klöckner pentaplast

white paper

DESIGN OPTIMIZATION AND RAPID PROTOTYPING SOLUTIONS FOR BLISTER PACK DESIGN, DEVELOPMENT, AND TESTING

a four-part series of white papers

INTRODUCTION

Lead times for the development and testing of pharmaceutical packaging have traditionally been a significant speed-bump in getting new drugs to market. But sophisticated predictive tools and cutting edge developments in rapid prototyping now offered by kp's Blister Technology Center allow pharmaceutical companies to move much more quickly from design to testing to production. These enhanced solutions will dramatically accelerate packaging design and testing times by substantially increasing the certainty of successfully passing through the stability testing phase. They also allow streamlined implementation of the new package with on-site troubleshooting support in the production facility.

With these new innovations in place, materials are used more efficiently, the number of samples to be tested for stability decreases, fewer people are required, less time is required, and less equipment needs to be used. The end result is decreased time-to-market for the product, increased accuracy in stability testing, and significant cost savings.

This series of four white papers introduces the new technologies and explores in detail the benefits they bring to blister pack design, testing, and production.

Paper 1: Summary Overview
Paper 2: Accelerated Stability Assessment
Paper 3: Package Prototyping
Paper 4: Sample Production

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PAPER 1
RAPID PROTOTYPING OVERVIEW: A SAMPLE CASE

A SAMPLE PRODUCT

This paper presents an overview of the blister design and development process for a sample pharmaceutical application. This example product is a demanding one – a chewable lozenge with a complex ingredient list requiring a packaging material with low MVTR and OTR transmission properties, as well as high formability to create a deep draw to hold the large shape of the lozenge. The product is being developed in the US, produced in South America, and will be marketed and sold globally.

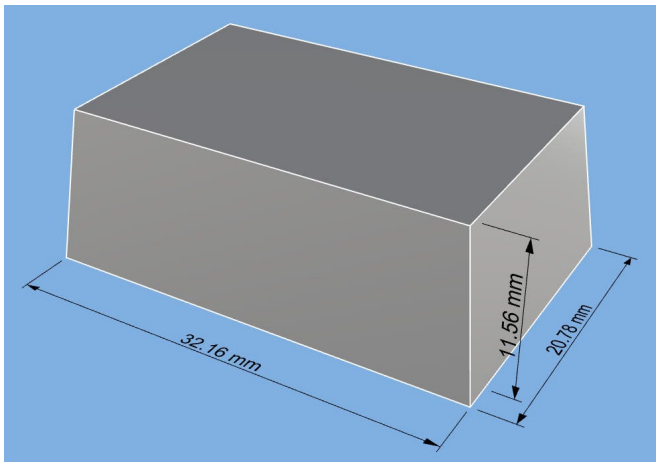
In general, avoiding a squared-off or cube-shaped blister and opting for a more rounded and spherical shape tends to provide benefits and robustness. More spherical geometries lead to thicker and more evenly distributed film. More uniform thickness helps reduce the likelihood of blowing holes during forming and helps prevent parts with poor rigidity or strength.

At the beginning of the process, the pharmaceutical company supplies the following information about the product:

- moisture sensitivity (low, high, none, etc.)
- oxygen sensitivity (low, high, none, etc.)
- light sensitivity (low, high, none, etc.)
- shape of the drug
- package configuration (quantity per card, position of drug within cavity, opening features)

Specification for Lozenge

Highly moisture sensitive (estimated at < 0.5 mg/day at 40°C & 75% RH storage)
Highly oxygen sensitive (estimated at < 2mm^3/day at 23°C & 50% RH storage)
Highly light sensitive (sensitive to light in the 290–450nm range)
Trapezoidal shaped product (needs to fit right side up & upside down in cavity)



The following sections give a step-by-step description of the design, testing, and implementation process. They show how a facility like kp's state-of-the-art Blister Technology Center can help pharmaceutical companies and packagers meet the complex challenges of such a product.

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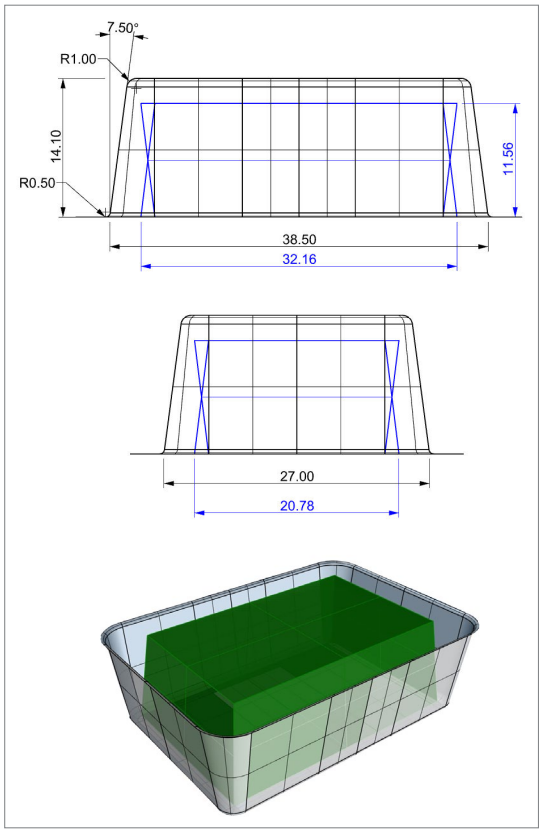
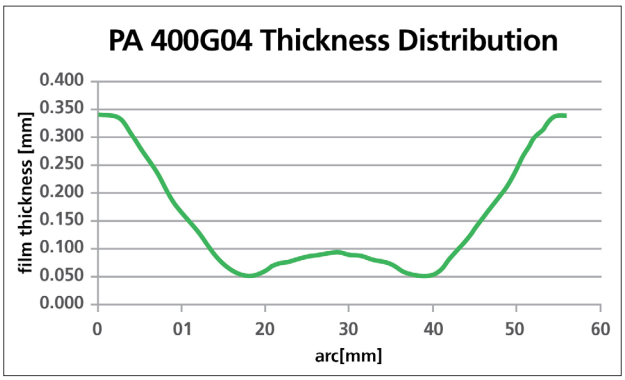
STEP 1: CAVITY AND CARD DESIGN

