Evaluation of Stability and Functional Packaging Effectiveness for Ferrous Ascorbate Tablets Coated with an Aqueous Moisture Barrier Film Coating Formulation

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Challenge

Many drugs degrade when exposed to moisture, especially those with high water affinity. Ferrous ascorbate tablets are highly hygroscopic, requiring moisture barrier coatings and functional packaging to maintain stability. The level of coating and packaging must be optimized based on substrate sensitivity. This study used Stablus® Simulation to predict desiccant needs and model the optimal combination of coating and packaging strategies to ensure product quality during storage.

Method

Formulation and Coating Process Details:

Ferrous ascorbate and folic acid tablets (100 mg iron, 1.5mg folic acid, 920 mg core) were used. Tablets were coated with a moisture barrier film (Opadry® AMB II 88ZA Brown) at 4% weight gain using 20% solids in water, applied in a 15-inch perforated pan (O'HARA Labcoat™, model LCM-5) with a 2 kg batch. Coating details are in Table 1.

Predicting Desiccant Requirements Using Stablus:

Moisture sorption profiles for core and coated tablets were measured at 25°C from 0–90% RH using dynamic vapor sorption (DVS Intrinsic Plus). Data was added into Stablus software to simulate desiccant loading, aiming for a 4% weight. Moisture vapor transmission rates of packaging and environmental conditions were included for modeling.

Selection of Functional Packaging:

Simulation selected two types of packaging to test the moisture barrier coatings for protecting core formulations.

Table 1: Coating Process Parameters

Process Parameter	Opadry AMB II
Pan speed (rpm)	11-14
Drying air volume (cu.ft/min)	148-155
Inlet temperature (°C)	62-64
Product temperature (°C)	45-46
Exhaust temperature (°C)	45-46
Spray rate (g/min)	7-8
Atomizing and pattern air pressure (bar)	1.4-1.5

Results

Tablets coated at 4% target weight gain (Figure 1) were smooth and uniform with no visual defects.

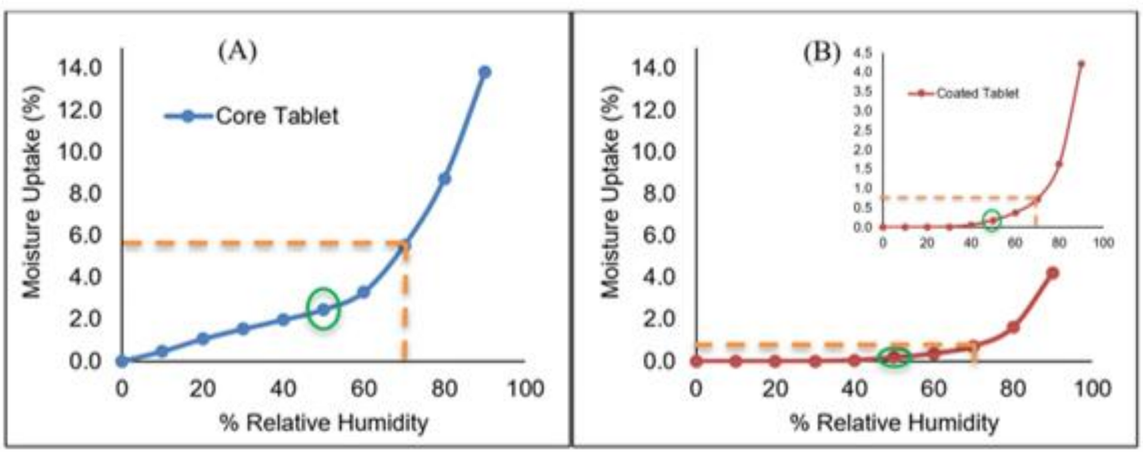
Figure 1. Visual Appearance of Core Tablets and Coated Tablets

Core Tablets **Coated Tablets**

Dynamic Vapor Sorption (DVS) Analysis:

DVS findings indicated a progressive moisture uptake in core tablets, with <2%uptake at 50% RH, ~5% uptake at 70% RH, and a sharp rise to ~14% at 90% RH (Figure 2A), while coated tablets had much lower uptake, under 4.5% at 90% RH. The coating effectively reduced moisture absorption compared to uncoated tablets. However, due to the hygroscopic nature of ferrous ascorbate, the increase in moisture uptake observed for both uncoated and coated tablets with over 50% RH.

