STUDYING THE STORAGE CONDITIONS AND EXPIRY DATES OF "SEDTAB" TABLETS

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Annotation: The analysis of the recommended sedative tablets was carried out. The stability and expiration dates of the recommended Sedtab tablets were carried out by the method of conventional storage and the method of "accelerated aging" according to temporary instructions I-42-2-82 at a temperature of 40 ° C. Recommendations were prepared as a result of the studies, the obtained data on the determination of the shelf life of the recommended tablets. These recommendations are intended for both developers and manufacturers of dosage forms.

Key words: drug stability, tablets, drug shelf life.

The study of the expiration dates and storage conditions of tablets is an important aspect in ensuring the safety and effectiveness of drug therapy. Improper storage and use of drugs can lead to a deterioration in the health of the patient, so it is necessary to take into account all factors that may affect the quality of medicines.

Expiry date of tablets is the period of time during which the drug retains its properties and can be used to treat diseases. It is indicated on the packaging and is determined by the results of research conducted by the manufacturer. Typically, the shelf life is 2 to 5 years, but may be shorter or longer depending on the type of drug. It is important to remember that after the expiration date, the tablets may lose their effectiveness and become hazardous to health. Therefore, drugs that have expired should not be used. In addition, the storage conditions of tablets also play an important role in maintaining their quality. Preparations should be stored in a dry and cool place, protected from direct sunlight and high humidity. Some drugs require refrigeration or protection from magnetic fields. It is also important to take into account the individual characteristics of the tablets. For example, some drugs should not be stored in close contact with other drugs, as this can lead to chemical reactions and loss of effectiveness. The quality, therapeutic efficacy and safety of drugs during storage directly depend on the ability of the drug to maintain properties within the limits established by regulatory documentation (RD) for a certain period under proper storage and transportation conditions, especially from its stability. Based on the results of the stability study, the expiration date is determined, the materials used and the type of primary and secondary packaging are selected, the storage conditions of the medicinal product are determined, which are indicated in the regulation documents and in the instructions for medical use, and also placed on the packaging.

In conclusion, the study of the expiration dates and storage conditions of tablets is an important aspect in the field of safety and efficacy of drug therapy.

The purpose of the study: to conduct an objective and unified assessment of the data provided on the stability of the recommended “Sedtab” tablets.

Materials and methods: The stability of dosage forms is greatly influenced by the physical state of the substance, storage temperature, ambient atmosphere, light, packaging, preparation method, selection of excipients, etc. When storing dosage forms, various processes occur that lead to a change in the chemical structure, which naturally leads either to a decrease in pharmacological activity or to its complete loss. The study of the shelf life of dosage forms is one of the main and final stages in the development of drug technology. Based on the above, the stability of the recommended tablets was studied. The materials of the study were tablets "Sedtab" obtained according to the recommended composition and technology. The experiments were carried out by the method of conventional storage and the method of "accelerated aging" according to the temporary instruction I-42-2-82 at a temperature of 40°C. As is known from the literature, among the physical factors, the greatest influence on the stability of drugs is exerted by temperature, light, and humidity. The first stage of the study was the study of physicochemical, qualitative and quantitative indicators of the original tablet samples. At the same time, such qualitative indicators as appearance, average weight and deviation from the average weight, solubility, disintegration, abrasion, humidity, microbiological purity, quantitative content of the active substance were evaluated. All of the above indicators were determined in accordance with GF XIII. At the next stage of the experiment, the tablets were packed in the following 4 types of packaging approved for use in medicine: clear glass jars (TU-64-228-84) with screw-on plastic lids and gaskets (TU-64-2-250-75); orange glass jars (OST 64-2-71-8) with screw-on plastic lids and gaskets (TU 64-2-250-75), blisterless packaging made of laminated paper with polyethylene coating according to TU13-7308001-477-85 , blister pack made of EP-73 polyvinyl chloride film and lacquered aluminum foil (TU 48-21-270-78). Results and Discussion: In the first phase of the study, we focused on the study of the qualities of tablets that were stored in vivo. Experimental studies in natural conditions were carried out as well as tablets on the cabinets of the laboratory room and in the racks. Every six months, the granules were subjected to analysis. After the experiment, the tablets packed in different types of packaging met the requirements for tablet preparations. For example, the appearance of the tablets did not change over the entire period of the study.

The study of the storage time for the strength of the tablets was checked for abrasion and fracture.

On fig 1. shows the results of studying the effect of time on the strength of Sedtab tablets.

