



DiluCap Antioxi

The right excipient for oxidation-sensitive APIs

The choice of the correct excipient is of great importance to ensure the clinical performance of an active pharmaceutical ingredient (API), as it can directly influence its bioavailability, solubility, stability, and other physical and chemical properties.

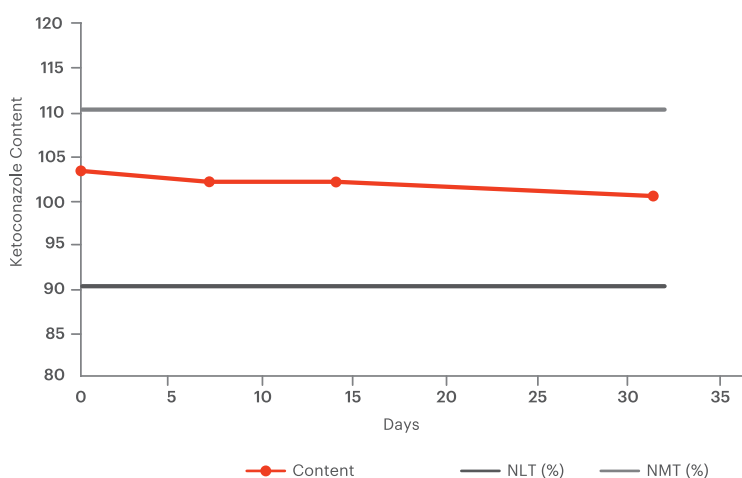
Defining a blend of ingredients to build an adequate excipient to a dosage form is not always a direct process and can be time-consuming as the evaluation of the performance needs to be done in a trial-and-error way.

Many APIs are prone to **oxidation**, a process that can lead to substance decomposition and consequent loss of function. External factors such as light, air, heat, contaminants in the environment, and pH, are examples of triggering agents for oxidation, with the formation of the so-called free radicals.

Antioxidants are substances that act as inhibiting the process of oxidation, by neutralizing the free radicals, preventing the spread of oxidating reactions. When compounding with oxidative APIs, the presence of antioxidants is indispensable to maintain the formulation stability and efficiency throughout its usage and storage.

DiluCap Antioxi is an antioxidant excipient that was carefully developed **to compound with APIs that are sensitive to oxidation**, while ensuring an adequate bioavailability of the drug, with no negative impact on their solubility and permeability.

DiluCap Antioxi is physiologically inert and free from allergens such as lactose, gluten, soy, and others.



Days	Average Content (%)
0	102.77
7	101.70
14	101.69
32	100.36

Accelerated stability of ketoconazole 200 mg capsules compounded with DiluCap Antioxi. Study conducted at 55°C and 75% RH. Specification: ketoconazole capsules contain not less than 90.0% and not more than 110.0% of the labelled amount of ketoconazole (C₂₆H₂₆Cl₂N₄O₄). Considering the temperature and humidity conditions of the climatic chamber used and the evaluation period of the accelerated study, **a minimum shelf-life of at least 186 days is estimated** (Q₁₀=1.8) for the ketoconazole 200 mg capsules compounded with DiluCap Antioxi.

DiluCap Antioxi provides to the pharmacist:

- Avoidance of segregation between particles
- The preservation of the API stability
- Dose accuracy among capsules due to adequate particle distribution
- High-performance formulations with adequate bioavailability
- Better handling of different powders and great flow properties
- Proven functionality
- Reproducibility in every batch
- Reduction of process time and number of items in stock

For each API, there is a right DiluCap excipient:



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