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# EVALUATING THE SHELF LIFE OF ESCIN

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**Abstract:** The determination of drug shelf life is vital for ensuring quality and stability, considering factors such as extraction, storage, transportation, and others to establish ideal storage conditions and expiration dates. While standard stability tests follow industry guidelines, the unique challenges posed by conducting accelerated tests for some temperature-sensitive drugs, such as herbal medicines, necessitate reliance on natural (continuous) tests as the primary method for determining stability. Positive results from accelerated tests may indicate that stability can be maintained despite short-term deviations under normal storage conditions. Consequently, real-time continuous testing plays a pivotal role in determining and validating the optimal shelf life following drug registration, simulating actual storage conditions during circulation. In light of these considerations, the shelf life of Escin was determined only through natural testing

**Keywords:** shelf life, quality, safety, storage conditions, stability, Escin



## Introduction

The shelf life of pharmaceutical drug products is determined through a series of stability studies, which involve thorough testing procedures. These studies are crucial to ensure that the drugs maintain their safety, quality, and effectiveness over time [1]. The expiration date or shelf life of a medication refers to the period during which the drug has been extensively tested and proven to retain its safety and effectiveness when exposed to varying environmental conditions, including temperature fluctuations, humidity, and light exposure [2]. Stability testing in pharmaceuticals encompasses a comprehensive and intricate set of procedures that require a substantial investment of resources including time, cost, and scientific expertise [3]. Stability, in this context, refers to the capability of a specific formulation in a particular container or closed system to preserve its physical, chemical, microbiological, therapeutic, and toxicological specifications throughout its designated shelf life. It is imperative for the drug to remain within these predefined specifications to ensure its safety and effectiveness. Officially, stability is defined as "the time lapse during which the drug product retains the same properties and characteristics as those processed at the time of manufacture [4]." This underscores the importance of ensuring that the drug's properties, including its efficacy and safety, remain consistent from the date of production to the end of its shelf life. This research aims to determine the shelf life of Escin substance. Therefore, the Escin substance has been comprehensively evaluated for quality indicators, including its physical and

chemical properties such as appearance, solubility, and identity. Additionally, assessments have been conducted for moisture content, absence of heavy metals, and TTG. Based on these considerations, the shelf life of Escin has been conclusively determined.

## Methods

Over a span of three years, a thorough and comprehensive study was undertaken to investigate various aspects of the substance. The study specifically delved into analyzing its appearance, solubility, identity, moisture content, presence of heavy metals, and triterpene glycoside (TTG) content. The identity of the Escin substance was determined using the thin layer chromatography (TLC) method. The extract was diluted and dripped onto a chromatographic plate (Merck, Germany) using a mixture of chloroform: anhydrous acetic acid: methanol: purified water (60:32:12: 8) as a solvent. The plate was left for 30 minutes to saturate, and a finish line was marked 12 cm away from the start line. Once the sample reached the finish line, the chromatography process was stopped, and the plate was removed. It was then treated with wet Iron (III) chloride and dried on a shelf at a temperature of 100 – 105 °C for 10 minutes. Subsequently, the plate was examined under a lamp at a wavelength of 366 nm. A noticeable purple stain was observed on both the Escin standard sample and the testing sample, indicating that they likely have the same Rf value. Furthermore, additional spots were also detected at various points within the testing solution. In addition, TTG was quantified using the high-performance liquid chromatography-mass spectrometry method, with a minimum requirement of 95.0% triterpene glycosides in the Escin substance compared to Escin.

## Results and Discussion

A thorough three-year study has confirmed the exceptional stability and shelf life of the Escin substance. The findings demonstrate that the quality of Escin consistently meets pharmacopeia standards for 2.5 years, covering its appearance, solubility, identity, moisture content, as well as the absence of heavy metals and TTG. However, upon concluding the third year, it was observed that the moisture content of the Escin substance surpassed the specified limit of 2%, measuring at 2.9%. Consequently, the shelf life of the Escin substance was determined to be two years, as no changes were observed when stored naturally for 2.5 years (Fig.1).

| | **Initial results** | **After 6 months** | **After a year** | **After 1.5 years** | **After 2 years** | **After 2.5 years** | **After 3 years** |
|---|---|---|---|---|---|---|---|
| **Appearance** | Yellow, characteristic-smelling mass | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard |
| **Solubility** | Soluble in water, methanol and ethanol | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard |
| **Identity** | Thin layer chromatography (TLC) | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Moisture** | No more than 2.0 % | 1,5% | 1,8% | 1,4% | 1,7% | 1,9% | 2,9% |
| **Heavy metals** | No more than 0,001% | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard | Meets standard |
| **TTG** | No less than 95,0 % | 98,45% | 99,28% | 99,78% | 99,22% | 98,21% | 98,18% |

Figure 1. Results of determining the shelf life of the Escin in a natural way..

## Conclusion

The Escin substance underwent a comprehensive evaluation of its quality indicators, including physical and chemical properties such as appearance, solubility, identity, moisture content, absence of heavy metals, and TTG. The findings confirm that the substance fully complies with the rigorous standards specified in the pharmacopeia article. Additionally, an extensive stability study demonstrated that the Escin substance showed no noticeable changes in its properties when stored under natural conditions for 2.5 years. Consequently, based on this thorough study, it has been determined that the shelf life of the Escin substance is two years

## References

[1]. Tembhare, E., Gupta, K. R., & Umekar, M. J. (2019). An approach to drug stability studies and shelf-life determination. *Archives of Current Research International*, *19*(1), 1-20.

[2]. FDA, U., & Food and Drug Administration. (2003). Guidance for industry-Photosafety Testing. *FDA, US: FDA Publishing*, 1-22.

[3]. Pokharana, M., Vaishnav, R., Goyal, A., & Shrivastava, A. (2018). Stability testing guidelines of pharmaceutical products. *Journal of Drug Delivery and Therapeutics*, *8*(2), 169-175.

[4]. Rao, G., & Goyal, A. (2016). Development of stability indicating studies for pharmaceutical products: an innovative step. *International Journal of Pharmaceutical Chemistry and Analysis*, *3*(3), 110-116.