

Update to work programme of the European Pharmacopoeia

(March 2025)

The following items have been added to or deleted from the work programme during the 181st 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			
2.6.14	Bacterial endotoxins (2.6.14.)	Essai des endotoxines bactériennes (2.6.14.)	Introduction of recombinant factor C as method G
2.7.13	Assay of human anti-D immunoglobulin (2.7.13.)	Dosage de l'immunoglobuline humaine anti-D (2.7.13.)	Removal of method A and addition of flexibility for the donor cells
General Texts			
5.1.10	Guidelines for using the test for bacterial endotoxins (5.1.10.)	Recommandations pour la réalisation de l'essai des endotoxines bactériennes (5.1.10.)	Better integration of rFC, introduction of a reference to recombinant cascade reagents (rCR)
5.1.13	Pyrogenicity (5.1.13.)	Pyrogénicité (5.1.13.)	Introduction of a statement on considering sustainability when choosing a BET method
General Monographs			
1063	Allergen products	Produits allergènes	General update of the chapter in order to reflect the current practices
Vaccines for human use			
0158	Influenza vaccine (split virion, inactivated)	Vaccin grippal inactivé à virion fragmenté	Introduction of a general statement on the establishment of an upper limit for the content of haemagglutinin antigen.
0869	Influenza vaccine (surface antigen, inactivated)	Vaccin grippal inactivé (antigène de surface)	Introduction of a general statement on the establishment of an upper limit for the content of haemagglutinin antigen.
2053	Influenza vaccine (surface antigen, inactivated, virosome)	Vaccin grippal inactivé (antigène de surface, virosomal)	Introduction of a general statement on the establishment of an upper limit for the content of haemagglutinin antigen.
2149	Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Vaccin grippal inactivé (antigène de surface, préparé sur cultures cellulaires)	Introduction of a general statement on the establishment of an upper limit for the content of haemagglutinin antigen.
0159	Influenza vaccine (whole virion, inactivated)	Vaccin grippal inactivé à virion entier	Introduction of a general statement on the establishment of an upper limit for the content of haemagglutinin antigen.

Vaccines for veterinary use

0441	Anthrax spore vaccine (live) for veterinary use	Vaccin vivant sporulé de la fièvre charbonneuse pour usage vétérinaire	Update and 3Rs proposal for Immunogenicity
0963	Porcine influenza vaccine (inactivated)	Vaccin inactivé de la grippe porcine	Addition of 3Rs compliant batch potency methods
0965	Porcine parvovirus vaccine (inactivated)	Vaccin inactivé de la parvovirose porcine	Addition of 3Rs compliant batch potency methods
2325	Rabbit haemorrhagic disease vaccine (inactivated)	Vaccin inactivé de la maladie hémorragique du lapin	To cover a new variant (RHDV 2)
1947	Salmonella Enteritidis vaccine (inactivated) for chickens	Vaccin inactivé de la salmonellose à Salmonella Enteritidis pour le poulet	General improvements to the monograph
2361	Salmonella Typhimurium vaccine (inactivated) for chickens	Vaccin inactivé de la salmonellose à Salmonella Typhimurium pour le poulet	General improvements to the monograph
0064	Swine erysipelas vaccine (inactivated)	Vaccin inactivé du rouget du porc	Addition of 3Rs compliant batch potency methods

Herbal drugs and herbal drug preparations

1866	Artichoke leaf	Artichaut (feuille d')	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.
2389	Artichoke leaf dry extract	Artichaut (feuille d'), extrait sec de	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.
2378	Liquorice dry extract for flavouring purposes	Réglisse (extrait sec de) pour aromatisation	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.
0277	Liquorice root	Réglisse (racine de)	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.
2071	Milk thistle dry extract, refined and standardised	Chardon marie (extrait sec purifié et titré de)	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.
1860	Milk thistle fruit	Chardon marie	Modernisation of identification test C: TLC replaced by an HPTLC procedure that complies with general chapter 2.8.25.

