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ASSESSING THE STABILITY OF ESCIN

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Abstract: Drug quality and stability are intricately linked, with temperature, light, and humidity playing crucial roles in their preservation. It is imperative for pharmacy experts to ascertain the shelf life of drugs by studying various factors such as extraction, storage, transportation, and more to establish ideal storage conditions and expiration dates. While standard stability tests are conducted based on industry guidelines, conducting accelerated tests for certain temperature-sensitive drugs, particularly herbal medicines, presents challenges. As a result, natural (continuous) tests are relied upon as the primary method for determining stability. Based on these considerations, the shelf life of Escin was determined solely through natural testing

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

Introduction

The shelf life of pharmaceutical drug products is established through a series of stability studies, which involve rigorous testing procedures. These studies are essential to ensure that the drugs maintain their safety, quality, and efficacy over time [1]. 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 [2]. 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 [3]." 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. 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 [4]. This research aims to determine the stability of Escin substance. Thus, Escin substance has been thoroughly evaluated for quality indicators, including its physical and chemical properties like appearance, solubility, and identity, as well as moisture content, absence of heavy metals, and TTG.

Methods

During a three-year period, a comprehensive study was carried out to thoroughly investigate various aspects of a substance, with a particular focus on 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

An extensive three-year study was conducted to evaluate the stability of the Escin substance. The findings indicated that the quality indicators of the Escin substance consistently met the standards outlined in the pharmacopeia article for 2.5 years, encompassing its appearance, solubility, identity, moisture content, as well as the presence 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 stability of the Escin in a natural way..

Conclusion

Escin substance underwent comprehensive evaluation of its quality indicators, encompassing physical and chemical properties such as appearance, solubility, identity, moisture content, absence of heavy metals, and TTG. The findings attest to the substance's full compliance with the exacting standards stipulated in the pharmacopeia article. Furthermore, an extensive stability study demonstrated that the Escin substance exhibited no discernible alterations in its properties when stored under natural conditions for 2,5 years. Consequently, based on this thorough study, it has been established that the shelf life of the Escin substance is two years.

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