplacement</b>	
	Acetazolamide for system suitability CRS 2	
	Aciclovir for peak identification 1 CRS 3	
	Aciclovir for peak identification 2 CRS 3	
	Articaine Impurity A CRS 3	
	Azithromycin for peak identification CRS 3	
	Azithromycin for system suitability CRS 7	
	Betahistine mesilate CRS 2	
	Betamethasone sodium phosphate CRS 4	
	Bisacodyl for system suitability CRS 2	
	Bromazepam CRS 4	
	Bupivacaine impurity E CRS 3	
	Cabergoline CRS 2	
	Calcitonin (salmon) CRS 11	
	Calcitonin (salmon) CRS 12	
	Caprylic acid CRS 2	
	Carisoprodol Impurity A CRS 2	
	Cefepime dihydrochloride monohydrate CRS 2	
	Cefotaxime sodium CRS 5	
	Chlorphenamine impurity C CRS 2	
	Chlorphenamine maleate CRS 2	
	Clobetasol Impurity J CRS 2	
	Clozapine for peak identification CRS 2	

	<b>Replacement batches / Lots de remplacement</b>	
	Codeine impurity A CRS 4	
	Crotamiton impurity A CRS 4	
	Diosmin CRS 4	
	Dithranol Impurity C CRS 4	
	Enalapril maleate CRS 3	
	Estradiol benzoate CRS 2	
	Ethinylestradiol CRS 5	
	Famotidine for system suitability CRS 2	
	Febantel CRS 2	
	Fenoterol hydrobromide CRS 3	
	Fentanyl for system suitability CRS 2	
	Filgrastim CRS 2	
	Fluconazole CRS 2	
	Flumetasone pivalate CRS 2	
	Flupentixol impurity D CRS 2	
	Ginkgo dry extract FPI CRS 2	
	Glycerol monocaprylocaprate CRS 2	
	Imidazole CRS 2	
	Interferon beta-1a CRS 3	
	Lidocaine CRS 2	
	Lidocaine HCl CRS 3	
	Lincomycin hydrochloride CRS 4	
	Lorazepam CRS 2	
	Malathion impurity A CRS	
	Meloxicam impurity A CRS 2	
	Meloxicam impurity B CRS 2	
	Meloxicam impurity D CRS 3	
	Methyl parahydroxybenzoate CRS 4	
	Mianserin hydrochloride CRS 3	
	Moxidectin for system suitability CRS 2	
	Naloxone for peak identification CRS 2	
	Nitrazepam CRS 2	
	Ofloxacin Impurity A CRS 3	
	Plastic additive 18 CRS 2	
	Potassium clavulanate impurity G CRS 2	

	<b>Replacement batches / Lots de remplacement</b>	
	Prednisolone CRS 8	
	Promazine hydrochloride CRS 2	
	Propofol Impurity J CRS 4	
	Propyl gallate CRS 3	
	Risperidone for system suitability CRS 5	
	Salbutamol Impurity F CRS 5	
	Sertraline hydrochloride CRS 3	
	Sulpiride impurity B CRS 3	
	Sultamicillin tosilate CRS 3	
	Thioctic acid containing impurity B CRS 2	
	Timolol for system suitability CRS 2	
	Valproic acid for system suitability CRS 2	
	Valsartan for peak identification CRS 2	
	Vinorelbine impurity B CRS 4	
	Vinorelbine tartrate CRS 3	
	Zidovudine impurity B CRS 3	
	<b>II. ITEMS DEFERRED – SCHEDULED FOR NEXT SESSION/ SUJETS REPORTEES – A INSCRIRE A LA PROCHAINE SESSION</b>	
24.1.1	Horse-chestnut / Marron d'Inde (1830)	
24.1.2	Horse-chestnut dry extract, standardised / Marron d'Inde (extrait sec titré de) (1829)	
30.5	Plastic syringes for aqueous solutions for injection -> a survey will be sent to NPAs seeking their opinion for this proposed addition to the work programme	
44.1.1	Monographies d'extraits à base de drogues végétales (chapitre informatif) (5.23.)	
44.2.1	Extracts / Extraits (0765)	
51.4.1	Homoeopathic preparations / Préparations homéopathiques (1038) (request for revision)	
<b>Item</b>	<b>III. REQUESTS FOR REVISION / DEMANDES DE REVISION</b>	
	<b>III.1 Approved by the Commission</b>	
51.4.2	Agaricus phalloides for homoeopathic preparations / Agaricus bulbosus pour préparations homéopathiques (2290) -> HOM WP	
24.4.1	Clove oil / Clou de girofle (huile essentielle de) (1091) -> Group 13A	

