Abstract

Charles University in Prague
Faculty of Pharmacy in Hradec Králové
Department of Analytical Chemistry
Candidate: Mgr. Barbora Sohrová
Consultant: PharmDr. Ludmila Matysová, Ph.D.
Thesis Title: Development of HPLC method for the determination of homatropine and scopolamine in eye drops

High performance liquid chromatography (HPLC) method for the determination of homatropine hydrobromide and its degradation product- scopolamine hydrobromide in eye drops at a concentration of 1% (with sodium chloride), 2% (with sodium chloride) and 2% (with buffer F 6.45) active substance was developed.

During the development of the method, various mobile and stationary phases were tested. For the validation was chosen column Ascentis Express F5 (100 x 4.6 mm, 2.7 µm). The mobile phase was composed of acetonitrile and phosphate buffer in a ratio of 9:91 (V/V). Phosphate buffer contained 3.12% aqueous solution of sodium dihydrogen phosphate dihydrate and 200 µl of triethylamine. Buffer pH was adjusted with phosphoric acid 85% to the value 2.5. Injection volume was 5 µl, flow rate was 1.1 ml/min and UV detection was performed at a wavelength of 210 nm. Analysis time was less than 6.5 minutes.

Analyzed solution contained standard solution homatropine hydrobromide at a concentration of 25 mg/100 ml, and its degradation product scopolamine hydrobromide at a concentration of 0.5 mg/100 ml.

The developed method was completely validated and test suitability of the chromatographic system has been worked out. Validation parameters were evaluated: precision, accuracy, selectivity, linearity, robustness, stability and detection limit. Validation method provides precise and accurate results; it is suitable for using in the routine analysis in the control laboratory.