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Kapi za nos kao galenski lekovi u svakodnevnoj apotekarskoj praksi

Nose Drops as Galenic Medicines in Daily Pharmacy Practice

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Apstrakt

Nazalna kongestija je čest simptom velikog broja virusnih infekcija gornjih disajnih puteva. Nazalni dekongestivi se najčešće primenjuju u obliku kapi i sprejeva za nos. Kapi za nos, kao farmaceutski oblik, imaju široku primenu u svakodnevnoj apotekarskoj praksi, jer su veoma efikasni i dostupni pacijentima bez recepta. Simpatomimetici kao aktivni principi u kapima i sprejevima za nos, svojim alfa adrenergičnim efektima izazivaju vazoknistrikciju, redistribuciju lokalnog protoka krvi, smanjuju edem nazalne sluzokože i time poboljšavaju nazalnu ventilaciju, drenažu i smanjuju zapušenosti nosa. Slabo se resorbuju sa nazalne sluzokože i nemaju izražene sistemske efekte, ali su značajni lokalni neželjni efekti koji se javljaju tokom produžene upotrebe: medikamentozni rinitis (kada nakon vazokonstrikcije nastaje vazodilatacija sa još težom kongestijom), hipereaktivnost i rezistencija na terapiju. Zbog toga upotrebu treba ograničiti na 3 do 5, najduže 7 uzastopnih dana, ako je moguće samo kada je neophodno. Pacijente treba savetovati da upotrebu ograniče na što manju dozu i što ređu primenu u toku dana. Od svih nazalnih dekongestiva sa simpatomimetičkim dejstvom, efedrin poseduje najmanji potencijal da dovede do kongestije i on je lek izbora naročito u pedijatrijskoj populaciji.

Galenski lekovi – kapi za nos pripadaju farmakopejskoj grupi preparati za nos (nasalia), izrađuju se u registrovanoj galenskoj laboratoriji, u skladu sa svim važećim zakonskim propisima i smernicama koje se odnose na izradu ove vrste lekova. Polazne sirovine su kvalitet za farmaceutsku primenu, izrada se vrši u prostoru registrovanom za izradu galenskih lekova, prema oficijalnim formulacijama, korišćenjem validirane opreme i postupaka koji obezbeđuju kvalitet preparata. U izradu su uključeni farmaceutski tehničari, uz nadzor specijaliste farmaceutske tehnologije. Izradu prate radni nalozi koji definišu svaku etapu procesa izrade preparate – od merenja aktivnih i pomoćnih supstanci, preko izrade detaljnog postupka i opreme na kojoj se izvode procesi, pa do završne faze signiranja, pakovanja i skladištenja gotovog proizvoda, uz evidentiranje odgovornih lica za svaku od faza.

U toku izrade vrši se međufazna procesna kontrola, a pre puštanja serije leka u promet, kontrola završnog proizvoda. Svaka izrađena serija ispituje se u skladu sa farmakopejskim zahtevima.

U cilju utvrđivanja roka upotrebe izrađenih galenskih lekova, ispitivana je dugotrajna studija stabilnosti u uslovima koji su definisani za internacionalnu klimatsku zonu II, prema smernicama ICH Q1A i ICH Q1E koje je izdala EMA (evropska agencija za lekove) i vodiča za stabilnost WHO (Svetske

Abstract

Nasal congestion is a common symptom of many viral infections of the upper respiratory tract. Nasal decongestants are most often applied in the form of drops and nasal sprays. Nasal drops as a pharmaceutical form are widely used in everyday pharmacy practice because they are very effective and available to patients without a prescription. Sympathomimetics, as active principles in drops and sprays for the nose, with their alpha-adrenergic effects cause vasoconstriction, redistribution of local blood flow, reduce edema of the nasal mucous membrane and thus improve nasal ventilation, and drainage, and reduce nasal congestion. They are poorly resorbed from the nasal mucosa and have no pronounced systemic effects, but local side effects that occur during prolonged use are significant: medicinal rhinitis (when after vasoconstriction, vasodilation occurs with even more severe congestion), hyperactivity, and resistance to therapy. Therefore, use should be limited to 3 to 5, no longer than 7 consecutive days, if possible, only when necessary. Patients should be advised to limit the use to the smallest possible dose and to use it as infrequently as possible during the day. Of all nasal decongestants with sympathomimetic effects, ephedrine has the least potential to cause congestion and is the drug of choice, especially in the pediatric population.

