

# Update to work programme of the European Pharmacopoeia

(November 2024)

The following items have been added to or deleted from the work programme during the 180<sup>th</sup> 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

<b>Methods of analysis</b>			
<b>2.4.5.</b>	Fluorides (2.4.5.)	Fluorures (2.4.5.)	The chapter will be reviewed to delete the reagent tetrachloroethane R
<b>2.4.8.</b>	Heavy metals (2.4.8.)	Métaux lourds (2.4.8.)	Removal of methods C and D, and addressing the limitations of other methods
<b>2.5.32.</b>	Water: micro determination (2.5.32.)	Microdosage de l'eau (2.5.32.)	Considering the evaporation, i.e. oven technique more directly, especially in terms of equipment qualification and verification of accuracy
<b>2.6.16.</b>	Tests for extraneous agents in viral vaccines for human use (2.6.16.)	Essai des agents étrangers dans les vaccins viraux pour usage humain (2.6.16.)	Update to take into account the recently revised ICH Q5A (R2) guideline
<b>2.7.6.</b>	Assay of diphtheria vaccine (adsorbed) (2.7.6.)	Titration de l'activité du vaccin diphtérique adsorbé (2.7.6.)	Introduction of a 'door opener' to point towards the use of <i>in vitro</i> alternatives
<b>2.7.8.</b>	Assay of tetanus vaccine (adsorbed) (2.7.8.)	Titration de l'activité du vaccin tétanique adsorbé (2.7.8.)	Introduction of a 'door opener' to point towards the use of <i>in vitro</i> alternatives
<b>2.7.16.</b>	Assay of pertussis vaccine (acellular) (2.7.16.)	Titration de l'activité du vaccin coquelucheux acellulaire (2.7.16.)	Introduction of a 'door opener' to point towards the use of <i>in vitro</i> alternatives
<b>General Texts</b>			
<b>5.2.3.</b>	Cell substrates for the production of vaccines for human use (5.2.3.)	Substrats cellulaires utilisés pour la production de vaccins pour usage humain (5.2.3.)	Update to take into account the recently revised ICH Q5A (R2) guideline
<b>5.2.14.</b>	Substitution of <i>in vivo</i> method(s) by <i>in vitro</i> method(s) for the quality control of vaccines (5.2.14.)	Substitution de méthode(s) <i>in vitro</i> aux méthodes <i>in vivo</i> pour le contrôle de la qualité des vaccins (5.2.14.)	Update to the example of substitution of animal tests for extraneous agent detection by broad molecular methods, to reflect current approaches

<b>5.34.</b>	Additional information on gene therapy medicinal products for human use (5.34.)	Informations complémentaires sur les médicaments de thérapie génique pour usage humain (5.34.)	Addition of a section on mRNA-based gene therapy medicinal products (GTMPs)
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### General Monographs

<b>0153</b>	Vaccines for human use	Vaccins pour usage humain	Update to reflect current practices for determining the expiry date
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### Dosage forms

<b>1502</b>	Glossary	Glossaire	Include definitions for different container types
<b>0520</b>	Parenteral preparations	Préparations parentérales	Revision of section Intravitreal preparations to cover all administration sites into the eye e.g. intracameral, periocular, subretinal injections

### Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

<b>2798</b>	Lutetium ( <sup>177</sup> Lu) solution for radiolabelling	Lutécium ( <sup>177</sup> Lu) pour radiomarquage, solution de	Review of Radiochemical and Radionuclidic Purity tests; inclusion of a specification for Specific Activity and a test for Apparent Molar Activity, modification of Labelling section
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### Herbal drugs

<b>1892</b>	Goldenrod	Solidage	Widening of the requirement for a minimum content of flavonoids, from 2.5 per cent to 2.0 per cent
<b>2431</b>	Ligusticum root and rhizome	Ligusticum (racine et rhizome de)	Definition: update of the botanical name

### Monographs

<b>1078</b>	Calcium hydroxide	Calcium (hydroxyde de)	Matter insoluble in hydrochloric acid: addition of a drying step for residues
<b>0379</b>	Cetylpyridinium chloride	Cétylpyridinium (chlorure de)	Revision of the second identification sub-section
<b>0575</b>	Cholecalciferol concentrate (oily form)	Cholécalciférol (concentrat de), forme huileuse	Test for peroxide value: replacement of chloroform
<b>1408</b>	Cilastatin sodium	Cilastatine sodique	Related substances: update of impurities specifications to reflect the quality of substances in approved products
<b>1973</b>	Cineole	Cinéole	Related substances: update of impurities specifications to reflect the quality of substances in approved products
<b>1413</b>	Dequalinium chloride	Déqualinium (chlorure de)	Revision of the second identification sub-section
<b>2049</b>	Econazole	Éconazole	Addition of a second identification section
<b>0767</b>	Fludrocortisone acetate	Fludrocortisone (acétate de)	Revision of the second identification sub-section
<b>1327</b>	Flumetasone pivalate	Flumétasone (pivalate de)	Revision of the second identification sub-section
<b>0905</b>	Flurazepam monohydrochloride	Flurazépam (monochlorhydrate de)	Fluorides: replacement of the current test by a potentiometric titration

