

ABSTRACT

Valuation of the biologically active substances by high performance liquid chromatography II.

(Validation of determination of metformin-hydrochloride by high performance liquid chromatography)

Thesis

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The method for determination of the metformin-hydrochloride by high performance liquid chromatography in pharmaceutical preparations Diaphage 500 and Diaphage 850 was optimised. Using the principle of ion exchange chromatography, the method was carried out on the μ Bondapak C₁₈ (10 μ m) column. A mobile phase composed of sodium pentanesulfonate and sodium chloride at a flow rate 1,5 ml/min was used for the separation. pH was adjusted to 3,5 using phosphoric acid. The temperature was set at 25,0 °C. Detection was carried out at 218 nm.

Following these conditions the method was validated. The accuracy, precision, linearity and specificity were also verified. All tested parameters satisfied the criteria.