Impact of Moisture Barrier Film Coating on Stability of Amoxicillin / Clavulanic Acid Tablets

Case Study

Opadry® amb II High Performance Moisture Barrier Film Coating Protects Moisture-Sensitive Dosage Forms

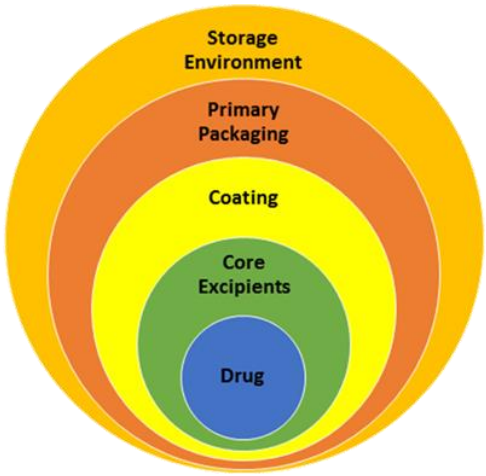
Product stability is affected by all elements of solid dosage development and manufacturing including core formulation, excipient choice, manufacturing conditions, packaging and end use storage conditions. Film coating can protect tablets from environmental factors such as moisture, light, or oxygen while presenting the opportunity to improve product identification and patient compliance.

Product Stability is Affected by Dosage Design and Manufacturing

While primary packaging and desiccants are considered a dosage form's most significant defense from the environment, specialized film coatings such as Opadry amb II can provide further moisture protection, as demonstrated in the case study below.

Film coatings can protect sensitive compounds from temperature and humidity excursions prior to packaging including instances of bulk product storage, transport, or repackaging.

In-use product integrity testing ensures product quality prior to or after removal from primary packaging during temperature and humidity excursions, bulk storage, transport, or repackaging. There is often limited consideration given to storage conditions when the dosage form has been dispensed by the pharmacist, caregiver, or patient. Film coatings help to protect the integrity of the dosage form when removed from the primary packaging.



Impact of Moisture Barrier Film Coating on Stability of Amoxicillin / Clavulanic Acid Tablets

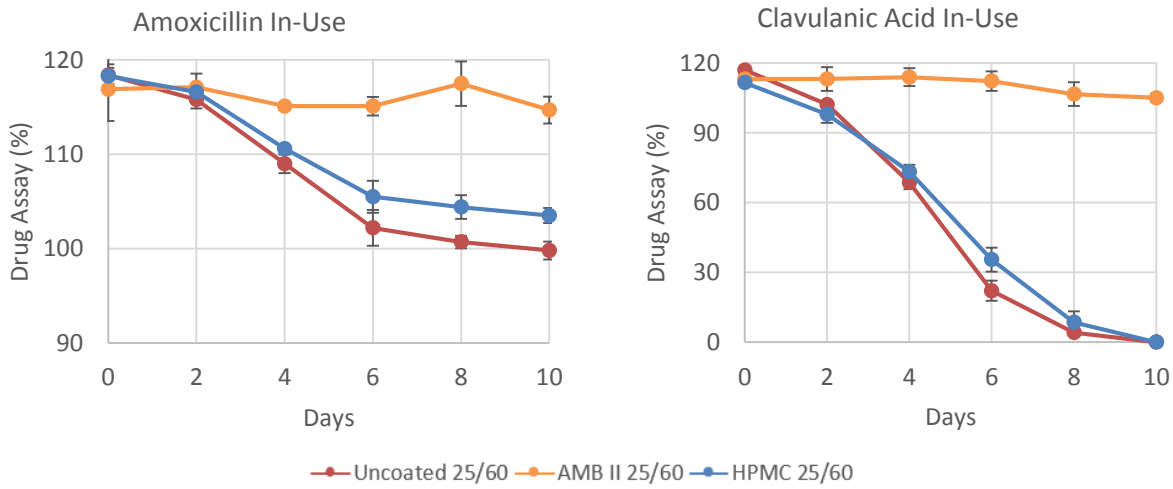
Amoxicillin and clavulanic acid are combined to produce an antibiotic with an increased spectrum of action against some amoxicillin-resistant bacteria. Due to the high sensitivity of clavulanic acid to moisture, this combination was selected to investigate the moisture protection properties of Opadry® amb II. This antibiotic combination product is typically coated with an hypromellose (HPMC) based film coating.

