

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 (36.2) dáva možnosť do 30.6.2024 pripomienkovať

Všeobecné texty:

- 5.32. Cell-based preparations for human use
- 5.36. Mrna vaccines for human use
- 5.37. Recombinant viral vectored vaccines for human use
- 5.39. Mrna substances for the production of mrna vaccines for human use
- 5.40. DNA template for the preparation of mrna substances

Všeobecné kontrolné metódy:

- 2.5.25. Carbon monoxide in gases
- 2.6.41. High-throughput sequencing for the detection of viral extraneous agents
- 2.9.17. Test for extractable volume of parenteral preparations
- 2.9.54. Uniformity of delivered dose of inhalation and nasal preparations

Monografie:

- Amlodipine besilate**/Amlopidini besilas (1491)
- Aprotinin**/Aprotininum (0580)
- Aprotinin concentrated solution**/Aprotinini solutio concentrata (0579)
- Bromperidol decanoate**/Bromperidoli decanoas (1397)
- Cefixime trihydrate**/Cefiximum trihydricum (1188)
- Cellulose acetate butyrate**/Cellulosi acetas butyras (1406)
- Cholesterol**/Cholesterolum (0993)
- Chymotrypsin**/Chymotrypsinum (0476)
- Clonazepam**/Clonazepamun (0890)
- Heparin calcium**/Heparinum calcicum (0332)
- Clopidogrel besilate**/Clopidogreli besilas (2790)
- Codergocrine mesilate**/Codergocrini mesilas (2060)
- Danaparoid sodium**/Danaparoidum natricum (2090)
- Daunorubicin hydrochloride**/Daunorubicini hydrochloridum (0662)
- Felodipine**/Felodipinum (1013)
- Glycerol monostearate 40-55**/Glyceroli monostearas 40-55 (0495)
- Heparin calcium**/Heparinum calcicum (0333)
- Hydroxyzine hydrochloride**/Hydroxyzini hydrochloridum (0916)
- Kanamycin acid sulfate**/Kanamycini sulfas acidus (0033)
- Kanamycin monosulfate monohydrate**/Kanamycini monosulfas monohydricum (0032)
- L-malic acid**/Acidum L-malicum (3143)
- Linagliptin**/Linagliptinum (3173)
- Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer**/Copolymerum macrogolo et poly(vinylis acetas)-poly(vinylcaprolactamo)constatum (3156)
- Macrogolglycerol hydroxystearate**/Macroglyceroli hydroxystearas (1083)
- Macrogolglycerol ricinoleate**/Macroglyceroli ricinoleas (1082)
- Metronidazole benzoate**/Metronidazoli benzoas (0934)
- Octenidine dihydrochloride**/Octenidini dihydrochloridum (3075)
- Procaine hydrochloride**/Procaini hydrochloridum (0050)
- Rifamycin sodium**/Rifamycinum natricum (0432)
- Sevelamer carbonate**/Sevelameri carbonas (2747)

Sevelamer hydrochloride/Sevelameri hydrochloridum (2748)
Streptomycin sulfate/Streptomycini sulfas (0053)
Sufentanil/Sufentanilum (1569)
Sufentanil citrate/Sufentanili citras (1269)
Suxamethonium chloride dihydrate/Suxamethonii chloridum dihydricum (0248)
Tiabendazole for veterinary use/Tiabendazolium ad usum veterinarium (0866)
Tobramycin/Tobramycinum (0645)
Trypsin/Trypsinum (0694)
Urokinase/Urokinasum (0695)
Ursodeoxycholic acid/Acidum ursodeoxycholicum (1275)
Zanamivir hydrate/Zanamivirum hydricum (2611)

Liekové formy:

Ear preparations/Auricularia (0652)
Nasal preparations/Nasalia (0676)
Preparations for inhalation/Inhalanda (0671)
Pressurised pharmaceutical preparations/Praeparationes pharmaceuticae in vasis cum pressu (0523)

Homeopatické prípravky:

Calendula for homoeopathic preparations/Calendula officinalis ad praeparationes homoeopathicas (2492)
Chamomilla for homoeopathic preparations/Matricaria recutita ad praeparationes homoeopathicas (2493)

Rastlinné drogy a silice:

Fleeceflower root/Polygoni multiflori radix (2433)
Fourstamen stephania root/Stephaniae tetrandrae radix (2478)
Myrtle oil/Myrti aetheroleum (2823)

Očkovacie látky:

Foot-and-mouth disease (ruminants) vaccine (inactivated)/Vaccinum aphtharum epizooticarum inactivatum ad ruminantes (0063)
Vaccines for human use/Vaccina ad usum humanum (0153)

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

Termín pripomienkovania je **do 30. júna 2024**.

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