

## DEVELOPMENT OF A SPECTROPHOTOMETRIC METHOD FOR THE QUANTITATIVE DETERMINATION OF KETOTIFEN FUMARATE IN TABLETS

*El Sahily Aly, Grynenko V.V., Amjad Abu Shark, Bevz N.Yu.*

**National University of Pharmacy, Kharkiv**

**Introduction.** Recently, there has been a sharp increase in the incidence of allergies. According to WHO data, 20 to 40% of the world's population suffer from this disease today. Thus, every 3rd person is allergic, regardless of age and nationality. Allergic diseases negatively affect the quality of life of patients and lead to significant economic losses. For symptomatic treatment of allergic conditions, including allergic rhinitis and conjunctivitis, over-the-counter antihistamines, which include ketotifen fumarate, are most commonly used.

**Purpose of the study.** To develop a spectrophotometric method for the quantitative determination of ketotifen fumarate in tablets and calculate its cost.

**Research methods.** Absorption spectrophotometry in ultraviolet and visible regions, metrological characteristics of the methods, system analysis, economic analysis.

**Main results.** The aromatic structure and physicochemical properties of ketotifen make it possible to use the method of absorption spectrophotometry in the ultraviolet region to identify and quantify the active pharmaceutical ingredient in the substance and medicines. To develop a method for the quantitative determination of the compound, the spectral characteristics of the substance in ethanol and 0.1 M hydrochloric acid solution were studied.

It was established that the UV-spectrum of an alcohol solution of ketotifen fumarate is characterized by an absorption maximum at a wavelength of 299 nm, which is due to the presence of aromatic and thiophene rings in the drug molecule. When the solvent is replaced by a 0.1 M hydrochloric acid solution, the nature of the spectrum does not change, and the maximum is observed at a wavelength of 300 nm. Experimental data indicate that compliance with the Bouguer-Lambert-Beer law is observed for alcoholic solutions of ketotifen fumarate within the compound concentrations from  $5,0 \cdot 10^{-4}$  to  $2,5 \cdot 10^{-3}\%$ , the specific absorption rate is from 336 to 343, for solutions of the substance of the substance in a 0.1 M solution of hydrochloric acid in the concentration range of  $7,5 \cdot 10^{-4}$ - $3,0 \cdot 10^{-3}\%$ , specific absorption rate from 274 to 286.

The cost of the analysis was calculated based on the cost of the main reagents that are needed for the analysis in accordance with the Sigma Aldrich catalog. The cost of a standard sample of ketotifen fumarate, labor costs, depreciation of the device and electricity were not considered, since both methods are reproduced on the same device and take the same amount of time, so these parameters will be the same. Thus, the cost of materials for the determination of ketotifen fumarate in 0.1 M hydrochloric acid solution is 0.62 euros, for analysis in an ethanol medium - 1.25 euros.

**Conclusions.** The metrological characteristics and the calculated cost of the spectrophotometric method of ketotifen fumarate in a 0.1 M hydrochloric acid solution indicate the prospect of using it in the routine analysis of ketotifen fumarate in tablets.