

ABSTRACT

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HPLC quantification of Amlodipine and Perindopril in Combined Dosage form

Rigorous Thesis

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Chromatographic conditions for the analysis of amlodipine and perindopril in a combined dosage form were elaborated in this thesis. For the stationary phase LiChroCART 250-4 column with LiChrospher 100 C 18 cartridge was chosen and a mixture of mobile phase in composition of ammonium hydrogen phosphate and ammonia in ratio 30 : 70 with addition of 0,1% triethylamine was evaluated as optimal. The mixture was adjusted to pH of 3,5 by 30% phosphoric acid. Flow rate was set for 1 ml/min and temperature of column for 50°C. Detection was performed by UV detector at 210 nm wave length. Benetazon was used as an internal standard.

Chromatographic conditions were optimized first by examination of elution dependence on pH of mobile phase. As pH of mobile phase decreased, retention times of all researched substances extended. Then the capacity ratios of all researched substances were examined in dependence on mobile phase composition. It is obvious according to results, that as the amount of methanol in mobile phase composition increases, capacity ratios of particular substances decrease.

Method validation was verified by linearity, precision, accuracy and selectivity. For linearity a calibration curve was used. Calibration curve parameter of amlodipine is an equation : $y = 7,2013x + 0,0281$ with a correlation coefficient : $R^2 = 0,9975$. An equation for perindopril is : $y = 2,1789x + 0,0224$. Correlation coefficient equals : $R^2 = 0,9990$. Precision of the method was valuated as a reproducibility. From results of six samples their volumes

and relative standard deviations were calculated. 101,4 % of declared amount of amlodipine and 102,4 % of declared amount of perindopril was quantified from results. Average relative standard deviation for amlodipine was 0,69 %, for perindopril it was 0,63 %. Accuracy of the method was verified by recovery and it ranged between 98,2 - 100,5 %. Selectivity was verified by injection of placebo solution.