STUDY OF THE STABILITY OF A PHARMACEUTICAL COMPOSITION BASED ON A LIPOSOMAL SYSTEM UNDER VARIOUS STORAGE CONDITIONS

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Liposomes are phospholipid vesicles capable of encapsulating hydrophilic and lipophilic compounds, which improves the pharmacokinetics and therapeutic efficacy of drugs. Due to their multicomponent nature, liposomal systems require careful stability assessment, as changes in physicochemical properties can reduce efficacy, affect the release profile and compromise drug safety. Stability assessment plays a key role in the development of vitamin C preparations, widely used for their antioxidant and metabolic properties. Chemically unstable, vitamin C is sensitive to oxygen, light, temperature and moisture, which reduce its activity. Encapsulation of vitamin C improves stability and bioavailability but requires careful testing at all stages of development and storage.

The aim of the work is to investigate the stability of liposomal vitamin C in the form of solid capsules obtained using the developed technology, with an assessment of the main physicochemical indicators: appearance, active ingredient content, mass homogeneity and disintegration under different storage conditions. The study will determine the preservation of pharmacotechnological properties and assess the suitability of the drug for further use and industrial production.

The stability study was conducted in accordance with the requirements of the current edition of the European Pharmacopoeia. The tests were performed on three batches of liposomal vitamin C in the form of hard capsules. The samples were stored in their original packaging, which provided protection from moisture, light and mechanical stress. Stability was assessed over a period of 6 months at control points 0, 3 and 6 months. Real-time storage conditions were 25±2 °C at a relative humidity of 60±5 %, accelerated storage conditions were 40±2 °C at a relative humidity of 75±5 %.

The results of visual assessment of the capsules after storage under both real-time and accelerated stability conditions for 6 months did not reveal any deviations from the initial state and established regulatory requirements. This indicates that the organoleptic properties of both the capsule itself and its contents were preserved throughout the study period.

Analysis of dosage uniformity showed that the capsule filling weight remained stable at all control points, confirming the reproducibility of the technological process and the stability of the liposomal complex distribution in the capsules during storage.

Analysis of the active ingredient content showed that vitamin C decreased by an average of 3,53 % during 6 months of real-time storage and by 3,54 % during accelerated storage. These values remain within pharmacopoeia standards, confirming the chemical stability of the liposomal system.

Tests showed that after 6 months, the capsules completely disintegrated within 10 minutes, meeting the standards. The shell swelled evenly, and the contents dispersed completely without significant residue, confirming the preservation of pharmaceutical properties even under accelerated storage conditions.

Based on the results of real-time and accelerated stability studies over 6 months, it was established that liposomal vitamin C in the form of hard capsules, packaged in blisters and cardboard boxes, has high stability during storage. The active ingredient content remains within the normal range, and the appearance, uniformity of mass and disintegration of the capsules are stable, confirming the reliability of the technology and compliance with regulatory requirements.