

Update to work programme of the European Pharmacopoeia

(November 2025)

The following items have been added to or deleted from the work programme during the 183rd 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			
2.6.16	Tests for extraneous agents in viral vaccines for human use	Essai des agents étrangers dans les vaccins viraux pour usage humain	Proposal to reduce the number of positive controls used in the test for avian leucosis viruses
2.9.18	Preparations for inhalation: aerodynamic assessment of fine particles	Préparations pour inhalation : évaluation aérodynamique des particules fines	Addition of the abbreviated impactor apparatus and test procedure
2.9.27	Uniformity and accuracy of delivered doses from multidose containers	Uniformité et exactitude de la dose délivrée par les récipients multidoses	Deletion of “accuracy” from the title of the general chapter
General texts			
5.32	Cell-based preparations for human use	Produits cellulaires pour usage humain	Addition of sections on keratinocyte-, fibroblast- and lymphocyte-based preparations
General monographs			
2619	Pharmaceutical preparations	Préparations pharmaceutiques	Modification of wording for microbiological quality requirements
Dosage forms			
0676	Nasal preparations	Préparations nasales	Alignment of the requirements for testing for the uniformity of delivered dose of nasal preparations with the new EMA guideline
Vaccines for human use			
0216	Rabies vaccine for human use prepared in cell cultures	Vaccin rabique pour usage humain préparé sur cultures cellulaires	Following BSP148 success, replacement of the in vivo challenge assay with an ELISA standardised method
Herbal drugs and herbal drug preparations			
2428	Schisandra fruit	Schisandra de Chine (fruit de)	Revision of Identification C to update it to an HPTLC test

Monographs

1586	Adipic acid	Adipique (acide)	Loss on drying: addition of a drying time assay: change to potentiometric end-point detection
1094	Cyproterone acetate	Cyprotérone (acétate de)	Assay: replacement of UV absorbance by the HPLC from related substances test
0603	Disulfiram	Disulfirame	Replacement of the TLC procedure in the test for related substances by an HPLC procedure; alignment of the acceptance criteria of the test for related substances with general monograph 2034. Moreover, consideration will be given to replacing the current titrimetric assay with an HPLC procedure based on the new HPLC method used in the test for related substances
1912	Fish oil, rich in omega-3 acids	Poisson (huile de) riche en acides oméga-3	Alosidae and Dorosomatidae families to be included in the Definition
1428	Glycerol distearate	Glycérol (distéarate de)	Revision of wording in Definition for origin
0495	Glycerol monostearate 40-55	Glycérol (monostéarate de) 40-55	Revision of wording in Definition for origin
0922	Ketoprofen	Kétoprofène	Assay: replacement of current method by HPLC in the related substances test
0728	Liothyronine sodium	Liothyronine sodique	Replacement of the loss on drying test by micro-determination of water. Update of the limits of assay content and specific optical rotation test
2031	Monoclonal antibodies for human use	Anticorps monoclonaux pour usage humain	General update
2073	Oleyl alcohol	Oléique (alcool)	Revision of wording in Definition for origin
2063	Omega-3-acid ethyl esters 60	Oméga-3 (esters éthyliques 60 d'acides)	Alosidae and Dorosomatidae families to be included in the Definition
1250	Omega-3-acid ethyl esters 90	Oméga-3 (esters éthyliques 90 d'acides)	Identification of the ethyl ester C20:2 (RRT 0.68) and inclusion in identified fatty acid ethyl esters in the assay chromatogram Separate revision: Alosidae and Dorosomatidae families to be included in the Definition
1352	Omega-3-acid triglycerides	Oméga-3 (triglycérides d'acides)	Alosidae and Dorosomatidae families to be included in the Definition
1630	Squalane	Squalane	Revision of wording in Definition for origin
1268	Stearoyl macroglycerides	Macrogolglycérides stéariques	Composition of fatty acids - change of reference from method A to method C
0358	Sulfamerazine	Sulfamérazine	Revision of the second identification tests

0743	Urea	Urée	Replacement of the test for biuret, a colorimetric procedure, by an HPLC test for related substances covering biuret, triuret and unspecified impurities; alignment of the acceptance criteria of the test for related substances with general monograph 2034 Moreover, consideration will be given to replacing the current titrimetric assay with an HPLC procedure based on the new HPLC method used in the new test for related substances
1378	Valproic acid	Valproïque (acide)	Addition of a water test determination
0134	Wool fat	Graisse de laine	Revision of pesticide residue test

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

Methods of analysis

2.5.48	Nitrites in excipients	Nitrites dans les excipients
2.5.49	Capillary gel electrophoresis for recombinant therapeutic monoclonal antibodies	Électrophorèse capillaire sur gel appliquée aux anticorps monoclonaux thérapeutiques recombinants

Monographs

3293	Anakinra	Anakinra
3294	Anakinra injection	Anakinra (préparation injectable d')
3295	Cannabidiol, synthetic	Cannabidiol synthétique
3298	Dexrazoxane	Dexrazoxane
3292	Nicotine resinate with glycerol	Nicotine (résinate de) avec glycérol
3301	Pegaspargase	Pégaspargase
3302	Pegaspargase powder for injection	Pégaspargase (poudre pour injection de)
3303	Peginterferon alfa-2a	Peginterféron alfa-2a
3304	Peginterferon alfa-2a injection	Peginterféron alfa-2a
3305	Riluzole	Riluzole
3306	Tocopheryl polyethylene glycol succinate	Tocophéryle polyéthylène glycol, succinate de

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

2108	Star anise oil	Badiane (huile essentielle de)
0577	Amoxicillin sodium	Amoxicilline sodique
0260	Amoxicillin trihydrate	Amoxicilline trihydratée