



## Drug Stability: Factors Affecting Shelf Life and Methods for Evaluation

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### Description

Drug stability refers to the ability of a drug to maintain its physical, chemical, and microbiological properties over time, which is critical for ensuring its safety, efficacy, and quality. The stability of a drug is influenced by various factors, including its chemical composition, physical form, packaging, storage conditions, and interactions with other substances. Therefore, it is essential for pharmaceutical manufacturers, regulatory authorities, and healthcare professionals to understand the principles of drug stability and the methods for evaluating it.

The shelf life of a drug is the period during which it is expected to remain stable and effective when stored under the recommended conditions. The shelf life of a drug is determined through stability testing, which involves exposing the drug to various conditions and monitoring its physical, chemical, and microbiological properties over time. The stability testing is conducted throughout the development, manufacturing, and post-marketing stages of a drug to ensure its safety, efficacy, and quality. Several factors can affect the stability of a drug, such as temperature, humidity, light, pH, oxygen, and contaminants. Temperature is one of the most essential factors that affect drug stability because it can accelerate chemical reactions and degradation. For example, high temperatures can cause hydrolysis,

oxidation, and degradation of proteins, which can result in loss of potency and formation of toxic impurities. On the other hand, low temperatures can cause crystallization, precipitation, and denaturation of proteins, which can also affect drug stability.

Humidity is another factor that can affect drug stability, especially for drugs that are hygroscopic, meaning they can absorb moisture from the environment. Moisture can cause physical changes in the drug, such as softening, sticking, and caking, which can affect its dissolution and bioavailability. Additionally, moisture can promote microbial growth and accelerate chemical reactions, leading to degradation and loss of potency.

Light is another factor that can affect drug stability, especially for drugs that are light-sensitive. Light can cause photochemical reactions, such as oxidation, isomerization, and degradation, which can affect drug stability. Therefore, drugs that are sensitive to light are usually packaged in opaque containers or wrapped in foil to protect them from light exposure; pH is also a critical factor that can affect drug stability, especially for drugs that are acidic or basic. Changes in pH can cause hydrolysis or degradation of drugs, leading to loss of potency or formation of impurities. Therefore, it is essential to control the pH of the drug during manufacturing and storage to ensure its stability.

Contaminants are another factor that can affect drug stability, such as impurities from raw materials, degradation products, or microorganisms. Contaminants can accelerate chemical reactions, promote microbial growth, or react with the drug, leading to degradation and loss of potency. Therefore, it is crucial to ensure the purity and quality of raw materials and manufacturing processes to prevent contamination and ensure drug stability. To evaluate the stability of a drug, several methods are used, such as accelerated stability testing, real-time stability testing, and stress testing. Accelerated stability testing involves exposing the drug to harsher conditions than those recommended for storage, such as high temperature and humidity, to accelerate the degradation and predict the shelf life of the drug. Real-time stability testing involves monitoring the drug's stability under the recommended storage conditions over an extended period to ensure its stability during the shelf life. Stress testing involves exposing the drug to extreme conditions, such as high temperature, humidity, light, and pH, to identify its degradation pathways and potential impurities.

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