Update to work programme of the European Pharmacopoeia

(June 2025)

The following items have been added to or deleted from the work programme during the 182nd 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

Materials and containers			
3.1.11	Materials based on non-plasticised poly(vinyl chloride) for containers for solid dosage forms for oral administration	Matériaux à base de poly(chlorure de vinyle) non plastifié pour conditionnement de formes pharmaceutiques solides pour administration par voie orale	Update of the absorption maxima
3.2.9	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders	Fermetures en caoutchouc pour récipients destinés aux préparations parentérales aqueuses, aux poudres et aux poudres cryodesséchées	Revision of the volatile sulfides test to find suitable alternatives for the reagent *sodium sulfide nonahydrate R*
Herbal drugs and herbal drug preparations			
3028	Cannabis flower	Cannabis (fleur de)	In identification test C, it is proposed to widen the acceptance criterion for the zone due to Δ9-tetrahydrocannabinol for the THC-dominant type to include cases in which this zone is very faint or even absent. In the test for foreign matter, it is also proposed to widen the acceptance criteria applicable to the herbal drug prescribed to patients as a medicinal product: with this change, the presence of seeds, other than mature seeds, will be permitted, and a limit for leaf length will no longer be given
1851	Dandelion herb with root	Pissenlit (partie aérienne et racine de)	It is proposed to modernise identification test C by replacing the current TLC procedure with an HPTLC method in accordance with general chapter 2.8.25.
1852	Dandelion root	Pissenlit (racine de)	It is proposed to modernise identification test C by replacing the current TLC procedure with an HPTLC method in accordance with general chapter 2.8.25. It is also proposed to add a test for chicory adulteration, based on the new HPTLC method for identification

1522	Ginger	Gingembre	Replacement of TLC by improved HPTLC
1880	Oregano	Origan	Improvement of GC method for the determination of thymol and carvacrol
0865	Thyme	Thym	Improvement of GC method for the determination of thymol and carvacrol
Homoeopathic preparation			
2710	Ephedra vulgaris for homoeopathic preparations	Ephedra vulgaris pour préparations homéopathiques	Content: revision to slightly increase the range of ephedrine and pseudoephedrine content in the mother tincture (proposal to replace the lower limit of 0.03 by 0.02 per cent *m/m*)
Monographs			
1383	*N*-Acetyltryptophan	*N*-Acétyltryptophane	Iron: solubility in acid conditions and optimisation of description of method
0544	Chloroquine phosphate	Chloroquine (phosphate de)	Revision of the second identification
0545	Chloroquine sulfate	Chloroquine (sulfate de)	Revision of the second identification
0574	Cholecalciferol concentrate (powder form)	Cholécalciférol (concentrat de), forme pulvérulente	Assay: optimisation of the highly complex LC analytical procedure
2397	Cholesterol for parenteral use	Cholestérol pour usage parentéral	Related substances: replacement of the GC using derivatisation with other sterols/assay to have a single GC procedure
0994	Ciclosporin	Ciclosporine	Addition of a new impurity
1651	Clarithromycin	Clarithromycine	Improvement of symmetry factor in the assay.
0996	Clindamycin phosphate	Clindamycine (phosphate de)	Deletion of bacterial endotoxins test
0487	Ephedrine hydrochloride	Éphédrine (chlorhydrate d')	It is proposed to validate the test for related substances as a quantitative test in order to express its acceptance criteria in the quantitative style. Moreover, consideration will be given to replacing the test for specific optical rotation with a state-of-the-art chiral HPLC test for enantiomeric purity, and to replacing the current titrimetric assay with an HPLC procedure based on the HPLC method used in the test for related substances
1317	Ethanol (96 per cent)	Éthanol à 96 pour cent	Adapt volatile impurities test (decrease of number of injections/quantities of solvent)
1318	Ethanol, anhydrous	Éthanol anhydre	Adapt volatile impurities test (decrease of number of injections/quantities of solvent)
0141	Ethionamide	Éthionamide	It is proposed to add a new specified impurity (i.e. 2-methyl-4-thioisonicotinicamide) with a limit of maximum 0.15 per cent, to be covered by the current test for related substances
2768	Fluticasone furoate	Fluticasone (furoate de)	Review the water content limit in view of new sources approved on the market

0923	Labetalol hydrochloride	Labétalol (chlorhydrate de)	Related substances: addition of new impurity in the transparency list
3115	Levocetirizine dihydrochloride	Lévocétirizine (dichlorhydrate de)	Review the monograph to introduce a S/N ratio in the Enantiomeric purity test and harmonise the style in line with Technical and style guides
1654	Lymecycline	Lymécycline	Structures and limits of impurities E and F
0365	Maleic acid	Maléique (acide)	Fumaric acid (Related substances test): replacement of the TLC procedure by LC procedure
1452	Nicotine	Nicotine	Related substances test: change of the pH of the mobile phase and introduction of new impurity H
2599	Nicotine ditartrate dihydrate	Nicotine (ditartrate de) dihydraté	Related substances test: change of the pH of the mobile phase and introduction of new impurity H
1792	Nicotine resinate	Nicotine (résinate de)	Water determination: introduction of a KF method for Nicotine containing glycerol
0515	Noscapine hydrochloride hydrate	Noscapine (chlorhydrate de) hydraté	Improvement of the LC procedure to control additional impurities
1458	Oxfendazole for veterinary use	Oxfendazole pour usage vétérinaire	It is proposed to validate the test for related substances as a quantitative test in order to express all its acceptance criteria in the quantitative style
2455	Oxygen (93 per cent)	Oxygène à 93 pour cent	Harmonisation of composition of reference gases
3098	Oxygen (98 per cent)	Oxygène à 98 pour cent	Harmonisation of composition of reference gases
3011	*all-rac*-Phytomenadione	*tout-rac*-Phytoménadione	Impurity A: Change from TLC to LC procedure, which would also control additional impurities
2777	Pregabalin	Prégabaline	Review of enantiomeric purity test and addition of new impurities to the related substances test
0567	Procainamide hydrochloride	Procaïnamide (chlorhydrate de)	Revision of the second identification
1367	Pseudoephedrine hydrochloride	Pseudoéphédrine (chlorhydrate de)	It is proposed to bring the test for related substances in line with ICH Q3A by replacing the limit of maximum 0.5 per cent for any other impurity with a limit for unspecified impurities of maximum 0.10 per cent. Moreover, consideration will be given to replacing the test for specific optical rotation with a state-of-the-art chiral HPLC test for enantiomeric purity, and to replacing the current titrimetric assay with an HPLC procedure based on the HPLC method used in the test for related substances
0432	Rifamycin sodium	Rifamycine sodique	Change of the diluent used to prepare solutions
1479	Triethyl citrate	Triéthyle (citrate de)	Related substances: comparison with USP procedure/improvement of sensitivity

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

Monographs		
3287	Citicoline sodium	Citicoline sodique
3288	Dapagliflozin	Dapagliflozine
3289	Lenalidomide hemihydrate	Lénalidomide (hémihydrate de)
3290	Milrinone	Milrinone
3291	Treosulfan	Tréosulfan

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

Methods of analysis		
2.2.68	Congealing point determination	Détermination du point de congélation
Monographs		
3125	Darunavir ethanolate oral suspension	Darunavir (éthanolate de), suspension buvable de