



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ  
ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ

ΜΕΣΟΓΕΙΩΝ 284, 15562, ΧΟΛΑΡΓΟΣ

ΔΙΕΥΘΥΝΣΗ ΕΡΓΑΣΤΗΡΙΩΝ

ΤΜΗΜΑ ΦΑΡΜΑΚΟΠΟΙΑΣ

ΑΝΑΡΤΗΤΕΑ ΣΤΟ ΔΙΑΔΙΚΤΥΟ

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Αθήνα, 09-12-2019  
Αριθ. Πρωτ. 153957  
Προς: Όπως ο πίνακας αποδεκτών

## ΕΓΚΥΚΛΙΟΣ

### Θέμα: Θέση σε ισχύ της Δέκατης (10.0) Έκδοσης της Ευρωπαϊκής Φαρμακοποιίας

Σας κοινοποιούμε τα νέα, αναθεωρημένα και διορθωμένα κείμενα που περιέχονται στη Δέκατη (10.0) Έκδοση της Ευρωπαϊκής Φαρμακοποιίας και τίθενται σε ισχύ από την 1<sup>η</sup>/1/2020.

**Η Δέκατη Έκδοση αποτελείται από νέα κείμενα καθώς και όλα τα κείμενα της 9ης έκδοσης της Ευρ.Φ., κάποια εκ των οποίων έχουν αναθεωρηθεί ή διορθωθεί.**

Υπενθυμίζεται ότι η 9<sup>η</sup> έκδοση της Ευρωπαϊκής Φαρμακοποιίας έχει τεθεί σε ισχύ με τις υπ' αριθμ. πρωτ. 94712/8-12-2016 (έκδοση 9.0), 19402/8-3-2017 (συμπλ. 9.1), 59960/3-7-2017 (συμπλ. 9.2), 110583/07-12-2017 (συμπλ. 9.3), 41275/13-04-2018 (συμπλ. 9.4), 68755/26-6-2018 (συμπλ. 9.5), 125974/10-12-2018 (συμπλ. 9.6), 27356/13-3-2019 (συμπλ. 9.7) & 74462/11-6-2019 (συμπλ. 9.8) σχετικές εγκυκλίους μας.

Ο κατάλογος των μονογραφιών και των κεφαλαίων γενικού μέρους της 10ης Έκδοσης τα οποία είναι νέα, αναθεωρημένα, διορθωμένα ή ο τίτλος ή η αρίθμηση των οποίων έχουν αλλάξει παρατίθεται στη συνέχεια.

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.

Ο ΠΡΟΕΔΡΟΣ ΔΣ/ΕΟΦ

ΔΗΜΗΤΡΙΟΣ ΦΙΛΙΠΠΟΥ

**Αποδέκτες για ενέργεια:**

1. **Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης**  
Δ/νση 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 & Αργινίου 3, 15232, Χαλάνδρι, Αθήνα ([sfee@sfee.gr](mailto:sfee@sfee.gr))
4. **Πανελλήνια Ένωση Φαρμακοβιομ/νίας**  
Λ. Κηφισίας 324-326, Ν. Ψυχικό, Τ.Κ. 15451 ([pef@pef.gr](mailto:pef@pef.gr))
5. **Σύνδεσμος Αντιπροσώπων, Εισαγωγέων & Παρασκευαστών Κτην/κών Φαρμάκων**  
Αγίου Κωνσταντίνου 40, Εμπορικό κέντρο ΑΙΘΡΟ, Μαρούσι, 15124, Αττική.
6. **ΔΥΓ/ΓΕΕΘΑ**  
Μεσογείων 227, Τ.Κ. 11525, Στρατοπ. Παπάγου  
(με την παράκληση ενημέρωσης των Νοσηλευτικών Ιδρυμάτων δικαιοδοσίας του)
7. **ΔΥΠΕΕ**  
(με την παράκληση ενημέρωσης των Νοσηλευτικών Ιδρυμάτων & Κέντρων Υγείας της περιφέρειάς τους)

**Εσωτερική Διανομή (μόνο με ηλεκτρονικό ταχυδρομείο):**

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

**ΝΕΑ, ΑΝΑΘΕΩΡΗΜΕΝΑ ΚΑΙ ΔΙΟΡΘΩΜΕΝΑ ΚΕΙΜΕΝΑ ΤΗΣ ΔΕΚΑΤΗΣ (10.0)  
ΕΚΔΟΣΗΣ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

**ΝΕΑ ΚΕΙΜΕΝΑ ΣΤΗ ΔΕΚΑΤΗ (10.0) ΕΚΔΟΣΗ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ  
ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

*Τα παρακάτω κείμενα εμφανίζονται για πρώτη φορά στην Ευρωπαϊκή Φαρμακοποιία. Θα τεθούν σε εφαρμογή το αργότερο την **1<sup>η</sup> Ιανουαρίου 2020**.*

**ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ**

- 2.6.35. Quantification and characterisation of residual host-cell DNA
- 2.9.49. Powder flow properties by shear cell methods
- 2.9.52. Scanning electron microscopy
- 3.3. Containers for human blood and blood components, and materials used in their manufacture, transfusion sets and materials used in their manufacture, syringes
- 5.25. Process analytical technology

**ΜΟΝΟΓΡΑΦΙΕΣ**

**Εμβόλια για κτηνιατρική χρήση**

Infectious pancreatic necrosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (3063)

**Φυτικές δρόγες και σκευάσματα φυτικών δρογών**

Abelmoschi corolla (2827)

Serratula coronata herb (2754)

**Μονογραφίες**

Benzylamine hydrochloride  
(2759)

Cocoa butter (2607)

Dronedarone hydrochloride  
(3039)

Octreotide (2414)

Prasugrel hydrochloride (3040)

Squalene (2805)

Tapentadol hydrochloride (3035)

Tetracaine (2909)

Topiramate (2616)

Vincamine (1800)

**ΚΕΙΜΕΝΑ ΠΟΥ ΕΧΟΥΝ ΑΝΑΘΕΩΡΗΘΕΙ ΣΤΗ ΔΕΚΑΤΗ (10.0) ΕΚΔΟΣΗ ΤΗΣ  
ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

*Τα παρακάτω κείμενα έχουν αναθεωρηθεί τεχνικά σε σχέση με την προηγούμενη δημοσίευσή τους. Θα τεθούν σε εφαρμογή την **1<sup>η</sup> Ιανουαρίου 2020** το αργότερο.*

**ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ**

- 2.2.25. Absorption spectrophotometry, ultraviolet and visible
- 2.6.8. Pyrogens
- 2.6.33. Residual pertussis toxin
- 2.7.2. Microbiological assay of antibiotics

- 2.7.23. Numeration of CD34/CD45+ cells in haematopoietic products
- 2.7.35. Immunonephelometry for vaccine component assay
- 2.8.25. High-performance thin-layer chromatography of herbal drugs and herbal drug preparations
- 2.9.1. Disintegration of tablets and capsules
- 2.9.20. Particulate contamination: visible particles
- 3.1.13. Plastic additives
- 3.3.1. Materials for containers for human blood and blood components
- 3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components
- 3.3.3. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components
- 3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution
- 3.3.7. Sets for the transfusion of blood and blood components
- 3.3.8. Sterile single-use plastic syringes
- 4. Reagents
- 5.3. Statistical analysis of results of biological assays and tests
- 5.8. Pharmacopoeial harmonisation
- 5.21. Chemometric methods applied to analytical data
- 5.22. Names of herbal drugs used in traditional Chinese medicine
- 5.24. Chemical imaging

## **ΜΟΝΟΓΡΑΦΙΕΣ**

### **Φαρμακοτεχνικές μορφές**

Powders, oral (1165)

### **Εμβόλια για ανθρώπινη χρήση**

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (2764)

Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)

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

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (1934)

Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2329)

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)

Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)

Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) (2149)

Influenza vaccine (whole virion, inactivated, prepared in cell cultures) (2308)

Pertussis vaccine (acellular, component, adsorbed) (1356)

Pertussis vaccine (acellular, co-purified, adsorbed) (1595)

Poliomyelitis vaccine (oral) (0215)

Yellow fever vaccine (live) (0537)

#### **Εμβόλια για κτηνιατρική χρήση**

Enteric redmouth disease vaccine (inactivated) for rainbow trout (1950)

Immunosera for human use

Botulinum antitoxin (0085)

#### **Φυτικές δρόγες και σκευάσματα φυτικών δρογών**

Indigo plant leaf (2727)

#### **Μονογραφίες**

Alfacalcidol (1286)

Aluminium magnesium silicate (1388)

Anticoagulant and preservative solutions for human blood (0209)

Apomorphine hydrochloride hemihydrate (0136)

Arachis oil, hydrogenated (1171)

Benserazide hydrochloride (1173)

Biotin (1073)

Boldine (2971)

Borage (starflower) oil, refined (2105)

Caffeine (0267)

Caffeine monohydrate (0268)

Candesartan cilexetil (2573)

Carmellose sodium (0472)

Carmellose sodium, low-substituted (1186)

Carmustine (1187)

Castor oil, hydrogenated (1497)

Castor oil, refined (2367)

Castor oil, virgin (0051)

Cellulose, microcrystalline (0316)

Cetyl palmitate (1906)

Chlorpromazine hydrochloride (0475)

Chlortalidone (0546)

Cholesterol for parenteral use (2397)

Cod-liver oil (type A) (1192)

Cod-liver oil (type B) (1193)

Copovidone (0891)

