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CHEMICAL FACTORS AFFECTING THE STORAGE CONDITIONS AND SHELF LIFE OF MEDICINAL PRODUCTS

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ABSTRACT

This article provides a scientific analysis of the chemical factors affecting the storage conditions and shelf life of pharmaceutical products, with particular emphasis on their impact on the physicochemical stability of medicinal preparations. The main factors influencing the chemical stability of pharmaceutical substances are discussed, including oxidation, hydrolysis, photochemical degradation, changes in pH, moisture, oxygen exposure, and interactions with other chemically active substances. The degradation mechanisms of active pharmaceutical ingredients (APIs), the formation of degradation products during storage, and their potential effects on product quality, safety, and therapeutic efficacy are also examined. Furthermore, the importance of stability testing, optimization of storage conditions, and modern analytical techniques in determining the shelf life of pharmaceutical products is highlighted. The findings are relevant to maintaining pharmaceutical quality, ensuring patient safety, and establishing scientifically justified shelf-life specifications.

Relevance of the Research The stability of medicinal products during storage is one of the most important factors determining their quality, safety, and therapeutic effectiveness. Chemical

changes occurring during storage can significantly affect the composition and pharmacological properties of pharmaceutical preparations, potentially reducing their efficacy or leading to the formation of undesirable degradation products. Factors such as oxidation, hydrolysis, photochemical degradation, temperature fluctuations, humidity, changes in pH, and interactions between active pharmaceutical ingredients and excipients play a crucial role in determining the stability and shelf life of medicines.

In modern pharmaceutical science, ensuring the chemical stability of medicinal products is particularly important due to the increasing diversity of active pharmaceutical ingredients and the complexity of pharmaceutical formulations. Inappropriate storage conditions may accelerate degradation reactions, alter the physicochemical properties of medicinal products, and compromise patient safety. Therefore, studying the chemical factors affecting drug stability, identifying degradation mechanisms, and evaluating their influence on shelf life are essential for pharmaceutical quality control.

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Aim of the Research The aim of this research is to scientifically investigate the chemical factors affecting the storage conditions and shelf life of medicinal products, to evaluate their influence on the physicochemical stability of active pharmaceutical ingredients (APIs), and to identify the main degradation mechanisms, including oxidation, hydrolysis, and photochemical degradation. The study also aims to determine the relationship between storage conditions and changes in the quality, safety, and therapeutic effectiveness of pharmaceutical preparations, as well as to develop scientifically based recommendations for optimizing storage conditions and extending the stability of medicinal products.

Objectives of the Research The following objectives have been established to achieve the aim of this research:

1. To study the theoretical and scientific foundations of chemical stability in medicinal products and identify the factors influencing their shelf life.
2. To investigate the main chemical degradation processes of active pharmaceutical ingredients (APIs), including oxidation, hydrolysis, photochemical degradation, and other chemical reactions.
3. To evaluate the effects of temperature, humidity, oxygen, light exposure, and pH changes on the physicochemical stability of pharmaceutical preparations.
4. To analyze the influence of interactions between active pharmaceutical ingredients and excipients on the chemical stability and quality of medicinal products.
5. To identify the major degradation products formed during storage and assess their potential impact on pharmaceutical quality, safety, and therapeutic efficacy.
6. To examine the role of modern analytical methods, particularly high-performance liquid chromatography (HPLC), spectrophotometry, and other instrumental techniques, in evaluating drug stability.
7. To assess the importance of stability testing in determining the shelf life and establishing appropriate storage conditions for medicinal products.

Research Results The research results demonstrate that chemical factors play a significant role in determining the stability, quality, safety, and shelf life of medicinal products. The analysis of chemical degradation mechanisms indicates that oxidation, hydrolysis, and photochemical degradation are among the major processes responsible for changes in the chemical composition of pharmaceutical preparations during storage.