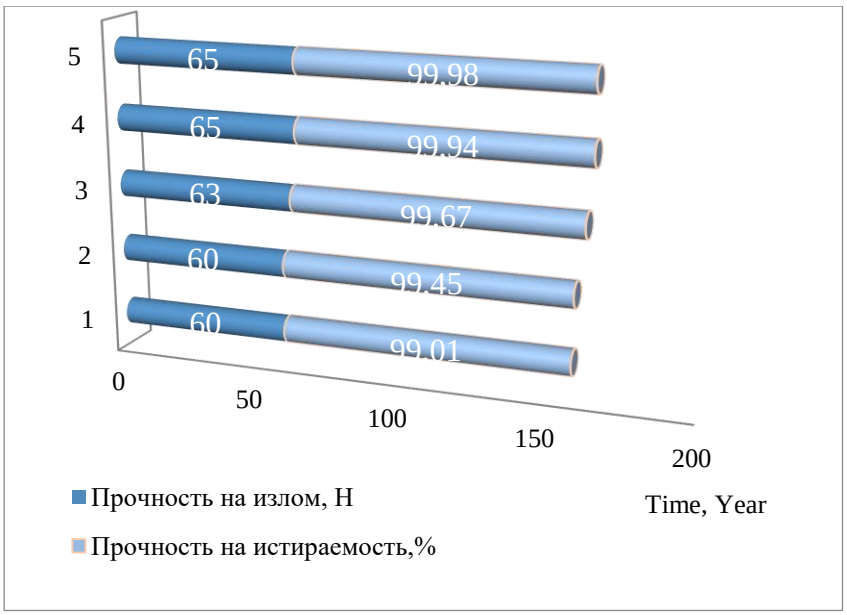
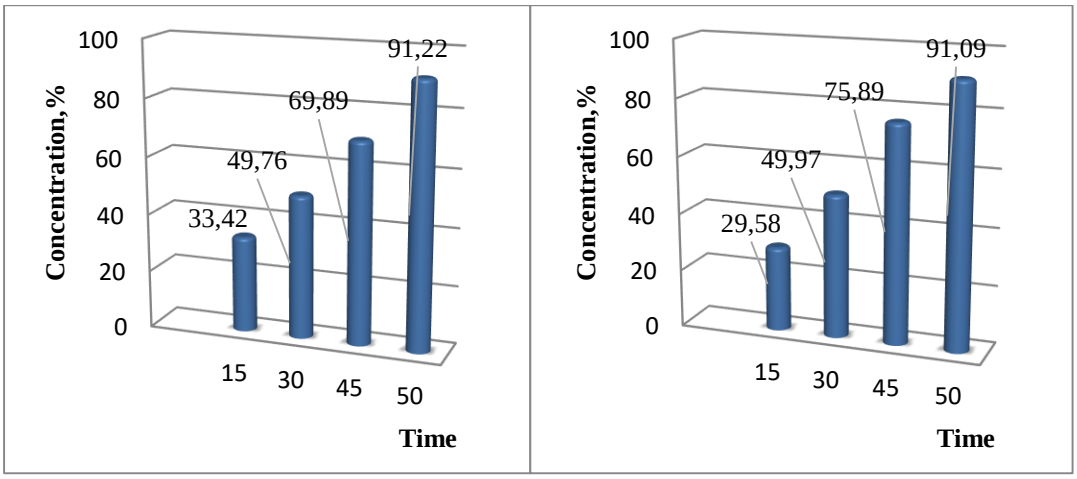


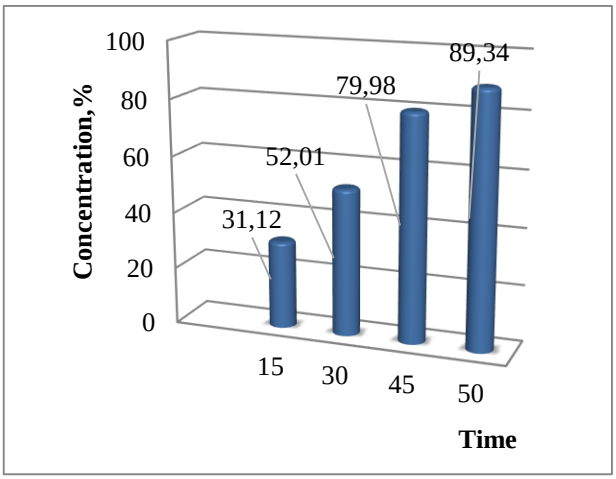
Fig.1. The results of studying the effect of time on strength tablets "Sedtab"

As can be seen from the figure, the strength of the tablets during storage increases slightly, i.e. time affects the stability of tablets directly, but moderately.

At the next stage of the study, the influence of storage time on the release of active substances from Sedtab tablets was studied.



after 6 months **after 12 months**



after 24 months **after 36 months**

Fig.2. Storage Time Study Results for the release of flavanoids from pills "Sedtab"

As can be seen from Figure 2, the time and storage conditions do not affect the solubility of the active ingredients.

The results of studying the influence of storage time on the quantitative content of active substances, passing several years, showed that the quantitative content almost does not change.

The next stage of research was devoted to the analysis of tablets stored in a thermostat, i.e. kept in “accelerated aging”. The data obtained are shown in Table 1.

The results of studies of the qualitative and quantitative indicators of tablets "Sedtab" by the method of "accelerated aging" at a temperature of 400C

Studied indicators	"Sedtab" tablets "Sedtab" tablets U - №1, U-№2, U-№3, U-№4 Storage time, days 23 | 46 | 69 Storage time, days		
Appearance (description)	Tablets of brown color with a brownish tint, interspersed.		
Average weight (g) and deviation from it,%	0,299±3,76	0,303±2,01	0,299±2,95
Disintegration, min.	10	10	11
Disintegration, min.	99,11	98,99	98,94
Breaking strength, N	60	60	59
Dissolution, %	99,76	98,96	98,99
Quantitative content, g	99,11	98,99	98,99

Conclusion. Thus, the selected composition and recommended technology of Sedtab tablets, as well as the types of packaging used, ensure the stability of the tablets for 3 years, both in studies using the “accelerated aging” method and in natural storage.

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