

Update to work programme of the European Pharmacopoeia

(March 2024)

The following items have been added to or deleted from the work programme during the 178th 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 | | | |
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| 2.5.25. | Carbon monoxide in gases (2.5.25.) | Monoxyde de carbone dans les gaz (2.5.25.) | Deletion of method 1, to avoid the use of chromium trioxide (REACH) |
| Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations | | | |
| 2351 | lobenguane sulfate for radiopharmaceutical preparations | lobenguane (sulfate d') pour préparations radiopharmaceutiques | Related substances: addition of a test, Assay: review the limits |
| Herbal drugs | | | |
| 0824 | Fennel, bitter | Fenouil amer (fruit de) | Revision of the essential oil and estragol content |
| 2433 | Fleeceflower root | Polygonum multiflorum (racine de) | Identification B: introduction of illustration of powdered herbal drug, Identification C: analytical procedure improvement |
| 2478 | Fourstamen stephania root | Stéphania (racine de) | Identification B: introduction of illustration of powdered herbal drug, Identification C: analytical procedure improvement |
| 2474 | Moutan bark | Paeonia suffruticosa (écorce de) | Assay: modification of limits for paeonol and paeoniflorin |
| 1897 | Nettle leaf | Ortie (feuille d') | Revision of identification tests A and B (macroscopic and microscopic identifications) to provide separate acceptance criteria for <i>Urtica dioica</i> L. and <i>Urtica urens</i> L. Identification test C: TLC replaced by HPTLC in accordance with general chapter 2.8.25. |
| 0406 | Peppermint leaf | Menthe poivrée (feuille de) | Identification C: replacement of TLC by HPTLC |
| 2382 | Peppermint leaf dry extract | Menthe poivrée (feuille de), extrait sec de | Identification: replacement of TLC by HPTLC |
| 1848 | Saw palmetto fruit | Palmier de Floride (fruit de) | Revision of the milling procedure and the sieving for the assay |
| 2108 | Star anise oil | Badiane (huile essentielle de) | Revision to widen the definition to cover fresh leaves and fresh terminal branchlets |

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| 1854 | Verbena herb | Verveine officinale | Revision of total ash and ash insoluble in hydrochloric acid limits |
| Monographs | | | |
| 1064 | Almond oil, refined | Amande (huile d') raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1171 | Arachis oil, hydrogenated | Arachide (huile d') hydrogénée | Unsaponifiable matter - test moved from Tests section to Production section |
| 0263 | Arachis oil, refined | Arachide (huile d') raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 2105 | Borage (starflower) oil, refined | Bourrache (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 2367 | Castor oil, refined | Ricin (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1406 | Cellulose acetate butyrate | Cellulose (acétate butyrate de) | Introduction of Functionality-related Characteristics section |
| 0379 | Cetylpyridinium chloride | Cétylpyridinium (chlorure de) | Introduction of a test for related substances |
| 0890 | Clonazepam | Clonazépam | Related substances: specifications updated to reflect the levels of impurities in products approved on the European market; the monograph has been aligned with the requirements of general monograph 2034 |
| 1410 | Coconut oil, refined | Coco (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1305 | Cottonseed oil, hydrogenated | Coton (huile de) hydrogénée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1591 | Ethacridine lactate monohydrate | Éthacridine (lactate d') monohydraté | Related substances: limit for unspecified impurities |
| 2104 | Evening primrose oil, refined | Onagre (huile d') raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1670 | Glutathione | Glutathion | Related substances: Improvement - determination by UPLC |
| 0255 | Human albumin solution | Albumine humaine (solution d') | Protein composition: deletion of the cellulose acetate method and introduction of capillary zone electrophoresis as an alternative procedure |
| 1019 | Isotretinoin | Isotrétinoïne | Revision of the related substances test, introducing an LC assay |
| 1083 | Macroglycerol hydroxystearate | Macroglycérol (hydroxystéarate de) | Functionality-related characteristics section added, Identification D: wet chemical reaction replaced by infrared absorption spectrophotometry |
| 1082 | Macroglycerol ricinoleate | Macroglycérol (ricinoléate de) | Identification D: wet chemical reaction replaced by infrared absorption spectrophotometry |
| 1342 | Maize oil, refined | Maïs (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1236 | Maltitol, liquid | Maltitol liquide | Potential adulteration: Addition of a test for ethylene glycol/diethylene glycol |