Figure 2. DVS Plot, Moisture Uptake verses Relative Humidity for(A) Core and (B) Coated Tablets



Stablus Model Simulation

By integrating DVS data into the Stablus model, simulations estimated that the internal relative humidity (RH) for uncoated (core) tablets was approximately 60% (Figure 3A) from the start when no silica gel (desiccant) was present.

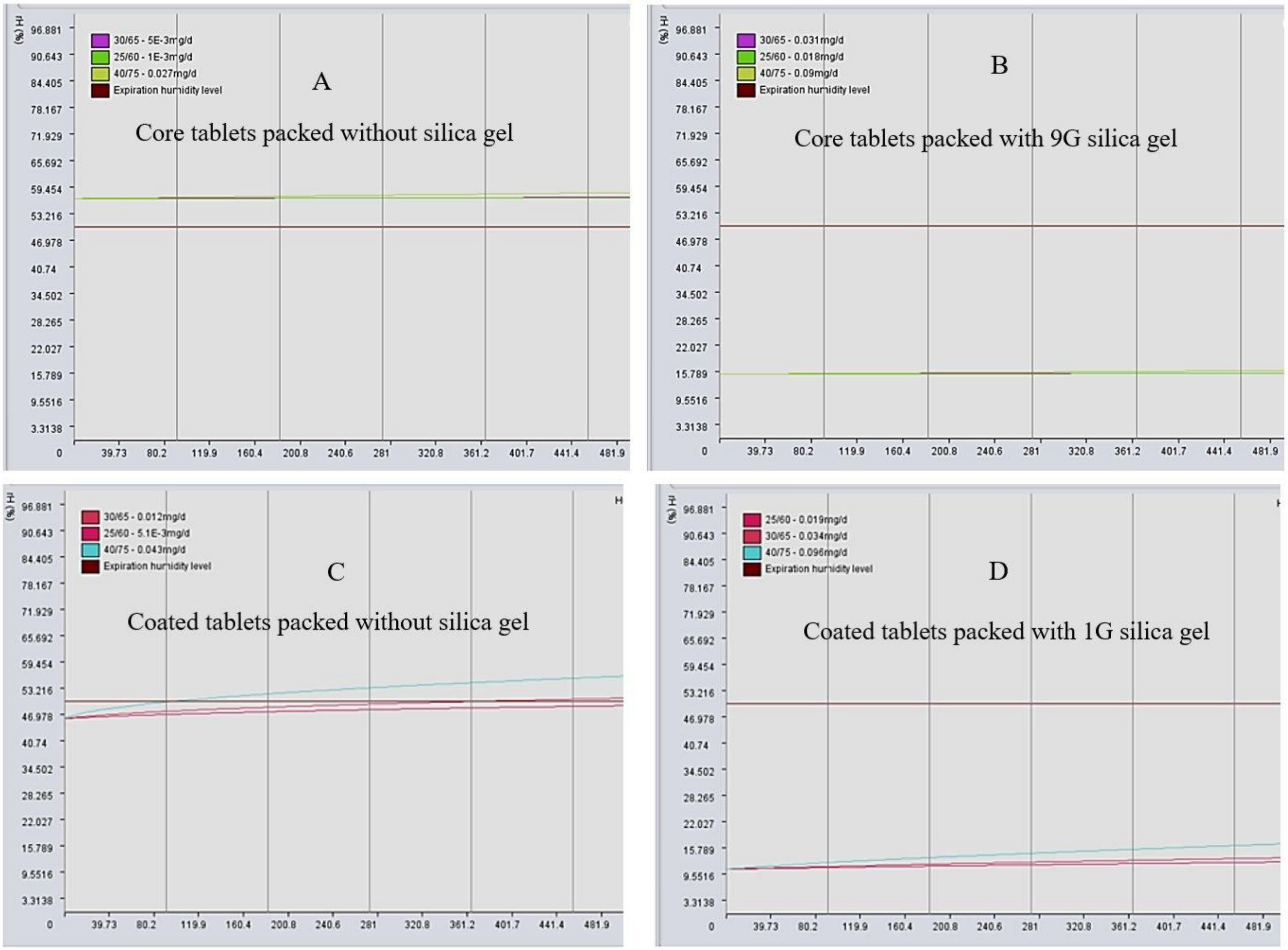
The simulation indicated that adding 1 g of silica gel reduced RH to about 50%. Increasing the silica amount to 2 g lowered RH to roughly 35%, and 3 g brought it down to near 30%. To maintain an RH close to 15% throughout the study, 9 g of silica was required (Figure 3B).

