



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ

ΜΕΣΣΟΓΕΙΩΝ 284, 15562, ΧΟΛΑΡΓΟΣ

ΔΙΕΥΘΥΝΣΗ ΕΡΓΑΣΤΗΡΙΩΝ

ΤΜΗΜΑ ΦΑΡΜΑΚΟΠΟΙΑΣ

ΑΝΑΡΤΗΤΕΑ ΣΤΟ ΔΙΑΔΙΚΤΥΟ

Πληροφορίες: Α. Μακρίτης
Τηλέφωνο: 213 2040379
Fax: 213 2040562
e-mail: amak@eof.gr

Αθήνα, 08 -12-2016
Αριθ. Πρωτ. 94712
Προς: Όπως ο πίνακας αποδεκτών

ΕΓΚΥΚΛΙΟΣ

Θέμα: Θέση σε ισχύ της 9^{ης} Έκδοσης της Ευρωπαϊκής Φαρμακοποιίας

Σας κοινοποιούμε τα **νέα, διορθωμένα και αναθεωρημένα** κείμενα που περιέχονται στην 9^η Έκδοση της Ευρωπαϊκής Φαρμακοποιίας και τίθενται σε ισχύ από την 1^η/1/2017.

Η 9^η έκδοση της Ευρωπαϊκής Φαρμακοποιίας περιλαμβάνει τα *νέα κείμενα* καθώς και *όλα τα ισχύοντα κείμενα της 8^{ης} έκδοσης*, κάποια εκ των οποίων έχουν αναθεωρηθεί ή διορθωθεί.

Σύμφωνα με την Οδηγία 2001/83/EC “the Community code relating to medicinal products for human use”, την κατευθυντήρια οδηγία EMEA/42371/2008 “Scientific guidelines and European Pharmacopoeia monographs” και το Νόμο 1425 “Κύρωση της Σύμβασης για την εκπόνηση Ευρωπαϊκής Φαρμακοποιίας και άλλες διατάξεις”, η προσαρμογή στις απαιτήσεις, που τίθενται σε ισχύ στις αναφερθείσες ημερομηνίες, είναι υποχρεωτική.

Η ΠΡΟΕΔΡΟΣ ΔΣ/ΕΟΦ

Α. ΑΝΤΩΝΙΟΥ

Αποδέκτες για ενέργεια:

1. **Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης**
Δ/ση Φαρμάκων και Φαρμακείων
2. **Σύλλογος Αντιπροσώπων Φαρ/κών Ειδών και Ειδικοτήτων**
Οδός Τατοίου.18ο χλμ. Εθνικής Οδού Αθηνών-Λαμίας, 146 71- Νέα Ερυθραία.
3. **Σ.Φ.Ε.Ε**
Λ. Κηφισίας 280 & Αγρινίου 3, 15232, Χαλάνδρι, Αθήνα (sfee@sfee.gr)
4. **Πανελλήνια Ένωση Φαρμακοβιομ/νίας**
Λ. Κηφισίας 324-326, Ν. Ψυχικό, Τ.Κ. 15451 (pef@pef.gr)
5. **Σύνδεσμος Αντιπροσώπων, Εισαγωγέων & Παρασκευαστών Κτην/κών Φαρμάκων**
Αγίου Κωνσταντίνου 40, Εμπορικό κέντρο ΑΙΘΡΙΟ, Μαρούσι, 15124, Αττική.
6. **ΔΥΠΕΕ**
(με την παράκληση ενημέρωσης των Νοσηλευτικών Ιδρυμάτων & Κέντρων Υγείας της περιφέρειάς τους)

Εσωτερική Διανομή (μόνο με ηλεκτρονικό ταχυδρομείο):

1. Δ/ση Δ/ση Δ/κών Υπηρεσιών Ελέγχου Προϊόντων
2. Δ/ση Αξιολόγησης Προϊόντων
3. Δ/ση Διεθνών, Δημοσίων Σχέσεων & Πληροφόρησης
4. Δ/ση Ελέγχου Παραγωγής & Κυκλοφορίας Προϊόντων
5. Δ/ση Εργαστηρίων
6. Δ/ση Φαρ/κών Μελετών & Ερευνών
7. Τμήμα Φαρμακοποιίας Δ/σης Εργαστηρίων

**ΝΕΑ, ΑΝΑΘΕΩΡΗΜΕΝΑ ΚΑΙ ΔΙΟΡΘΩΜΕΝΑ ΚΕΙΜΕΝΑ ΤΗΣ ΕΝΑΤΗΣ (9^{ΗΣ})
ΕΚΔΟΣΗΣ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΑΣ**

ΝΕΑ ΚΕΙΜΕΝΑ

Τα παρακάτω κείμενα εμφανίζονται για πρώτη φορά στην Ευρωπαϊκή Φαρμακοποιία. Θα τεθούν σε εφαρμογή το αργότερο την 1^η Ιανουαρίου 2017.

ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ

- 2.7.35. Immunonephelometry for vaccine component assay
- 2.8.25. High-performance thin-layer chromatography of herbal drugs and herbal drug preparations
- 5.2.12. Raw materials of biological origin for the production of cell-based and gene therapy medicinal products
- 5.2.13. Healthy chicken flocks for the production of inactivated vaccines for veterinary use

ΜΟΝΟΓΡΑΦΙΕΣ

Εμβόλια για κτηνιατρική χρήση

Infectious bovine rhinotracheitis vaccine (inactivated) (2674)

Φυτικές δρόγες και σκευάσματα φυτικών δρογών

Akebia stem (2472)	Paeony root, white (2424)
Cape jasmine fruit (2565)	Polygonum cuspidatum rhizome and root (2724)
Codonopsis root (2714)	Polygonum orientale fruit (2726)
Horse-chestnut (1830)	Uncaria stem with hooks (2729)
Horse-chestnut dry extract, standardised (1829)	Zanthoxylum bungeanum pericarp (2656)
Paeony root, red (2425)	

Ομοιοπαθητικά σκευάσματα

Magnesium fluoratum for homoeopathic preparations (2676)

Μονογραφίες

Animal epithelia and outgrowths for allergen products (2621)	Irinotecan hydrochloride trihydrate (2675)
Aprepitant (2757)	Mites for allergen products (2625)
Clopidogrel besilate (2790)	Moulds for allergen products (2626)
Clopidogrel hydrochloride (2791)	Pollens for allergen products (2627)
Escitalopram (2758)	Tacalcitol monohydrate (2272)
Hydroxychloroquine sulfate (2849)	Temozolomide (2780)
Hymenoptera venoms for allergen products (2623)	Teriparatide (2829)

ΚΕΙΜΕΝΑ ΠΟΥ ΕΧΟΥΝ ΑΝΑΘΕΩΡΗΘΕΙ ΣΤΗΝ 9^Η ΕΚΔΟΣΗ

Τα παρακάτω κείμενα έχουν αναθεωρηθεί τεχνικά σε σχέση με την προηγούμενη δημοσίευσή τους. Θα τεθούν σε εφαρμογή την 1^η Ιανουαρίου 2017.

ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ

- 2.4.24. Identification and control of residual solvents
- 2.5.28. Water in gases
- 2.9.6. Uniformity of content of single-dose preparations
- 4. Reagents
- 5.2.3. Cell substrates for the production of vaccines for human use
- 5.8. Pharmacopoeial harmonisation

ΜΟΝΟΓΡΑΦΙΕΣ

Γενικές Μονογραφίες

- Allergen products (1063)
- Vaccines for human use (0153)
- Vaccines for veterinary use (0062)

Φαρμακοτεχνικές μορφές

Powders for cutaneous application (1166)

Tampons, medicated (1155)

Εμβόλια για κτηνιατρική χρήση

- | | |
|--|---|
| Aujeszký's disease vaccine (inactivated) for pigs (0744) | Equine influenza vaccine (inactivated) (0249) |
| Avian infectious bronchitis vaccine (inactivated) (0959) | Feline calicivirus vaccine (inactivated) (1101) |
| Avian infectious bursal disease vaccine (inactivated) (0960) | Feline chlamydiosis vaccine (inactivated) (2324) |
| Avian paramyxovirus 3 vaccine (inactivated) for turkeys (1392) | Feline infectious enteritis (feline panleucopenia) vaccine (inactivated) (0794) |
| Bovine leptospirosis vaccine (inactivated) (1939) | Feline leukaemia vaccine (inactivated) (1321) |
| Bovine viral diarrhoea vaccine (inactivated) (1952) | Feline viral rhinotracheitis vaccine (inactivated) (1207) |
| Calf coronavirus diarrhoea vaccine (inactivated) (1953) | Foot-and-mouth disease (ruminants) vaccine (inactivated) (0063) |
| Calf rotavirus diarrhoea vaccine (inactivated) 1954) | Fowl cholera vaccine (inactivated) (1945) |
| Canine adenovirus vaccine (inactivated) (1298) | Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521) |
| Canine leptospirosis vaccine (inactivated) (0447) | Infectious chicken anaemia vaccine (live) (2038) |
| Canine parvovirus vaccine (inactivated) (0795) | Mannheimia vaccine (inactivated) for cattle (1944) |
| Egg drop syndrome '76 vaccine (inactivated) (1202) | Mannheimia vaccine (inactivated) for sheep (1946) |
| Equine herpesvirus vaccine (inactivated) (1613) | Mycoplasma gallisepticum vaccine (inactivated) (1942) |

Neonatal piglet colibacillosis vaccine (inactivated) (0962)	Rabies vaccine (inactivated) for veterinary use (0451)
Neonatal ruminant colibacillosis vaccine (inactivated) (0961)	Salmonella Enteritidis vaccine (inactivated) for chickens (1947)
Newcastle disease vaccine (inactivated) (0870)	Salmonella Typhimurium vaccine (inactivated) for chickens (2361)
Pasteurella vaccine (inactivated) for sheep (2072)	Swine erysipelas vaccine (inactivated) (0064)
Porcine enzootic pneumonia vaccine (inactivated) (2448)	Vibriosis (cold-water) vaccine (inactivated) for salmonids (1580)
Porcine influenza vaccine (inactivated) (0963)	Vibriosis vaccine (inactivated) for salmonids (1581)
Porcine parvovirus vaccine (inactivated) (0965)	Yersiniosis vaccine (inactivated) for salmonids (1950)
Rabbit haemorrhagic disease vaccine (inactivated) (2325)	

Φυτικές δρόγες και σκευάσματα φυτικών δρογών

Aloes, Cape (0258)	Common selfheal fruit-spike (2439)
Birch leaf (1174)	Mastic (1876)
Butcher's broom (1847)	St. John's wort (1438)
Cascara dry extract, standardised (1844)	St. John's wort dry extract, quantified (1874)
Chamomile flower, Roman (0380)	