1750	Fluticasone propionate	Fluticasone (propionate de)	Related substances: review of CRS strategy regarding the material for the replacement batch of fluticasone propionate for SST CRS and the preparation of the CRS
1427	Glycerol dibehenate	Glycérol (dibéhénate de)	Addition of FRC section
1428	Glycerol distearate	Glycérol (distéarate de)	Addition of FRC section
0106	Hyoscine hydrobromide	Scopolamine (bromhydrate de)	Related substances: update of impurities specifications to reflect the quality of substances in approved products
2771	Ibandronate sodium monohydrate	Ibandronate sodique monohydraté	Introduction of a test to control phosphate
0146	Isoniazid	Isoniazide	Revision of the second identification sub-section
1332	Isoprenaline hydrochloride	Isoprénaline (chlorhydrate d')	Optimisation of the analytical procedure for the related substances test to cover additional impurities
2217	Lamivudine	Lamivudine	Related substances: replacement of area comparison by quantitative style and review of limits to reflect the quality of substances in approved products
2162	Manganese gluconate	Manganèse (gluconate de)	Zinc: modification of the test and standard solution to increase the sensitivity
1243	Mitoxantrone hydrochloride	Mitoxantrone (chlorhydrate de)	Related substances: update of impurities specifications to reflect the quality of substances in approved products
0681	Pancuronium bromide	Pancuronium (bromure de)	Related substances: replacement of TLC by HPLC
3008	Rosuvastatin calcium tablets	Rosuvastatine calcique (comprimés de)	Related substances: review of the peak-to-valley requirement, the need for an autosampler and the stability of reference solutions
0687	Salbutamol sulfate	Salbutamol (sulfate de)	Optimisation of the analytical procedure for the related substances test to quantify impurity Q versus an external reference standard of impurity Q
0195	Sodium hydrogen carbonate	Sodium (bicarbonate de)	Ammonium: replacement of the current test (2.4.1) with an IC method
1706	Thiamazole	Thiamazol	Revision of the second identification sub-section
0150	Titanium dioxide	Titane (dioxyde de)	Assay: replacement of the current analytical procedure with an ICP-OES method
0219	Vitamin A concentrate (oily form), synthetic	Vitamine A synthétique (concentrat de), forme huileuse	Test for peroxide value: replacement of chloroform

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

2.4.37.	Apparent molar activity determination (2.4.37.)	Détermination de l'activité molaire apparente (2.4.37.)
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<b>2.4.38.</b>	Recovery determination in radiochemical purity testing (2.4.38.)	Détermination de la récupération dans les tests de pureté radiochimique (2.4.38.)
<b>5.47.</b>	Gene-edited cells for human use (5.47.)	Cellules génétiquement modifiées pour usage humain (5.47.)
<b>3275</b>	Respiratory Syncytial Virus vaccine (rDNA)	Vaccin du virus syncytial respiratoire (ADNr)
<b>3272</b>	Bilastine	Bilastine
<b>1896</b>	Wheat extract	Blé (extrait de)

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

<b>2784</b>	Haemofiltration and haemodiafiltration solutions, concentrated, water for diluting	Solutions concentrées pour hémofiltration et pour hémodiafiltration (eau pour dilution des)
<b>2539</b>	Oat caryopsis powder	Avoine (poudre d')
<b>2618</b>	Oat herb	Avoine (partie aérienne de)
<b>2903</b>	Acetylene intermix (1 per cent) in nitrogen	Acétylène à 1 pour cent dans l'azote (mélange intermédiaire d')
<b>0375</b>	Carbon dioxide	Carbone (dioxyde de)
<b>2904</b>	Carbon monoxide intermix (5 per cent) in nitrogen	Carbone (monoxyde de) à 5 pour cent dans l'azote, mélange intermédiaire de
<b>2905</b>	Methane intermix (2 per cent) in nitrogen	Méthane à 2 pour cent dans l'azote (mélange intermédiaire de)
<b>1131</b>	Methylprednisolone hydrogen succinate	Méthylprednisolone (hydrogénosuccinate de)
<b>1166</b>	Powders for cutaneous application	Poudres pour application cutanée
<b>1116</b>	Preparations for irrigation	Préparations pour irrigation
<b>1155</b>	Tampons, medicated	Tampons médicamenteux