

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 (38.3)** dáva možnosť do **30.09.2026** pripomienkovať

Všeobecné články:

- 2.4.37. Apparent molar radioactivity of radiometal solutions for radiolabelling
- 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests⁽¹⁾
- 2.6.13. Microbiological examination of non-sterile products: test for specified microorganisms⁽¹⁾
- 2.8.13. Pesticide residues
- 2.9.27. Uniformity and accuracy of delivered doses from multidose containers
- 3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components
- 3.3.9. Prefillable plastic syringes for liquid preparations for injection
- 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use⁽¹⁾

Monografie:

- Adipic acid**/Acidum adipicum (1586)
- Alectinib hydrochloride**⁽¹⁾/Alectinibi hydrochloridum (3219)
- Boldo leaf dry extract**/Boldi folii extractum siccum (1816)
- Cabazitaxel concentrate for infusion**⁽¹⁾/Cabazitaxelum densatum ad infusionem (3233)
- Cinacalcet hydrochloride**/Cinacalceti hydrochloridum (3100)
- Cyproterone acetate**/Cyproteroni acetas (1094)
- Deferasirox**/Deferasiroxum (2933)
- Dexmedetomidine hydrochloride**/Dexmedetomidini hydrochloridum (3215)
- Diclofenac diethylamine**/Diclofenacum diethylaminum (2792)
- Dioscorea nipponica rhizome**/Dioscoreae nipponicae rhizoma (2890)
- Donepezil hydrochloride**/Donepezili hydrochloridum (2582)
- Ezetimibe**/Ezetimibum (2767)
- Fluoxetine hydrochloride**/Fluoxetini hydrochloridum (1104)
- Heparin calcium**/Heparinum calcicum (0332)
- Heparin sodium**/Heparinum natricum (0333)
- Hydrocortisone**/Hydrocortisonum (0335)
- Hypromellose acetate succinate**/Hypromellosi acetas succinas (3101)
- Ipratropium bromide monohydrate**/Ipratropii bromidummonohydricum (0919)
- Lenalidomide capsules**⁽¹⁾/Lenalidomidi capsulae (3081)
- Lenalidomide hydrochloride capsules**⁽¹⁾/Lenalidomidi hydrochloridi capsulae (3243)
- Lithium citrate tetrahydrate**/Lithii citras tetrahydricus (0621)
- Macrogols**/Macrogola (1444)
- Nutgrass galingale rhizome**/Cyperi rotundi rhizoma (3263)
- Potassium citrate monohydrate**/Kalii citras monohydricus (0400)
- Respiratory Syncytial Virus vaccine (rDNA)**/Vaccinum viri syncytialis meatus spiritus (ADNr) (3275)

Riboflavin sodium phosphate hydrate/Riboflavini natrii phosphas hydricus (0786)
Sodium nitroprusside dihydrate/Natrii nitroprussias dihydricus (0565)
Southern Schisandra fruit/Schisandrae sphenantherae fructus (3266)
Thiocolchicoside crystallised from ethanol/Thiocolchicosidum ex ethanollo cristallisatum (2896)
Thiocolchicoside hydrate/ Thiocolchicosidum hydricum (2814)
Vismodegib/Vismodegibum (3269)
Vismodegib capsules⁽¹⁾/Vismodegibi capsulae (3270)

<https://www.edqm.eu/en/-/pharmeuropa-38.3-just-released>

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

Termín pripomienkovania je **do 30. septembra 2026**.

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