SUMMARY

Analytical evaluation of drugs by liquid chromatography VI

Degree paper

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The aim of this degree paper was to optimize conditions for the determination of 6-aminocaproic acid, hydrolytic degradation product of accelerant of transdermal penetration transkarbam 12, using high-performance liquid chromatography (HPLC) and subsequently to validate this method. 3,5-dinitrobenzoyl chloride was used before HPLC analysis for derivatization of 6-aminocaproic acid. Analysis of derivatized acid was performed on Separon SGX C-18 analytical column (150 x 3mm I.D, 5µm). The gradient elution was used for the separation. The mobile phase was consisted of acetonitrile and sodium acetate buffer pH 4,5 and the flow rate was 1 ml/min. 20 ul sample volumes were injected into the chromatographic system. Wavelength used for the detection was 230 nm. The method of internal standard was used for quantitative evaluation of derivatized 6-aminocaproic acid and 7-aminocaprylic acid was chosen as the most suitable internal standard. After the development of the method, these validation parametres were evaluated: precision, accuracy, linearity, selectivity, ruggedness, limit of detection and limit of quantification. The method was found as precise, accurate, linear (correlation coeficient value was 0,9998), selective and rugged enough. The limit of detection was 0,75 µg/ml and limit of quantification was $1.8 \mu g/ml$.