ABSTRACT

Charles University in Prague, Faculty of Pharmacy in Hradec Králové

Department of Analytical Chemistry

Candidate: Zuzana Saifrová

Supervisor: Ludmila Matysová

Title of Diploma Thesis: Developement and validation of HPLC method for analysis of pharmaceutical preparation Dexamethasoni acetas solutio.

This diploma thesis was aimed on developement and subsequent validation of method for determination of dexamethasone acetate and its impurity in pharmaceutical preparation Dexamethasoni acetas solutio.
The developement was based on method refered as the test of impurities of dexamethasone acetate described in Czech Pharmacopoeia 2009.
The HPLC method with UV-VIS detection set at 254 nm was used.
The developement was based on modification of some conditions of analysis, especially composition of mobile phase and parametres of the chromatographic column were optimised. The lenth of analysis and also resolution and symmetry of peaks of the active substance and its impurity were mainly observed. In the final version of the method isocratic elution with mobile phase ACN:H_2O 50:50 and with flow 1,5 ml/min was chosen and the column HS-C18 100 × 4,6 mm was used. The samples were soluted right in the mobile phase and injected on the column in volume of 10 µl. Significant shortening of analysis was achieved and validation aproved that this methode is appropriet for intended use and that it provides accurate and precise results.