UV-SPECTROPHOTOMETRIC ANALYSIS METHOD FOR FLUOCINOLONE ACETONIDE

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In the manufacture of medicines, the most important requirement of good manufacturing practice (GMP) is the cleaning of equipment, which is carried out to prevent cross-contamination when moving from one drug to another.

One of the objects selected is fluocinolone acetonide, which is a corticosteroid used to treat skin conditions like eczematous otitis externa, diabetic macular edema, and non-infectious uveitis of the posterior segment of the eye.

The spectrophotometric method was chosen as the method for the quantitative determination of residual amounts of fluocinolone acetonide. UV spectroscopy is a type of absorption spectroscopy in which light from the UV region (200–400 nm) is absorbed by the molecule. Absorption of UV radiation results in the excitation of electrons from the ground state to a higher energy state.

UV/Vis spectroscopy is routinely used in analytical chemistry for the quantitative determination of different analytes, such as transition metal ions, highly conjugated organic compounds, and certain biological macromolecules. Measurement is usually carried out in solution.

According to the British Pharmacopoeia (BP), fluocinolone acetonide is soluble in acetone and methanol.

Materials and instruments used were: Fluocinolone acetonide (NES211001, China), spectrophotometer "Evolution 60s" (Thermo Fisher Scientific, USA), analytical scales "AXIS" (Poland), class A volumetric glassware, and reagents that meet the requirements of the State Pharmacopoeia of Ukraine (SPhU).

Fluocinolone acetonide is soluble in methanol, so methanol is used as the solvent.

The standard stock solution of fluocinolone acetonide (FLU) was prepared by transferring an accurately weighed 50.0 mg of fluocinolone acetonide into a 50.0 ml volumetric flask containing methanol dissolved properly. The volume was then increased by using methanol to achieve a concentration of 1.0 mg/ml. From this, 1.0 ml of the solution was transferred to a 50.0 ml volumetric flask and made up the volume with methanol to give a concentration of 0.02 mg/ml.

The standard stock solution of 0.02 mg/ml was scanned in the range of 200–400 nm to determine the wavelength of maximum absorption. The drug showed an absorption maxima at 237 nm (Fig. 1).

To study the limit of detection, fluocinolone acetonide was investigated, and the subordination of solutions of the substance to the basic law of light absorption was also investigated. A series of standard methanolic solutions of the compound were prepared, and the optical density of these solutions was determined at a wavelength of 237 nm. It was found that the subordination of solutions of fluocinolone acetonide in methanol is observed in the concentration range from 0.002 mg/ml to 0.024 mg/ml (Fig. 2).

