76d Blister Push through Force and Tablet Three Point Bend Strength as Means of Predicting Deblistering Performance

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Push-through aluminum foil blisters are commonly used packages for pharmaceutical products. An important criterion for product and package development is to ensure that the dosage form (tablet or capsule) will not break when the patient pushes it out of the package. Package deblistering trials are time-consuming and relatively expensive. Tablet three-point bend and foil blister push through force tests were used as predictive, and narrowly focused, tools to identify key components in the blister package and tablet strengths contributing to tablet breakage.

The primary package evaluated is a push-through aluminum foil blister. Blinded deblistering studies were used to evaluate the performance of tablets at varying hardnesses in different package designs. A T\XT2i texture analyzer was fitted with a cylindrical probe with a diameter approximately the size of the blister cavity. The blister was secured on a stand and the force at rupture was measured. The tablet three point bend strength was measured using a T\XT2i texture analyzer.

The defect levels of appreciable frequency observed in the deblistering trials were broken tablets. Tablets have the least amount of strength when placed in three point bend situations and forces similar to these may arise during deblistering. Our hypothesis was that tablet breakage will be minimized as long as the tablet three point bend strength is greater than the blister push through force. This hypothesis was confirmed as the percent of broken tablets during deblistering decreased exponentially and approached zero as the ratio of tablet three point bend to blister push through force increased and tended towards 1. The effect of different blister components on the blister push through force is listed here in order of increasing impact: 15 lb. paper support for aluminum foil, # nicks on perforated cardboard push out (6 vs 4), hard vs soft tempered foil, and 20 vs 25 micron foil thickness. The impact of different sections of the blister package was used in conjunction with the tablet three point bend strength to make package modifications and enhance deblistering performance.

The design of a blister package is a balancing act between acceptable tablet hardness range and blister package integrity. This rational and fundamentally based approach resulted in effective use of resources focused on fewer package design options and identifying an appropriate tablet hardness range that would ensure a high probability of success (i.e., no breakage).