

ABSTRACT

Title: The usage of HPLC in pharmaceutical analysis

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This labour deals with determination and validation of method suitable for qualitative and quantitative analysis of dimetinden maleas in Fenistil[®] gel trough the use of high performance liquid chromatography with UV detection.

There were two differential analytical columns tested (C18 and ZIC[™] column).

Acceptable outcomes were got with these chromatographic conditions:

- wavelength $\lambda = 258$ nm.
- analytical column: SeQuant ZIC[™] Column(50 x 2.1 mm; 5 μ m)
- compound of mobile phase: acetonitrile : aqueous solution of acetic acid (25 mM) and ammonium acetate (2,5 mM), (87,5:12,5)
- flow rate $f_m = 0,3$ ml/min
- internal standard: diltiazem hydrochloride

Recovery, effectivity of column, assymetry and resolution of chromatographic peaks were tested in validation tehse method. Each of them reposed in licenced range.