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| 0627 | Nifedipine | Nifédipine | Related substances: specifications updated to reflect the levels of impurities in products approved on the European market; the monograph has been aligned with the requirements of the general monograph 2034 |
| 1456 | Olive oil, refined | Olive (huile d') raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1251 | Oxybuprocaine hydrochloride | Oxybuprocaïne (chlorhydrate d') | Related substances: limit for unspecified impurities and disregard limit |
| 1369 | Rapeseed oil, refined | Colza (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 2088 | Safflower oil, refined | Carthame (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 0433 | Sesame oil, refined | Sésame (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 2778 | Sitagliptin phosphate monohydrate | Sitagliptine (phosphate de) monohydraté | Revision of the Definition (an antioxidant may be added) and Identification of phosphates |
| 0436 | Sorbitol, liquid (crystallising) | Sorbitol liquide (cristallisable) | Potential adulteration: Addition of a test for ethylene glycol/diethylene glycol |
| 0437 | Sorbitol, liquid (non-crystallising) | Sorbitol liquide (non cristallisable) | Potential adulteration: Addition of a test for ethylene glycol/diethylene glycol |
| 2048 | Sorbitol, liquid, partially dehydrated | Sorbitol liquide partiellement déshydraté | Potential adulteration: Addition of a test for ethylene glycol/diethylene glycol |
| 1265 | Soya-bean oil, hydrogenated | Soja (huile de) hydrogénée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1473 | Soya-bean oil, refined | Soja (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1371 | Sunflower oil, refined | Tournesol (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 1379 | Wheat-germ oil, refined | Germes de blé (huile de) raffinée | Unsaponifiable matter - test moved from Tests section to Production section |
| 0134 | Wool fat | Graisse de laine | Identification A: modification of reagent and sample quantity to improve visualisation of the result |

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

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| 2.9.57. | Water activity determination of liquids | Détermination de l'activité de l'eau des liquides |
| 5.43. | Actinium (²²⁵ Ac) solution for radiolabelling | Actinium (²²⁵ Ac) pour radiomarquage, solution d' |
| 5.45. | Liposomal preparations | Préparations liposomales |
| 3252 | Fluoroestradiol (¹⁸ F) injection | Fluoroestradiol (¹⁸ F) (solution injectable de) |
| 88886 | Cannabis liquid extract, standardised | Cannabis (extrait fluide titré de) |
| 3255 | Mycoplasma synoviae vaccine (live) for chickens | Vaccin vivant de Mycoplasma synoviae pour le poulet |
| 3250 | Bosentan | Bosentan |

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| 3251 | Famciclovir | Famciclovir |
| 3253 | Itopride hydrochloride | Itopride (chlorhydrate d') |
| 3256 | Pegylated liposomal doxorubicin hydrochloride concentrate for infusion | Chlorhydrate de doxorubicine liposomal pégylé (préparation à diluer pour perfusion de) |
| 3259 | Sugammadex sodium injection | Sugammadex sodique (préparation injectable de) |
| 3260 | Tioguanine | Tioguanine |

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

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| 2429 | Carmichael aconite root | Aconit de carmichael (racine d') |
| 2471 | Kusnezoff monkshood root, prepared | Aconit de Kusnezoff (racine préparée d') |
| 2470 | Monkshood root, processed | Aconit (racine préparée d') |
| 2469 | Common monkshood daughter root, prepared | Aconit (racine fille préparée d') |
| 2181 | Trimebutine | Trimébutine |