Ομοιοπαθητικά σκευάσματα

Homoeopathic preparations (1038)
Methods of preparation of homoeopathic stocks and potentisation (2371)
Mother tinctures for homoeopathic preparations (2029)
Pillules for homoeopathic preparations (2153)
Agaricus phalloides for homoeopathic preparations (2290)
Ammonium carbonicum for homoeopathic preparations (2916)
Aurum chloratum natronatum for homoeopathic preparations (2141)
Barium chloratum for homoeopathic preparations (2142)
Calcium iodatum for homoeopathic preparations (2144)
Ignatia for homoeopathic preparations (2513)
Magnesium phosphoricum for homoeopathic preparations (2505)
Nux-vomica for homoeopathic preparations (2514)

Μονογραφίες

Abacavir sulfate (2589)	N-Acetyltyrosine (1384)
Acamprosate calcium (1585)	Acitretin (1385)
Acarbose (2089)	Adapalene (2445)
Acebutolol hydrochloride (0871)	Adenine (0800)
Aceclofenac (1281)	Adipic acid (1586)
Acemetacin (1686)	Alanine (0752)
Acesulfame potassium (1282)	Alfadex (1487)
Acetazolamide (0454)	Alginic acid (0591)
Acetic acid, glacial (0590)	Allopurinol (0576)
Acetylcholine chloride (1485)	Almagate (2010)
Acetylcysteine (0967)	Alprenolol hydrochloride (0876)
Acetylsalicylic acid (0309)	Alum (0006)
N-Acetyltryptophan (1383)	Aluminium chloride hexahydrate (0971)

Aluminium hydroxide, hydrated, for adsorption (1664)
Aluminium oxide, hydrated (0311)
Aluminium phosphate gel (2166)
Aluminium phosphate, hydrated (1598)
Aluminium sulfate (0165)
Alverine citrate (2156)
Amantadine hydrochloride (0463)
Ambroxol hydrochloride (1489)
Amidotrizoic acid dihydrate (0873)
4-Aminobenzoic acid (1687)
Aminocaproic acid (0874)
Aminoglutethimide (1291)
Amiodarone hydrochloride (0803)
Amisulpride (1490)
Amitriptyline hydrochloride (0464)
Ammonia solution, concentrated (0877)
Ammonio methacrylate copolymer (type A) (2081)
Ammonio methacrylate copolymer (type B) (2082)
Ammonium bromide (1389)
Ammonium chloride (0007)
Ammonium glycyrrhizate (1772)
Ammonium hydrogen carbonate (1390)
Amoxicillin sodium (0577)
Ampicillin (0167)
Ampicillin sodium (0578)
Antazoline hydrochloride (0972)
Arginine (0806)
Arginine aspartate (2096)
Arginine hydrochloride (0805)
Articaine hydrochloride (1688)
Ascorbic acid (0253)
Ascorbyl palmitate (0807)
Asparagine monohydrate (2086)
Aspartame (0973)
Aspartic acid (0797)
Atomoxetine hydrochloride (2640)
Atorvastatin calcium trihydrate (2191)
Azithromycin (1649)
Barium sulfate (0010)
Basic butylated methacrylate copolymer (1975)
Beclometasone dipropionate (0654)
Benazepril hydrochloride (2388)
Benserazide hydrochloride (1173)
Bentonite (0467)
Benzbromarone (1393)
Benzoic acid (0066)
Betacarotene (1069)
Betadex (1070)
Betahistine mesilate (1071)
Betaxolol hydrochloride (1072)
Bezafibrate (1394)
Bicalutamide (2196)
Biotin (1073)
Biperiden hydrochloride (1074)
Borax (0013)
Boric acid (0001)
Brompheniramine maleate (0977)
Buflomedil hydrochloride (1398)
Bupivacaine hydrochloride (0541)
Butylhydroxyanisole (0880)
Caffeine (0267)
Caffeine monohydrate (0268)
Calcipotriol (2011)
Calcium acetate (2128)
Calcium ascorbate (1182)
Calcium carbonate (0014)
Calcium chloride dihydrate (0015)
Calcium chloride hexahydrate (0707)
Calcium dobesilate monohydrate (1183)
Calcium folinate (0978)
Calcium glucoheptonate (1399)
Calcium gluconate (0172)
Calcium gluconate, anhydrous (2364)
Calcium gluconate for injection (0979)
Calcium glycerophosphate (0980)
Calcium hydrogen phosphate (0981)
Calcium hydrogen phosphate dihydrate (0116)
Calcium hydroxide (1078)
Calcium lactate (2118)
Calcium lactate monohydrate (2117)
Calcium lactate pentahydrate (0468)
Calcium lactate trihydrate (0469)
Calcium levofolinate pentahydrate (1606)
Calcium levulinate dihydrate (1296)
Calcium pantothenate (0470)
Calcium phosphate (1052)
Calcium sulfate dihydrate (0982)
Caprylic acid (1401)
Caprylocaproyl macrogolglycerides (1184)
Captopril (1079)
Carbachol (1971)
Carbamazepine (0543)
Carbasalate calcium (1185)
Carbidopa (0755)
Carbocysteine (0885)
Carbomers (1299)
Carisoprodol (1689)
Carmellose (2360)
Carmellose calcium (0886)
Carmellose sodium (0472)

