

# CONTENTS OF SUPPLEMENT 11.3

*Lists of the monographs and general chapters that, for supplement 11.3, are new, revised or corrected or have had their titles changed, are given below.*

*As of the 11<sup>th</sup> Edition, all revised, corrected or deleted parts of a text published in the online version of the European Pharmacopoeia are indicated by change marks in the form of triangles. For reasons of readability, these triangles are not shown in the print version.*

*Corrected texts are to be taken into account as soon as possible and not later than the end of the month following the month of publication of the edition or supplement. New and revised texts are to be taken into account not later than the implementation date.*

*A QR code is included at the start of each text, providing a link to further information on the text (stored in the Knowledge database) for smartphones and tablets with a camera and a compatible app.*

*Individual copies of texts published in this edition will not be supplied.*

*Subscribers to the current version (print or online) of the European Pharmacopoeia have access to an online archive version of all obsolete editions and supplements of the European Pharmacopoeia in PDF format.*

## NEW TEXTS

*The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2024 at the latest.*

### GENERAL CHAPTERS

2.9.48. Particle size and shape determination by image analysis

### MONOGRAPHS

#### Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Gallium (<sup>68</sup>Ga) DOTANOC injection (3051)

Gallium (<sup>68</sup>Ga) oxodotreotide injection (3050)

#### Herbal drugs and herbal drug preparations

Adhatoda vasica leaf (2738)

Burdock root (2943)

Chrysanthemum flower (3162)

Eclipta herb with root (2852)

Horse-chestnut bark (2945)

Immortelle flower (3089)

Lonicera japonica flower (3159)

#### Monographs

Bupivacaine (2761)

Dabigatran etexilate mesilate (3095)

Levocetirizine dihydrochloride (3115)

## REVISED TEXTS

*The following texts have been technically revised since their last publication. They will be implemented on 1 January 2024 at the latest.*

### GENERAL CHAPTERS

2.2.35. Osmolality

2.2.46. Chromatographic separation techniques

2.6.16. Tests for extraneous agents in viral vaccines for human use

2.7.28. Colony-forming cell assay for human haematopoietic progenitor cells

2.7.29. Nucleated cell count and viability

2.9.7. Friability of uncoated tablets

4. Reagents

5.22. Names of herbal drugs used in traditional Chinese medicine

### MONOGRAPHS

#### General monographs

Pharmaceutical preparations (2619)

Substances for pharmaceutical use (2034)

#### Vaccines for human use

Influenza vaccine (live, nasal) (2772)

Yellow fever vaccine (live) (0537)

#### Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Alovudine (<sup>18</sup>F) injection (2460)

Fludeoxyglucose (<sup>18</sup>F) injection (1325)

Fluorocholine (<sup>18</sup>F) injection (2793)

Fluorodopa (<sup>18</sup>F) (prepared by nucleophilic substitution) injection (2481)

Fluoromisonidazole (<sup>18</sup>F) injection (2459)

Technetium (<sup>99m</sup>Tc) sestamibi injection (1926)

#### Herbal drugs and herbal drug preparations

Agnus castus fruit (2147)

Black horehound (1858)

Bogbean leaf (1605)

Cola (1504)

Guarana (2669)

Ispaghula husk (1334)

Mate leaf (2678)

Milk thistle dry extract, refined and standardised (2071)

Milk thistle fruit (1860)

Oak bark (1887)

