

Update to work programme of the European Pharmacopoeia

(June 2022)

The following items have been added to or deleted from the work programme during the 173rd 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			
2.5.28.	Water in gases	Teneur en eau dans les gaz	Revision to add further analytical procedures for the determination of water in gases.
2.6.27.	Microbiological examination of cell-based preparations	Contrôle microbiologique des produits cellulaires	Revision of the growth promotion test to harmonise incubation times with chapter 2.6.1, taking into consideration collaborative studies for <i>B. fragilis</i> .
Materials and containers			
3.1.13.	Plastic additives	Additifs pour plastiques	Revision due to revision of REACH regulation (Annex XIV to (EC) No. 1907/2006), deletion of plastic additive 01.
3.1.14.	Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion	Matériaux à base de poly(chlorure de vinyle) plastifié pour récipients destinés à contenir les solutions aqueuses pour perfusion intraveineuse	Revision due to revision of REACH regulation (Annex XIV to (EC) No. 1907/2006).
3.3.2.	Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components	Matériaux à base de poly(chlorure de vinyle) plastifié pour récipients destinés à contenir le sang humain et les produits du sang	Revision due to revision of REACH regulation (Annex XIV to (EC) No. 1907/2006), deletion of plastic additive 01.
3.3.3.	Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components	Matériaux à base de poly(chlorure de vinyle) plastifié pour tubulures utilisées dans les nécessaires pour transfusion du sang et des composants sanguins	Revision due to revision of REACH regulation (Annex XIV to (EC) No. 1907/2006), deletion of plastic additive 01.

3.3.5.	Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components	Réipients vides et stériles en matériau à base de poly(chlorure de vinyle) plastifié pour le sang humain et les produits du sang	Revision due to revision of REACH regulation (Annex XIV to (EC) No. 1907/2006), deletion of plastic additive 01.
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General monographs

2619	Pharmaceutical preparations	Préparations pharmaceutiques	Revision to introduce relevant guidance for the control of pyrrolizidine alkaloids and a reference to chapter 2.8.26.
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Vaccines

2520	Salmonella Enteritidis vaccine (live, oral) for chickens	Vaccin vivant oral de la salmonellose à Salmonella Enteritidis pour le poulet	2-2-2. Immunogenicity: clarification that all the samples recovered during the observation period (from vaccinates and controls) should be taken into account.
2521	Salmonella Typhimurium vaccine (live, oral) for chickens	Vaccin vivant oral de la salmonellose à Salmonella Typhimurium pour le poulet	2-2-2. Immunogenicity: clarification that all the samples recovered during the observation period (from vaccinates and controls) should be taken into account.

Herbal drugs

2554	Amomum fruit	Amomun (fruit de)	Extension of the scope of the revision: replacement of Identification C TLC by HPTLC.
1294	Belladonna leaf dry extract, standardised	Belladone (feuille de), extrait sec titré de	Revision of identification and purity testing: in line with the requests for revision that have already been accepted for other belladonna monographs (0221, 0222 and 1812), the TLC tests for identification and atropine are intended to be replaced by an optimised, more convenient and state-of-the-art HPTLC procedure in accordance with general chapter 2.8.25. Revision of the assay: in line with the requests for revision that have already been accepted for other belladonna monographs (0221, 0222 and 1812), the titration method is intended to be replaced by a specific and more convenient LC-UV procedure based on the assay method described in monograph 2489.
2555	Round amomum fruit	Amomum (fruit rond d')	Extension of the scope of the revision: replacement of Identification C TLC by HPTLC.

2634	Szechwan lovage rhizome	Ligusticum chuanxiong (rhizome de)	Revision to replace the loss on drying test by determination of water by distillation (2.2.13).
Monographs			
0883	Calcitriol	Calcitriol	Revision of the assay: update of upper limit for content to 102.0 per cent, in line with general approach, and deletion of the RSD requirement (2.2.46 applies); Storage: addition of a mention to store under inert gas.
0758	Colchicine	Colchicine	Revision of the test for related substances to add a new specified impurity.
2933	Deferasirox	Déférasirox	Revision of the test for impurity F, consideration of alternative analytical procedures.
0822	Ethylcellulose	Ethylcellulose	Revision to add molecular mass distribution to the Functionality-related characteristics section.
1212	Fluocortolone pivalate	Fluocortolone (pivalate de)	Revision of the test for related substances: increase of the limit for impurity A to list it as specified impurity.
0750	Glutamic Acid	Glutamique (Acide)	Revision of the test for related substances.
0128	Haemodialysis, solutions for	Solutions pour hémodialyse	Revision to align the content and title, and to focus on the requirements for solutions for haemodialysis.
0337	Hydroxypropylcellulose	Hydroxypropylcellulose	Revision to add molecular mass distribution to the Functionality-related characteristics section.
1082	Macrogolglycerol ricinoleate	Macrogolglycérol (ricinoléate de)	Addition of a Functionality-related characteristics section.
0097	Morphine hydrochloride	Morphine (chlorhydrate de)	Revision of the title to add the degree of hydration and of the related substances test to change to the quantitative style.
1244	Morphine sulfate	Morphine (sulfate de)	Revision of the title to add the degree of hydration and of the related substances test to change to the quantitative style.
0199	Oxytetracycline dihydrate	Oxytétracycline dihydratée	Revision of the test for related substances to specify impurity F.

0780	Oxytocin	Oxytocine	Revision of the test for related substances to improve the method, include additional impurities and revise limits.
0426	Polysorbate 20	Polysorbate 20	Revision of the identification IR: replacement of IR spectrum by CRS.
1914	Polysorbate 40	Polysorbate 40	Revision of the identification IR: replacement of IR spectrum by CRS.
0427	Polysorbate 60	Polysorbate 60	Revision of the identification by IR: replacement of IR spectrum by CRS.
0428	Polysorbate 80	Polysorbate 80	Revision of the Identification by IR: replacement of IR spectrum by CRS.
1566	Sodium starch glycolate (type C)	Carboxyméthylamidon sodique (type C)	Addition of a Functionality-related characteristics section.
1570	Sugar spheres	Sphères de sucre	Revision of Identification TLC test to replace ethylene chloride with an alternative solvent; review of methods for particle size control.

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

2.5.46.	Phenolic antioxidants in plastic materials	Antioxydants phénoliques dans les plastiques
5.3.7.	Recombinant viral-vectored vaccines for human use	Vaccins à vecteur viral recombinant pour usage humain
3208	Medicinal gases	Gaz médicaux
3209	Methacholine chloride	Chlorure de méthacholine
3210	Methocarbamol	Méthocarbamol
3211	Tenofovir disoproxil fumarate	Fumarate de ténofovir disoproxil

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

0931	Metformin hydrochloride	Metformine (chlorhydrate de)
2313	Olive leaf dry extract	Olivier (feuille d'), extrait sec de
2974	Shrub chastetree fruit	(Vicitus fructus)