ABSTRACT

OPTIMIZATION AND VALIDATION OF HPLC METHOD FOR DETERMINATION OF PARACETAMOL, EPHEDRINE HCl AND GLYCERYL GUAIACOLATE IN COUGH - COLD SYRUP

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The aim of the present study was to obtain a valid HPLC method for determination of paracetamol, ephedrine HCl and glyceryl guaiacolate simultaneously in cough-cold syrup. Optimum separation of the compounds was obtained using a C-18 Lichrospher 5 μm column with a mixture of methanol:water containing acetic acid glacial 0.5% and sodium hexane sulfonate 5 mM as mobile phase (35:65) in isocratic system at flow rate of 1 ml/min. The analysis was performed with PDA detector at 262 nm and temperature of column of 30°C. Retention time of paracetamol was 3.212 minutes, glyceryl guaiacolate was 8.430 minutes and ephedrine HCl can not be detected using this method. Resolution (Rs) between paracetamol and glyceryl guaiacolate was 13.73, respectively. A good linearity was achieved in the range of concentration from 100.2 to 300.7 mg/ml for parasetamol and between 40.4 and 121.2 mg/ml for glyceryl guaiacolate. Recoveries of paracetamol and glyceryl guaiacolate were (99.36±0.55)% and (99.71±0.17)%, respectively. The relative standard deviation (RSD) values was less than 2% for each compounds. The methods showed good result and fulfill the validation requirements.

Keywords: paracetamol, glyceryl guaiacolate, ephedrine HCl, HPLC, method validation, cough-cold syrup formulation