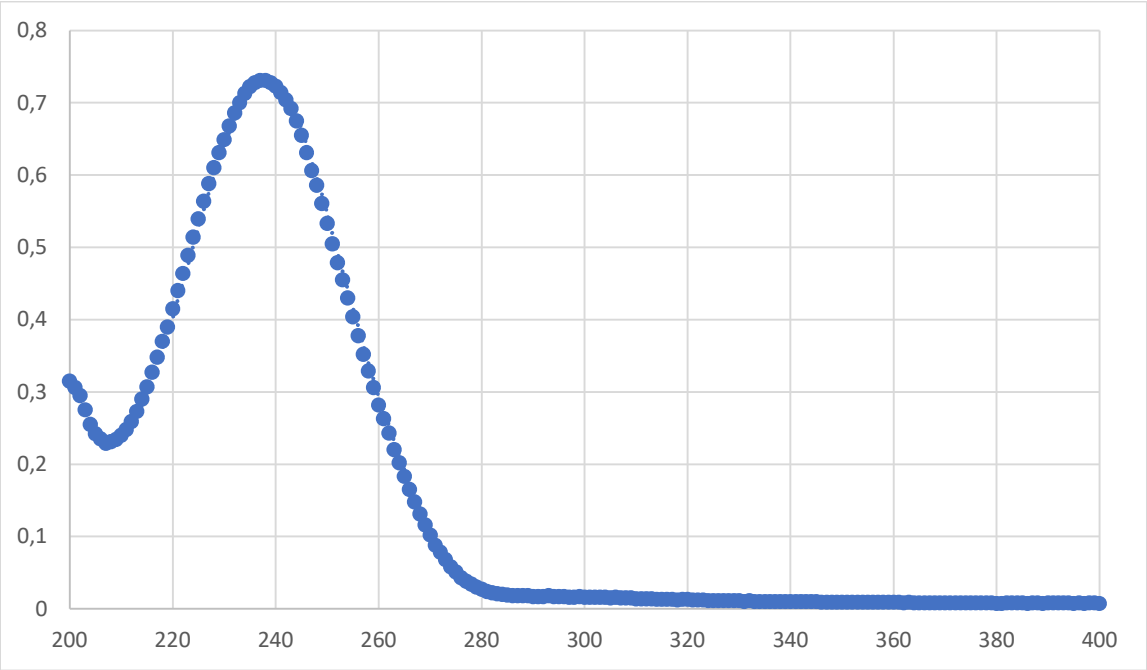

Fig. 1: Absorption spectrum of a 0.002% methanol solution containing fluocinolone acetonide

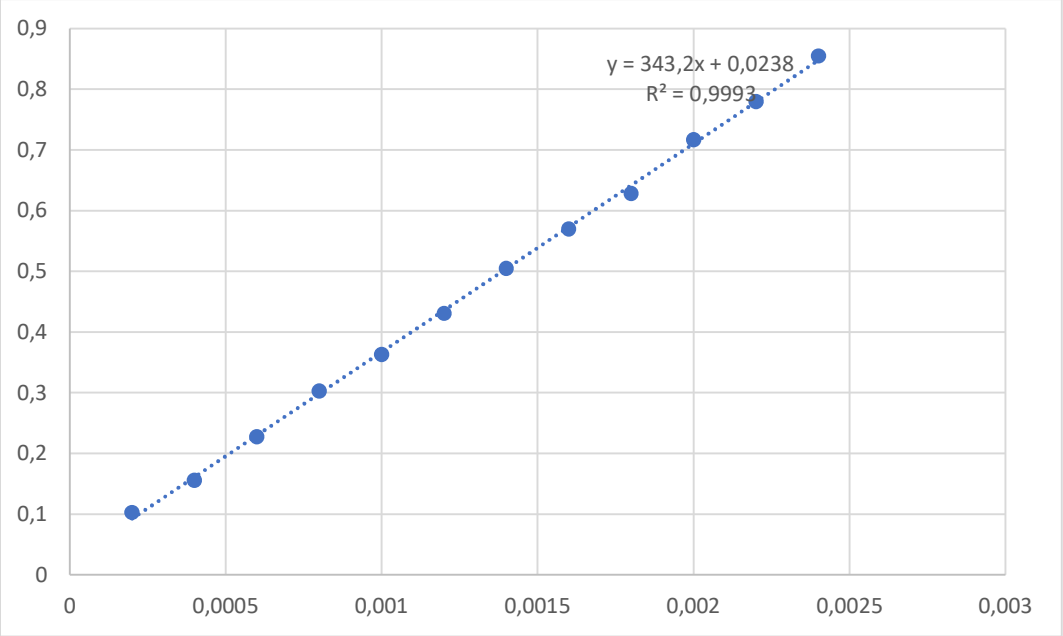

Fig. 2: Calibration graph showing optical density dependence on fluocinolone acetonide concentration in the methanol solution

Thus, the proposed method allows quantifying the residual content of the active pharmaceutical ingredient fluocinolone acetonide up to 16% of the maximum allowable value (0.0003 mg/l (ppm)).

Finally, the obtained data will allow determining the quantitative content of residual amounts of the active pharmaceutical ingredient fluocinolone acetonide on the equipment after production and cleaning.