Pelargonium root (2264)	Letrozole (2334)
Psyllium seed (0858)	Mepyramine maleate (0278)
Tormentil (1478)	Neostigmine bromide (0046)
<b>Homoeopathic preparations</b>	Omega-3-acid triglycerides (1352)
Calcium iodatum for homoeopathic preparations (2144)	Pimozide (1254)
Nux-vomica for homoeopathic preparations (2514)	Potassium acetate (1139)
<b>Monographs</b>	Rabeprazole sodium (2868)
Amikacin (1289)	Raloxifene hydrochloride (2375)
Ampicillin sodium (0578)	Raltegravir potassium chewable tablets (2939)
Atracurium besilate (1970)	Raltegravir potassium tablets (2938)
Benzylpenicillin (benzathine) tetrahydrate (0373)	Salbutamol (0529)
Bismuth subcarbonate (0012)	Salbutamol sulfate (0687)
Bismuth subgallate (1493)	Sitagliptin tablets (2927)
Bismuth subnitrate, heavy (1494)	Sotalol hydrochloride (2004)
Bismuth subsalicylate (1495)	Soya-bean oil, refined (1473)
Cefaclor (0986)	Stavudine (2130)
Cholecalciferol (0072)	Thiamine nitrate (0531)
Clarithromycin (1651)	<i>RRR</i> - $\alpha$ -Tocopheryl acetate (1257)
Donepezil hydrochloride (2582)	Trimethoprim (0060)
Fluocortolone pivalate (1212)	Vitamin A concentrate (oily form), synthetic (0219)
Halofantrine hydrochloride (1979)	Voriconazole (2576)
Iodixanol (2215)	Xanthan gum (1277)
Isopropyl myristate (0725)	Xylose (1278)
Latanoprost (2230)	Zinc acetate dihydrate (1482)
	Ziprasidone mesilate trihydrate (2649)

## CORRECTED TEXTS

*The following texts have been corrected for Supplement 11.3 and specify 'corrected 11.3' above the title. These corrections are to be taken into account as soon as possible and not later than 31 August 2023 (the end of the month following the month of publication of Supplement 11.3).*

### GENERAL CHAPTERS

5.12. Reference standards

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

Rhubarb (0291)

Rhubarb dry extract, standardised (1845)

Wild thyme (1891)

### Monographs

Calcium dobesilate monohydrate (1183)

Cinchocaine hydrochloride (1088)

Codeine hydrochloride dihydrate (1412)

Glycerol distearate (1428)

Levodropropizine (1535)

Potassium sorbate (0618)

Vitamin A concentrate (powder form), synthetic (0218)

Vitamin A concentrate (solubilisate/emulsion), synthetic (0220)

## TEXTS WHOSE TITLE HAS CHANGED

*The titles of the following texts have been changed in Supplement 11.3.*

### MONOGRAPHS

Raltegravir potassium chewable tablets (2939) (*previously Raltegravir chewable tablets*)

Raltegravir potassium tablets (2938) (*previously Raltegravir tablets*)

## SUSPENDED TEXT

*The following text is suspended as of 1 July 2022.*

### MONOGRAPHS

Gonadotrophin, equine serum, for veterinary use (0719)

## SUPPRESSED TEXTS

*The following text is suppressed as of 1 January 2024.*

### MONOGRAPHS

Donepezil hydrochloride monohydrate (3067)

*The following texts are suppressed as of 1 July 2023.*

### MONOGRAPHS

#### Vaccines for human use

Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)

Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)

Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)

#### Monographs

Ether, anaesthetic (0367)

*The following text is suppressed as of 1 April 2023.*

### MONOGRAPHS

Diethylstilbestrol (0484)

## ERRATA

**Monograph on Human coagulation factor IX (1223):** an error has been detected in the English version of the corrected monograph published in the 11<sup>th</sup> Edition of the Ph. Eur.: three lines of the Labelling section were erroneously deleted. This erratum does not concern the French version.

**Monographs on Infliximab concentrated solution (2928), Isoniazid (0146), Lactose (1061), Lactose monohydrate (0187), Levomepromazine hydrochloride (0505) and Sevoflurane (2269):** due to a technical issue, the figures (chemical structures in all six cases and the chromatogram from Infliximab concentrated solution) are missing from the English-language print version of these monographs published in Ph. Eur. Supplement 11.1. This issue does not concern the French version of the monographs or Ph. Eur. online (English and French).