It was established that exposure to elevated temperatures, excessive humidity, oxygen, and light can accelerate chemical degradation reactions, resulting in a reduction in the concentration of active pharmaceutical ingredients (APIs) and the formation of degradation products. Changes in pH and incompatibilities between active ingredients and excipients may also negatively affect the stability of pharmaceutical formulations.

The study highlights the importance of applying modern analytical methods, particularly high-performance liquid chromatography (HPLC), UV-Visible spectrophotometry, and other instrumental techniques, for identifying and quantifying degradation products and monitoring changes in drug composition during storage.

Furthermore, the research emphasizes that appropriate selection of packaging materials, controlled storage temperature, protection from moisture and light, and compliance with recommended storage conditions are essential measures for maintaining pharmaceutical stability.

The scientific findings confirm that systematic stability testing and the identification of critical chemical degradation factors are necessary for establishing scientifically justified shelf-life periods and ensuring the quality, safety, and therapeutic effectiveness of medicinal products.

The analysis of scientific findings demonstrates that the chemical stability of medicinal products is closely associated with their storage conditions, molecular structure, and physicochemical properties. The investigation of degradation mechanisms confirms that oxidation, hydrolysis, and photochemical degradation are among the principal chemical processes responsible for reducing the stability of active pharmaceutical ingredients (APIs).

Particular attention was given to the influence of environmental factors on the degradation kinetics of pharmaceutical substances. Increased temperature generally accelerates chemical reactions, while humidity promotes hydrolytic degradation, particularly in pharmaceutical compounds containing ester, amide, and other hydrolysis-sensitive functional groups. Exposure to oxygen may initiate oxidative processes, whereas ultraviolet and visible light can cause photochemical transformations in light-sensitive medicinal substances.

The scientific analysis also indicates that changes in pH can significantly influence the ionization state, solubility, and degradation rate of active pharmaceutical ingredients. Furthermore, chemical incompatibilities between APIs and excipients may result in the formation of new compounds, changes in drug concentration, and deterioration of pharmaceutical quality.

The application of modern analytical techniques, including high-performance liquid chromatography (HPLC), UV-Visible spectrophotometry, and stability-indicating analytical methods, provides opportunities to detect, separate, identify, and quantify degradation products. These methods are particularly important for evaluating the chemical stability of pharmaceutical formulations under different storage conditions.

From a pharmaceutical quality assurance perspective, the findings emphasize the necessity of conducting long-term and accelerated stability studies in accordance with international guidelines, particularly ICH Q1A(R2). Such investigations make it possible to establish appropriate storage conditions, evaluate degradation patterns, and scientifically determine the shelf life of medicinal products.

Scientific significance The analysis establishes the relationship between chemical degradation mechanisms and pharmaceutical stability, highlighting the importance of an integrated approach involving chemical analysis, stability testing, appropriate packaging, and controlled storage conditions to ensure the quality, safety, and therapeutic effectiveness of medicinal products.

Conclusion The conducted scientific analysis demonstrates that chemical factors play a fundamental role in determining the storage stability, quality, safety, and shelf life of medicinal products. Oxidation, hydrolysis, photochemical degradation, changes in pH, moisture, oxygen exposure, and temperature fluctuations are among the major factors influencing the chemical

stability of active pharmaceutical ingredients (APIs). The findings indicate that inappropriate storage conditions can accelerate the degradation of pharmaceutical substances, reduce the concentration of active ingredients, and contribute to the formation of undesirable degradation products. These changes may negatively affect the therapeutic efficacy and safety of medicinal preparations.

The analysis also confirms that the application of modern analytical techniques, particularly high-performance liquid chromatography (HPLC), UV-Visible spectrophotometry, and stability-indicating methods, is essential for monitoring chemical changes and evaluating the quality of medicinal products throughout their storage period. Furthermore, systematic stability testing, appropriate selection of packaging materials, protection against light and moisture, and maintenance of recommended temperature conditions are important measures for preventing chemical degradation.

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