Monographs

0454	Acetazolamide	Acétazolamide	Second Identification
0972	Antazoline hydrochloride	Antazoline (chlorhydrate d')	Related substances: TLC replaced by an LC
0977	Brompheniramine maleate	Bromphéniramine (maléate de)	Evaluation of the need to keep the reference to the test for optical rotation in the first identification series; replacement of the GC procedure for related substances by a more robust LC procedure; evaluation of the need to optimise the assay procedure.

0455	Citric acid	Citrique (acide)	Alumium test: replacement of the current procedure with an AAS procedure
0456	Citric acid monohydrate	Citrique (acide) monohydraté	Alumium test: replacement of the current procedure with an AAS procedure
1307	Decyl oleate	Décyle (oléate de)	Oleic acid: improvement of the analytical procedure
2410	2,4-Dichlorobenzyl alcohol	2,4-Dichlorobenzylque (alcool)	Water: change of the procedure (i.e. direct sample introduction instead of the evaporation technique).
1696	Flunixin meglumine for veterinary use	Flunixin méglumine pour usage vétérinaire	Evaluation of the need to optimise the test for specific optical rotation and for an alternative LC procedure for the test for related substances; alignment of the acceptance criterion for unspecified impurities and the reporting threshold with general monograph 2034; provision of the means for identifying impurity D in chromatograms of test solutions; evaluation of the need to optimise the assay procedure.
1212	Fluocortolone pivalate	Fluocortolone (pivalate de)	Review of the water content limits and the corresponding analytical procedure.
0255	Human albumin solution	Albumine humaine (solution d')	General update of the chapter to reflect current practices
1115	Iopamidol	Iopamidol	Related substances test: limits updated based on data from manufacturers and the requirements of general monograph 2034 (impurity C now limited at 0.10%, impurities A, B, D, E, F, G, J, K listed as unspecified impurities and limit for unspecified impurities at 0.05% introduced); disregard limit updated based on the maximum daily dose (2 g /day) and in accordance with general monograph 2034; introduction of a new reference solution to identify impurity C.
0401	Levothyroxine sodium	Lévothyroxine sodique	Title updated to introduced 'hydrate'. Impurities: structure added for impurity G.
0560	Methotrexate	Méthotrexate	Enantiomeric purity: analytical procedure optimised to ensure specificity.
0516	Noscapine	Noscapine	Improvement of the LC procedure to control additional impurities
1461	Penbutolol sulfate	Penbutolol (sulfate de)	Related substances: limits updated based on the requirements of general monograph 2034 (introduction of a limit of NMT 0.10% for the unspecified impurities)
0290	Resorcinol	Résorcinol	Related substances: TLC replaced by an LC; acceptance criteria aligned with general monograph 2034.
0592	Sorbic acid	Sorbique (acide)	Second identification
0294	Sulfadiazine	Sulfadiazine	Second identification
0108	Sulfamethoxazole	Sulfaméthoxazole	Second identification
1571	Sulfanilamide	Sulfanilamide	Second identification

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

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

3278	Copper (⁶⁴ Cu) solution for radiolabelling	Cuivre (⁶⁴ Cu) pour radiomarquage (solution de)
-------------	--	---

Monographs

3279	Emtricitabine	Emtricitabine
2250	Mifepristone	Mifépristone
3282	Procabazine hydrochloride	Procabazine (chlorhydrate de)
3283	Pseudoephedrine sulfate	Pseudoéphédrine (sulfate de)
3284	Sodium patent blue	Bleu patenté sodique
3285	Sodium patent blue solution for injection	Bleu patenté sodique pour solutions injectables
3286	Thalidomide	Thalidomine

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

Dosage forms

1163	Eye preparations	Préparations ophtalmiques
1806	Intrauterine preparations for veterinary use	Préparations intra-utérines pour usage vétérinaire
0676	Nasal preparations	Préparations nasales

Monographs

1077	Buserelin	Buséreliné
1036	Phytomenadione	Phytoménadione