Carmellose sodium, low-substituted (1186)
Carvedilol (1745)
Cefaclor (0986)
Cefamandole nafate (1402)
Cefoperazone sodium (1404)
Cefprozil monohydrate (2342)
Ceftazidime pentahydrate (1405)
Celecoxib (2591)
Cellulose acetate (0887)
Cellulose acetate butyrate (1406)
Cellulose acetate phthalate (0314)
Cellulose, microcrystalline (0316)
Cellulose, powdered (0315)
Cetostearyl isononanoate (1085)
Chenodeoxycholic acid (1189)
Chitosan hydrochloride (1774)
Chloral hydrate (0265)
Chlorobutanol (0382)
Chloroquine phosphate (0544)
Chloroquine sulfate (0545)
Chlorphenamine maleate (0386)
Chlorpromazine hydrochloride (0475)
Chlorpropamide (1087)
Chlorprothixene hydrochloride (0815)
Chlortetracycline hydrochloride (0173)
Cholecalciferol concentrate (powder form) (0574)
Cholecalciferol concentrate (water-dispersible form) (0598)
Cholesterol for parenteral use (2397)
Chondroitin sulfate sodium (2064)
Ciclesonide (2703)
Ciclopirox (1407)
Ciclopirox olamine (1302)
Ciclosporin (0994)
Cilastatin sodium (1408)
Cimetidine (0756)
Cimetidine hydrochloride (1500)
Cinchocaine hydrochloride (1088)
Cinnarizine (0816)
Ciprofloxacin (1089)
Ciprofloxacin hydrochloride (0888)
Citalopram hydrobromide (2288)
Citalopram hydrochloride (2203)
Citric acid (0455)
Citric acid monohydrate (0456)
Clarithromycin (1651)
Clebopride malate (1303)
Clodronate disodium tetrahydrate (1777)
Clofazimine (2054)
Clomipramine hydrochloride (0889)
Clopamide (1747)
Clopidogrel hydrogen sulfate (2531)
Clozapine (1191)
Colestyramine (1775)
Copovidone (0891)
Copper sulfate (0893)
Croscarmellose sodium (0985)
Crospovidone (0892)
Cyclophosphamide (0711)
Cysteine hydrochloride monohydrate (0895)
Cystine (0998)
Deferoxamine mesilate (0896)
Demeclocycline hydrochloride (0176)
Deptropine citrate (1308)
Desipramine hydrochloride (0481)
Desloratadine (2570)
Dexamethasone acetate (0548)
Dexchlorpheniramine maleate (1196)
Dexpanthenol (0761)
Dextran 1 for injection (1506)
Dextran 40 for injection (0999)
Dextran 60 for injection (1000)
Dextran 70 for injection (1001)
Dextranomer (2238)
Dextrin (1507)
Diazepam (0022)
Diclofenac potassium (1508)
Diclofenac sodium (1002)
Didanosine (2200)
Diethylcarbamazine citrate (0271)
Diltiazem hydrochloride (1004)
Dimethyl sulfoxide (0763)
Dimethylacetamide (1667)
Dimeticone (0138)
Diosmin (1611)
Dipotassium phosphate (1003)
Diprophylline (0486)
Dirithromycin (1313)
Disodium edetate (0232)
Disodium phosphate (1509)
Disodium phosphate dihydrate (0602)
Disodium phosphate dodecahydrate (0118)
Disopyramide (1006)
Disopyramide phosphate (1005)
Disulfiram (0603)
Dobutamine hydrochloride (1200)
Docetaxel (2593)
Docetaxel trihydrate (2449)
Docusate sodium (1418)
Dodecyl gallate (2078)
Domperidone (1009)
Domperidone maleate (1008)
Dopamine hydrochloride (0664)

Dopexamine dihydrochloride (1748)
Dosulepin hydrochloride (1314)
Doxapram hydrochloride (1201)
Doxepin hydrochloride (1096)
Doxycycline hyclate (0272)
Doxycycline monohydrate (0820)
Droperidol (1010)
Duloxetine hydrochloride (2594)
Dutasteride (2641)
Edetic acid (1612)
Enalapril maleate (1420)
Enalaprilat dihydrate (1749)
Enoxolone (1511)
Entacapone (2574)
Ephedrine (0488)
Epinastine hydrochloride (2411)
Ergocalciferol (0082)
Ergotamine tartrate (0224)
Erythromycin (0179)
Erythromycin estolate (0552)
Erythromycin ethylsuccinate (0274)
Erythromycin lactobionate (1098)
Erythromycin stearate (0490)
Esketamine hydrochloride (1742)
Etacrynic acid (0457)
Etamsylate (1204)
Ethacridine lactate monohydrate (1591)
Ethambutol hydrochloride (0553)
Ethionamide (0141)
Ethosuximide (0764)
Ethylcellulose (0822)
Ethylenediamine (0716)
Etidronate disodium (1778)
Etilefrine hydrochloride (1205)
Etodolac (1422)
Etofenamate (1513)
Etoposide (0823)
Famotidine (1012)
Fenbufen (1209)
Fenofibrate (1322)
Ferric chloride hexahydrate (1515)
Ferrous gluconate (0493)
Fexofenadine hydrochloride (2280)
Flavoxate hydrochloride (1692)
Flecainide acetate (1324)
Fluconazole (2287)
Flucytosine (0766)
Fludarabine phosphate (1781)
Flumequine (1517)
Fluorouracil (0611)
Fluoxetine hydrochloride (1104)
Flupentixol dihydrochloride (1693)
Fluphenazine decanoate (1014)
Fluphenazine dihydrochloride (0904)
Fluphenazine enantate (1015)
Flurbiprofen (1519)
Flutamide (1423)
Flutrimazole (1424)
Fluvastatin sodium (2333)
Fluvoxamine maleate (1977)
Foscarnet sodium hexahydrate (1520)
Fosfomycin calcium (1328)
Fosfomycin sodium (1329)
Fosfomycin trometamol (1425)
Fosinopril sodium (1751)
Fulvestrant (2443)
Furosemide (0391)
Gabapentin (2173)
Galantamine hydrobromide (2366)
Ganciclovir (1752)
Gemcitabine hydrochloride (2306)
Gemfibrozil (1694)
Glibenclamide (0718)
Gliclazide (1524)
Glucosamine hydrochloride (2446)
Glucosamine sulfate potassium chloride (2708)
Glucosamine sulfate sodium chloride (2447)
Glucose (0177)
Glucose, liquid (1330)
Glucose, liquid, spray-dried (1525)
Glutamic acid (0750)
Glutathione (1670)
Glycerol (0496)
Glycerol (85 per cent) (0497)
Glycerol formal (1671)
Glycerol monolinoleate (1429)
Glycerol mono-oleate (1430)
Glycerol monostearate 40-55 (0495)
Glycine (0614)
Guaifenesin (0615)
Guanethidine monosulfate (0027)
Halofantrine hydrochloride (1979)
Heparin calcium (0332)
Heparin sodium (0333)
Heparins, low-molecular-mass (0828)
Heptaminol hydrochloride (1980)
Hexetidine (1221)
Histidine (0911)
Histidine hydrochloride monohydrate (0910)
Hydralazine hydrochloride (0829)
Hydrochloric acid, concentrated (0002)
Hydrochloric acid, dilute (0003)
Hydroxycarbamide (1616)

