

ABSTRACT

Determination of Selected Active Substance in the Preparation

VI.

Thesis

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Suitable UPLC methods for the determination of cinchocainum-hydrochloridum and for the determination purity of dexamethasonum were searched. The chromatographic column Kinetex™ C18 (150 x 2,1 mm, 1,7 µm) was chosen.

A suitable mobile phase for the determination of cinchocainum-hydrochloridum was a mixture of acetonitrile:solution of triethylamine in concentration 30 mmol/l (1,05 ml triethylamine in 250 ml of water), 75:25. pH of the mobile phase was adjusted to 7,0 by orthophosphoric acid. Flow rate was 0,2 ml/min. UV detector scanned at 325 nm. The column temperature was maintained at 30 °C. Linearity, repeatability and accuracy were tested under these conditions.

Method for determination purity of dexamethasonum was running under conditions of gradient elution. Composition of mobile phase: Mobile phase A was acetonitrile:water, 30:70. Mobile phase B mixture of acetonitrile:solution of triethylamine in concentration 30 mmol/l (1,05 ml triethylamine in 250 ml of water), 75:25. pH of the mobile phase was adjusted to 7,0 by orthophosphoric acid. Flow rate 0,2 ml/min. Detection UV at 238 nm, the column temperature 30 °C. Specificity, linearity, LOQ, precision were tested under these conditions.

Replicate injections and the symmetry factor of the principal peak were examined in system suitability test.