This RH level is similar to the internal RH observed in coated tablets containing 1 g of silica desiccant. Without desiccant, RH rose above 50% in 80 days at 40°C/75% RH. Using 1 g silica gel kept RH near 16% throughout the study under various conditions.

Using a moisture barrier coating with 1 g of silica gel keeps container humidity low (15–16%) for nearly three years, as shown by Stablus simulation.

Stablus Model Simulation: Core and Coated Tablets

Figure 3. Impact of desiccant in Stablus predicted humidity profiles for coretablets (A and B) and coated tablets (C and D). Note: Y axis represents %RH and X axis represents number of days.



Stability Study

To verify the accuracy of simulation, coated tablets were packed in 50 cc HDPE (high-density polyethylene) bottles with 38 mm CR (child resistant) closures, along with different desiccants (DryGuard).

The bottles were induction sealed and screw-capped, then subjected to accelerated storage conditions of 30°C/65% RH and 40°C/75% RH for one, three, and six months.

These coated tablets were evaluated for physical appearance, weight variation, loss on drying (Sartorius Moisture IR Balance, MA 35M), and disintegration time (Electrolab, EDI-2I) at predetermined intervals of exposure conditions. Tablets coated with Opadry AMB II 88ZA Brown and stored in HDPE containers with 1G silica gel remained stable at 40°C/75% RH for 6 months. Moisture absorption was minimal, with LOD rising slightly in desiccant samples but higher in controls. Disintegration time increased slightly but stayed within acceptable limits. Weight variation was negligible.

Table 1: Stability Data at 40°C/75% RH (Initial vs. 6 Months)

Functional Packaging Type	Loss on Drying (LoD)	Disintegration Time (min)	Weight Variation (mg)
Initial	10.88	16 ± 0.8	955 ± 7.9
Control Sample	13.84	21 ± 0.8	951 ± 4.8
DryGuard 1G Silica Gel Packet	12.08	20 ± 0.5	943 ± 5.7
DryGuard 1G Silica Gel Canister	11.08	22 ± 0.8	949 ± 8.8

Conclusion

Desiccant requirements were accurately predicted using Stablus Simulation, supported by moisture sorption profiles obtained from DVS studies, enabling a science-based approach to moisture management. This modified Arrhenius based predictive modeling guided the selection of appropriate configuration of desiccant loading to maintain internal humidity within target limits.

Under accelerated stability conditions (40°C/75% RH) for 6months, coated ferrous ascorbate and folic acid tablets showed a minor increase in LOD indicating limited moisture uptake. A slight increase in disintegration time that remained within acceptable limits, suggesting minimal impact on tablet matrix and overall acceptable stability in the selected coating and packaging configuration.

These findings highlight the synergistic benefit of optimized film coating formulation at lower weight gain and appropriate configuration of functional packaging for preserving tablet integrity at accelerated stability conditions.

References

1. Banerjee PG, Paul A, Chakraborty A, Porel A, Mallick P. Stability, characterization, and manufacturing optimization of ferrous Ascorbate: A Comprehensive Study by West Bengal Chemical Industries Ltd., Kolkata, India. International Journal of Pharmaceutical Research and Development. 2025 Jan 1;7(1):32–7.

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