Hydroxyethylcellulose (0336)
Hydroxypropylbetadex (1804)
Hydroxypropylcellulose (0337)
Hydroxyzine hydrochloride (0916)
Hymecromone (1786)
Hypromellose (0348)
Hypromellose phthalate (0347)
Ibuprofen (0721)
Ifosfamide (1529)
Imipramine hydrochloride (0029)
Indapamide (1108)
Indinavir sulfate (2214)
Indometacin (0092)
Iodixanol (2215)
Iohexol (1114)
Iopamidol (1115)
Iopromide (1753)
Iotrolan (1754)
Ioxaglic acid (2009)
Irbesartan (2465)
Isoleucine (0770)
Isoniazid (0146)
Isotretinoin (1019)
Isoxsuprine hydrochloride (1119)
Ivermectin (1336)
Josamycin (1983)
Kaolin, heavy (0503)
Ketamine hydrochloride (1020)
Ketoconazole (0921)
Ketoprofen (0922)
Ketorolac trometamol (1755)
Labetalol hydrochloride (0923)
Lactic acid (0458)
(S)-Lactic acid (1771)
Lactobionic acid (1647)
Lactose (1061)
Lactose monohydrate (0187)
Lamivudine (2217)
Lamotrigine (1756)
Lauroyl macrogolglycerides (1231)
Leflunomide (2330)
Leucine (0771)
Levamisole hydrochloride (0726)
Levetiracetam (2535)
Levocarnitine (1339)
Levodopa (0038)
Lidocaine hydrochloride (0227)
Lincomycin hydrochloride (0583)
Linoleoyl macrogolglycerides (1232)
Lithium carbonate (0228)
Lithium citrate (0621)
Lopinavir (2615)
Losartan potassium (2232)
Lovastatin (1538)
Lufenuron for veterinary use (2177)
Lysine acetate (2114)
Lysine hydrochloride (0930)
Macrogol 20 glycerol monostearate (2044)
Macrogol stearate (1234)
Macrogolglycerol hydroxystearate (1083)
Macrogolglycerol ricinoleate (1082)
Macrogols (1444)
Magaldrate (1539)
Magnesium acetate tetrahydrate (2035)
Magnesium aspartate dihydrate (1445)
Magnesium carbonate, heavy (0043)
Magnesium carbonate, light (0042)
Magnesium chloride 4.5-hydrate (1341)
Magnesium chloride hexahydrate (0402)
Magnesium citrate (2339)
Magnesium citrate dodecahydrate (2401)
Magnesium citrate nonahydrate (2402)
Magnesium gluconate (2161)
Magnesium glycerophosphate (1446)
Magnesium hydroxide (0039)
Magnesium lactate dihydrate (2160)
Magnesium oxide, heavy (0041)
Magnesium oxide, light (0040)
Magnesium peroxide (1540)
Magnesium pidolate (1619)
Magnesium sulfate heptahydrate (0044)
Magnesium trisilicate (0403)
Maleic acid (0365)
Malic acid (2080)
Maltodextrin (1542)
Manganese gluconate (2162)
Manganese glycerophosphate, hydrated (2163)
Manganese sulfate monohydrate (1543)
Mannitol (0559)
Mefloquine hydrochloride (1241)
Meglumine (2055)
Meloxicam (2373)
Mepivacaine hydrochloride (1242)
Meprobamate (0407)
Mepyramine maleate (0278)
Meropenem trihydrate (2234)
Mesalazine (1699)
Mesna (1674)
Metamizole sodium monohydrate (1346)
Metformin hydrochloride (0931)
Methenamine (1545)
Methionine (1027)
DL-Methionine (0624)
Methotrexate (0560)
Methylcellulose (0345)