	<b>III.1 Approved by the Commission</b>	
15.2.2	Demeclocycline hydrochloride / Déméclocycline (chlorhydrate de) (0176) -> Group 7	
23.4.1	Intraruminal devices / Dispositifs intraruminaux (1228) -> Group 12	
28.4.1	Meningococcal group C conjugate vaccine / Vaccin conjugué méningococcique groupe C (2112) -> Group 15	
28.4.1	Meningococcal polysaccharide vaccine/Vaccin méningococcique polysidique (0250) -> Group 15	
25.4.1	Olive leaf / Olivier (feuille d') (1878) -> Group 13B	
25.4.1	Olive leaf dry extract / Olivier (feuille d'), extrait sec de (2313) -> Group 13B	
28.4.1	Pneumococcal polysaccharide conjugate vaccine (adsorbed) / Vaccin pneumococcique polysidique conjugué adsorbé (2150) -> Group 15	
28.4.1	Pneumococcal polysaccharide vaccine / Vaccin pneumococcique polysidique (0966) -> Group 15	
23.4.2	Premixes for medicated feeding stuffs for veterinary use / Prémélanges pour aliments médicamenteux pour usage vétérinaire (1037) -> Group 12	
77.2	Rotary evaporator -> PCM	
39.2.2	Sorbitol / Sorbitol (435) -> CRB Working Party	
19.4.1	Testosterone / Testostérone (1373) -> Group 10B	
28.4.1	Typhoid polysaccharide vaccine / Vaccin typhoïdique polysidique (1160) -> Group 15	
77.1	Volumetric analysis / Volumétrie (4.2.) -> PCM	
77.3	Warning sentence on "overheating" in monographs -> PCM	
	<b>IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
8.1	Ceftiofur -> Group 7	
8.1	Ceftiofur sodium salt -> Group 7	
8.1	Esomeprazole sodium -> Group 10C	
8.1	Euonymus europaeae semen ad praeparationes homoeopathica -> HOM Working Party	
8.1	Everolimus -> Group P4	
8.1	Florfenicol for veterinary use -> Group 7	
8.1	Healthy chicken flocks for the production of inactivated vaccines for veterinary use -> Group 15V	
8.1	Imidacloprid -> Group 10D	
8.1	Iomeprol -> Group 10B	



8.1	Permethrin 40/60 for veterinary use -> Group 10C	
	<b>IV ADDITIONS TO THE WORK PROGRAMME / PROGRAMME DE TRAVAIL (NEW ITEMS)</b>	
54.1	Pilot Phase MAB Working Party	
	<b>V.1 DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)</b>	
8.1	Atropinum ad praeparationes homoeopathicas	
8.1	Mepifiline	
28.5.1	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)	
28.5.1	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)	
28.5.1	Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et de l'hépatite B (ADNr) adsorbé (1933)	
28.5.1	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyéлитique (inactive) adsorbé (1934)	
28.5.1	Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique et de l'hépatite B (ADNr), adsorbé (2062)	
28.5.1	Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) / Vaccin diphtérique, tétanique et poliomyéлитique (inactive), adsorbé, à teneur réduite en antigène (s) (2328)	
28.5.1	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed. Reduced antigen(s) content) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyéлитique (inactivé). Adsorbé à teneur réduite en antigène (2329)	
28.5.1	Diphtheria, tetanus, pertussis (acellular, component), polyomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyéлитique (inactivé) et conjugué de l'haemophilus type b, adsorbé (2065)	
28.5.1	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyéлитique (inactivé)	

