

Update to work programme of the European Pharmacopoeia

(November 2022)

The following items have been added to or deleted from the work programme during the 174th 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 | | | |
|----------------------------|---|---|---|
| 2.9.38. | Particle-size distribution estimation by analytical sieving | Estimation de la distribution granulométrique par tamisage analytique | Revision to align the text with the current ISO standard. |
| 2.9.42. | Dissolution test for lipophilic solid dosage forms | Essai de dissolution des formes solides lipophiles | Revision to align the description and operation with those presented in 2.9.3. and to allow alternative suitable heating devices to the water-bath. |
| 2.9.43. | Apparent dissolution | Dissolution apparente | Revision to correct the cell dimensions and the sieve aperture, to align the description and operation with those presented in 2.9.3 and to allow alternative suitable heating devices to the water-bath. |
| General texts | | | |
| 5.30. | Monographs on essential oils (information chapter) | Monographies d'huiles essentielles (chapitre informatif) | Revision to clarify the applicability of individual herbal drug monographs as starting materials in essential oil production. |
| Herbal drugs | | | |
| 2943 | Burdock root | Bardane (grande), racine de | Revision to include a test for adulteration with species of Solanaceae, based on the detection by microscopy of starch granules. |
| 1822 | Pale coneflower root | Echinacea pallida (racine d') | Revision of Identifications C and D and the test for other Echinacea species and Parthenium integrifolium. |

General monographs

| | | | |
|------|-----------------------------|--------------------------------|---|
| 0062 | Vaccines for veterinary use | Vaccins pour usage vétérinaire | To cover also recombinant viral vectored vaccines for veterinary use. |
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Vaccines

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|------|-------------------------------|----------------------------|--|
| 0443 | Diphtheria vaccine (adsorbed) | Vaccin diphtérique adsorbé | Test for absence of toxin and irreversibility of toxoid: remove the irreversibility part of the test and 6-week incubation step. |
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Radiopharmaceutical preparations

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| 1492 | Ammonia (¹³ N) injection | Ammoniaque (¹³ N) (solution injectable d') | Radiochemical purity test -recommended column no longer available. |
| 2376 | Technetium (^{99m} Tc) oxidronate injection | Technétium (^{99m} Tc) (oxidronate-), solution injectable d' | Radiochemical purity test - Replacement of TLC test by paper chromatographic test |
| 1582 | Water (¹⁵ O) injection | Eau (¹⁵ O) injectable | Radiochemical purity test - review of procedure and limits. |

Herbal drugs

| | | | |
|------|-------------------------------|--|---|
| 2147 | Agnus castus fruit | Gattilier (fruit de) | Identification B: introduction of illustration of powdered herbal drug. |
| 1605 | Bogbean leaf | Ményanthe | Identification B: introduction of illustration of powdered herbal drug. |
| 1301 | Centauray | Centaurée (petite) | Identification B: introduction of illustration of powdered herbal drug. |
| 1504 | Cola | Kola | Identification B: introduction of illustration of powdered herbal drug. |
| 1860 | Milk thistle fruit | Chardon marie | Identification B: introduction of illustration of powdered herbal drug. |
| 1821 | Narrow-leaved coneflower root | Echinacea angustifolia (racine d') | Revision of first and second identification. |
| 2538 | Nettle root | Ortie (racine d') | Identification A and B: updated to take account of the differences between <i>Urtica dioica</i> and <i>U. urens</i> . Identification B: introduction of illustration of powdered herbal drug. |
| 1887 | Oak bark | Chêne (écorce de) | Identification B: introduction of illustration of powdered herbal drug. |
| 2264 | Pelargonium root | Pélargonium (racine de) | Identification B: introduction of illustration of powdered herbal drug. |
| 1823 | Purple coneflower herb | Echinacea purpurea (parties aériennes fleuries d') | Revision of first and second identification. |
| 1824 | Purple coneflower root | Echinacea purpurea (racine d') | Revision of first and second identification. |
| 1478 | Tormentil | Tormentille | Identification B: introduction of illustration of powdered herbal drug. |

Monographs

| | | | |
|-------------|---|--|---|
| 2191 | Atorvastatin calcium | Atorvastatine calcique | Revision to replace the identification test for calcium based on reaction (b) of calcium (2.3.1) with a more user-friendly test based on a modified reaction (a) of calcium (2.3.1.). Additionally, to widen the specification for impurity I to maximum 0.15% and modify the CRS strategy accordingly and to replace (widen) the system suitability acceptance criteria for the test for Enantiomeric purity by a peak-to-valley ratio of minimum 5.0. |
| 1330 | Glucose, liquid | Glucose liquide | Revision of Molecular weight (Mw) and molecular weight distribution: system suitability limit to be widened. |
| 1167 | Haemodialysis solutions, concentrated, water for diluting | Solutions concentrées pour hémodialyse (eau pour dilution des) | Modification of the microbiological controls. |
| 1804 | Hydroxypropylbetadex | Hydroxypropylbétadex | Revision to introduce a test for propylene oxide and to review the test for related substances and the assay. |
| 0344 | Maize starch | Amidon de maïs | Revision of Identification: maize starch granule diameter limit widened. |
| 2599 | Nicotine ditartrate dihydrate | Nicotine (ditartrate de) dihydraté | Revision of the test for optical rotation. |
| 2057 | Octyl gallate | Octyle (gallate d') | Replacement of the current thin layer chromatography test for impurity A and UV assay by a liquid chromatography procedure for a test for related substances and assay. In addition, the possibility to introduce identification by IR will be investigated. |
| 0782 | Phenylalanine | Phénylalanine | Revision of the test for optical rotation. |
| 2740 | Sodium selenite | Sodium (sélénite de) | Revision of the test for pH: change of specification. |
| 2165 | Starch, hydroxypropyl | Amidon hydroxypropylé | Revision of Identification: maize starch granule diameter limit widened. |
| 1785 | Starches, hydroxyethyl | Amidons hydroxyéthylés | Revision of Molecular weight (Mw) and molecular weight distribution: system suitability limit to be widened. |
| 0593 | Wool alcohols | Alcools de graisse de laine | Revision to clarify the applicability of individual herbal drug monographs as starting materials in essential oil production. |

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

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|-------------|-------------------------------|-----------------------------------|
| 3212 | Apixaban | Apixaban |
| 3213 | Apixaban tablets | Apixaban (comprimés d') |
| 3214 | Butamirate citrate | Butamirate (citrate de) |
| 3215 | Dexmedetomidine hydrochloride | Dexmédétomidine (chlorhydrate de) |
| 3216 | Indigotin disulfonate sodium | Indigotine (sulfonate d') sodique |
| 3218 | Neotame | Néotame |

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

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|-------------|----------------------------|--------------------------------------|
| 3007 | Cajeput oil | Cajeput (huile essentielle de) |
| 2892 | Candle bush leaflet | Dartrier (foliole de) |
| 2730 | Macrogol isotridecyl ether | Macrogol (éther isotridécyclique de) |