STUDY OF THE STABILITY OF "ERIKSIN" INJECTION SOLUTION 1% BY ACCELERATED AGING METHOD

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Abstract: The aim of this study was to investigate the stability of "Eriksin" injection solution 1% during storage using the accelerated aging method at an elevated temperature (60°C) and to substantiate the shelf life under recommended storage conditions. Experiments were conducted in accordance with the "Guidelines for Shelf Life Determination of Pharmaceutical Products Using the Accelerated Aging Method at Elevated Temperature" (1-42-2-82, Moscow, 1983) [1]. The results showed that changes in the parameters of the product during the shelf life were within the permissible limits according to the requirements of the FSP project 42 Uz-25441372-2022.
Keywords: Eriksin, accelerated aging, stability, shelf life, storage temperature.

INTRODUCTION

The stability of pharmaceutical products is a critical factor in determining their safety, efficacy, and quality over their shelf life [2]. Given the global increase in demand for innovative pharmaceutical products, special attention is given to methods for accelerated shelf life determination. These methods help reduce time and material costs during the development of new drugs, which is crucial for the timely market introduction of modern pharmaceuticals.

"Eriksin" is an innovative product derived from the biomass of the Eryx miliaris snake species [3]. The unique composition of the drug provides its immunomodulatory properties, making it promising for the treatment of a wide range of diseases related to immune system disorders. However, like any pharmaceutical product, ensuring the stability of "Eriksin" over its shelf life is a key requirement.

The accelerated aging method is a recognized approach for assessing the stability of drugs, as it allows data equivalent to several months of storage under normal conditions to be obtained within a short period [4]. This study aims to investigate the changes in the physical and chemical parameters of "Eriksin" at an elevated temperature to confirm its shelf life and determine optimal storage conditions.

MATERIALS AND METHODS OF RESEARCH. The object of study was "Eriksin" 1% injection solution, produced according to the approved technology and

in compliance with the FSP project 42 Uz-25441372-2022 requirements. The accelerated aging method was used for stability assessment, based on storing the drug at an elevated temperature of 60°C. The experiments were conducted in accordance with the "Guidelines for Shelf Life Determination of Pharmaceutical Products Using the Accelerated Aging Method at Elevated Temperature" (1-42-2-82, Moscow, 1983) [1]. According to these guidelines, a period equivalent to 6 months of storage at 20°C corresponds to 11.5 days at 60°C. The corresponding time intervals for longer storage periods are presented in Table 1.

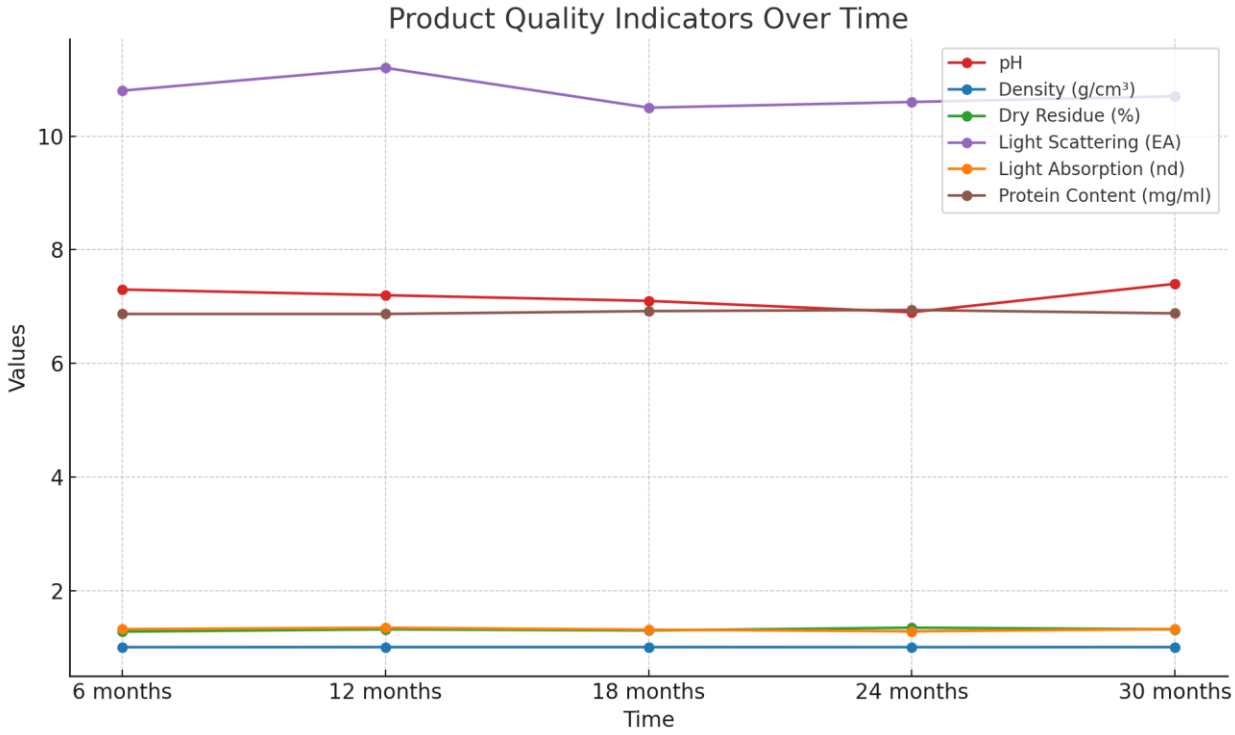
Table 1. Storage Time Equivalence at 60°C and 20°C

