

Update to work programme of the European Pharmacopoeia

(November 2023)

The following items have been added to or deleted from the work programme during the 177th session of the European Pharmacopoeia Commission. Consult the [Knowledge Database](#) to follow the work on individual texts.

Interested parties are invited to contact the EDQM via the [HelpDesk](#) with a view to participating in the work on items of interest.

TEXTS TO BE REVISED

Methods of analysis			
2.1.7.	Balances for analytical purposes (2.1.7.)	Balances d'analyse (2.1.7.)	Clarification of certain terms and definitions, with special emphasis on the definition of minimum weight
2.2.15.	Melting point - open capillary method (2.2.15.)	Point de fusion - méthode au tube capillaire ouvert (2.2.15.)	To allow the use of automated instruments
2.7.23.	Numeration of CD34/CD45+ cells in haematopoietic products (2.7.23.)	Numération des cellules CD34/CD45+ dans les produits hématopoïétiques (2.7.23.)	General update of the chapter in order to reflect the current practices
General Texts			
5.2.6.	Evaluation of safety of veterinary vaccines and immunosera (5.2.6.)	Évaluation de l'innocuité des vaccins et immunosérum vétérinaires (5.2.6.)	Clarification that the worst case scenario for assessing safety of avian live vaccines for oculonasal use is administration by eye drop
5.25.	Process analytical technology (5.25.)	Contrôle analytique des procédés (5.25.)	General update of the chapter
General Monographs			
0062	Vaccines for veterinary use	Vaccins pour usage vétérinaire	Linked to the revision of chapter 2.6.7 Mycoplasmas, removal of the indication that a culture method should be used
Vaccines for human use			
1107	Hepatitis A vaccine (inactivated, adsorbed)	Vaccin de l'hépatite A (inactivé, adsorbé)	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0158	Influenza vaccine (split virion, inactivated)	Vaccin grippal inactivé à virion fragmenté	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0869	Influenza vaccine (surface antigen, inactivated)	Vaccin grippal inactivé (antigène de surface)	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
2149	Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Vaccin grippal inactivé (antigène de surface, préparé sur cultures cellulaires)	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested

2053	Influenza vaccine (surface antigen, inactivated, virosome)	Vaccin grippal inactivé (antigène de surface, virosomal)	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0159	Influenza vaccine (whole virion, inactivated)	Vaccin grippal inactivé à virion entier	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0214	Poliomyelitis vaccine (inactivated)	Vaccin poliomyélitique inactivé	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0164	Smallpox vaccine (live)	Vaccin vivant de la variole	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
1375	Tick-borne encephalitis vaccine (inactivated)	Vaccin inactivé de l'encéphalite verno-estivale	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested
0537	Yellow fever vaccine (live)	Vaccin vivant de la fièvre jaune	Mycoplasmas: removal of the sample volume indication and verification of the production stage to be tested

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

2390	Fluoride (¹⁸ F) solution for radiolabelling	Fluorure (¹⁸ F) pour radiomarquage (solution de)	pH: review of the range
3109	Gallium (⁶⁸ Ga) chloride (accelerator-produced) solution for radiolabelling	Gallium (⁶⁸ Ga) (chlorure de) pour radiomarquage, produit dans un accélérateur, solution de	Tests for iron and zinc: replacement by Apparent molar activity test

Herbal drugs

1812	Belladonna leaf tincture, standardised	Belladone (feuille de), teinture titrée de	Replace the TLC tests for identification and for atropine by an optimised, more convenient and state-of-the-art HPTLC procedure. Replace the current titration method by a specific and more convenient LC-UV procedure based on the assay method described in monograph 2489, Belladonna for homoeopathic preparations
0222	Belladonna, prepared	Belladone (poudre titrée de)	Replace the TLC tests for identification and for atropine by an optimised, more convenient and state-of-the-art HPTLC procedure. Replace the current titration method by a specific and more convenient LC-UV procedure based on the assay method described in monograph 2489, Belladonna for homoeopathic preparations
1218	Guar	Guar	Replace the TLC test for identification by a state-of-the-art HPTLC procedure
1334	Ispaghula husk	Ispaghul (graine d'), tégument de la	Replace the TLC test for identification by a state-of-the-art HPTLC procedure
0858	Psyllium seed	Psyllium (graine de)	Replace the TLC test for identification by a state-of-the-art HPTLC procedure

