

Update to work programme of the European Pharmacopoeia

(June 2020)

The following items have been added to or deleted from the work programme during the 167th 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			
2.8.13.	Pesticide residues	Résidus de pesticides	Qualitative and quantitative analysis of pesticide residues: consideration of naturally occurring bromide.
2.9.1.	Disintegration of tablets and capsules	Désagrégation des comprimés et des capsules	Harmonisation of Test B.
2.9.7.	Friability of uncoated tablets	Friabilité des comprimés non enrobés	Revision to provide uniform presentation of the dimensional requirements for the apparatus, a rational division of the chapter text and to clarify the test criteria.
Dosage forms			
1807	Oromucosal preparations	Préparations buccales	Revision to define sublingual lyophilisates and clarify orodispersable films.
Vaccines			
0158	Influenza vaccine (split virion, inactivated)	Vaccin grippal inactivé à virion fragmenté	Total protein: revision of limit to accommodate quadrivalent influenza vaccines and high-dose influenza vaccines.
0869	Influenza vaccine (surface antigen, inactivated)	Vaccin grippal inactivé (antigène de surface)	Total protein: revision of limit to accommodate quadrivalent influenza vaccines.
2149	Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Vaccin grippal inactivé (antigène de surface, préparé sur cultures cellulaires)	Total protein: revision of limit to accommodate quadrivalent influenza vaccines.
Herbal drugs			
1091	Clove oil	Clou de girofle (huile essentielle de)	Revision of chromatographic profile.

Homoeopathic preparations

2144	Calcium iodatum for homoeopathic preparations	Calcarea iodata pour préparations homéopathiques	Revision of identification method of calcium (replacement of chloroform). This revision is linked with the use of REACH reagents and the revision of chapter 2.3.1 Identification reactions of ions and functional groups.
2146	Cuprum aceticum for homoeopathic preparations	Cuprum aceticum pour préparations homéopathiques	Revision of identification method of acetates. This revision is linked with the use of REACH reagents and the revision of chapter 2.3.1 Identification reactions of ions and functional groups.
2371	Methods of preparation of homoeopathic stocks and potentisation	Méthodes de préparation des souches homéopathiques et déconcentration	Introduction of a new homoeopathic preparation method.

Monographs

1585	Acamprosate calcium	Acamprosate calcique	Revision of identification method of calcium (replacement of chloroform).
0541	Bupivacaine hydrochloride	Bupivacaïne (chlorhydrate de)	Related substances: optimisation or replacement the current GC method.
0470	Calcium pantothenate	Calcium (pantothénate de)	Revision of identification method of calcium (replacement of chloroform).
0982	Calcium sulfate dihydrate	Calcium (sulfate de) dihydraté	Revision of identification method of calcium (replacement of chloroform).
1185	Carbasalate calcium	Carbasalate calcique	Revision of identification method of calcium (replacement of chloroform).
0657	Chlorhexidine diacetate	Chlorhexidine (diacétate de)	Revision of identification method of acetates.
0382	Chlorobutanol	Chlorobutanol	Impurities A & B: optimisation of the current GC method.
0383	Chlorobutanol hemihydrate	Chlorobutanol hémihydraté	Impurities A & B: optimisation of the current GC method.
0997	Clomifene citrate	Clomifène (citrate de)	Related substances: update of specifications.
1192	Cod-liver oil (type A)	Foie de morue (huile de) (type A)	Merge with cod-liver oil type B (1193).
1193	Cod-liver oil (type B)	Foie de morue (huile de) (type B)	Merge with cod-liver oil type A (1192).
0758	Colchicine	Colchicine	Revision of the second identification.
2285	Follitropin	Follitropine	Oxidised follitropin - inclusion of the peak due to mono-oxidised form of the follitropin alpha-subunit in the calculation of total oxidised follitropin.

