ABSTRACT

Charles University in Prague
Faculty of Pharmacy in Hradec Králové
Department of Pharmaceutical Chemistry and Drug Analysis
Candidate: Mgr. Jana Kašková
Consultant: RNDr. Milan Mokrý, CSc.
Title of Thesis:
Validation of HPLC evaluation of amlodipine and atorvastatin in combinated dosage forms

The topic of this thesis is the validation of chromatographic method. Validated method is the simultaneous HPLC analysis of amlodipine besilate and atorvastatin in combinated dosage form. Chromatografic column Nucleosil 125x4 mm 120-5 C18, Macherey-Nagel was used as stationary phase. Mobile phase was formed by mixture of acetonitrile and dibasic sodium phosphate dodecahydrate solution (0.025 mol / l), acidified with phosphoric acid at pH 4.4 in the ratio 55 : 45. A flow rate was 1.0 ml/min and the temperature was 25 ° C. There was used the internal standard propylparaben. The detection was performed at 210 nm using an UV-VIS detector. The method was validated for linearity, precision, accuracy, robustness and selectivity.
Linearity was confirmed by analyzing samples of standards in the range 50-150 % of their expected concentration. To verify the accuracy there were prepared six samples of the same composition and then relative standard deviation was calculated. RSD ranged from 0.04 to 1.38 %. Accuracy was assessed by analyzing the model samples that were prepared by adding known amounts of active substances to placebo. The recovery ranged from 97.93 to 101.98 %. The robustness of the method was verified by changing the parameters of the mobile phase. There were changed pH, concentration of buffer and ratio of aqueous and organic components of the mobile phase. During the selectivity experiments there weren't found any substances which would interfere with each other.