

# ABSTRACT

## **Analytical drug evaluation by chromatographical methods II. ( Determination of ambroxol in pharmaceutical preparation )**

Diploma paper

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In this diploma paper is described elaboration of one possible method of HPLC analysis of ambroxol and methylparaben ( and its degradation product, p-hydroxybenzoic acid ) in pharmaceutical preparations. Optimal results are provided by analysis made on column Separon SGX C 18 from Tessek, using mobile phase in composition acetonitril : phosphate buffer (  $\text{KH}_2\text{PO}_4$  0,08 mol/l; pH 5,8 ) 40:60 v/v, with flow rate of 0,5 ml/min. Detection was performed at 254 nm by UV detector.

For verification of linearity was used a method of calibration curve, constructed from results from analysis of five solutions with various concentration of components. Precision was verified by analysis of six solutions simulating real composition of pharmaceutical preparation. Validation was performed using propylparaben as internal standard.

This method was used for quantification of MUCOSIN® components. Amount of ambroxol was determined on 7,5642 mg/ml which corresponds to 100,86 % of declaration amount ( 7,5 mg/ml ). The amount of methylparaben was determined on 1,7383 mg/ml.