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STUDY OF THE EXPIRATION DATE AND STORAGE CONDITIONS OF ANTISPASMOLYTIC TABLETS

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Introductions: Stability is an important indicator of the quality of medicinal products since it ensures the preservation of their therapeutic or prophylactic properties, in most cases, for several years during distribution and storage. Since serial goods are not checked for stability as part of output, consumer, or government quality control, it should be the object of special attention at the stages of drug development and registration. One of the main problems of modern pharmaceutical technology is the development of medical forms based on medicinal plants that are easy to use and stable during storage. The stability of the DF largely depends on the conditions of the technological process and the chemical composition and properties of the packaging material. The assessment of stability is carried out by examining the physical and chemical changes of the DF.

Aim: The aim of the study is to study the effect of different conditions on the stability of simeverin tablets by developed composition.

Materials and methods: The experiments were carried out by the conventional storage method (the studies were carried out in climate-controlled wards and rooms that had devices that allowed automatically adjusting the specified storage conditions: temperature, humidity, and light) and by the "accelerated aging" method according to the temporary instruction I-42-2-82 at a temperature of 60 °C. Investigations by the method of natural storage were carried out in laboratory rooms

at a temperature of 22±2 °C. The assessment of the above-mentioned qualitative and quantitative indicators was carried out every 6 months. Studies by the "Accelerated Aging" method were carried out in accordance with the temporary instruction for carrying out works in order to determine the expiry date of medicinal products based on the "Accelerated Aging" method at high temperatures. In this series of experiments, the following temperature regime was used: 60° C. A study on the compliance of the recommended tablets with the required standards was carried out every 11.5 months.

Results and discussion. The first stage of the study was the study of physicochemical, qualitative, and quantitative indicators of the original samples. At the same time, such qualitative indicators as appearance, average weight and deviation from it, humidity, authenticity, solubility, disintegration, microbiological purity, and quantitative content of the active substance were assessed. All of the above indicators were determined in accordance with the requirements of the SP XI presented to the tableted dosage forms and in accordance with the methods given in the STD. The nature of the packaging material has a direct impact on the stability of the developed dosage forms, which is why it receives so much attention. Therefore, at the next stage of the experiment, the recommended tablets were packed in the following 4 types of packaging approved for use in medicine: blister packaging by IS 64-074-91 from polyvinyl chloride envelope by SS 25250-88, blister packaging by IS 64-074-91 from lacquered aluminum foil by TC 48-21-270-78, colorless glass jars type by TC 13-7308001-477-85, jars of sun-protective glass melt type BDS-25 by TC 64-228-84.

Conclusion: Thus, the production technology we recommend, as well as the types of packaging used, ensures the stability of simeverin tablets with an improved composition for 3 years both in studies by the "accelerated aging" method and during storage under normal conditions.