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EGARDING THE STANDARDIZATION OF GLYCINE AND THIOTRIAZOLINE IN THE MODEL MIXTURE BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

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Every year in Ukraine, about 150 thousand strokes occur and more than 100 thousand people die from impaired blood flow in the brain. Most people who survive a stroke suffer from its physical, cognitive, mental and socio-economic consequences throughout their lives, which causes a huge burden of this disease for families, communities and the state. Therefore, the urgent task of modern pharmacy is to create new highly effective drugs for the treatment of these pathologies. Glycine as a neuroprotector is a drug that protects against the development of the ischemic cascade within the therapeutic window. It belongs to the neurotransmitter amino acids that provide protective inhibition in the CNS. Numerous studies have revealed the ability of the amino acid glycine to protect tissues during hypoxia, intoxication or reperfusion. It has been established that the simultaneous use of neurometabolic cerebroprotectors - a basic therapy drug, with antioxidants in most cases potentiates the therapeutic effect of the main active ingredient. At present, one of the well-known domestic antioxidants is thiotriazoline. Thiotriazoline has antioxidant, membrane-stabilizing, anti-ischemic, antiarrhythmic, immunomodulatory, anti-inflammatory, hepatoprotective, and cardioprotective effects. Therefore, the creation of a new combined drug, which includes glycine and thiotriazoline, is currently appropriate and relevant. A rational dosage form in the form of tablets was proposed and created for the new combined drug. For the created combined tablets, it is necessary to develop methods for their standardization. Today, for the standardization of active substances that are part of the finished dosage forms, it is advisable to use new, more sensitive methods of analysis, in particular, high-performance liquid chromatography (HPLC). Therefore, it is this method that attracted our attention and allows us to simultaneously standardize active substances in one sample.

The purpose of the work is to develop a method of standardization of glycine and thiotriazoline in the model mixture by HPLC.

Materials and methods: Certified glycine and thiotriazoline substances were used in the studies. The studies were conducted using a chromatograph model LC-20 Prominence Shimadzu in the following configuration: two LC-20AD pumps, SIL-20A autosampler, SPD-20AV detector, CTO-20A thermostat, CBM-20 ALITE system controller. The Hypersil ODS-C18-5u column was used, 4.6×250 mm, particle diameter 5 μ m; eluent: aqueous solution of $3.4 \text{ g/l Bu}_4\text{NHSO}_4$ and 0.05% trifluoroacetic acid; mobile phase speed: 1 ml/min; analytical detector wavelength: 220 nm; sample volume: 20 μ l. In previous studies, we proposed to perform simultaneous determination of glycine and thiotriazoline content by ion-pair chromatography using an acidic buffer – 0.05% trifluoroacetic acid solution.

Results and discussion. Six series of a model mixture of glycine and thiotriazoline in a ratio of 4: 1 were produced in the laboratory. The test solution and the working standard sample solution were chromatographed alternately to obtain at least three chromatograms for each solution. It is established: the content of glycine in the model mixture is in the range from 198.46 mg to 201.11 mg, and thiotriazoline - from 49.59 mg to 50.86 mg. Thus, according to the content of active substances, the investigated series of model mixture of glycine and thiotriazoline in the ratio 4:1 meet the requirements of HFC.

Conclusion: in the course of research, we have developed a method of standardization of the active substances of glycine and thiotriazoline in the model mixture by HPLC. The developed technique is reproducible, accurate and in the future, after its validation, can be used for standardization of active substances in dosage forms.

In further studies, it is advisable to perform full validation of the developed HPLC method to confirm its suitability for routine quality control of combined dosage forms containing glycine and thiotriazoline. Future work should also include optimization of chromatographic conditions for various formulations, evaluation of the method's robustness and stability-indicating properties, and comparison with other analytical techniques.

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