Abstrak

PENGEMBANGAN METODE ANALISIS GLISERIL GUAIAKOLAT DAN DEKSTROMETORFAN HBr PADA TABLET KOMBINASI DENGAN METODE KCKT

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Batuk merupakan pertahanan tubuh di saluran pernafasan karena adanya lendir atau mukus. Sediaan tablet obat batuk biasanya terdiri dari kombinasi gliseril guaiakolat dan dekstrometorfan HBr sehingga diperlukan pengembangan metode analisi gliseril guaiakolat dan dekstrometorfan HBr secara simultan. Penelitian ini bertujuan untuk melakukan validasi metode dalam menetapkan kadar campuran gliseril guaiakolat dan dekstrometorfan HBr dalam sediaan tablet kombinasi. Pengembangan metode validasi dapat dilakukan dengan metode kromatografi cair kinerja tinggi.Validasi metode menggunakan kolom C18 (150×4,6 mm) fase gerak metanol : air : asam ortofosfat 0,1% (60:35:5 v/v), laju alir 0,5 ml/menit, waktu elusi 10 menit, sistem elusi isokratik, detektor ultraviolet dan panjang gelombang 279 nm. Dari uji validasi metode yang dilakukan, diperoleh nilai koefisien korelasi (R) gliseril guaiakolat 0,9991 dan dekstrometorfan HBr 0,9982. Nilai BD dan BK gliseril guaiakolat 1,070 bpj dan 3,568 bpj dan dekstrometorfan HBr 0,303 bpj dan 1,010 bpj. Uji presisi gliseril guaiakolat 0,96% dan dekstrometorfan HBr 1,69%. Uji akurasi dengan nilai persen perolehan kembali gliseril guaiakolat dan dekstrometorfan HBr berturut-turut 100,03% dan 99,82%. Uji spesifisitas diperoleh nilai resolusi gliseril guaiakolat dan dekstrometorfan HBr berturut-turut sebesar 7,562 dan 8,135 untuk larutan standar 7,535 dan 8,311 untuk larutan sampel. Hasil validasi menunjukkan bahwa metode analisis yang dilakukan memenuhi syarat validasi metode.

Kata kunci : Dekstrometorfan HBr, Gliseril Guaiakolat, KCKT, Validasi.

Abstract

DEVELOPMENT OF THE METHOD OF GLYCERIL GUAIAKOLATE AND DEXTROMETHORPHAN HBr ANALYSIS OF COMBINATION TABLET USING HPLC METHODS

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Cough is the body's defense in the respiratory tract because of the presence of mucus or mucus. Tablets for cough medicine usually consist of a glyceryl guaiakolate and dextromethorphan HBr combination. The simultaneous method for developing glyceryl guaiakolate and dextromethorphan development methods is needed. This study aims to validate the method in approving glyceryl guaiacolate and dextromethorphan HBr mixture levels in combination tablet preparations. The development of validation methods can be done by high performance liquid chromatography method. Validation method uses C18 column (150 × 4.6 mm) mobile phase methanol: water: orthophosphate acid 0.1% (60: 35: 5 v / v), flow rate 0.5 ml / minute, 10 minutes elution time, isocratic elution system, ultraviolet detector and wavelength of 279 nm. From the method validation test, the value of the glyceryl guaiakolate correlation coefficient (R) of 0.9991 and dextromethorphan HBr 0.9982 was obtained. Glyceryl guaiakolate LoD and LoQ values of 1.070 ppm and 3.568 ppm and dextromethorphan HBr were 0.303 ppm and 1,010 ppm. The glyceryl guaiakolate 0,96% precision test and dextromethorphan HBr were 1,69%. Accuracy test with glyceryl guaiakolate and dextromethorphan HBr percent recovery values were 100.03% and 99.82%, respectively. Specificity test obtained the resolution of glyceryl guaiakolate and HBr dextromethorphan in the amount of 7,562 and 8,135 for standard solutions 7,535 and 8,311 for the sample solution. The validation results show that the analysis method carried out meets the method validation requirements.

Keywords : Dextromethorphan HBr, Glyceryl Guaiacolate, HPLC, Validation.