

Update to work programme of the European Pharmacopoeia

(June 2019)

The following items have been added to or deleted from the work programme during the 164th 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			
2.2.48	Raman spectroscopy	Spectroscopie Raman	Revision to update the general chapter in view of the latest developments.
2.6.16	Tests for extraneous agents in viral vaccines for human use	Essai des agents étrangers dans les vaccins viraux pour usage humain	Revision to update the test description for avian leucosis viruses.
2.6.30	Monocyte-activation test	Essai d'activation des monocytes	Monocytic cell lines: detection of non-endotoxin pyrogens.
2.9.5	Uniformity of mass of single-dose preparations	Uniformité de masse des préparations unidoses	Revision to expand Table 2.9.5-1 to add additional pharmaceutical dosage forms which refer to general chapter 2.9.5.
Reagents			
4.1.1 (1095503)	Water for chromatography	Eau pour chromatographie	Revision of the definition.
General Monographs			
2902	Chemical precursors for radiopharmaceutical preparations	Précurseurs chimiques pour préparations radiopharmaceutiques	Review of the limits for the test for bacterial endotoxins.
0125	Radiopharmaceutical preparations	Préparations radiopharmaceutiques	Continuation of general revision, including the addition of a test for visible particles and a review of filter integrity testing for the sterility test.
Vaccines			
2772	Influenza vaccine (live, nasal)	Vaccin grippal nasal vivant	Revision to update the test description of avian leucosis viruses.
0537	Yellow fever vaccine (live)	Vaccin vivant de la fièvre jaune	Revision to update the test description of avian leucosis viruses.

Radiopharmaceutical preparations

2547	Copper tetramibi tetrafluoroborate for radiopharmaceutical preparations	Cuivre (tétrafluoroborate de tétramibi-) pour préparations radiopharmaceutiques	Revision of the pH test.
2464	Gallium (⁶⁸ Ga) chloride solution for radiolabelling	Gallium (⁶⁸ Ga) (chlorure de) pour radiomarquage, solution de	Review of the title, Definition, sterility test, bacterial endotoxins test, Labelling.
2482	Gallium (⁶⁸ Ga) edotreotide injection	Gallium (⁶⁸ Ga) édotréotide (solution injectable de)	Addition of a Production section to take into account different routes of GaCl ₃ production; revision of the tests for radiochemical purity and ethanol.
0296	Technetium (^{99m} Tc) macrosalb injection	Technétium (^{99m} Tc) (macrosalb-), suspension injectable de	Revision to transfer the test for physiological distribution from the test section to the Production section; and to review the specifications of the test for non-filterable radioactivity.
2294	Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations	Tétra-O-acétyl-mannose (triflate de) pour préparations radiopharmaceutiques	Revision of the test for related substances and the Assay: replacement of the LC procedure.

Monographs

1286	Alfacalcidol	Alfacalcidol	Revision of the test for related substances: update of the description for preparation of reference solution (c) and system suitability criteria.
1069	Betacarotene	Bétabarotène	Revision to replace the test for loss on drying, if possible, by a test for water.
1076	Bumetanide	Bumétanide	Revision of the test for related substances: update of specifications.
0316	Cellulose, microcrystalline	Cellulose microcristalline	Revision to introduce loss on drying in the FRC section.
0315	Cellulose, powdered	Cellulose en poudre	Revision to introduce loss on drying in the FRC section.
0575	Cholecalciferol concentrate (oily form)	Cholécalciférol (concentrat de), forme huileuse	Revision to change the maximum absorbance value to 265 nm and introduce a method for the related substances test.
0757	Clotrimazole	Clotrimazole	Revision of the test for related substances: dilution of reference solution (b) in order to avoid saturated peaks in the corresponding chromatograms; and adjustment of the resolution requirement accordingly.
0388	Dexamethasone	Dexaméthasone	Revision of the Assay: replacement of the UV absorbance method by LC.

1008	Domperidone maleate	Dompéridone (maléate de)	Revision of the test for related substances: update of specifications.
0457	Etacrynic acid	Étacrynique (acide)	Revision of the test for loss on drying to use milder vacuum conditions.
1514	Etomidate	Étomidate	Revision of the test for related substances: update of specifications.
1912	Fish oil, rich in omega-3 acids	Poisson (huile de) riche en acides oméga-3	Revision of the acid value and peroxide value.
1524	Gliclazide	Gliclazide	Revision of the test for related substances to decrease stationary phase particle size to 4 µm.
0496	Glycerol	Glycérol	Revision of the Definition.
1805	<i>myo</i> -Inositol	<i>myo</i> -Inositol	Revision of the test for related substances (elution order, resolution).
1082	Macrogolglycerol ricinoleate	Macrogolglycérol (ricinoléate de)	Revision of the hydroxyl value test.
2854	Magnesium aluminometasilicate	Magnésium (aluminométilicate de)	Addition of an FRC section.
0935	Miconazole	Miconazole	Revision of the test for related substances: update of specifications.
0676	Nasal preparations	Préparations nasales	Revision to include a test to control small particles/droplets (less than 10 µm) in nasal preparations.
3011	Phytomenadione, racemic	Phytoménadione racémique	Revision to replace dioxan in the test for optical rotation test; and to modify the title, definition and impurity B description to cover the 8 possible stereoisomers.
0733	Polyacrylate dispersion 30 per cent	Polyacrylate (dispersion de) à 30 pour cent	Revision of the Definition.
0734	Prednisolone acetate	Prednisolone (acétate de)	Revision of the Assay: replacement of the UV absorbance method by LC.
0786	Riboflavin sodium phosphate	Riboflavine (phosphate sodique de)	Revision to add hydrate to the title; to update the Definition to include all the phosphorylation products (mono- and diphosphates); to add a test for composition and to update the test for related substances; and to harmonize the tests for impurity E and inorganic phosphate with the USP.
0204	Sucrose	Saccharose	Addition of an FRC section.
1059	Zidovudine	Zidovudine	Revision of the test for related substances: update of specifications and amendment of the system suitability criterion.

1707	Zuclopenthixol decanoate	Zuclopenthixol (décanoate de)	Revision of the test for loss on drying to use milder vacuum conditions.
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ADDITIONS TO THE WORK PROGRAMME (new texts to be elaborated)

2.4.35	Extractable elements in plastic materials for pharmaceutical use	Eléments extractibles dans les plastiques pour usage pharmaceutique
2.9.56	Nasal preparations: mass fraction less than 10 micrometres	Préparations nasales : fraction en masse inférieure à 10 micromètres

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

3.2.6	Sets for the transfusion of blood and blood components	Nécessaires pour la transfusion du sang et des produits du sang
3.2.8	Sterile single-use plastic syringes	Seringues en matière plastique non réutilisables, stériles
0416	Nitrous oxide	Azote (protoxyde d')