Methyldopa (0045)
Methylene chloride (0932)
Methylhydroxyethylcellulose (0346)
Methylphenidate hydrochloride (2235)
N-Methylpyrrolidone (1675)
Metoclopramide (1348)
Metoclopramide hydrochloride (0674)
Metolazone (1757)
Metoprolol succinate (1448)
Metoprolol tartrate (1028)
Metrifonate (1133)
Metronidazole (0675)
Metronidazole benzoate (0934)
Mexiletine hydrochloride (1029)
Minocycline hydrochloride dihydrate (1030)
Minoxidil (0937)
Modafinil (2307)
Molsidomine (1701)
Montelukast sodium (2583)
Mycophenolate mofetil (1700)
Nabumetone (1350)
Nadolol (1789)
Naftidrofuryl hydrogen oxalate (1594)
Nalidixic acid (0701)
Naproxen (0731)
Naproxen sodium (1702)
Nateglinide (2575)
Neohesperidin-dihydrochalcone (1547)
Nevirapine (2255)
Nevirapine hemihydrate (2479)
Niclosamide (0679)
Nicotinamide (0047)
Nicotinic acid (0459)
Niflumic acid (2115)
Nifuroxazide (1999)
Nikethamide (0233)
Nilutamide (2256)
Nimesulide (1548)
Nitric acid (1549)
Nizatidine (1453)
Nonoxinol 9 (1454)
Norethisterone acetate (0850)
Norfloxacin (1248)
Nortriptyline hydrochloride (0941)
Nystatin (0517)
Octoxinol 10 (1553)
Octyl gallate (2057)
Octyldodecanol (1136)
Ofloxacin (1455)
Olanzapine (2258)
Oleoyl macrogolglycerides (1249)
Olmesartan medoxomil (2600)
Olsalazine sodium (1457)
Omeprazole sodium (1032)
Orciprenaline sulfate (1033)
Orphenadrine citrate (1759)
Orphenadrine hydrochloride (1760)
Oxolinic acid (1353)
Oxybuprocaine hydrochloride (1251)
Oxybutynin hydrochloride (1354)
Oxytetracycline dihydrate (0199)
Oxytetracycline hydrochloride (0198)
Paclitaxel (1794)
Pamidronate disodium pentahydrate (1779)
Pantoprazole sodium sesquihydrate (2296)
Paracetamol (0049)
Paroxetine hydrochloride (2283)
Paroxetine hydrochloride hemihydrate (2018)
Pefloxacin mesilate dihydrate (1460)
Pemetrexed disodium heptahydrate (2637)
Penbutolol sulfate (1461)
Penicillamine (0566)
Pentamidine diisethionate (1137)
Pentobarbital sodium (0419)
Pentoxifylline (0851)
Phenazone (0421)
Pheniramine maleate (1357)
Phenolphthalein (1584)
Phenylalanine (0782)
Phenylbutazone (0422)
Phenylpropanolamine hydrochloride (0683)
Phenytoin (1253)
Phenytoin sodium (0521)
Phloroglucinol (2301)
Phloroglucinol dihydrate (2302)
Phosphoric acid, concentrated (0004)
Phosphoric acid, dilute (0005)
Phthalylsulfathiazole (0352)
Picotamide monohydrate (1358)
Pindolol (0634)
Pioglitazone hydrochloride (2601)
Pipemidic acid trihydrate (1743)
Piperacillin (1169)
Piperacillin sodium (1168)
Piperazine adipate (0423)
Piperazine citrate (0424)
Piperazine hydrate (0425)
Piracetam (1733)
Piretanide (1556)
Piroxicam (0944)
Pivmecillinam hydrochloride (1359)
Polyacrylate dispersion 30 per cent (0733)

Polysorbate 20 (0426)
Polysorbate 40 (1914)
Polysorbate 60 (0427)
Polysorbate 80 (0428)
Poly(vinyl acetate) (1962)
Poly(vinyl alcohol) (1961)
Potassium acetate (1139)
Potassium bromide (0184)
Potassium carbonate (1557)
Potassium chloride (0185)
Potassium citrate (0400)
Potassium dihydrogen phosphate (0920)
Potassium hydrogen aspartate hemihydrate (2076)
Potassium hydrogen carbonate (1141)
Potassium hydrogen tartrate (1984)
Potassium hydroxide (0840)
Potassium iodide (0186)
Potassium metabisulfite (2075)
Potassium nitrate (1465)
Potassium perchlorate (1987)
Potassium sodium tartrate tetrahydrate (1986)
Potassium sorbate (0618)
Potassium sulfate (1622)
Povidone (0685)
Pramipexole dihydrochloride monohydrate (2416)
Pravastatin sodium (2059)
Prazepam (1466)
Praziquantel (0855)
Prilocaine (1362)
Prilocaine hydrochloride (1363)
Primidone (0584)
Probenecid (0243)
Procainamide hydrochloride (0567)
Procaine hydrochloride (0050)
Proline (0785)
Promethazine hydrochloride (0524)
Propacetamol hydrochloride (1366)
Propafenone hydrochloride (2103)
Propranolol hydrochloride (0568)
Propyl gallate (1039)
Propylene glycol (0430)
Propylene glycol monolaurate (1915)
Propylthiouracil (0525)
Propyphenazone (0636)
Protamine sulfate (0569)
Proxyphylline (0526)
Pyrantel embonate (1680)
Pyrazinamide (0859)
Pyridostigmine bromide (1255)
Pyridoxine hydrochloride (0245)
Pyrrolidone (2180)
Quetiapine fumarate (2541)
Quinapril hydrochloride (1763)
Raloxifene hydrochloride (2375)
Ranitidine hydrochloride (0946)
Ribavirin (2109)
Riboflavin sodium phosphate (0786)
Rifampicin (0052)
Rifamycin sodium (0432)
Rifaximin (2362)
Risedronate sodium 2.5-hydrate (2572)
Ritonavir (2136)
Rivastigmine (2629)
Rivastigmine hydrogen tartrate (2630)
Rizatriptan benzoate (2585)
Rocuronium bromide (1764)
Ropivacaine hydrochloride monohydrate (2335)
Rosuvastatin calcium (2631)
Roxithromycin (1146)
Saccharin (0947)
Saccharin sodium (0787)
Salicylic acid (0366)
Saquinavir mesilate (2267)
Selegiline hydrochloride (1260)
Serine (0788)
Sertraline hydrochloride (1705)
Shellac (1149)
Sildenafil citrate (2270)
Silica, colloidal anhydrous (0434)
Silica, colloidal hydrated (0738)
Silica, dental type (1562)
Silica, hydrophobic colloidal (2208)
Simeticone (1470)
Simvastatin (1563)
Sodium acetate trihydrate (0411)
Sodium alendronate trihydrate (1564)
Sodium alginate (0625)
Sodium amidotrizoate (1150)
Sodium aminosalicylate dihydrate (1993)
Sodium ascorbate (1791)
Sodium benzoate (0123)
Sodium bromide (0190)
Sodium calcium edetate (0231)
Sodium caprylate (1471)
Sodium carbonate (0773)
Sodium carbonate decahydrate (0191)
Sodium carbonate monohydrate (0192)
Sodium chloride (0193)
Sodium citrate (0412)
Sodium cromoglicate (0562)
Sodium cyclamate (0774)