Cottonseed oil, hydrogenated (1305)

Croscarmellose sodium (0985)

Desipramine hydrochloride (0481)

Diacerein (2409)

Diethylene glycol palmitostearate (1415)

Ethylene glycol monopalmitostearate (1421)

Evening primrose oil, refined (2104)

Fenoterol hydrobromide (0901)

Fish oil, rich in omega-3 acids (1912)

Follitropin (2285)	Palmitic acid (1904)
Follitropin concentrated solution (2286)	Penicillamine (0566)
Galactose (1215)	Phenylpropanolamine hydrochloride (0683)
Galantamine hydrobromide (2366)	Phytomenadione, racemic (3011)
Gelatin (0330)	Propranolol hydrochloride (0568)
Glycerol dibehenate (1427)	Propyl gallate (1039)
Glycerol distearate (1428)	Propylene glycol monopalmitostearate (1469)
Glycerol monostearate 40-55 (0495)	Protamine sulfate (0569)
Gonadotrophin, chorionic (0498)	Pyridoxine hydrochloride (0245)
Hard fat (0462)	Safflower oil, refined (2088)
Hard fat with additives (2731)	Sodium starch glycolate (type A) (0983)
Heparin calcium (0332)	Sodium starch glycolate (type B) (0984)
Heparin sodium (0333)	Sodium starch glycolate (type C) (1566)
Human measles immunoglobulin (0397)	Solutions for organ preservation (1264)
Human plasma for fractionation (0853)	Soya-bean oil, hydrogenated (1265)
Human plasma (pooled and treated for virus inactivation) (1646)	Soya-bean oil, refined (1473)
Imidacloprid for veterinary use (2924)	Squalane (1630)
Infliximab concentrated solution (2928)	Sucralfate (1796)
Irbesartan (2465)	Terbutaline sulfate (0690)
Lauromacrogol 400 (2046)	Tilidine hydrochloride hemihydrate (1767)
Levodropropizine (1535)	Triglycerides, medium-chain (0868)
Losartan potassium (2232)	Urofollitropin (0958)
Macrogol 15 hydroxystearate (2052)	Urokinase (0695)
Macrogol 30 dipolyhydroxystearate (2584)	Valsartan (2423)
Mesterolone (1730)	Vigabatrin (2305)
Olmesartan medoxomil (2600)	Vinorelbine tartrate (2107)
Oxytetracycline hydrochloride (0198)	Wheat starch (0359)
	Wheat-germ oil, refined (1379)
	Wheat-germ oil, virgin (1480)

**ΚΕΙΜΕΝΑ ΠΟΥ ΕΧΟΥΝ ΔΙΟΡΘΩΘΕΙ ΣΤΗ ΔΕΚΑΤΗ (10.0) ΕΚΔΟΣΗ ΤΗΣ  
ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

Τα παρακάτω κείμενα έχουν διορθωθεί στη Δέκατη έκδοση της Ευρωπαϊκής Φαρμακοποιίας και φέρουν πάνω από τον τίτλο τη σημείωση "διόρθωση 10.0". Οι

διορθώσεις πρέπει να λαμβάνονται υπ' όψιν το συντομότερο δυνατό και όχι αργότερα από την 31 Αυγούστου 2019.

#### **ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ**

1. General notices
- 2.2.5. Relative density
- 2.2.29. Liquid chromatography
- 2.2.31. Electrophoresis
- 2.4.23. Sterols in fatty oils
- 2.4.25. Ethylene oxide and dioxan
- 2.4.26. N,N-Dimethylaniline
- 2.4.32. Total cholesterol in oils rich in omega-3 acids
- 2.5.19. O-Acetyl in polysaccharide vaccines
- 2.5.37. Methyl, ethyl and isopropyl methanesulfonate in methanesulfonic acid
- 2.5.38. Methyl, ethyl and isopropyl methanesulfonate in active substances
- 2.5.39. Methanesulfonyl chloride in methanesulfonic acid
- 2.5.40. Methyl, ethyl and isopropyl toluenesulfonate in active substances
- 2.5.41. Methyl, ethyl and isopropyl benzenesulfonate in active substances
- 2.7.8. Assay of tetanus vaccine (adsorbed)
- 2.8.9. Residue on evaporation of essential oils
- 2.9.10. Ethanol content
- 2.9.11. Test for methanol and 2-propanol
- 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion
- 3.2. Containers
- 5.1.2. Biological indicators and related microbial preparations used in the manufacture of sterile products
- 5.1.6. Alternative methods for control of microbiological quality
- 5.2.12. Raw materials of biological origin for the production of cell-based and gene therapy medicinal products
- 5.9. Polymorphism
- 5.10. Control of impurities in substances for pharmaceutical use
- 5.12. Reference standards
- 5.15. Functionality-related characteristics of excipients
- 5.16. Crystallinity