Storage Time at 20°C (Months)	Storage Time at 60°C (Days)
6	11.5
12	23
18	34.5
24	46

RESULTS AND DISCUSSION

Over a 30-month period, every 6 months the following parameters were studied: appearance, authenticity, transparency, color, pH, density, dry residue, light absorption, refractive index, mechanical impurities (visible and invisible particles), fill volume, toxicity, pyrogenicity, activity, sterility, and quantitative analysis (protein content and total nitrogen content).
The physicochemical characteristics, including appearance, transparency, color, pH, density, and dry residue, remained stable and within normative values at all time points of the study (6, 12, 18, 24, and 30 months). The appearance of the drug did not change, remaining a transparent light yellow or yellow-brown liquid with a characteristic odor, indicating the absence of undesirable structural changes. Figure 1 shows the changes in the drug's parameters.

Figure 1. Product quality indicators over time



The transparency and color of the solution also met the standards. The transparency remained high without any signs of cloudiness, and the color intensity did not exceed the established reference values (V7 and H7), indicating the absence of destructive processes in the system.

The pH of the solution at the start of the study was 7.3 and gradually changed, reaching a minimum value of 6.9 at 18 months and returning to 7.35 at 30 months. These fluctuations are within the acceptable range of 6.7 to 8.7 and do not affect the overall stability of the drug. The solution density ranged from 1.007 to 1.009 g/cm³, which corresponds to the norm of 1.005 to 1.010 g/cm³, and the dry residue exceeded the minimum permissible value of 1% at all time points.

Optical properties, including light absorption at 274 nm and refractive index, remained stable. The light absorption ranged from 10.5 to 11.2 EA, which is well above the minimum acceptable value of 10 EA. The refractive index remained between 1.285 and 1.348 nd, also meeting the normative requirements for this product.

Mechanical impurities were absent throughout the study period. Visible particles were not detected, and invisible particles met the established requirements, confirming the purity of the drug.

Microbiological and biological parameters, such as sterility, pyrogenicity, and toxicity, showed no deviations. The drug remained sterile and apyrogenic, with no signs of toxicity or adverse effects, indicating its safety for use.

Quantitative analysis confirmed the stability of the drug's composition. The protein content exceeded the minimum acceptable value of 5 mg/ml, ranging from 6.87 to 6.97 mg/ml. The total nitrogen content also remained above the normative value of

1.6%, showing slight fluctuations from 1.95% to 2.12%. This indicates the preservation of the drug's activity and stability throughout the observation period.
Thus, the results confirm that the tested drug demonstrates stability of all parameters over a 30-month storage period. The drug maintains its physicochemical, microbiological, and biological properties within the established normative limits, indicating its high quality, safety, and efficacy.

CONCLUSION

The results of the stability study of "Eriksin" by the accelerated aging method at 60°C confirm that all parameter changes are within the limits allowed by regulatory documentation. The drug maintains stability when stored in a light-protected place at a temperature between 15°C and 25°C for 2 years.

References

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