Sodium dihydrogen phosphate dihydrate (0194)
Sodium ethyl parahydroxybenzoate (2134)
Sodium glycerophosphate, hydrated (1995)
Sodium hyaluronate (1472)
Sodium hydrogen carbonate (0195)
Sodium hydroxide (0677)
Sodium iodide (0196)
Sodium lactate solution (1151)
Sodium (*S*)-lactate solution (2033)
Sodium metabisulfite (0849)
Sodium methyl parahydroxybenzoate (1262)
Sodium molybdate dihydrate (1565)
Sodium nitrite (1996)
Sodium perborate, hydrated (1997)
Sodium phenylbutyrate (2183)
Sodium polystyrene sulfonate (1909)
Sodium propionate (2041)
Sodium propyl parahydroxybenzoate (1263)
Sodium salicylate (0413)
Sodium starch glycolate (type A) (0983)
Sodium starch glycolate (type B) (0984)
Sodium starch glycolate (type C) (1566)
Sodium sulfate, anhydrous (0099)
Sodium sulfate decahydrate (0100)
Sodium sulfite (0775)
Sodium sulfite heptahydrate (0776)
Sodium thiosulfate (0414)
Sodium valproate (0678)
Sorbic acid (0592)
Sorbitan laurate (1040)
Sorbitan oleate (1041)
Sorbitan palmitate (1042)
Sorbitan sesquioleate (1916)
Sorbitan stearate (1043)
Sorbitan trioleate (1044)
Sotalol hydrochloride (2004)
Spiramycin (0293)
Stannous chloride dihydrate (1266)
Starches, hydroxyethyl (1785)
Stearoyl macrogolglycerides (1268)
Sucralfate (1796)
Sucralose (2368)
Sucrose monopalmitate (2319)
Sucrose stearate (2318)
Sugar spheres (1570)
Sulbactam sodium (2209)
Sulfacetamide sodium (0107)
Sulfadiazine (0294)
Sulfadimethoxine (2741)
Sulfadimidine (0295)
Sulfadoxine (0740)
Sulfafurazole (0741)
Sulfaguanidine (1476)
Sulfamerazine (0358)
Sulfamethizole (0637)
Sulfamethoxazole (0108)
Sulfanilamide (1571)
Sulfasalazine (0863)
Sulfathiazole (0742)
Sulfinpyrazone (0790)
Sulfuric acid (1572)
Sulindac (0864)
Sulpiride (1045)
Sultamicillin (2211)
Sultamicillin tosilate dihydrate (2212)
Sumatriptan succinate (1573)
Suxibuzone (1574)
Tamsulosin hydrochloride (2131)
Tartaric acid (0460)
Teicoplanin (2358)
Tenoxicam (1156)
Terazosin hydrochloride dihydrate (2021)
Tetracaine hydrochloride (0057)
Tetracycline (0211)
Tetracycline hydrochloride (0210)
Theobromine (0298)
Theophylline (0299)
Theophylline monohydrate (0302)
Theophylline-ethylenediamine (0300)
Theophylline-ethylenediamine hydrate (0301)
Thiamazole (1706)
Thiamine hydrochloride (0303)
Thiamine nitrate (0531)
Thiamphenicol (0109)
Thioridazine (2005)
Thioridazine hydrochloride (0586)
Threonine (1049)
Tiabendazole (0866)
Tiapride hydrochloride (1575)
Tiaprofenic acid (1157)
Ticlopidine hydrochloride (1050)
Tilidine hydrochloride hemihydrate (1767)
Timolol maleate (0572)
Tinidazole (1051)
Tiotropium bromide monohydrate (2420)
Titanium dioxide (0150)
Tizanidine hydrochloride (2578)
DL- α -Tocopheryl hydrogen succinate (1258)
RRR- α -Tocopheryl hydrogen succinate (1259)

Tolbutamide (0304)	Tyrosine (1161)
Torasemide (2132)	Urea (0743)
Tramadol hydrochloride (1681)	Ursodeoxycholic acid (1275)
Tranexamic acid (0875)	Valaciclovir hydrochloride (1768)
Trapidil (1576)	Valaciclovir hydrochloride, hydrated (2751)
Trehalose dihydrate (2297)	Valine (0796)
Tretinoin (0693)	Valproic acid (1378)
Triamcinolone hexacetonide (0867)	Valsartan (2423)
Tribenoside (1740)	Vancomycin hydrochloride (1058)
Tributyl acetylcitrate (1770)	Venlafaxine hydrochloride (2119)
Tri- <i>n</i> -butyl phosphate (1682)	Verapamil hydrochloride (0573)
Triethyl citrate (1479)	Vigabatrin (2305)
Triflusal (1377)	Voriconazole (2576)
Triglycerides, medium-chain (0868)	Wool fat, hydrogenated (0969)
Trimebutine maleate (2182)	Xylose (1278)
Trimethadione (0440)	Zidovudine (1059)
Trimethoprim (0060)	Zinc gluconate (2164)
Trimipramine maleate (0534)	Ziprasidone hydrochloride monohydrate (2421)
Trolamine (1577)	Zopiclone (1060)
Trometamol (1053)	Zuclopenthixol decanoate (1707)
Troxerutin (2133)	
Tryptophan (1272)	

