

Update to work programme of the European Pharmacopoeia

(June 2024)

The following items have been added to or deleted from the work programme during the 179th 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			
2.2.39.	Molecular mass distribution in dextrans (2.2.39.)	Distribution de la masse moléculaire des dextrans (2.2.39.)	Review of system suitability criteria
2.2.43.	Mass spectrometry (2.2.43.)	Spectrométrie de masse (2.2.43.)	General update of the chapter, especially in terms of applications and technical innovations in the field
2.2.44.	Total organic carbon in water for pharmaceutical use (2.2.44.)	Carbone organique total dans l'eau pour usage pharmaceutique (2.2.44.)	Introduction of new Total organic carbon method B and replacement of reagents by chemical reference substances
Materials for containers and containers			
3.2.9.	Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders (3.2.9.)	Fermetures en caoutchouc pour récipients destinés aux préparations parentérales aqueuses, aux poudres et aux poudres cryodesséchées (3.2.9.)	Revision of the extractable zinc test
General monographs			
2098	Essential oils	Huiles essentielles	Revision to clarify requirements regarding the herbal starting material
Vaccines for human use			
2067	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélitique (inactivé) et conjugué de l'haemophilus type b, adsorbé	Control of pyrogenicity for the vaccine formulated with the Hib component conjugated to OMP
0452	Tetanus vaccine (adsorbed)	Vaccin tétanique adsorbé	Introduction of a reference to BINACLE as an <i>in vitro</i> alternative to the test for absence of tetanus toxin in guinea pigs

Vaccines for veterinary use

0697	Tetanus vaccine for veterinary use	Vaccin tétanique pour usage vétérinaire	Introduction of a reference to BINACLE as an <i>in vitro</i> alternative to the test for absence of tetanus toxin in guinea pigs
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Herbal drugs and herbal drug preparations

1826	Bitter-fennel fruit oil	Fenouil amer (fruit de), huile essentielle de	Revision to reduce the estragole content
1370	Sage leaf (<i>Salvia officinalis</i>)	Sauge officinale (feuille de)	Revision: limit of total ash content

Homoeopathic preparations

2371	Methods of preparation of homoeopathic stocks and potentisation	Méthodes de préparation des souches homéopathiques et déconcentration	Revision of method 5.3
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Monographs

2262	Bovine serum	Sérum bovin	General revision to reflect current practices
0596	Bromocriptine mesilate	Bromocriptine (mésilate de)	New LC method to control impurity E at ppm level
1773	Cabergoline	Cabergoline	Related substances: update of impurity limits and Assay: introduction of a requirement for symmetry factor
0597	Carnauba wax	Carnauba (cire de)	Identification: replacement of thin-layer chromatography by infrared absorption spectrophotometry
0657	Chlorhexidine diacetate	Chlorhexidine (diacétate de)	Revision of the second identification sub-section, Related substances: review of analytical procedure following recent revision of chlorhexidine digluconate solution monograph (0658)
0658	Chlorhexidine digluconate solution	Chlorhexidine (digluconate de), solution de	Revision of the second identification sub-section, Related substances: based on experimental work, the system suitability criterion will be reviewed
0659	Chlorhexidine dihydrochloride	Chlorhexidine (dichlorhydrate de)	Revision of the second identification sub-section, Related substances: review of analytical procedure following recent revision of chlorhexidine digluconate solution monograph (0658)
0384	Chlorocresol	Chlorocrésol	Experimental verification of the current Ph. Eur. procedure (or alternative procedure, if considered necessary) as a quantitative test, aiming to achieve sufficient sensitivity. Introduction of other improvements considered, e.g. prescribing a stationary phase covering the use of a capillary column, introducing a suitable injection volume and validating the procedure for relevant impurities that could be added to the transparency list. Addition of state-of-the-art procedures for identification by IR and for a test for loss on drying or water, also to be evaluated