Monographs

1383	<i>N</i> -Acetyltryptophan	<i>N</i> -Acétyltryptophane	Related substances: addition of two impurities and clarification of limits applicable to already listed impurities
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0580	Aprotinin	Aprotinine	Remove references to animal test for histamine from Production section
0579	Aprotinin concentrated solution	Aprotinine (solution concentrée d')	Remove references to animal test for histamine from Production section
0476	Chymotrypsin	Chymotrypsine	Remove references to animal test for histamine from Production section
1747	Clopamide	Clopamide	Revision of the statement on nitrosamines as part of the strategy for <i>N</i> -nitrosamine impurities in individual monographs
2790	Clopidogrel besilate	Clopidogrel (bésilate de)	Identification test D (besilate): revision based on feedback from users
0711	Cyclophosphamide monohydrate	Cyclophosphamide monohydraté	Related substances: general update of the test based on feedback from CEP holders
1195	Dalteparin sodium	Daltéparine sodique	Delete the Production section and review the Tests section as part of the strategy for <i>N</i> -nitrosamine impurities in individual monographs
2090	Danaparoid sodium	Danaparoïde sodique	Remove references to histamine and depressor substances from Production section
0662	Daunorubicin hydrochloride	Daunorubicine (chlorhydrate de)	Remove references to histamine and depressor substances from Production section
0491	Ethylmorphine hydrochloride	Éthylmorphine (chlorhydrate d')	Title: addition of the hydrate form, Identification by IR: introduction of a CRS, Related substances: update of the limits and quantitative determination of impurities
1013	Felodipine	Félodipine	Revision of the second identification section
2173	Gabapentin	Gabapentine	Related substances, method A: a disregard statement would be introduced based on feedback from users
0908	Guar galactomannan	Guar (galactomannane du)	Replace the TLC test for identification by a state-of-the-art HPTLC procedure
0332	Heparin calcium	Héparine calcique	Remove references to histamine and depressor substances from Production section
0333	Heparin sodium	Héparine sodique	Remove references to histamine and depressor substances from Production section
0500	Homatropine hydrobromide	Homatropine (bromhydrate d')	Related substances: update of the limits and quantitative determination of impurities
1616	Hydroxycarbamide	Hydroxycarbamide	Revision of the test for related substances, to introduce a limit for unspecified impurities of maximum 0.05 per cent and to set the reporting threshold at 0.03 per cent, thus aligning the monograph with ICH Q3A
0033	Kanamycin acid sulfate	Kanamycine (sulfate acide de)	Remove references to histamine and depressor substances from Production section

0032	Kanamycin monosulfate	Kanamycine (monosulfate de)	Remove references to histamine and depressor substances from Production section
1444	Macrogols	Macrogols	Ethylene glycol and diethylene glycol: improvement of analytical procedure
1792	Nicotine resinate	Nicotine (résinate de)	Introduction of a new impurity
2073	Oleyl alcohol	Oléique (alcool)	Composition of fatty alcohols: improvement of analytical procedure
0049	Paracetamol	Paracétamol	Assay: optimisation of the analytical procedure (e.g. replacing titration by liquid chromatography), particularly since the current assay is cumbersome to carry out and requires visual detection of the end-point
2602	Polyoxypropylene stearyl ether	Polyoxypropylène (éther stéarylique de)	Propylene oxide: improvement of analytical procedure
0432	Rifamycin sodium	Rifamycine sodique	Remove references to histamine and depressor substances from Production section
2335	Ropivacaine hydrochloride monohydrate	Ropivacaïne (chlorhydrate de) monohydraté	Revision of the test for impurity H to improve the selectivity of the LC procedure, especially with regard to ensuring that impurity C does not coelute with impurity H
1565	Sodium molybdate dihydrate	Sodium (molybdate de) dihydraté	Content: change in the limits
0053	Streptomycin sulfate	Streptomycine (sulfate de)	Remove references to histamine and depressor substances from Production section
0645	Tobramycin	Tobramycine	Remove references to histamine and depressor substances from Production section
0694	Trypsin	Trypsine	Remove references to animal test for histamine from Production section
0695	Urokinase	Urokinase	Remove references to histamine and depressor substances from Production section
2611	Zanamivir hydrate	Zanamivir hydraté	Replacement of the loss on drying test by a water determination using coulometric Karl-Fischer

ADDITIONS TO THE WORK PROGRAMME (new texts to be elaborated)

2.5.47.	Histamine in active substances	Histamine dans les substances actives
2.8.27.	Determination of toxic compounds in essential oils and herbal drugs containing essential oils	Dosage des composés toxiques dans les huiles essentielles et les drogues végétales contenant des huiles essentielles
5.42.	Recommendations for control of extractable elements in plastic materials	Recommandations pour le contrôle des éléments extractibles dans les plastiques
3244	Azelaic acid	Azélaïque (acide)
3243	Lenalidomide hydrochloride capsules	Lénalidomide (chlorhydrate de), capsules de

3242	Lenalidomide hydrochloride monohydrate	Lénalidomide (chlorhydrate de) monohydraté
3245	Macitentan	Macitentan
3246	Macitentan tablets	Macitentan (comprimés de)
3249	Olopatadine hydrochloride	Olopatadine (chlorhydrate d')
3247	Penciclovir	Penciclovir
3248	Sugammadex sodium	Sugammadex sodique

DELETIONS FROM THE WORK PROGRAMME (new texts or requests for revision)

5.2.2.	Chicken flocks free from specified pathogens for the production and quality control of vaccines (5.2.2.)	Élevages de poulets exempts de microorganismes pathogènes spécifiés pour la production et le contrôle de qualité des vaccins (5.2.2.)
1388	Aluminium magnesium silicate	Aluminium (silicate d') et de magnésium
1764	Rocuronium bromide	Rocuronium (bromure de)
2515	Sulfur for homoeopathic preparations	Sulfur pour préparations homéopathiques