#### **ΜΟΝΟΓΡΑΦΙΕΣ**

##### **Γενικές Μονογραφίες**

Chemical precursors for radiopharmaceutical preparations (2902)  
Immunosera for human use, animal (0084)

Immunosera for veterinary use (0030)  
 Live biotherapeutic products for human use (3053)  
 Vaccines for human use (0153)  
 Vaccines for veterinary use (0062)

#### **Φαρμακοτεχνικές μορφές**

Ear preparations (0652)  
 Eye preparations (1163)  
 Intramammary preparations for veterinary use (0945)  
 Liquid preparations for cutaneous application (0927)  
 Nasal preparations (0676)  
 Parenteral preparations (0520)  
 Rectal preparations (1145)  
 Semi-solid preparations for cutaneous application (0132)  
 Vaginal preparations (1164)

#### **Εμβόλια για ανθρώπινη χρήση**

Anthrax vaccine for human use (adsorbed, prepared from culture filtrates) (2188)  
 Diphtheria and tetanus vaccine (adsorbed) (0444)  
 Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) (0647)  
 Diphtheria, tetanus and pertussis (whole cell) vaccine (adsorbed) (0445)  
 Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2328)  
 Diphtheria vaccine (adsorbed) (0443)  
 Diphtheria vaccine (adsorbed, reduced antigen content) (0646)  
 Influenza vaccine (live, nasal) (2772)  
 Influenza vaccine (split virion, inactivated) (0158)  
 Influenza vaccine (surface antigen, inactivated) (0869)  
 Influenza vaccine (surface antigen, inactivated, virosome) (2053)  
 Influenza vaccine (whole virion, inactivated) (0159)  
 Measles, mumps, rubella and varicella vaccine (live) (2442)  
 Pneumococcal polysaccharide vaccine (0966)  
 Poliomyelitis vaccine (inactivated) (0214)  
 Shingles (herpes zoster) vaccine (live) (2418)  
 Tetanus vaccine (adsorbed) (0452)  
 Typhoid polysaccharide vaccine (1160)  
 Varicella vaccine (live) (0648)  
 Immunosera for human use  
 Viper venom antiserum, European (0145)

#### **Ραδιοφαρμακευτικά σκευάσματα και πρώτες ύλες για την παρασκευή τους**

Choline ([<sup>11</sup>C]methyl) injection (2462)  
 Copper tetramibi tetrafluoroborate for radiopharmaceutical preparations (2547)  
 Fluorocholine (<sup>18</sup>F) injection (2793)



**Ράμματα για ανθρώπινη χρήση**

Sutures for human use: introduction (90004)

Sutures, sterile non-absorbable (0324)

**Φυτικές δρόγες και σκευάσματα φυτικών δρογών**Herbal drugs: introduction  
(90029)Achyranthes bidentata root  
(2999)

Akebia stem (2472)

Aloes dry extract, standardised  
(0259)

Amomum fruit (2554)

Artichoke leaf (1866)

Belladonna, prepared (0222)

Capsicum soft extract,  
standardised (2529)

Cassia oil (1496)

Cinnamon bark oil, Ceylon (1501)

Fennel, bitter (0824)

Fennel, sweet (0825)

Gentian tincture (1870)

Ginger (1522)

Goldenseal rhizome (1831)

Juniper oil (1832)

Long pepper (2453)

Mandarin oil (2355)

Mastic (1876)

Myrrh tincture (1877)

Nutmeg oil (1552)

Opium tincture, standardised  
(1841)

Oregano (1880)

Pepper (2477)

Roselle (1623)

Round amomum fruit (2555)

Sage tincture (1889)

Saw palmetto extract (2579)

Saw palmetto fruit (1848)

Star anise (1153)

Stramonium, prepared (0247)

Sweet orange oil (1811)

Thyme oil, thymol type (1374)

Turmeric rhizome (2543)

Homoeopathic preparations

Homoeopathic preparations:  
introduction (90006)Agaricus phalloides for  
homoeopathic preparations  
(2290)Anacardium for homoeopathic  
preparations (2094)Belladonna for homoeopathic  
preparations (2489)Cocculus for homoeopathic  
preparations (2486)Hydrastis canadensis for  
homoeopathic preparations  
(2500)Ignatia for homoeopathic  
preparations (2513)Magnesium phosphoricum for  
homoeopathic preparations  
(2505)Nux-vomica for homoeopathic  
preparations (2514)Staphysagria for homoeopathic  
preparations (2289)**Μονογραφίες**

N-Acetyltyrosine (1384)

Alimemazine hemitartrate (2650)

Almagate (2010)

Alprazolam (1065)

Alprenolol hydrochloride (0876)

Aluminium hydroxide, hydrated,  
for adsorption (1664)

