

BilcareOptima™

Packaging Solutions, backed by Science

Research Services

BilcareOptima™

✓ **Reduced development time and cost**

✓ **Determines barrier requirements**

✓ **Effective packaging cost reduction tool**

✓ **Best solution for extending shelf life**

The first scientific packaging development study that through FDA recommended QBD principles identifies the sensitivity profile of the product and recommends optimal packaging in 6 weeks.

The highly sophisticated techniques practiced by BilcareOptima™ stand in significant contrast to the current packaging selection methods, which, in most cases, lead to over-protection. Over-protection is generally a consequence of not fully realizing a product's true barrier requirement.

BilcareOptima™ provides answers to the following questions:

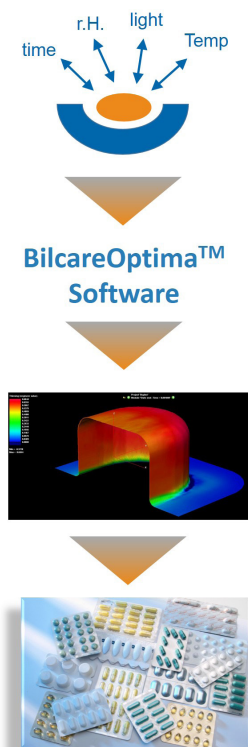
Is my packaging material the right choice?

What is the best packaging for my product?

Which environmental parameters affect my products stability?

What is the reason for my product stability failure?

How can I avoid "Over-Protection" for my product?



With BilcareOptima™ over-protection is avoided. We achieve this by placing your product through rigorous evaluation examinations, including our **Forced Degradation Study** which:

- Measures effects of independent parameters: temperature, light moisture, oxygen and time
- Estimates critical factors determining failure mode
- Determines threshold values and needed barrier properties
- Designs the final blister cavity using 3D Software
- Simulates cavity thinning & moisture permeation through FEA Software
- Selects the most optimum packaging material





The BilcareOptima™ Methodology

- Degradation pattern of formulation is evaluated using a set of designed experiments
- Three fresh batches are studied under various climatic conditions to evaluate:
 - Hygroscopicity
 - Physical degradation
 - Chemical degradation
 - Drug release properties
 - Hardness & friability
 - Photo sensitivity
 - Gas liberation
- The blister is designed and the thermoforming process is simulated to predict formed blister WVTR

Even Faster?

Bilcare FastPack!

	BilcareOptima™	Bilcare FastPack
Duration	6 weeks	3 weeks
Customer Requirements		
No. of Tablets/Capsules Required	2500 each/batches	600
Analytical support	Yes (chemical analysis)	No
Current Information Regarding API Sensitivity	Not required	Desired
Customer Benefits		
Report on Optimum Packaging Selection	Yes	Yes
Product Sensitivity/ Characterization Report	Detailed	Abbreviated
Sensitivity Grading	Yes	Yes
Thermoforming simulation for Selected packaging	Yes	Yes
Which Service, When		
Packaging Selection for NDA/for NCE	Yes	No
Packaging Selection for ANDA	Yes	Yes
Packaging Selection for Clinical	Yes	Yes
Packaging Selection for Repackaging of existing product	Yes	Yes
To be part of the FDA Design space documentation	Yes	No

Any questions ? If so, let's talk about meeting your needs quickly and efficiently...now!