ΚΕΙΜΕΝΑ ΠΟΥ ΕΧΟΥΝ ΔΙΟΡΘΩΘΕΙ ΣΤΗΝ 9^Η ΕΚΔΟΣΗ

Τα παρακάτω κείμενα έχουν διορθωθεί στην 9^η έκδοση της Ευρωπαϊκής Φαρμακοποιίας και φέρουν πάνω από τον τίτλο τη σημείωση "διόρθωση 9.0". Οι διορθώσεις πρέπει να λαμβάνονται υπ' όψιν το συντομότερο δυνατό και όχι αργότερα από την 31^η Αυγούστου 2016.

ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ

2.2.27. Thin-layer chromatography

ΜΟΝΟΓΡΑΦΙΕΣ

Ραδιοφαρμακευτικά σκευάσματα και πρώτες ύλες για την παρασκευή τους

Iobenguane sulfate for radiopharmaceutical preparations (2351)

Ομοιοπαθητικά σκευάσματα

Hedera helix for homoeopathic preparations (2092)

Hydrastis canadensis for homoeopathic preparations (2500)

Hyoscyamus for homoeopathic preparations (2091)

Hypericum for homoeopathic preparations (2028)

Sulfur for homoeopathic preparations (2515)

Μονογραφίες

Acacia, spray-dried (0308)

Amorolfine hydrochloride (2756)

Calcium stearate (0882)

Guar (1218)

Guar galactomannan (0908)

Isoflurane (1673)

Mirtazapine (2338)

Poly(vinyl acetate) dispersion 30 per cent (2152)	Starch, pregelatinised (1267)
Selamectin for veterinary use (2268)	Stearic acid (1474)
Sodium stearyl fumarate (1567)	Xanthan gum (1277)
	Zinc chloride (0110)

ΕΝΑΡΜΟΝΙΣΜΕΝΑ ΚΕΙΜΕΝΑ

Τα παρακάτω κείμενα έχουν εναρμονισθεί στα πλαίσια της εναρμόνισης των Φαρμακοποιιών

ΜΟΝΟΓΡΑΦΙΕΣ

Μονογραφίες

Carmellose (2360)
Cellulose, microcrystalline (0316)
Cellulose, powdered (0315)
Croscarmellose sodium (0985)
Povidone (0685)

ΚΕΙΜΕΝΑ ΤΩΝ ΟΠΟΙΩΝ Ο ΤΙΤΛΟΣ ΑΛΛΑΞΕ ΣΤΗΝ 9^Η ΕΚΔΟΣΗ

ΜΟΝΟΓΡΑΦΙΕΣ

Μονογραφίες

Ampicillin (0167) (προηγούμενος *Ampicillin, anhydrous*)
Beclometasone dipropionate (0654) (προηγούμενος *Beclometasone dipropionate, anhydrous*)
Calcipotriol (2011) (προηγούμενος *Calcipotriol, anhydrous*)
Calcium acetate (2128) (προηγούμενος *Calcium acetate, anhydrous*)
Calcium hydrogen phosphate (0981) (προηγούμενος *Calcium hydrogen phosphate, anhydrous*)
Calcium lactate (2118) (προηγούμενος *Calcium lactate, anhydrous*)
Chlorobutanol (0382) (προηγούμενος *Chlorobutanol, anhydrous*)
Citric acid (0455) (προηγούμενος *Citric acid, anhydrous*)
Copper sulfate (0893) (προηγούμενος *Copper sulfate, anhydrous*)
Disodium phosphate (1509) (προηγούμενος *Disodium phosphate, anhydrous*)
Docetaxel (2593) (προηγούμενος *Docetaxel, anhydrous*)
Ephedrine (0488) (προηγούμενος *Ephedrine, anhydrous*)
Glucose (0177) (προηγούμενος *Glucose, anhydrous*)
Lactose (1061) (προηγούμενος *Lactose, anhydrous*)
Lufenuron for veterinary use (2177) (προηγούμενος *Lufenuron (anhydrous) for veterinary use*)
Magnesium citrate (2339) (προηγούμενος *Magnesium citrate, anhydrous*)
Nevirapine (2255) (προηγούμενος *Nevirapine, anhydrous*)
Niclosamide (0679) (προηγούμενος *Niclosamide, anhydrous*)
Paroxetine hydrochloride (2283) (προηγούμενος *Paroxetine hydrochloride, anhydrous*)
Phloroglucinol (2301) (προηγούμενος *Phloroglucinol, anhydrous*)
Sodium carbonate (0773) (προηγούμενος *Sodium carbonate, anhydrous*)
Sodium sulfite (0775) (προηγούμενος *Sodium sulfite, anhydrous*)
Theophylline-ethylenediamine (0300) (προηγούμενος *Theophylline-ethylenediamine, anhydrous*)
Torasemide (2132) (προηγούμενος *Torasemide, anhydrous*)
Valaciclovir hydrochloride (1768) (προηγούμενος *Valaciclovir hydrochloride, anhydrous*)