Aluminium stearate (1663)

Alverine citrate (2156)

Amantadine hydrochloride (0463)

Amikacin sulfate (1290)

4-Aminobenzoic acid (1687)

Amoxicillin sodium (0577)

Amphotericin B (1292)

Ampicillin sodium (0578)  
 Anti-T lymphocyte immunoglobulin for human use, animal (1928)  
 Aprotinin (0580)  
 Aprotinin concentrated solution (0579)  
 Arginine hydrochloride (0805)  
 Aripiprazole (2617)  
 Articaine hydrochloride (1688)  
 Atazanavir sulfate (2898)  
 Atropine (2056)  
 Atropine sulfate (0068)  
 Azelastine hydrochloride (1633)  
 Bacitracin (0465)  
 Bacitracin zinc (0466)  
 Benzalkonium chloride (0372)  
 Benzalkonium chloride solution (0371)  
 Benzyl alcohol (0256)  
 Benzyl benzoate (0705)  
 Benzylpenicillin (benzathine) tetrahydrate (0373)  
 Benzylpenicillin potassium (0113)  
 Benzylpenicillin (procaine) monohydrate (0115)  
 Benzylpenicillin sodium (0114)  
 Biperiden hydrochloride (1074)  
 Bismuth subsalicylate (1495)  
 Bleomycin sulfate (0976)  
 Botulinum toxin type A for injection (2113)  
 Botulinum toxin type B for injection (2581)  
 Brimonidine tartrate (2760)  
 Bromhexine hydrochloride (0706)  
 Brompheniramine maleate (0977)  
 Bupivacaine hydrochloride (0541)  
 Buserelin (1077)  
 Calcitonin (salmon) (0471)  
 Calcium folinate hydrate (0978)  
 Calcium glucoheptonate (1399)  
 Calcium levofolinate hydrate (1606)  
 Captopril (1079)  
 Carbimazole (0884)  
 Cefalotin sodium (0987)  
 Cefamandole nafate (1402)  
 Cefapirin sodium (1650)  
 Cefazolin sodium (0988)  
 Cefepime dihydrochloride monohydrate (2126)  
 Cefoperazone sodium (1404)  
 Cefotaxime sodium (0989)  
 Cefoxitin sodium (0990)  
 Ceftazidime pentahydrate (1405)  
 Ceftazidime pentahydrate with sodium carbonate for injection (2344)  
 Ceftriaxone sodium (0991)  
 Cefuroxime axetil (1300)  
 Cefuroxime sodium (0992)  
 Cetostearyl alcohol (0702)  
 Cetostearyl alcohol (type A), emulsifying (0801)  
 Cetostearyl alcohol (type B), emulsifying (0802)  
 Cetyl alcohol (0540)  
 Chloramphenicol (0071)  
 Chloramphenicol palmitate (0473)  
 Chloramphenicol sodium succinate (0709)  
 Chlorobutanol (0382)  
 Chlorobutanol hemihydrate (0383)  
 Chlorocresol (0384)  
 Chlortetracycline hydrochloride (0173)  
 Cholesterol (0993)  
 Ciclopirox (1407)  
 Ciclosporin (0994)  
 Cilastatin sodium (1408)  
 Cladribine (2174)  
 Clemastine fumarate (1190)  
 Clindamycin phosphate (0996)  
 Clioquinol (2111)  
 Clodronate disodium tetrahydrate (1777)  
 Clofibrate (0318)  
 Clonidine hydrochloride (0477)  
 Clopidogrel besilate (2790)  
 Clopidogrel hydrochloride (2791)  
 Clopidogrel hydrogen sulfate (2531)  
 Cloxacillin sodium (0661)