2286	Follitropin concentrated solution	Follitropine (solution concentrée de)	Oxidised follitropin - inclusion of the peak due to mono-oxidised form of the follitropin alpha-subunit in the calculation of total oxidised follitropin.
1724	Formoterol fumarate dihydrate	Formotérol (fumarate de) dihydraté	Related substances: update of specifications.
1328	Fosfomycin calcium	Fosfomycine calcique	Revision of identification method of calcium (replacement of chloroform).
0333	Heparin sodium	Héparine sodique	Replacement of LoD test with determination of residual solvents and water content.
0828	Heparins, low-molecular-mass	Héparines de basse masse moléculaire	Assay (reagent) - revision to allow the use of automated methods.
0913	Hydroxocobalamin acetate	Hydroxocobalamine (acétate d')	Revision of identification method of acetates.
1108	Indapamide	Indapamide	Revision of the test for impurity A.
2114	Lysine acetate	Lysine (acétate de)	Revision of identification method of acetates.
1543	Manganese sulfate monohydrate	Manganèse (sulfate de) monohydraté	Revision of tests for zinc and iron.
1348	Metoclopramide	Métoclopramide	Impurity E: optimisation or replacement of the current TLC method.
0674	Metoclopramide hydrochloride monohydrate	Métoclopramide (chlorhydrate de) monohydraté	Impurity E: optimisation or replacement of the current TLC method.
0675	Metronidazole	Métronidazole	Related substances: alignment with ICH Q3A (introduction of a limit for unspecified impurities of maximum 0.05% and a reporting threshold of 0.03%).
0934	Metronidazole benzoate	Métronidazole (benzoate de)	Related substances: alignment with ICH Q3A (introduction of a limit for unspecified impurities of maximum 0.05% and a reporting threshold of 0.03%).
1451	Mupirocin calcium	Mupirocine calcique	Revision of identification method of calcium (replacement of chloroform).
2637	Pemetrexed disodium heptahydrate	Pémétréxed disodique heptahydraté	Revision of Identification and Related substances.
0148	Phenoxymethylpenicillin	Phénoxy méthylpénicilline	Related substances: addition of a new impurity.
1139	Potassium acetate	Potassium (acétate de)	Revision of identification method of acetates.
2572	Risedronate sodium 2.5-hydrate	Riséronate sodique 2,5-hydraté	Related substances: stricter limit for impurity A.
1474	Stearic acid	Stéarique (acide)	Revision to include freezing point alternative apparatus.

1048	Testosterone enantate	Testostérone (énantate de)	Replacement of impurities A and H tests by LC method.
0644	Tetracosactide	Tétracosactide	Extension of the currently ongoing revision on Related peptides test to potentially apply the same method in the Identification and Assay sections.
1659	Tiamulin hydrogen fumarate for veterinary use	Tiamuline (hydrogénofumarate de) pour usage vétérinaire	Revision of test for related substances: addition of a new impurity.
1482	Zinc acetate dihydrate	Zinc (acétate de) dihydraté	Revision of identification method of acetates.

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

3138	Coffea cruda/arabica for homoeopathic preparations	Coffea cruda pour préparations homéopathiques
3168	Phenprocoumon	Phénprocoumone

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

	English	Français	Latin
Methods of analysis			
20267	Hardness according to Mohs for homoeopathic preparations	Échelle de dureté de Mohs pour préparations homéopathiques	
Homoeopathic manufacturing methods			
2371	Methods of preparation of homoeopathic stocks and potentisation	Méthodes de préparation des souches homéopathiques et déconcentration	
Subsection	HAB method 31 (Vervallen)	N/A	N/A
Subsection	HAB method 32 (buffered aqueous mother tinctures and liquid dilutions thereof)	N/A	N/A
Subsection	HAB method 33 (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 33 a, b, c, d, e, f (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 34 a-i (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A

Subsection	HAB method 35 a,b,c (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 36 (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 37 a,b (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 38 (cold-treated aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 46 (liquid vinous dilutions)	N/A	N/A
Subsection	HAB method 51 (heat-treated and fermented aqueous mother tinctures and liquid dilutions)	N/A	N/A
Subsection	HAB method 52 (mother tinctures from a distillate and liquid dilutions thereof)	N/A	N/A
Subsection	HAB method 53 (fermented mother tinctures and liquid dilutions thereof)	N/A	N/A
Subsection	HAB methods 25, 26 (Zimpel's spagyric mother tinctures and dilutions thereof)	N/A	N/A
Subsection	HAB methods 27, 28, 29, 30 (Krauss spagyric mother tinctures and dilutions thereof)	N/A	N/A
Subsection	HAB methods 47 a,b (Pekana's spagyric mother tinctures and dilutions thereof)	N/A	N/A
Subsection	HAB methods 48 (Ointments containing powdered metal)	N/A	N/A
Subsection	HAB methods 50 a/b (Strathmeyers's spagyric mother tinctures and dilutions thereof/ for use in the productions of Strathmeyer ointments)	N/A	N/A
Subsection	HAB methods 54 a-c (Glückselig's spagyric mother tinctures and dilutions thereof)	N/A	N/A
Subsection	HAB methods 56 a-f/ h/ i-j (Von Bernus spagyric mother tinctures/mixtures/ mother tinctures and dilutions thereof)	N/A	N/A

