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OPTIMIZATION OF THE METHOD OF THIOTRIAZOLINE QUANTITATIVE DETERMINATION BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

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In medicine and pharmacy, thiotriazoline is used as a cardio- and hepatoreactor because it exhibits antioxidant, membrane-stabilizing, anti-ischemic, antiviral and regenerative effects. The medicine belongs to the essentials of life and every year it is used more and more widely.

Quality control of medicinal products is carried out in accordance with regulated methods. Currently, thiotriazoline in medicinal products is quantitatively determined amperometrically, spectrophotometrically, by the method of high performance liquid chromatography (HPLC), by the method of acid-base titration with the preliminary release of nitrogen according to the Kjeldahl method, gravimetry, direct non-aqueous titration, etc. [1,2]. Since the HPLC method occupies a leading position in pharmaceutical analysis, the research is focused on the method of determining thiotriazoline by this method [2].

The aim of the work was to optimize the conditions for the quantitative determination of thiotriazoline in dosage forms by liquid chromatography.

Solid and liquid dosage forms, which include thiotriazoline, were chosen as the object of the study. Sample 1 (tablet form) contains 200 mg of the active substance and auxiliary substances: starch, povidone, powdered sugar, cellulose, calcium stearate in a tablet, sample 2 (solution for injections) - 25 mg of thiotriazoline in a milliliter of solution (solvent - water for injections) .

As a standard, the Pharmacopoeia standard sample of SPhU Thiotriazolin Morpholinium tizotate Morpholine salt thiazotic acid (Tiotriazolin), catalog number T0406, registration number 357172-63-5 was used.

In this paper, the dependence of the pressure in the Nucleosil C18 100-5, 2504.6 mm column on temperature, the influence of the rate of the liquid phase on the process of chromatography and UV detection of thiotriazoline was investigated. As a result, it

was established that the optimal conditions for the chromatographic determination of thiotriazoline using a Nucleosil C18 100-5, 2504.6 mm column are an elution rate of 1 ml/min and 35°C. A solution of 20 ml of methanol and 80 ml of phosphate buffer solution with pH = 3.0 and UV detection of thiotriazoline at a wavelength of 220 nm was chosen as the mobile phase, as suggested by the authors of the paper [2].

The results of the research made it possible to develop a modified method of quantitative determination of the content of thiotriazoline in drug samples by the HPLC method. Before chromatography of the tablet form, sample preparation was carried out according to the standard method [1]. In optimal conditions of chromatography, excipients of the solid dosage form (sample 1) do not affect the results of the analysis.

In order to determine the linearity of the proposed method [3], the dependence of the area of the chromatographic peak on the concentration of standard solutions (80, 100 and 120 µg/ml) was investigated and the linear regression equation was calculated. It has been established that the linear function is described by the equation $y = 72162x + 86198$ with a correlation coefficient of 0.9998 and meets the requirements of the SPhU [1,3].

The content of thiotriazoline according to the results of the chromatographic analysis by the proposed method is: in the sample of the liquid dosage form 25.4 ± 0.3 mg/ml; in a sample of a solid dosage form – 199.2 ± 2.1 mg in a tablet.

Verification of correctness by the "added-found" method indicates sufficient accuracy and reproducibility of the method. It has been established that the relative error of the mean value meets the requirements of the SPhU.

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