Codeine hydrochloride dihydrate (1412)  
 Codeine monohydrate (0076)  
 Codeine phosphate hemihydrate (0074)  
 Colestyramine (1775)  
 Colistimethate sodium (0319)  
 Colistin sulfate (0320)  
 Crospovidone (0892)  
 Cyclizine hydrochloride (1092)  
 Cysteine hydrochloride monohydrate (0895)  
 Cytarabine (0760)  
 Dacarbazine (1691)  
 Danaparoid sodium (2090)  
 Daunorubicin hydrochloride (0662)  
 Deferiprone oral solution (2987)  
 Deferoxamine mesilate (0896)  
 Demeclocycline hydrochloride (0176)  
 Desflurane (1666)  
 Desloratadine (2570)  
 Desmopressin (0712)  
 Detomidine hydrochloride for veterinary use (1414)  
 Dexchlorpheniramine maleate (1196)  
 Dibutyl phthalate (0762)  
 Diclofenac potassium (1508)  
 Diclofenac sodium (1002)  
 Dicloxacillin sodium (0663)  
 Dicycloverine hydrochloride (1197)  
 Diethyl phthalate (0897)  
 Diethylene glycol monoethyl ether (1198)  
 Dihydrostreptomycin sulfate for veterinary use (0485)  
 Dimetindene maleate (1417)  
 Docusate sodium (1418)  
 Doxorubicin hydrochloride (0714)  
 Doxycycline hyclate (0272)  
 Doxycycline monohydrate (0820)  
 Doxylamine hydrogen succinate (1589)  
 Duloxetine hydrochloride (2594)  
 Edrophonium chloride (2106)  
 Enalapril maleate (1420)  
 Enilconazole for veterinary use (1720)  
 Enrofloxacin for veterinary use (2229)  
 Epirubicin hydrochloride (1590)  
 Erythromycin lactobionate (1098)  
 Erythropoietin concentrated solution (1316)  
 Estrogens, conjugated (1512)  
 Ethacridine lactate monohydrate (1591)  
 Ethanol (96 per cent) (1317)  
 Ethanol, anhydrous (1318)  
 Ethylcellulose (0822)  
 Etofenamate (1513)  
 Eugenol (1100)  
 Everolimus (2918)  
 Felypressin (1634)  
 Fentanyl citrate (1103)  
 Fenticonazole nitrate (1211)  
 Filgrastim concentrated solution (2206)  
 Filgrastim injection (2848)  
 Flucloxacillin sodium (0668)  
 Folic acid hydrate (0067)  
 Foscarnet sodium hexahydrate (1520)  
 Fosfomycin sodium (1329)  
 Framycetin sulfate (0180)  
 Fulvestrant (2443)  
 Gadobutrol monohydrate (2735)  
 Gadodiamide hydrate (2225)  
 Gemcitabine hydrochloride (2306)  
 Gentamicin sulfate (0331)  
 Glipizide (0906)  
 Glucagon, human (1635)  
 Glycerol (0496)  
 Glycerol (85 per cent) (0497)  
 Glycerol monocaprylate (2213)  
 Glycerol monocaprylocaprate (2392)  
 Gonadorelin acetate (0827)  
 Gonadotrophin, equine serum, for veterinary use (0719)  
 Gramicidin (0907)  
 Guaiacol (1978)  
 Halothane (0393)

Heparins, low-molecular-mass (0828)  
 Heptaminol hydrochloride (1980)  
 Histidine hydrochloride monohydrate (0910)  
 Human coagulation factor VIIa (rDNA) concentrated solution (2534)  
 Human coagulation factor IX (rDNA) concentrated solution (2522)  
 Hyaluronidase (0912)  
 Hydroxychloroquine sulfate (2849)  
 Hydroxyethylcellulose (0336)  
 Hydroxypropylcellulose (0337)  
 Hydroxypropylcellulose, low-substituted (2083)  
 Hyoscyamine sulfate (0501)  
 Hypromellose (0348)  
 Imipenem monohydrate (1226)  
 Insulin aspart (2084)  
 Insulin, bovine (1637)  
 Insulin glargine (2571)  
 Insulin, human (0838)  
 Insulin lispro (2085)  
 Insulin, porcine (1638)  
 Insulin preparations, injectable (0854)  
 Interferon alfa-2 concentrated solution (1110)  
 Interferon beta-1a concentrated solution (1639)  
 Interferon gamma-1b concentrated solution (1440)  
 Iohexol (1114)  
 Iopamidol (1115)  
 Irinotecan hydrochloride trihydrate (2675)  
 Isoprenaline sulfate (0502)  
 Isopropyl alcohol (0970)  
 Isopropyl myristate (0725)  
 Isopropyl palmitate (0839)  
 Isosorbide dinitrate, diluted (1117)  
 Isoxsuprine hydrochloride (1119)  
 Kanamycin acid sulfate (0033)  
 Kanamycin monosulfate (0032)  
 Labetalol hydrochloride (0923)  
 Lactose (1061)  
 Leuprorelin (1442)  
 Levocabastine hydrochloride (1484)  
 Lincomycin hydrochloride (0583)  
 Lomustine (0928)  
 Loratadine (2124)  
 Lynestrenol (0558)  
 Macrogol isotridecyl ether (2730)  
 Macrogol lauryl ether (1124)  
 Macrogol poly(vinyl alcohol) grafted copolymer (2523)  
 Magnesium aspartate dihydrate (1445)  
 Magnesium stearate (0229)  
 Maize starch (0344)  
 Meldonium dihydrate (2624)  
 Menadione (0507)  
 Mepivacaine hydrochloride (1242)  
 Mepyramine maleate (0278)  
 Meropenem trihydrate (2234)  
 Metacresol (2077)  
 Methadone hydrochloride (0408)  
 Methanol (1989)  
 Methyl salicylate (0230)  
 Methylcellulose (0345)  
 Methylene chloride (0932)  
 N-Methylpyrrolidone (1675)  
 Metoclopramide hydrochloride monohydrate (0674)  
 Mianserin hydrochloride (0846)  
 Minocycline hydrochloride dihydrate (1030)  
 Molgramostim concentrated solution (1641)  
 Naftidrofuryl hydrogen oxalate (1594)  
 Nandrolone decanoate (1992)  
 Naphazoline hydrochloride (0730)  
 Naphazoline nitrate (0147)  
 Neomycin sulfate (0197)  
 Neostigmine bromide (0046)  
 Neostigmine metilsulfate (0626)  
 Netilmicin sulfate (1351)  
 Nevirapine hemihydrate (2479)  
 Nifedipine hydrochloride (2776)  
 Norflurane (2257)