Subsection	HAB methods 57 (Liquid paraffin extracts)	N/A	N/A
Homoeopathic preparations			
2830	Achillea millefolium ferm 33d for homoeopathic preparations	N/A	Achillea millefolium ferm 33d ad praeparationes homoeopathicas
2831	Acidum benzoicum e resina for homoeopathic preparations	N/A	Acidum benzoicum e resina ad praeparationes homoeopathicas
2870	Alchemilla vulgaris for homoeopathic preparations	N/A	Alchemilla vulgaris ad homoeopathicas preparations
2913	Alfalfa for homoeopathic preparations	Luzerne pour préparations homéopathiques	Medicago sativa ad praeparationes homoeopathicas
2484	Allium cepa for homoeopathic preparations	Allium cepa pour préparations homéopathiques	Allium cepa ad praeparationes homoeopathicas
2955	Amanita muscaria for homoeopathic preparations	Agaricus muscarius pour préparations homéopathiques	Amanita muscaria ad praeparationes homoeopathicas
2485	Ambra for homoeopathic preparations	Ambra grisea pour préparations homéopathiques	Ambra grisea ad praeparationes homoeopathicas
2833	Apisinum for homoeopathic preparations	N/A	Apisinum ad praeparationes homoeopathicas
2696	N/A	N/A	Arnica Montana ex herba ad usum externum ad praeparationes homoeopathicas
2834	Arsenum iodatum for homoeopathic preparations	N/A	Arsenum iodatum ad praeparationes homoeopathicas
2835	Asa foetida for homoeopathic preparations	N/A	Asa foetida ad praeparationes homoeopathicas
2911	Ash for homoeopathic preparations	Frêne élevé pour préparations homéopathiques	Fraxinus excelsior ad praeparationes homoeopathicas
2863	Atropa belladonna Rh for homoeopathic preparations	Atropa belladonna Rh pour préparations homéopathiques	Atropa belladonna Rh ad praeparationes homoeopathicas
2698	Avena sativa ferm 33c for homoeopathic preparations	N/A	Avena sativa ferm 33c ad praeparationes homoeopathicas
2699	Baneberry for homoeopathic preparations	N/A	Actea spicata ad praeparationes homoeopathicas
2025	Bellis perennis for homoeopathic preparations	Bellis perennis pour préparations homéopathiques	Bellis perennis ad praeparationes homoeopathicas
2871	Betula pendula e foliis for homoeopathic preparations	N/A	N/A

2700	Blue flag for homoeopathic preparations	N/A	Iris versicolor ad praeparationes homoeopathicas
2709	Bryophyllum for homoeopathic preparations	N/A	Bryophyllum ad praeparationes homoeopathicas
2491	Conchae for homoeopathic preparations	Calcarea carbonica ostrearum pour préparations homéopathiques	Calcarea carbonica ostrearum ad praeparationes homoeopathicas
2494	Conium maculatum for homoeopathic preparations	N/A	Conium maculatum ad praeparationes homoeopathicas
2495	Crataegus (fructus) for homoeopathic preparations	Crataegus (fructus) pour préparations homéopathiques	Crataegi fructus ad praeparationes homoeopathicas
2632	Cydonia oblonga for homoeopathic preparations	Cydonia oblonga pour préparations homéopathiques	Cydonia oblonga ad praeparationes homoeopathicas
2960	Cypress pine for homoeopathic preparations	Cyprès pour préparations homéopathiques	Cupressus sempervirens ad praeparationes homoeopathicas
2836	Disci intervertebrales bovis GI for homoeopathic preparations	N/A	Disci intervertebrales bovis GI ad praeparationes homoeopathicas
2659	Dried lespedeza capitata for homoeopathic preparations	N/A	Dried lespedeza capita ad praeparationes homoeopathicas
2816	Drosera for homoeopathic preparations	Droséra pour préparations homéopathiques	Drosera ad praeparationes homoeopathicas
2496	Eucalyptus globulus for homoeopathic preparations	Eucalyptus globulus pour préparations homéopathiques	Eucalyptus globulus ad praeparationes homoeopathicas
2706	Euonymus europaea for homoeopathic preparations	N/A	Euonymus europaea ad praeparationes homoeopathicas
2919	Euonymus europaea seeds for homoeopathic preparations	Euonymus europaea (graines de) pour préparations homéopathiques	Euonymus europaea semen ad praeparationes homoeopathicas
2497	Ferrosferric phosphate for homoeopathic preparations	Phosphate ferroso-ferrique pour préparations homéopathiques	Ferrum phosphoricum ad praeparationes homoeopathicas
2872	Fluorite for homoeopathic preparations	N/A	Fluorit ad homoeopathicas praeparationes homoeopathicas
2658	Fresh lespedeza capitata for homoeopathic preparations	N/A	Fresh lespedeza capita ad praeparationes homoeopathicas
2817	Fumitory for homoeopathic preparations	Fumeterre pour préparations homéopathiques	Fumaria officinalis ad praeparationes homoeopathicas
2873	Galipea officinalis for homoeopathic preparations	N/A	Galipea officinalis ad homoeopathicas praeparationes
2958	Galium mollugo for homoeopathic preparations	Galium mollugo pour préparations homéopathiques	Galium mollugo ad praeparationes homoeopathicas

