SUMMARY

Determination of Transkarbam 12 and Its Impurities Using HPLC Coupled with MS Detection

Master paper

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Charles University in Prague, Faculty of Pharmacy in Hradec Králové, Department of Pharmaceutical Chemistry and Drug Control, Heyrovského 1203, Hradec Králové This paper deals with determination of Transakrbam 12 (T 12), its three impurities ε -aminocaproic acid (Ak), ε -caprolactam (Ka) and the adduct of T 12 and Ak, and of the internal standard which was 8-aminocatanoic acid (Ao). Transkarbam 12 is a new substance which belongs to the group of accelerators of transdermal penetration. Such substances facilitate or enable the drugs passing through the skin barrier into the system circulation. Chromatographic conditions were optimised for determination of the above listed substances using HPLC coupled with MS detection. Using the direct injection MS and MS/MS spectra of all substances were taken and conditions of their detection were optimised. Chromatographic separation was achieved using Luna Phenyl-Hexyl analytical column (5 μ m, 150 x 3.0 mm). Mobile phase contained water and acetonitril with 0.025 % addition of formic acid. Separation was carried out under the gradient elution with the profile 0. - 1. min 4 % acetonitrile; 1. - 25. min 4 \rightarrow 55 % acetonitrile; 25. - 30. min 4 % acetonitrile. Under these conditions following retention times were achieved: Rt (Ak) = 1.84 min; Rt (Ao) = 2.82 min; Rt (Ka) = 9.91 min; Rt (T 12) = 22.41 min; Rt (adduct) = 22.94 min.