Nystatin (0517)  
 Octyldodecanol (1136)  
 Oleyl alcohol (2073)  
 Olsalazine sodium (1457)  
 Orphenadrine citrate (1759)  
 Orphenadrine hydrochloride (1760)  
 Oseltamivir phosphate (2422)  
 Oxacillin sodium monohydrate (2260)  
 Oxeladin hydrogen citrate (1761)  
 Oxolinic acid (1353)  
 Oxytetracycline dihydrate (0199)  
 Oxytocin (0780)  
 Oxytocin concentrated solution (0779)  
 Paclitaxel (1794)  
 Papaverine hydrochloride (0102)  
 Pemetrexed disodium heptahydrate (2637)  
 Permethrin (25:75) (1762)  
 Phentolamine mesilate (1138)  
 Phytosterol (1911)  
 Piperacillin sodium (1168)  
 Piperazine hydrate (0425)  
 Poloxamers (1464)  
 Polymyxin B sulfate (0203)  
 Polyoxypropylene stearyl ether (2602)  
 Polysorbate 80 (0428)  
 Poly(vinyl acetate) (1962)  
 Poly(vinyl acetate) dispersion 30 per cent (2152)  
 Potassium clavulanate (1140)  
 Potassium dihydrogen phosphate (0920)  
 Pramipexole dihydrochloride monohydrate (2416)  
 Praziquantel (0855)  
 Propanol (2036)  
 Propofol (1558)  
 Protirelin (1144)  
 Pyrantel embonate (1680)  
 Pyridostigmine bromide (1255)  
 Pyrrolidone (2180)  
 Rabeprazole sodium (2868)  
 Rabeprazole sodium hydrate (2331)  
 Raltegravir potassium (2887)  
 Ranitidine hydrochloride (0946)  
 Remifentanil hydrochloride (2644)  
 Reserpine (0528)  
 Rifamycin sodium (0432)  
 Rilmenidine dihydrogen phosphate (2020)  
 Rivastigmine hydrogen tartrate (2630)  
 Rupatadine fumarate (2888)  
 Saccharin (0947)  
 Saccharin sodium (0787)  
 Salmeterol xinafoate (1765)  
 Sertraline hydrochloride (1705)  
 Sevoflurane (2269)  
 Sildenafil citrate (2270)  
 Sitagliptin phosphate monohydrate (2778)  
 Sitagliptin tablets (2927)  
 Sodium aminosalicylate dihydrate (1993)  
 Sodium aurothiomalate (1994)  
 Sodium cetostearyl sulfate (0847)  
 Sodium cyclamate (0774)  
 Sodium hyaluronate (1472)  
 Sodium (S)-lactate solution (2033)  
 Sodium phenylbutyrate (2183)  
 Sodium propionate (2041)  
 Sodium stearyl fumarate (1567)  
 Solifenacin succinate (2779)  
 Somatostatin (0949)  
 Somatropin (0951)  
 Somatropin concentrated solution (0950)  
 Somatropin for injection (0952)  
 Somatropin solution for injection (2370)  
 Spectinomycin dihydrochloride pentahydrate (1152)  
 Spectinomycin sulfate tetrahydrate for veterinary use (1658)  
 Spiramycin (0293)  
 Starch, hydroxypropyl (2165)  
 Starch, hydroxypropyl, pregelatinised (2645)

