STUDYING STORAGE CONDITIONS AND EXPIRATION DATES SEDTAB TABLETS

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The shelf life of medicinal products is understood as the period of time during which they must fully retain their therapeutic activity, harmlessness and, in terms of qualitative and quantitative characteristics, comply with the requirements of the State Pharmacopoeia or the Federal Law (FS11), in accordance with which they were released and stored under the conditions stipulated by the specified articles. 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 (ND) for a certain period under proper storage and transportation conditions, i.e. from its stability. Based on the results of the stability study, the shelf life is established, the materials used and the type of primary and secondary packaging are selected, the storage conditions of the drug are determined, which are indicated in the RD and in the instructions for medical use, and also placed on the packaging. The stability of dosage forms is greatly influenced by the physical state of the substance, storage temperature, ambient atmosphere, light, packaging, method of preparation, selection of excipients, etc. When storing dosage forms, various processes occur that lead to a change in the chemical structure, which naturally leads to either a decrease in pharmacological activity, or its complete loss. Studying the shelf life of dosage forms is one of the main and final stages in the development of drug technology.

Key words: Sedtab, quality indicators, accelerated aging, disintegration, abrasion, humidity.

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 materials of the study were “Sedtab” tablets obtained according to the recommended composition and technology. The experiments were carried out using the conventional storage method and the “accelerated aging” method according to temporary instructions I-42-2-82 at a temperature of 40˚C. As is known from the literature, temperature, light and humidity have the greatest influence on the stability of drugs among physical factors. 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 assessed. All of the above indicators were determined in accordance with the Global Fund XIII. At the next stage of the experiment, the tablets were packaged in the following 4 types of packaging approved for medical use: colorless glass jars (TU-64-228-84) with screw-on plastic lids and gasket (TU-64-2-250-75); jars made of orange glass (OST 64-2-71-8) with screw-on plastic lids and gasket (TU 64-2-250-75), contour-less packaging made of laminated paper with a polyethylene coating according to TU13-7308001-477-85 , contour-cell packaging made of polyvinyl chloride film EP-73 and varnished aluminum foil (TU 48-21-270-78).

Results and discussion: in the first stage of the study, the study was devoted to the study of the qualities of tablets that were stored under natural conditions. Experimental studies in natural conditions were carried out as well as tablets on cabinets in the laboratory room and in racks. Every six months, the granules were analyzed. The tablets packed in different types of packaging after the experiment met the requirements for tablet drugs. For example, the appearance of the tablets did not change during the entire period of the study. The appearance of the tablets was assessed with the naked eye and it was determined that the tablets were brown with inclusions, the average weight of one tablet and the deviation from it did not change until the end of the study, deviations from the average weight were up to 2.05%, disintegration

was from 8 to 10 minutes, strength was abrasion 98.9 - 99.2%, fracture strength 60-70 N, and the quantitative content of the active substance ranged from 98.4-102.0%.

Studying the storage time for the strength of the tablets, they tested them for abrasion and fracture. According to the results of the study, the strength of the tablet during storage decreases slightly, i.e. Time affects the stability of tablets directly, but moderately. The results of studying the effect of storage time on the quantitative content of active substances over several years showed that the quantitative content remains almost unchanged.

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

Conclusions. 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 when stored under natural conditions.

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