

IDENTIFICATION AND QUANTITATIVE DETERMINATION OF FUSIDIC ACID IN THE GEL FOR THE TREATMENT OF THE ACNE VULGARIS OF I-II STAGE

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With comprehensive research, we have proved the gel composition and technology of local action for the treatment of acne I-II stage.

As active substances were selected fuzidiyeva acid as a component with a strong antimicrobial activity and panthenol - like substance that is known reparative action.

At this stage, our objective of the study was to develop a method of high-performance liquid chromatography (HPLC) to determine panthenol developed in gel base.

Identification. In the chromatogram obtained with the test solution retention time peak panthenol must meet the retention time of the peak in the chromatogram panthenol reference solution.

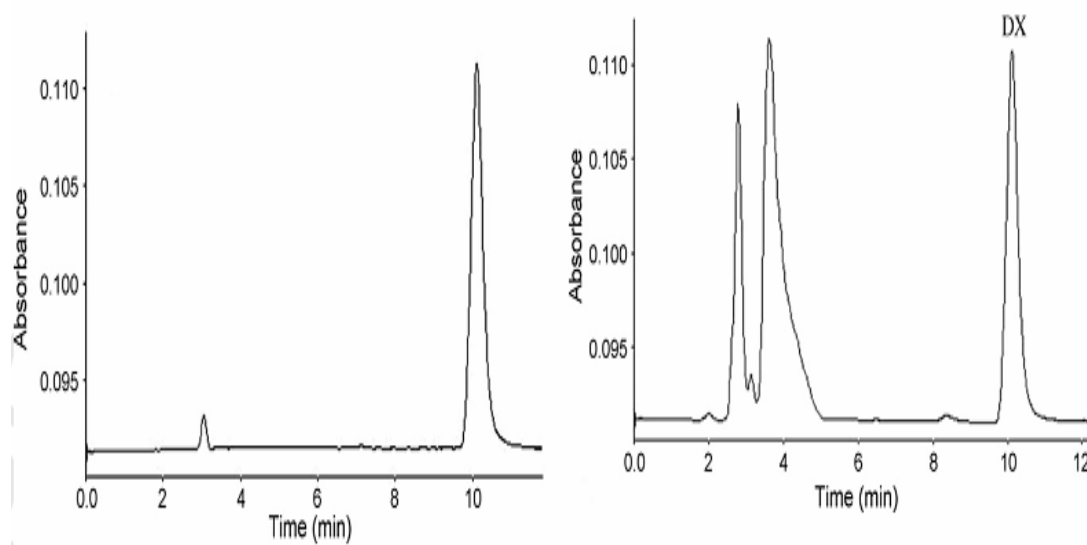


Fig. 1. Chromatogram obtained with reference solution (left) and test solution gel (right) for the identification of panthenol

Quantitative determination. Test solution: about 1.00 g (accurate weight) gel is placed in a volumetric flask of 100 ml, dilute the solution to the mark with the mobile phase, mixed and centrifuged at speed 7000 r / min. for 10 min.

If necessary nadosadkovu liquid was filtered through a teflon membrane filter with a pore size of 0.45 microns. Reference solution: approximately 50.0 mg (accurate weight) Panthenol standard sample is placed in a volumetric flask of 100

ml, dissolved in 30 ml of mobile phase, dilute the solution to the mark with mobile phase and mix. To 20 ml with reference solution and the test solution chromatographed on liquid chromatography with spectrophotometric detector receiving at least 3 chromatogram of the following conditions: column Vydac Protein C4, size 250 mm*4,6 mm, filled with sorbent particle size of 5 microns or equivalent; predkolumna: Vydac Protein C4 mm x 4.6 mm, filled with sorbent particle size of 5 microns or equivalent; mobile phase of 0.1% aqueous trifluoroacetic acid, degassed convenient way, the temperature of the column thermostat OS 30.0, the rate of mobile phase 1, 0 ml / min, detection at a wavelength of 206 nm.

Chromatographic system is considered suitable if the following conditions are met: the efficiency of the chromatographic system is designed for peak panthenol, shall be not less than 2000 volumes, peak symmetry factor triclosan should be not more than 2.0; inrelatively standard deviation of the peak areas panthenol must comply with 2.2. 46 (NPhU1.2).

Panthenol content in mg in 1 g of gel is calculated by the formula:

$$Y = \frac{S \cdot m_0 \cdot P \cdot 100}{S_0 \cdot 100 \cdot 100 \cdot m} = \frac{S \cdot m_0 \cdot P \cdot 0.01}{S_0 \cdot m}$$

where: S – the average peak area from panthenol calculated chromatogram of the test solution; S_0 – the average peak area from panthenol calculated chromatogram obtained with reference solution m_0 – mass of sample NW panthenol, mg P – Fixed substance in OT Panthenol.

Panthenol content in 1 g of gel should be between 47.5 to 52.5

Determination of content of panthenol in the developed formulation is proposed to HPLC under the following conditions : column Vydac Protein C4, size 250 mm x 4.6 mm, filled with sorbent particle size of 5 microns or equivalent ; predkolumna : Vydac Protein C4 mm x 4.6 mm , filled with sorbent particle size of 5 microns or equivalent ; mobile phase of 0.1 % aqueous trifluoroacetic acid, degassed convenient way , the temperature of the column thermostat 30.0 °C , Flow rate 1.0 ml / min , detection at 206 nm wavelength.

Under these conditions, the peak panthenol completely separated from the other components of the gel components.

Data obtained showed that the method is stable and reproducible in different days.