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DEVELOPMENT AND VALIDATION OF HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY METHOD FOR DETERMINATION OF FLUNIXIN-MEGLUMINE AND ITS IMPURITIES IN PREPARATIONS FOR VETERINARY USE

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Flunixin is a non-steroidal anti-inflammatory drug, as well as an analgesic that has an antipyretic effect. In veterinary medicine, it is used as salt flunixin meglumine. Flunixin shows strong inhibition of the cyclooxygenase system involved in the development of inflammation (1). The decrease in the production of certain inflammatory mediators explains its analgesic, antipyretic and anti-inflammatory properties. A large number of methods have been developed for the separation of flunixin meglumine and structurally related compounds in pharmaceutical preparations, such as: thin layer chromatography, UV/VIS spectroscopy, high pressure liquid chromatography and gas chromatography. The objective of this work is to develop, optimize and validate a method for separating flunixin meglumine and structurally related substances, in solution for injection. Optimal conditions were achieved on a Agilent Zorbax Eclipse Plus C18 column (150×4.6 mm, 5 μm). The mobile phase is a mixture of 0.1% (v/v) formic acid in water and methanol in a ratio of 40:60 (v/v). The flow rate is 1.0 mL/min, the injection volume is 20 μL, the detection wavelength is 270 nm and the column temperature is 25°C. The following parameters were examined: selectivity, linearity, precision, accuracy, detection limit, quantification limit, robustness and stability of the solution (2). All these parameters were in line with the criteria for accepting the results. Thereafter, the method was applied to determine the content of flunixin meglumine and its impurities in the solution for injection, and the result was also in accordance with the criteria for accepting the results.

References

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RAZVOJ I VALIDACIJA METODE TEČNE HROMATOGRAFIJE VISOKIH PERFORMANSI ZA ODREĐIVANJE FLUNIKSIN-MEGLUMINA I NJEGOVIH NEČISTOĆA U PREPARATIMA ZA VETERINARSKU UPOTREBU

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Fluniksin je nesteroidni antiinflamatorni lek, kao i analgetik koji ima antipiretički efekat. U veterinarskoj medicini se koristi u obliku soli fluniksin-meglumina. Fluniksin pokazuje snažnu inhibiciju enzima ciklooksigenaze koji je uključen u nastanak inflamacije (1). Smanjenjem produkcije određenih medijatora inflamacije objašnjavaju se njegova analgetička, antipiretička i antiinflamatorna svojstva. Razvijen je veliki broj metoda za odvajanje fluniksin meglumina i strukturno srodnih jedinjenja u farmaceutskim preparatima, kao što su: tankoslojna hromatografija, UV/VIS spektroskopija, visokoefikasna tečna hromatografija, gasna hromatografija. Cilj ovoga rada je razvoj, optimizacija i validacija metode za razdvajanje i određivanje fluniksin-meglumina i strukturno sličnih jedinjenja, u rastvoru za injekciju. Optimalni uslovi postignuti su na koloni Agilent Zorbax Eclipse Plus C18 (150×4,6 mm, 5 μm). Mobilnu fazu činila je smeša 0,1% v/v rastvora mravlje kiseline u vodi i metanola u odnosu 40:60 v/v. Protok mobilne faze je 1,0 mL/min, volumen injiciranja 20 μL, talasna dužina detekcije 270 nm i temperatura kolone 25°C. Ispitivani su sledeći parametri: selektivnost, linearnost, preciznost, tačnost, limit detekcije, limit kvantifikacije, robustnost i stabilnost rastvora (2). Dobijene vrednosti za ispitivane parametre su u skladu sa kriterijumima prihvatljivosti. Validirana metoda je primenjena za određivanje sadržaja fluniksin-meglumina i njegovih nečistoća u rastvoru za injekcije. Dobijeni rezultati zadovoljavali su zahteve specifikacije.

Literatura

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