DETERMINATION OF STABILITY OF THE COMBINED HEPATOPROTECTIVE DRUG "HEPATON"

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Relevance of the study: Stability is one of the key criteria of the quality of medicinal products, determining their effectiveness, safety, and shelf life. It is especially critical to take this parameter into account in the development and production of infusion solutions, since they are administered directly into the systemic bloodstream, bypassing the protective barriers of the body. This means that any changes in the composition or properties of such solutions can immediately affect the patient's condition. In this regard, infusion preparations must have a high degree of physicochemical stability and strictly comply with a number of parameters close to physiological ones: osmolarity, pH level, transparency, viscosity, and sterility.

The stability of combined infusion solutions is not just a pharmaceutical indicator but a critically important factor determining both the quality of the drug itself and its clinical applicability. Conducting comprehensive stability studies at all stages — from development to storage — is a necessary condition for guaranteeing the safety and effectiveness of therapy with such dosage forms.

Purpose of the study: To investigate the influence of different storage conditions on the stability and to determine the shelf life of the infusion solution "Hepaton".

Materials and Methods: In the course of the study, two methods were used to determine stability: the method of natural storage and the accelerated aging method according to the Temporary Instruction И-42-2-82. As research objects, 5 series of laboratory samples of the infusion solution "Hepaton" were used.

The study employed solvents, reagents, and consumables from MERCK (Germany), as well as ready-made nutrient media from HIMEDIA Laboratories Pvt. Ltd (India). The following auxiliary equipment was also used in the tests: magnetic stirrers, Sartorius BP-3105 analytical electronic balances (Germany), HS 32 AC sterilizer with automation, Seven Easy pH meters from Mettler Toledo (Switzerland), and 766 Calimatic Knick (Germany).

Qualitative and quantitative indicators were determined in accordance with the normative document for the studied drug; the methods listed in the State Pharmacopoeia of the Republic of Uzbekistan were applied. Studies under normal conditions were carried out by storing samples in the above-mentioned packaging on laboratory shelves and cabinets at a temperature of 20 ± 2 °C. Under natural conditions, samples were taken for analysis every six months, with quality indicators determined each time.

Studies by the accelerated aging method were carried out according to the Temporary Instruction И-42-2-82 at a temperature of 60 °C in an HS 32 AC thermostat. During the experiment, samples were taken every 11.5 days, which corresponds to an equivalent storage period under normal conditions, in accordance with the Instruction. The total duration of the experiment was 46 days.

Results: It was established that the quality indicators remained within the limits specified in the normative document.

Conclusions: Thus, the recommended composition and manufacturing technology, as well as the type of packaging used, ensure the stability of the infusion solution "Hepaton" for 2 years, both under natural storage conditions and by the accelerated aging method.