2874	Gentiana lutea for homoeopathic preparations	N/A	Gentiana lutea/ lutea, ethanol. Decoctum ad homoeopathicas preparationes
2912	Giant puffball for homoeopathic preparations	Vesse-de-loup géante pour préparations homéopathiques	Bovista gigantea ad praeparationes homoeopathicas
2875	Graphite for homoeopathic preparations	N/A	N/A
2806	Grindelia for homoeopathic preparations	Grindelia pour préparations homéopathiques	Grindelia ad praeparationes homoeopathicas
2876	Hekla lava for homoeopathic preparations	N/A	Hekla lava ad homoeopathicas preparationes
2670	Hematite for homoeopathic preparations	Hématite pour préparations homéopathiques	Hematitis ad praeparationes homoeopathicas
2499	Hepar sulfuris for homoeopathic preparations	N/A	Hepar sulfuris ad praeparationes homoeopathicas
2672	Horseradish for homoeopathic preparations	N/A	Cochlearia armoracia ad praeparationes homoeopathicas
2956	Humulus lupulus for homoeopathic preparations	Humulus lupulus pour préparations homéopathiques	Humulus lupulus ad praeparationes homoeopathicas
2877	Justicia adhatoda for homoeopathic preparations	N/A	Justicia adhatoda ad homoeopathicas preparationes
2878	Kalium stibyltartaricum for homoeopathic preparations	N/A	Kalium stibyltartaricum ad homoeopathicas preparationes
2879	Kieserite for homoeopathic preparations	N/A	Kieserite ad homoeopathicas preparationes
2502	Lachesis mutus for homoeopathic preparations	Lachesis mutus pour préparations homéopathiques	Lachesis mutus ad praeparationes homoeopathicas
2839	Lilium lancifolium for homoeopathic preparations	N/A	Lilium lancifolium ad praeparationes homoeopathicas
2880	Lophophytum leandri for homoeopathic preparations	N/A	Lophophytum leandri ad homoeopathicas preparationes
2819	Lungwort for homoeopathic preparations	Sticta pulmonaria pour préparations homéopathiques	Sticta pulmonaria ad praeparationes homoeopathicas
2504	Lytta vesicatoria for homoeopathic preparations	N/A	Lytta vesicatoria ad praeparationes homoeopathicas
2677	Malachit for homoeopathic preparations	N/A	Malachit ad praeparationes homoeopathicas
2864	Mandragora, ethanol. Decoctum for homoeopathic preparations	Mandragora, ethanol. Decoctum pour préparations homéopathiques	Mandragora, ethanol. Decoctum ad praeparationes homoeopathicas

2820	Marjoram for homoeopathic preparations	Marjolaine pour préparations homéopathiques	Origanum majorana ad praeparationes homoeopathicas
2653	Meadowsweet for homoeopathic preparations	Reine des prés pour préparations homéopathiques	Filipendula ulmaria ad praeparationes homoeopathicas
2291	Melissa officinalis for homoeopathic preparations	Mélisse officinale pour préparations homéopathiques	Melissa officinalis ad praeparationes homoeopathicas
2959	Motherwort for homoeopathic preparations	Agripaume pour préparations homéopathiques	Leonurus cardiaca ad praeparationes homoeopathicas
2914	Mullein for homoeopathic preparations	Bouillon-blanc pour préparations homéopathiques	Verbascum thapsus ad praeparationes homoeopathicas
2680	Natricum tetrachlorauratum for homoeopathic preparations	N/A	Aurum chloratum/ Aurum muriaticum ad homoeopathicas preparations
2841	Okoubaka aubrevillei for homoeopathic preparations	N/A	Okoubaka aubrevillei ad praeparationes homoeopathicas
2652	Oleander for homoeopathic preparations	Laurier rose pour préparations homéopathiques	Nerium oleander ad praeparationes homoeopathicas
2684	Peumus boldus for homoeopathic preparations	N/A	Peumus boldus ad praeparationes homoeopathicas
2509	Phosphorus for homoeopathic preparations	Phosphore pour préparations homéopathiques	Phosphorus ad praeparationes homoeopathicas
2881	Phytolacca americana for homoeopathic preparations	N/A	Phytolacca americana ad homoeopathicas preparations
2882	Prunus spinosa e summitatibus Rh for homoeopathic preparations	N/A	Prunus spinosa e summitatibus Rh
2510	Pulsatilla pratensis / Pulsatilla for homoeopathic preparations	N/A	Pulsatilla pratensis / Pulsatilla ad praeparationes homoeopathicas
2293	Pulsatilla vulgaris for homoeopathic preparations	Anémone pulsatile pour préparations homéopathiques	Pulsatilla vulgaris ad praeparationes homoeopathicas
2842	Punica granatum for homoeopathic preparations	N/A	Punica granatum ad praeparationes homoeopathicas
2843	Pyrogenium-Nosode for homoeopathic preparations	N/A	Pyrogenium-Nosode ad praeparationes homoeopathicas
2686	Quartz for homoeopathic preparations	Quartz pour préparations homéopathiques	Quartzum ad praeparationes homoeopathicas
2265	Raphanus for homoeopathic preparations	N/A	Raphanus ad praeparationes homoeopathicas
2651	Sage (salviae officinalis) for homoeopathic preparations	Sauge officinale pour préparations homéopathiques	Salviae officinalis ad praeparationes homoeopathicas

