

Pripomienkovanie článkov Európskeho liekopisu

Štátny ústav pre kontrolu liečiv informuje odbornú verejnosť o možnosti pripomienkovania návrhov nových a revidovaných článkov pred ich zaradením do Európskeho liekopisu.

Aktuálne vydanie **Pharmeuropa (37.2)** dáva možnosť **do 30.6.2025** pripomienkovať

Všeobecné texty a skúšobné metódy:

- 2.2.22. Atomic emission spectrometry
- 2.2.23. Atomic absorption spectrometry
- 2.2.57. Inductively coupled plasma-atomic emission spectrometry
- 2.2.58. Inductively coupled plasma-mass spectrometry
- 2.2.62. Evaporative light-scattering detection
- 2.6.14. Bacterial endotoxins
- 2.7.38. Bacteriophage potency determination
- 2.9.50. Particle size analysis by dynamic light scattering
- 5.1.13. Pyrogenicity
- 5.1.6. Alternative methods for control of microbiological quality
- 5.44. Characterisation of powder behaviour during compression

Monografie:

- Aluminium phosphate, hydrated, for adsorption**/Aluminii phosphas hydricus ad adsorptionem (3065)
- Cabazitaxel**/Cabazitaxelum (3223)
- 2,4-Dichlorobenzyl alcohol**/Alcohol 2,4-dichlorobenzylicus (2410)
- Chlorpromazine hydrochloride**/Chlorpromazini hydrochloridum (0475)
- Cholesterol for parenteral use**/Cholesterolum ad usum parenteralem (2397)
- Guar**/Cyamopsisidis seminis pulvis (1218)
- Histamine dihydrochloride**/Histamini dihydrochloridum (0143)
- Hydroxyethylcellulose**/Hydroxyethylcellulosum (0336)
- Indigotindisulfonate disodium hydrate**/Dinatrii indigotindisulfonas hydras (3216)
- Indigotindisulfonate disodium injection**/Dinatrii indigotindisulfonas iniectionabile (3226)
- Isoniazid**/Isoniazidum (0146)
- Lercanidipine hydrochloride**/Lercanidipini hydrochloridum (3052)
- Levothyroxine sodium hydrate**/Levothyroxinum natricum hydricum (0401)
- Linagliptin**/Linagliptinum (3173)
- Manganese gluconate**/Mangani gluconas (2162)
- Metformin hydrochloride**/Metformini hydrochloridum (0931)
- Metronidazole**/Metronidazolum (0675)
- Nintedanib esilate**/Nintedanibi esilas (3237)
- Penbutolol sulfate**/Penbutololi sulfas (1461)
- Sunitinib malate**/Sunitinibi malas (3085)
- Thiamazole**/Thiamazolum (1706)
- Vancomycin hydrochloride**/Vancomycini hydrochloridum (1058)

Homeopatické prípravky:

- Coffea for homoeopathic preparations**/Coffea ad praeparationes homoeopathicas (3138)

Rastlinné drogy:

Frangula bark/Frangulae cortex (0025)

Frangula bark dry extract, standardised/Frangulae corticis extractum siccum normatum (1214)

Mint haplocalyx herb/Menthae haplocalycis herba (3191)

Lieky:

Sunitinib malate capsules/Sunitinibi malatis capsulae (3086)

Radiofarmaceutické prípravky:

Gallium (⁶⁸Ga) chloride (accelerator-produced) solution for radiolabelling/Gallii (⁶⁸Ga) chloridi acceleratore formati solutio ad radio-signandum (3109)

Technetium (^{99m}Tc) bicisate injection/Technetii (^{99m}Tc) bicisati solutio iniectionabilis (2123)

Technetium (^{99m}Tc) colloidal rhenium sulfide injection/Rhenii sulfidi colloidalis et technetii (^{99m}Tc) solutio iniectionabilis (0126)

Technetium (^{99m}Tc) colloidal tin injection/Stanni colloidalis et technetii (^{99m}Tc) solutio iniectionabilis (0689)

Technetium (^{99m}Tc) etifenin injection/Technetii (^{99m}Tc) et etifenini solutio iniectionabilis (0585)

Technetium (^{99m}Tc) exametazime injection/Technetii (^{99m}Tc) exametazimi solutio iniectionabilis (1925)

Technetium (^{99m}Tc) gluconate injection/Technetii (^{99m}Tc) gluconatis solutio iniectionabilis (1047)

Technetium (^{99m}Tc) mebrofenin injection/Technetii (^{99m}Tc) mebrofenini solutio iniectionabilis (2393)

Technetium (^{99m}Tc) medronate injection/Technetii (^{99m}Tc) medronati solutio iniectionabilis (0641)

Technetium (^{99m}Tc) mertiatide injection/Technetii (^{99m}Tc) mertiatidi solutio iniectionabilis (1372)

Technetium (^{99m}Tc) microspheres injection/Technetii (^{99m}Tc) microsphaerarum suspensio iniectionabilis (0570)

Technetium (^{99m}Tc) pentetate injection/Technetii (^{99m}Tc) pentetatis solutio iniectionabilis (0642)

Technetium (^{99m}Tc) succimer injection/Technetii (^{99m}Tc) succimeri solutio iniectionabilis (0643)

Očkovacie látky:

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)/Vaccinum diphtheriae, tetani, pertussis sine cellulis ex elementis praeparatum, hepatitis B (ADNr), poliomyelitidis inactivatum et haemophili stirpis b coniugatum adsorbatum (2067)

Tetanus vaccine (adsorbed)/Vaccinum tetani adsorbatum (0452)

Očkovacie látky na veterinárne použitie:

Tetanus vaccine for veterinary use/Vaccinum tetani ad usum veterinarium (0697)

Úplné znenie aj s vyznačením zmien je dostupné na stránke EDQM <https://pharmeuropa.edqm.eu/home> .

Termín pripomienkovania je **do 30. júna 2025**.

Pripomienky posielajte na Liekopisné oddelenie ŠÚKL (liekopis@sukl.sk), ktoré sprostredkuje ich doručenie do EDQM.