	et conjugué de l'haemophilus type b, adsorbé (2067)	
	<b>V.1 DELETIONS FROM THE WORK PROGRAMME / SUPPRESSIONS DU PROGRAMME DE TRAVAIL (New items or requests for revision)</b>	
30.5.1	Plastic Containers for Aqueous solutions for Infusion (3.2.2.1)	
	<b>V.2 SUPPRESSIONS FROM THE PH.EUR / SUPPRESSIONS DE LA PH. EUR</b>	
8.1	Liquorice.ethanolic liquid extract standardised (1536)	
<b>Agenda Item No.</b>	<b>VI. PROCEDURES AND QUESTIONS OF PRINCIPLE/ PROCEDURES ET QUESTIONS DE PRINCIPE</b>	
6.6.1	Informal Working Group on Viscosity	
7.1	Nominations to Groups of Experts and Working Parties / Nominations pour Groupes d'Experts et Groupes de Travail (see Annex)	
7.3	Request for observership from Azerbaijan	
45.5.1	Guidance on finished product monographs	ALL
76.1	BSP Report	
	<b>VII. DATES OF FUTURE SESSIONS/DATE DE LA PROCHAINE SESSION DE LA COMMISSION</b>	
	17 & 18 June 25 & 26 November	

## ANNEX 1 - Nominations

**148<sup>th</sup> Session Nominations - ITEM 7.1****GROUPS OF EXPERTS****Group 1**

Ukraine	Mrs Kateryna ZHEMEROVA	Authorities
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**Group 6**

Algeria	Mrs Mokhtaria BEZAOUCHA	Authorities
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**Group 6B**

Israel	Ph.D. Ofra AXELROD	Licensing authority/OMCL
Croatia	Mrs Marta PIPIC-KOSANOVIC	Licensing authority
FDA/CBER/OBRR	Mr Mark WEINSTEIN	Licensing authority

**Group 7**

United Kingdom	Dr Vikas JAITLEY	Licensing authority
France	Ms Simona TEODOSIU	Licensing authority

**Group 12**

Ukraine	Mrs Nataliia ASMOLOVA	Authorities
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**Group 13A**

Austria	Dr Martin PUNZENGRUBER	Authorities
Germany	Dr Franck WAIMER (replacing Dr FRANCK)	Industry

**Group 15V**

Austria	Dr Dieter PULLIRSCH	Authorities
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**WORKING PARTIES****Bacterial endotoxins test (BET)**

The Netherlands	Dr Lucien AARDEN	Industry
Algeria	Mr Henni CHADER	Not given
Turkey	PhD Mehmet Kursat DERICI	NPA/Licensing Authority
Ukraine	Mrs Yuliya MERKULOVA	Authorities

**Carbohydrates Production and compounding of (CRB)**

Belgium	Dr Geertrui HAEST	Industry
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**Chromatographic separation techniques (CST)**

Switzerland	Prof. Dr. Veronika R MEYER	Authorities
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**Gene Therapy Products (GTP)<sup>3</sup>**

Austria	Dr Dieter PULLIRSCH (re-nomination)	Authorities
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**Propellants (HFA)<sup>3</sup>**

United Kingdom	Dr Tarlochan PUREWAL	Not given
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**Inhalanda (INH)**

Germany	Dr Cornelia NOPITSCH-MAI	Licensing authority
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**Live Biotherapeutic Products (LBP)**

France	Dr Natacha CHARLIER-BRET	NPA
Italy	Dr Maria Jesus GOMEZ MIGUEL	OMCL
Spain	PhD Ana SAGREDO	Licensing authority/OMCL
Italy	Dr Christina VON HUNOLSTEIN <b>Chair</b> (or member)	OMCL

**Non-biological complexes (NBC)**

Switzerland	Dr Fiona ROOS	Industry
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**Procedure 4 BIO (P4Bio)**

United Kingdom	Dr Meenu WADHWA	OMCL
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**Pharmaceutical preparations (PHP)**

Austria	Dr Erich LEITNER (re-nomination)	Industry
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**Standard Terms (ST)**

EMA	Dr Isabel CHICHARO	Licensing authority
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**Sutures (SUT)**

Germany	Dr Boris BATKE	Industry
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**Vitamins (VIT)**

France	Mr Pascal ANGER	Industry
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<sup>3</sup> “Dormant” groups: nomination will become effective when the group is reactivated