

# Update to work programme of the European Pharmacopoeia

(March 2020)

The following items have been added to or deleted from the work programme during the 166<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>			
20802	Foreign matter (2.8.2.)	Éléments étrangers (2.8.2.)	Revision of requirements regarding animal contamination
<b>Vaccines</b>			
0360	<i>Clostridium botulinum</i> vaccine for veterinary use	Vaccin botulinique pour usage vétérinaire	Revision of the potency test: addition of humane endpoints; cell-based assays specifically mentioned as a possible alternative for the batch potency test
<b>Radiopharmaceutical preparations</b>			
2551	Betiatide for radiopharmaceutical preparations	Bétiatide pour préparations radiopharmaceutiques	Revision of the test for water to replace semi-micro determination by micro determination
<b>Herbal drugs</b>			
2562	Bupleurum root	Bupleurum (racine de)	Revision of the test for loss on drying
1364	<i>Primula</i> root	Primevère (racine de)	Revision to add <i>Primula vulgaris</i>
1837	Tea tree oil	Mélaleuca (huile essentielle de)	Revision of the GC profile
<b>Monographs</b>			
0755	Carbidopa	Carbidopa	Revision of the test for hydrazine to replace the TLC method with LC
0574	Cholecalciferol concentrate (powder form)	Cholécalciférol (concentrat de), forme pulvérulente	Revision of Identification
0598	Cholecalciferol concentrate (water-dispersible form)	Cholécalciférol (concentrat de), forme hydrodispersible	Revision of Identification
0888	Ciprofloxacin hydrochloride	Ciprofloxacine (chlorhydrate de)	Revision of Identification of chlorides: replacement of identification test (b) (REACH)

<b>2125</b>	Doxazosin mesilate	Doxazosine (mésilate de)	Revision of Assay: improvement of the symmetry of the peak due to doxazosin in the test and reference solutions
<b>2357</b>	Dydrogesterone	Dydrogestérone	Revision of the test for related substances: update of specifications
<b>1979</b>	Halofantrine hydrochloride	Halofantrine (chlorhydrate d')	Revision of Identification of chlorides: replacement of ID test (b) (REACH)
<b>1339</b>	Levocarnitine	Lévocabarnitine	Revision of test for related substances
<b>0505</b>	Levomepromazine hydrochloride	Lévomépromazine (chlorhydrate de)	Revision of identification section: introduction of IR test. Revision of test for related substances: replacement of TLC method by LC covering new impurities
<b>2097</b>	Mebeverine hydrochloride	Mébévérine (chlorhydrate de)	Revision of Identification of chlorides and Assay
<b>1241</b>	Mefloquine hydrochloride	Méfloquine (chlorhydrate de)	Revision of Identification of chlorides: replacement of ID test (b) (REACH)
<b>1243</b>	Mitoxantrone hydrochloride	Mitoxantrone (chlorhydrate de)	Revision of Identification of chlorides: replacement of ID test (b) (REACH)
<b>0046</b>	Neostigmine bromide	Néostigmine (bromure de)	Revision of Identification of bromides: replacement of ID test (b) (REACH)
<b>1365</b>	Promazine hydrochloride	Promazine (chlorhydrate de)	Revision of the test for related substances: replacement of TLC method by LC covering new impurities
<b>0018</b>	Quinine hydrochloride	Quinine (chlorhydrate de)	Revision of Identification of chlorides: replacement of ID test (b) (REACH)
<b>0586</b>	Thioridazine hydrochloride	Thioridazine (chlorhydrate de)	Revision of Identification of chlorides: replacement of ID test (b) (REACH)
<b>0693</b>	Tretinoin	Trétinoïne	Revision of the second identification series
<b>1800</b>	Vincamine	Vincamine	Revision of the test for related substances: preparation of reference solution (b)

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

<b>20737</b>	Assay of Phl p 5 allergen (2.7.37.)	Dosage de l'allergène Phl p 5 (2.7.37.)
<b>53100</b>	Phages API (5.31.)	Phages - substance pour usage (5.31.)
<b>3147</b>	Adalimumab	Adalimumab

<b>3161</b>	<i>Alpinia oxyphylla</i> fruit	<i>Alpinia oxyphylla</i> (fruit d')
<b>3163</b>	Chinese date	Jujubier (fruit de)
<b>3162</b>	Chrysanthemum flower	Chrysanthemum (fleur de)
<b>3159</b>	<i>Lonicera japonica</i> flower	<i>Lonicera japonica</i> (fleur de)
<b>3164</b>	Mulberry leaf	Mûrier (feuille de)
<b>3160</b>	<i>Phyllanthus</i> fruit	<i>Phyllanthus</i> (fruit de)
<b>3158</b>	PSMA-1007 for radiopharmaceutical preparations	PSMA-1007 pour préparations radiopharmaceutiques
<b>3166</b>	Saxagliptin tablets	Saxagliptine (comprimés de)
<b>3167</b>	Sitagliptin hydrochloride monohydrate	Sitagliptine (chlorhydrate de) monohydraté

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

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