2288	Citalopram hydrobromide	Citalopram (bromhydrate de)	Related substances: modification of correction factor for impurity G following feedback and additional experimental verification
1409	Clenbuterol hydrochloride	Clenbutérol (chlorhydrate de)	Related substances: update of impurity limits
1776	Dihydrocodeine hydrogen tartrate	Dihydrocodéine (hydrogénotartrate de)	IR: use of a reference substance as an alternative to reference spectrum and Related substances: update of impurity limits
1416	Dihydroergocristine mesilate	Dihydroergocristine (mésilate de)	Related substances: update of impurity limits
2582	Donepezil hydrochloride	Donépézil (chlorhydrate de)	Test for water: evaluation of suitability of different sample sizes, given wide range of water content covered by the monograph
2285	Follitropin	Follitropine	Introduction of <i>in vitro</i> bioassay
2286	Follitropin concentrated solution	Follitropine (solution concentrée de)	Introduction of <i>in vitro</i> bioassay
0143	Histamine dihydrochloride	Histamine (dichlorhydrate d')	Revision of the second identification sub-section
0918	Human normal immunoglobulin for intravenous administration	Immunoglobuline humaine normale pour administration par voie intraveineuse	Inclusion of the reference to new chapter 2.6.42. Test for procoagulant activity in immunoglobulin
2788	Human normal immunoglobulin for subcutaneous administration	Immunoglobuline humaine normale pour administration par voie sous-cutanée	Inclusion of the reference to new chapter 2.6.42. Test for procoagulant activity in immunoglobulin
0335	Hydrocortisone	Hydrocortisone	Related substances: review of limit for impurity G following feedback from manufacturers and recent batch and stability data
1699	Mesalazine	Mésalazine	Optimisation of the test for impurity K, ensuring sufficient method robustness
1132	Methylthioninium chloride hydrate	Méthylthioninium (chlorure de) hydraté	Optimisation of the assay procedure, ensuring better peak symmetry
1136	Octyldodecanol	Octyldodécanol	Addition of upper limit for content
1137	Pentamidine diisetonate	Pentamidine (diisétionate de)	Related substances: update of impurity limits and SST requirement
1555	Pergolide mesilate	Pergolide (mésilate de)	Related substances: update of impurity limits and Assay: deletion of the requirement for symmetry factor
0633	Pilocarpine hydrochloride	Pilocarpine (chlorhydrate de)	Related substances: update of impurity limits
0104	Pilocarpine nitrate	Pilocarpine (nitrate de)	Related substances: update of impurity limits
1272	Tryptophan	Tryptophane	Related substances: deletion of test solution (b); deletion of sentence "disregard the peak due to <i>N</i> -acetyltryptophan"; deletion of sentence referring to correction of area of <i>N</i> -acetyltryptophan peak; correction of factors (XX times the area) for sum of impurities

0169	Water for injections	Eau pour préparations injectables	Replacement of the Oxidisable substances test by the Total organic carbon test in the Tests section of Sterilised water for injections
0008	Water, purified	Eau purifiée	Designation of the Total organic carbon test on section Purified water in bulk as Method A

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

3261	<i>Arctii fructus</i>	
3262	<i>Aurantii fructus immaturus</i>	
3254	Bitter fennel, cut	Fenouil amer divisé
3263	<i>Cyperii rhizoma</i>	
3264	<i>Descurainiae semen</i>	
3265	<i>Iridis tectori rhizoma</i>	
3266	<i>Schisandrae sphenantherae fructus</i>	
3267	Sitagliptin malate	Sitagliptine (malate de)
3268	TBSCT-FP for radiopharmaceutical preparations	TBSCT-FP pour préparations radiopharmaceutiques

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

3111	Atazanavir sulfate oral powder	Atazanavir (sulfate d'), poudre orale de
2943	Burdock root	Bardane (grande), racine de
1718	Diclazuril for veterinary use	Diclazuril pour usage vétérinaire
1912	Fish oil, rich in omega-3 acids	Poisson (huile de) riche en acides oméga-3
3255	Mycoplasma synoviae vaccine (live) for chickens	Vaccin vivant de Mycoplasma synoviae pour le poulet