Part I: In-Use Product Integrity

The in-use stability of an uncoated amoxicillin / clavulanic acid dosage form was compared against similar tablets coated using a standard HPMC-based film coating and Opadry® amb II aqueous moisture barrier coating.

Uncoated and coated tablets were removed from their primary packaging and transferred to a typical consumer-use tablet organizer and stored for the prescribed ten-day regimen at 25°C/60% RH. On each day, tablets were removed from the organizer and assayed according to the USP method for each drug component.

Results showed significant degradation of the clavulanic acid for uncoated and HPMC-coated tablets. At the end of the ten-day dose regimen, amoxicillin levels were shown to have decreased by 20% of the initial amount, but still within the USP assay specification of 90-120%. In contrast, clavulanic acid levels were totally depleted at the end of ten days; however, tablets coated with Opadry amb II maintained acceptable levels. Application of the Opadry amb II coating resulted in improved tablet stability, even when removed from the primary packaging.

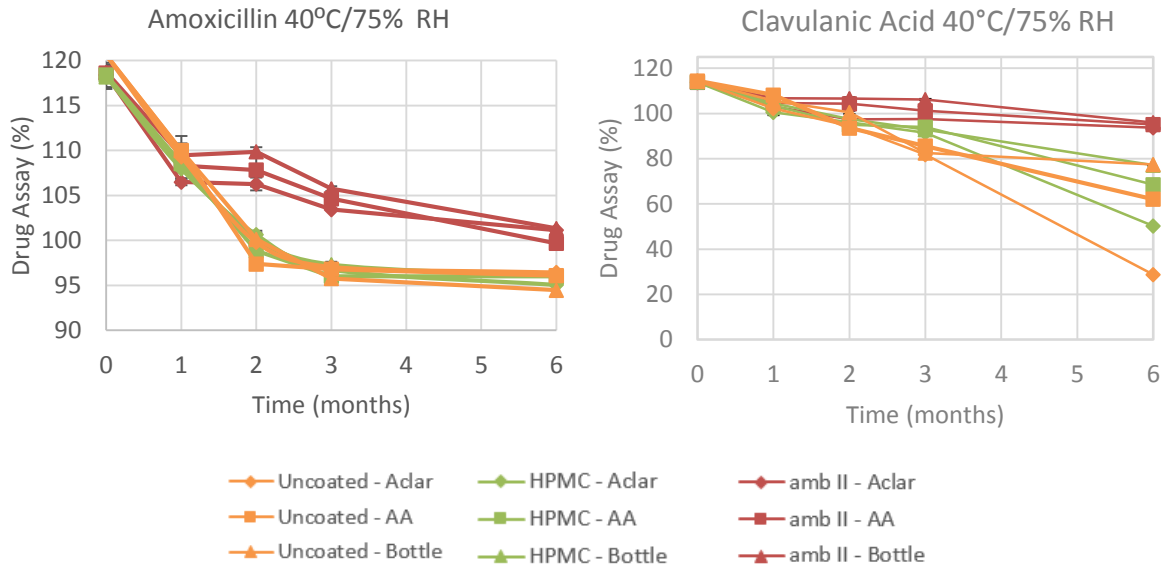


Part II: Accelerated Stability in Multiple Packaging Formats

A second case study was performed to determine the effects of Opadry amb II moisture barrier coating on the long-term (accelerated) stability for the same amoxicillin / clavulanic acid tablets. The uncoated and coated tablets were packaged in various commercial configurations including ACLAR blisters, aluminum foil blisters (AA), and HDPE bottles (with desiccant), all stored at 40°C/75% RH for six months.

After six months, tablets from all packaging formats met the USP amoxicillin assay limits (USP 90-120%). Opadry amb II coated tablets showed 5% more amoxicillin present compared to HPMC-coated and uncoated tablets. The impact of Opadry amb II film coating on the stability of clavulanic acid was significant.

Regardless of packaging formats, after six months accelerated stability, clavulanic acid levels fell below acceptable levels for the uncoated and HPMC-coated tablets. In comparison, all tablets coated with Opadry amb II, regardless of packaging, passed the USP assay for clavulanic acid. These results confirm coating with Opadry amb II maintained the integrity of the dosage form, while HPMC-coated and uncoated tablets failed.



Result confirm that Opadry amb II protects the integrity of moisture-sensitive compounds beyond the primary packaging.

- Fully formulated aqueous film coating system with high productivity
- Decreased impurity or allergen concerns - no polyethylene glycol (PEG) or soy lecithin
- Approved for use in pharmaceuticals around the world

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