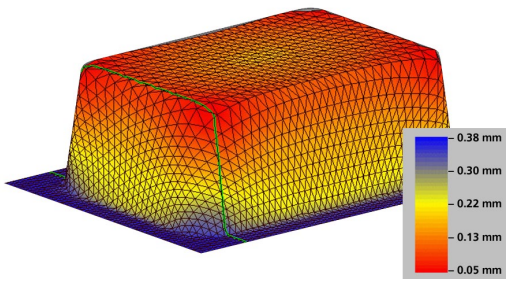
The initial design challenge for this product application is the deep draw required by the lozenge shape. The shape and size of the lozenge demands a high-end film that will maintain its integrity and performance even after thermoforming into a deep cavity shape. Step one is to use 3D design software to design a blister cavity that maintains an optimal thickness distribution for the high-performance packaging material. Design optimization also considers mechanical functionality that will protect the drug from external conditions (environment, tamper resistance, etc.). With one or more potential cavity designs in place, the software is then used to develop initial designs and configurations for the complete blister card.



STEP 2: STABILITY PREDICTION WITH FINITE ELEMENT ANALYSIS SOFTWARE

The use of kp's BlisterPro® Finite Element Analysis (FEA) software allows package designers to predict the stability performance of blister designs with great accuracy. The software is able to model Moisture Vapor Transmission Rate (MVTR) and Oxygen Transmission Rate (OTR) performance of package geometry using specific films for a variety of environmental conditions. The FEA software generates performance curves for each, making clear performance comparisons of a number of different design considerations possible. The effects of a blister design change and material selection can be determined and directly related to shelf life by day. This means that only the most promising and most likely to succeed designs can be brought through prototype and testing, thus greatly reducing time and cost. The customer can choose among the 3D renderings which package options they want to pursue.





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STEP 3: RAPID PROTOTYPE DEVELOPMENT AND EVALUATION

Software designs can now be rapidly turned into prototypes. The software generates an electronic template that is used by Computer Numerical Control (CNC) machinery to produce tools that are used to manufacture prototype packaging. CNC tool production can literally take place in a matter of hours, thus making it possible to prototype multiple cavity and card designs for evaluation.

Combining CNC technology with the presence of a state-of-the-art blister machine, kp's Blister Technology Center can immediately move into production of prototypes. The machine can produce marketing mockups of blisters in various designs and configurations that can be used by the customer to aid in the final decision-making process. This process can take from days to weeks depending upon complexity.

The ease and speed of producing prototypes with these new technologies means that testing for shelf-life, marketing and labeling, and other user acceptance considerations can proceed in a tight feedback loop with requests for design refinements and newly-revised prototypes, thus speeding progress toward the final design.

STEP 4: PERFORMANCE TESTING OF PROTOTYPE SAMPLES

Once packaging considerations are reviewed and accepted, production of samples containing actual product (or a dessicant) can begin. This allows kp to validate the performance of the sample packaging against the FEA software's virtual models.

Once performance is validated, the Blister Technology Center can produce product sample runs, thus eliminating the need for the customer to set up costly and time-consuming production runs at their sites for testing. The customer then uses the samples for stability testing, child resistance testing, and any other testing requirements which must be met for production to begin.

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STEP 5: SUPPORT SERVICES

With the growing dispersal of drug and packaging production to low-cost zones around the world, kp's full-service Blister Technology Center can provide essential technical expertise, training, and support for global production. The experience of producing prototypes and samples means that our engineers can help establish standards, practices, techniques, and training to ensure quality in a globally dispersed production environment.

CONCLUSION

Using cutting-edge software and technology, kp's Blister Technology Center offers services that will greatly accelerate packaging design for pharmaceutical products. This suite of services is designed to improve speed-to-market while also increasing the accuracy of design and testing, thus bringing significant cost savings to the customer.

This white paper offered a brief overview of that process. Future papers in the series will give a detailed look at the most significant and task-critical features of the design and testing process.

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