

Update to work programme of the European Pharmacopoeia

(November 2020)

The following items have been added to or deleted from the work programme during the 168th 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			
2.1.3.	Ultraviolet ray lamps for analytical purposes	Lampes à rayonnement ultraviolet pour analyses	Revision to include lamps other than Hg lamps.
2.2.25.	Absorption spectrophotometry, ultraviolet and visible	Spectrophotométrie d'absorption dans l'ultraviolet et le visible	Revision to add information to help the implementation and assist in the use of nicotinic acid for absorbance accuracy.
2.5.42.	N-Nitrosamines in active substances	N-Nitrosamines dans les substances actives	Extension of the scope to cover other active substances and medicinal products.
2.9.37.	Optical microscopy	Microscopie optique	Revision to include a new section for size accuracy, to update the section Photographic characterisation and add a new section on hot/cold stage microscopy.
3.2.1.	Glass containers for pharmaceutical use	Récipients de verre pour usage pharmaceutique	Revision of the test for spectral transmission.
General monographs			
0062	Vaccines for veterinary use	Vaccins pour usage vétérinaire	Revision to work on sterility requirements for non-liquid veterinary vaccines intended for non-parenteral administration.
Vaccines			
0451	Rabies vaccine (inactivated) for veterinary use	Vaccin rabique inactivé pour usage vétérinaire	Revision to delete the test for residual live virus on final product batches because it is redundant with the routine test on the inactivated harvest.

Radiopharmaceutical preparations

0129	Technetium (^{99m} Tc) tin pyrophosphate injection	Technétium (^{99m} Tc) (pyrophosphate d'étain et de), solution injectable de	Radiochemical purity: replacement of TLC test by paper chromatography test.
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Herbal drugs

2069	Black cohosh	Actée à grappes	Revision of the peak-to-valley ratio in the assay.
2400	Valerian dry aqueous extract	Valériane (extrait aqueux sec de)	Revision of the identification by TLC.
1898	Valerian dry hydroalcoholic extract	Valériane (extrait hydroalcoolique sec de)	Revision of the identification by TLC.
0453	Valerian root	Valériane (racine de)	Revision of the identification by TLC.
2526	Valerian root, cut	Valériane (racine de) divisée	Revision of the identification by TLC.
1899	Valerian tincture	Valériane (teinture de)	Revision of the identification by TLC.

Monographs

1170	Alteplase for injection	Altéplase pour solution injectable	General revision; analytical improvement.
0807	Ascorbyl palmitate	Ascorbyle (palmitate d')	Introduction of a test for related substances.
1173	Benserazide hydrochloride	Bensérazide (chlorhydrate de)	Related substances: verification of the correction factor of impurity B, as well as the whole test for related substances as a quantitative test, so to express acceptance criteria in the quantitative style.
1077	Buserelin	Buséreléline	Revision of the assay (adjustment of limit).
2397	Cholesterol for parenteral use	Cholestérol pour usage parentéral	Revision of the test for peroxide value - replacement of chloroform.
2013	Ciprofibrate	Ciprofibrate	Revision of the related substances: update of specifications.
1777	Clodronate disodium tetrahydrate	Clodronate disodique tétrahydraté	Revision of the test for related substances.
0077	Dapsone	Dapsone	Revision of the test for related substances.
2078	Dodecyl gallate	Dodécyle (gallate de)	Revision to introduce a LC or GC test for related substances and to replace the UV assay by LC, GC or titrimetry.
1511	Enoxolone	Énoxolone	Revision of the test for related substances
2918	Everolimus	Évérolimus	Revision of the test for related substances.
1722	Flunarizine dihydrochloride	Flunarizine (dichlorhydrate de)	Related substances: update of specifications.

2110	Isradipine	Isradipine	Revision of the related substances test: update of specifications.
1455	Ofloxacin	Ofloxacin	Revision of the related substances test: addition of a new specified impurity.
2750	Podophyllotoxin	Podophyllotoxine	Revision of the storage conditions.
2604	Ropinirole hydrochloride	Ropinirole (chlorhydrate de)	Revision of the related substances test: method improvement.
1795	Rutoside trihydrate	Rutoside trihydraté	Revision of the related substances test: addition of an impurity.
1148	Sertaconazole nitrate	Sertaconazole (nitrate de)	Related substances: alternative HPLC method.
0123	Sodium benzoate	Sodium (benzoate de)	Revision to introduce a test for related substances and replace the use of mercuric thiocyanate solution R.
2048	Sorbitol, liquid, partially dehydrated	Sorbitol liquide partiellement déshydraté	Revision to the chromatographic conditions for the assay.
2804	Sulfobutylbetadex sodium	Sulfobutylbétadex sodique	Revision of the test for impurities A, C and D to use a more readily available column.
0866	Tiabendazole	Tiabendazole	Revision to replace the TLC and colorimetric methods for related substances and o-phenylenediamine tests, by a new LC or GC method.
1660	Tiamulin for veterinary use	Tiamuline pour usage vétérinaire	Impurities: correction of impurity D structure.
1659	Tiamulin hydrogen fumarate for veterinary use	Tiamuline (hydrogénofumarate de) pour usage vétérinaire	Impurities: correction of impurity D structure.

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

53200	Cell-based preparations (5.32.)	Produits cellulaires (5.32.)
3169	Clorsulon for veterinary use	Clorsulon pour usage vétérinaire
3171	Darunavir	Darunavir
3172	Darunavir tablets	Darunavir (comprimés de)
3186	Gene therapy medicinal products for human use	Médicaments de thérapie génique pour usage humain
3170	Lutetium (¹⁷⁷ Lu)-ITG-PSMA-1	Lutécium (¹⁷⁷ Lu)-ITG-PSMA-1

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

0989	Cefotaxime sodium
2822	Mouse-ear hawkweed herb with root
3043	PSMA-617 for radiopharmaceutical preparations