Galenic medicines-nose drops belong to the pharmacopeial group Nasal preparations (Nasalia) are made in a registered Galenic laboratory, following all valid legal regulations and guidelines related to the production of this type of medicine. The starting raw materials are quality for pharmaceutical use, the production is carried out in an area registered for the production of galenic drugs, according to official formulations, using validated equipment and procedures that ensure the quality of the preparation. Pharmaceutical technicians are involved in the production under the supervision of a specialist in pharmaceutical technology. Production is followed by work orders that define each stage of the preparation process - from the measurement of active and auxiliary substances, through the production-detailed procedure and the equipment on which the processes are carried out, to the final stage of signing, packaging, and storage of the finished product, with the recording of the responsible persons for each of the stages.

Interphase process control is performed during production, and final product control is performed before releasing a batch of medicine into circulation. Each manufactured batch is tested by pharmacopeialstandards.

To determine the shelf life of the manufactured galenic drugs, a long-term stability study was conducted under the conditions defined for the international climate zone II, according to the ICH Q1A and ICH Q1E guidelines issued by the EMA (Euro-

zdravstvene organizacije). Uzorci se čuvaju na temperaturi od 25°C ± 2°C i vlažnosti 60% RH ± 5% koji su definisani za internacionalnu klimatsku zonu II.

Rezultati su prikazani grafički. Jednačine prave zavisnosti sadržaja od vremena su za: efedrin-hidrohlorid, kapi za nos 0,25% y = 0,0003x + 0,247; efedrin-hidrohlorid, kapi za nos 0,5% y = 0,0003x + 0,4919; efedrin-hidrohlorid, kapi za nos 1% y = 0,0001x + 0,9901; efedrin-hidrohlorid, kapi za nos 2% y = -0,00009x + 1,9541; nafazolin-hidrohlorid, kapi za nos 0,05% y = 0,0005x + 0,04972; nafazolin-hidrohlorid, kapi za nos 0,1% y = 0,0002x + 0,0978; ksilometazolin-hidrohlorid, kapi za nos 0,1% y = 0,0002x + 0,1054 i ukazuju da su galenski lekovi stabilni i da su u dozvoljenim specifikacijskim granicama.

Na osnovu dobijenih rezultata naznačeni galenski lekovi su stabilni, odgovarajućeg kvaliteta i efikasni u terapiji.

pean Medicines Agency) and the WHO (World Health Organization) stability guide). The samples are stored at a temperature of 25°C ±2°C and a humidity of 60%RH ±5% which are defined for the international climate zone II.

The results are presented graphically. The equations for the true dependence of content on time are for Ephedrine-hydrochloride, nasal drops 0.25% y=0.0003x+0.247; Ephedrine hydrochloride, nasal drops 0.5% y=0.0003x+0.4919; Ephedrine hydrochloride, nasal drops 1% y=0.0001x+0.9901; Ephedrine hydrochloride, nasal drops 2% y=-0.00009x+1.9541; Naphazoline hydrochloride, nasal drops 0.05% y=0.0005x +0.04972; Naphazoline hydrochloride, nasal drops 0.1% y=0.0002x+0.0978; Xylometazoline-hydrochloride, nasal drops 0.1% y=0.0002x+0.1054 and indicate that the galenic drugs are stable and within the allowed specification limits.

Based on the obtained results, the indicated galenic drugs are stable, of appropriate quality, and effective in therapy.