

Pengembangan Metode Analisis Campuran Neomisin Sulfat dan Polimiksin B Sulfat pada Sediaan Tetes Mata Secara Kromatografi Cair Kinerja Tinggi Detektor Evaporative Light Scattering dan Mikrobiologi = Development Method of Neomycin Sulfate and Polymyxin B Sulfate in Eye Drops by High Performance Liquid Chromatography Evaporative Light Scattering Detector and Microbiology.

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Abstrak

ABSTRAK

Penentuan kadar secara Kromatografi Cair Kinerja Tinggi (KCKT) atau potensi antibiotik diperlukan untuk menjamin kualitas produk antibiotik. Uji antibiotik secara mikrobiologi dan kimia, masing-masing menunjukkan kelebihan dan kekurangan. Penelitian ini bertujuan mendapatkan metode penetapan kadar neomisin sulfat dan polimiksin B sulfat dalam tetes mata secara simultan dengan KCKT Evaporative Light Scattering Detector (ELSD) dan secara mikrobiologi. Parameter validasi yang dilakukan adalah spesifisitas, linearitas, akurasi, presisi dan ketegaran. Analisis secara KCKT-ELSD dilakukan dengan menggunakan kolom fenil X Bridge Waters, suhu penguapan 50oC, tekanan nitrogen 320 kPa, fase gerak terdiri dari kombinasi metanol dan asam trikloroasetat (40 mM; pH 1,70-1,80) dalam mode gradien, laju alir 1,0 mL/menit, detector gain 6, waktu analisis 35 menit. Pengujian mikrobiologi neomisin sulfat dan polimiksin B sulfat dalam sediaan tetes mata dilakukan dengan metode Farmakope Indonesia. Hasil validasi metode KCKT-ELSD dan mikrobiologi memenuhi kriteria keberterimaan. Hasil penetapan kadar sampel neomisin sulfat dan polimiksin B sulfat dengan metode KCKT-ELSD adalah 102,27% dan 100,79%. Hasil uji potensi sampel neomisin sulfat dan polimiksin B sulfat adalah 105,12% dan 104,6%. Dari hasil uji T dua sampel bebas dengan tingkat kepercayaan 95% ($\alpha = 0,05$) disimpulkan bahwa tidak ada perbedaan bermakna antara hasil dengan metode KCKT-ELSD dan mikrobiologi.

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ABSTRACT

Determination of antibiotics is needed to ensure the quality of antibiotic products. High Performance Liquid Chromatography (HPLC) and microbiological assay methods are both used to quantify antibiotics, and each method has advantages and disadvantages. This study aims to obtain a method for simultaneous quantification of neomycin sulphate and polymyxin B sulphate in eye drops, using an HPLC Evaporative Light Scattering Detector (ELSD) and microbiology. The method was validated with parameters of specificity, linearity, accuracy, precision and robustness. The HPLC-ELSD method used a phenyl XBridge column, an evaporation temperature of 50oC, a nitrogen pressure of 320 kPa, a mobile phase consisting of a combination of methanol and trichloroacetic acid (40 mM, pH 1.70-1.80) in gradient mode at a flow rate of 1.0 mL/minute, a detector gain of 6, and an analysis time of 35 minutes. The microbiological testing of neomycin sulphate and polymyxin B sulphate in eye drops used Indonesian Pharmacopoeia methods. The results of method validation showed that the HPLC-ELSD and the microbiology method fulfil the acceptance criteria. The method has been validated and used for sample analysis in the market. The results of neomycin sulphate and polymyxin B sulphate with the HPLC-ELSD method were 102.27% and 100.79%.

The microbiology results for neomycin sulphate and polymyxin B sulphate were 105.12% and 104.6%. Based on the T-test results of two samples with a 95% confidence level ($\alpha = 0.05$), it was concluded that there was no significant difference between HPLC-ELSD and microbiological methods for determining neomycin and polymyxin B.