2883	Sedum acre for homoeopathic preparations	N/A	Sedum acre ad homoeopathicas preparationes
2095	Semen contra for homoeopathic preparations	Semen contra pour préparations homéopathiques	Artemisia cina ad praeparationes homoeopathicas
2884	Senecio cineraria for homoeopathic preparations	N/A	Senecio cineraria ad homoeopathicas preparationes
2512	Sepia officinalis (dried secretion / dried ink pouch) for homoeopathic preparations	N/A	Sepia officinalis dried secretion / dried ink pouch ad praeparationes homoeopathicas
2885	Siderite for homoeopathic preparations	N/A	Siderite ad homoeopathicas preparationes
2807	Silver fir for homoeopathic preparations	Sapin pour préparations homéopathiques	Abies alba ad praeparationes homoeopathicas
2516	Sulfur iodatum for homoeopathic preparations	N/A	Sulfur iodatum ad praeparationes homoeopathicas
2711	Szygii cumini for homoeopathic preparations	N/A	Sizygii cumini ad praeparationes homoeopathicas
2517	Taraxacum officinale for homoeopathic preparations	Taraxacum officinale pour préparations homéopathiques	Taraxacum officinale ad praeparationes homoeopathicas
2688	Thallium sulfuricum for homoeopathic preparations	N/A	Thallium sulfuricum ad praeparationes homoeopathicas
2689	Traveller's joy for homoeopathic preparations	N/A	Clematis vitalba ad praeparationes homoeopathicas
2690	Tussilago farfara for homoeopathic preparations	N/A	Tussilago farfara ad praeparationes homoeopathicas
2826	Umbellate wintergreen for homoeopathic preparations	Chimaphila umbellata pour préparations homéopathiques	Chimaphila umbellata ad praeparationes homoeopathicas
2691	Upright virgin's bower for homoeopathic preparations	N/A	Clematis erecta ad praeparationes homoeopathicas
2845	Ustilago maydis for homoeopathic preparations	N/A	Ustilago maydis ad praeparationes homoeopathicas
2846	Veronica officinalis for homoeopathic preparations	N/A	Veronica officinalis, ethanol. Decoctum ad praeparationes homoeopathicas
2692	Vinca minor for homoeopathic preparations	N/A	Vinca minor ad praeparationes homoeopathicas
2915	Walnut for homoeopathic preparations	Noyer pour préparations homéopathiques	Juglans regia ad praeparationes homoeopathicas
2886	Witherite for homoeopathic preparations	N/A	Witherite ad homoeopathicas preparationes

Monographs

1663	Aluminium stearate	Aluminium (stéarate d')
0010	Barium sulfate	Baryum (sulfate de)
1070	Betadex	Bétadex
1493	Bismuth subgallate	Bismuth (sous-gallate de)
1494	Bismuth subnitrate, heavy	Bismuth (sous-nitrate de) lourd
1495	Bismuth subsalicylate	Bismuth (sous-salicylate de)
1646	Human plasma (pooled and treated for virus inactivation)	Plasma humain (mélange de) traité pour viro-inactivation
0853	Human plasma for fractionation	Plasma humain pour fractionnement
0039	Magnesium hydroxide	Magnésium (hydroxyde de)
1149	Shellac	Gommes laques
0953	Sulfur	Soufre
0306	Zinc stearate	Zinc (stearate de)