Validation of the method of quantitative determination of the active substance ((S)-2,6-diaminohexanoic acid 3-methyl-1,2,4-triazolyl-5-thioacetate in eye drops

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Introduction. According to the Ministry of Health of Ukraine, eye diseases are now the sixth most common disease. Due to the severity of the consequences of eye diseases and the social costs of compensating blindness and poor vision, such pathologies require a lot of resources and continuous prevention and treatment. In today's context, given the military operations taking place in Ukraine, various injuries to the visual apparatus are one of the most complex clinical and social problems. Bruises and burns of the eye rank second only to penetrating injuries among injuries to the structures of the visual apparatus, accounting for 20%–42.2% of cases. One of the most urgent tasks of medicine and pharmacy is the development of new ophthalmic drugs, namely eye drops, which remain the most common and convenient form of medication due to their ease of use.

A new compound derived from 1,2,4-triazole was synthesized at the Department of Pharmaceutical, Organic and Bioorganic Chemistry of Zaporizhzhia State Medical and Pharmaceutical University. It refers to ((S)-2,6-diaminohexanoic acid 3-methyl-1,2,4-triazolyl-5-thioacetate), which exhibits anti-inflammatory, wound-healing and reparative effects.

Materials and methods. Department of Pharmaceutical, Organic and Bioorganic Chemistry of ZSMPhU, six series of Angiolin eye drops were produced. Certified substances were used: Angiolin, working standard sample, sodium chloride, purified water as auxiliary substances, liquid chromatograph with UV detector; column Hypersil ODS C-18250 X 4.6 with a particle size of 5μm.

Results and discussions. During the determination of validation parameters, it is established that the method is characterized by sufficient correctness, since the criterion of insignificance of the systematic error of the method is fulfilled. The systematic error of the method satisfies the requirements of statistical and practical insignificance. The high value of the correlation coefficient r=0.9999 satisfies the requirements of the acceptance criterion (r=0.99810) and confirms the linearity of the dependence between the amount of Angiolin taken and found in the range from 80% to 120%, following its nominal content in the preparation. The requirements for parameters of linear dependence (a, SD0/b, r) of the Angiolin determination method are met in the entire concentration range from 80% to 120% of the nominal value.

Conclusions. The method of determining Angiolin by HPLC in the range of application of the method meets the acceptance criteria for validation characteristics: specificity, correctness, precision (convergence) and linearity. The total predicted uncertainty of the analyses results does not exceed the critical value regulated by the SPhU, and can be entered into the project of Quality Control Methods.

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