Starches, hydroxyethyl (1785)  
 Stearyl alcohol (0753)  
 Streptokinase concentrated solution (0356)  
 Streptomycin sulfate (0053)  
 Sufentanil citrate (1269)  
 Sulbactam sodium (2209)  
 Sulfadimethoxine sodium for veterinary use (2745)  
 Sulfaguanidine (1476)  
 Sulfamerazine (0358)  
 Sulfobutylbetadex sodium (2804)  
 Sultamicillin (2211)  
 Sultamicillin tosilate dihydrate (2212)  
 Sumatriptan succinate (1573)  
 Tacalcitol monohydrate (2272)  
 Tacrolimus monohydrate (2244)  
 Tadalafil (2606)  
 Tamsulosin hydrochloride (2131)  
 Teriparatide (2829)  
 Terpin monohydrate (2940)  
 Testosterone decanoate (1736)  
 Testosterone enantate (1048)  
 Testosterone isocaproate (1737)  
 Tetracycline hydrochloride (0210)  
 Tetryzoline hydrochloride (2101)  
 Thiamazole (1706)  
 Thiamine hydrochloride (0303)  
 Thiamine nitrate (0531)  
 Thiocolchicoside crystallised from ethanol (2896)  
 Thiocolchicoside hydrate (2814)  
 Thiomersal (1625)  
 Tianeptine sodium (2022)  
 Tiapride hydrochloride (1575)  
 Ticarcillin sodium (0956)  
 Tigecycline (2825)  
 Tizanidine hydrochloride (2578)  
 Tobramycin (0645)  
 all-rac- $\alpha$ -Tocopherol (0692)  
 RRR- $\alpha$ -Tocopherol (1256)  
 all-rac- $\alpha$ -Tocopheryl acetate (0439)  
 RRR- $\alpha$ -Tocopheryl acetate (1257)  
 $\alpha$ -Tocopheryl acetate concentrate (powder form) (0691)  
 DL- $\alpha$ -Tocopheryl hydrogen succinate (1258)  
 RRR- $\alpha$ -Tocopheryl hydrogen succinate (1259)  
 Tolterodine tartrate (2781)  
 Tosylchloramide sodium (0381)  
 Tributyl acetylcitrate (1770)  
 Tri-n-butyl phosphate (1682)  
 Triethyl citrate (1479)  
 Trimebutine maleate (2182)  
 Trimetazidine dihydrochloride (1741)  
 Trimethoprim (0060)  
 Trolamine (1577)  
 Troxerutin (2133)  
 Tuberculin purified protein derivative, avian (0535)  
 Tuberculin purified protein derivative, bovine (0536)  
 Tylosin for veterinary use (1273)  
 Tylosin phosphate for veterinary use (2802)  
 Tylosin tartrate for veterinary use (1274)  
 Vancomycin hydrochloride (1058)  
 Vardenafil hydrochloride trihydrate (2782)  
 Vecuronium bromide (1769)  
 Vinblastine sulfate (0748)  
 Vincristine sulfate (0749)  
 Vindesine sulfate (1276)  
 Voriconazole (2576)  
 Wool alcohols (0593)  
 Wool fat (0134)  
 Wool fat, hydrogenated (0969)  
 Xylitol (1381)  
 Ziprasidone mesilate trihydrate (2649)

**ΚΕΙΜΕΝΑ ΤΩΝ ΟΠΟΙΩΝ Ο ΤΙΤΛΟΣ ΑΛΛΑΞΕ ΣΤΗ ΔΕΚΑΤΗ (10.0) ΕΚΔΟΣΗ  
ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

**ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ**

2.6.33. Residual pertussis toxin (προηγούμενως Residual pertussis toxin and irreversibility of pertussis toxoid)

**ΜΟΝΟΓΡΑΦΙΕΣ**

**Εμβόλια για κτηνιατρική χρήση**

Enteric redmouth disease vaccine (inactivated) for rainbow trout (1950) (προηγούμενως Yersiniosis vaccine (inactivated) for salmonids)

**Ράμματα για ανθρώπινη χρήση**

Sutures for human use: introduction (90004) (προηγούμενως Introduction)

**Φυτικές δρόγες και σκευάσματα φυτικών δρογών**

Herbal drugs: introduction (90029) (προηγούμενως Introduction)

**Ομοιοπαθητικά σκευάσματα**

Homoeopathic preparations: introduction (90006) (προηγούμενως Introduction)

**ΚΕΙΜΕΝΑ ΤΩΝ ΟΠΟΙΩΝ Η ΑΡΙΘΜΗΣΗ ΑΛΛΑΞΕ ΣΤΗ ΔΕΚΑΤΗ (10.0)  
ΕΚΔΟΣΗ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΦΑΡΜΑΚΟΠΟΙΙΑΣ**

**ΚΕΦΑΛΑΙΑ ΓΕΝΙΚΟΥ ΜΕΡΟΥΣ**

3.3.1. Materials for containers for human blood and blood components (προηγούμενως 3.1.1)

3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components (προηγούμενως 3.1.1.1)

3.3.3. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components (προηγούμενως 3.1.1.2)

3.3.4. Sterile plastic containers for human blood and blood components (προηγούμενως 3.2.3)

3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components (προηγούμενως 3.2.4)

3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution (προηγούμενως 3.2.5)

3.3.7. Sets for the transfusion of blood and blood components (προηγούμενως 3.2.6)

3.3.8. Sterile single-use plastic syringes (προηγούμενως 3.2.8)