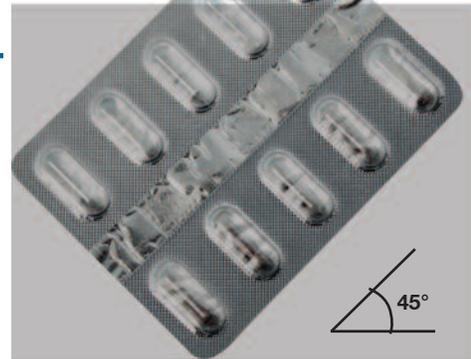


Instructions for Using Polarized Film

OVERVIEW:

Using polarized film is a simple, quick, non-destructive, qualitative test of blister cards that can be performed immediately after thermoforming and sealing. This test can reveal stress-forming in your blisters, which can cause weakened seals, micro channels and, ultimately, higher failure rates in stability tests and possible launch.

Illustration 1



Polarized Film Sheet

HOW TO USE:

To examine a blister card using this polarized film you need to follow a few simple rules:

1. The blister must be made of transparent film.
2. The blister must be backed with a reflective background such as foil lid stock or a second piece of polarized film.
3. Hold the blister card under the polarized film and at a 45 degree angle to the film (see illustration 1).
4. Check for stress in the sealed area. If stress is present here, you will notice a color differential (see illustrations 2 and 3). As heat is applied during the sealing cycle, the stress in the blister begins to relax. This relaxation can cause micro-channeling.
5. Check for stress in the formed blister cavity. If stress is present here, you will notice color changes from brown to blue and then to more brilliant colors as the stress increases.

By using polarized film, stress or molecular orientation becomes visible in the formed blisters. Of particular concern is stress that appears in the sealing flange. The intensity of color changes from brown to blue and then to more brilliant colors as stress increases. This shows that the molecules have changed during thermoforming from a random relaxed state to a stretched spring-like chain – an oriented state. The temperature at which this orientation or stress is locked into the blister is often at the same temperature or lower than the temperature required to activate the heat seal coating of most lidding foils. As heat is applied during the sealing cycle, the stress in the blister begins to relax. This causes the sealing flange of the blister to shrink and pull away from the adhesive coating of the lidding material. The sealing area is decreased as the edge of the cavity deforms, thus causing weakened seals, micro channels and finally high failure rates in stability testing. Methylene-Blue testing in most cases is not a sufficient test to verify leakage caused by micro channeling. If a blister

card is cross-perforated there is even a higher likelihood of failing as each single dose unit has four surrounding edges that allow moisture ingress to the drug product.

Illustration 2 shows examples of how a bad (stress-formed) blister (left) and a well-formed (low stress) blister (right) looks when using polarized film.

Illustration 2



Color differential in the sealed area is an indication of stress-forming. Relaxation can cause micro-channeling

Uniform color distribution in the sealed area indicates homogeneous inner tensions distribution and a low risk of leakage

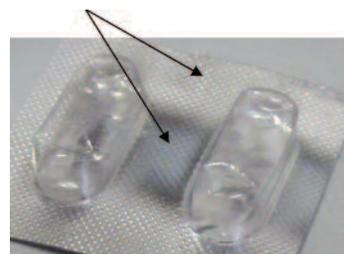


Illustration 3

HOW TO CORRECT COMMON CAUSES OF STRESS IN BLISTERS:

Cause	Corrective Action
Cold forming	<ul style="list-style-type: none">• Increase the pre-heater temperature.• Increase the pre-heating dwell time.• Clean the pre-heater platens.• Increase mold temperature. Recommended set point is 20°C.• Minimize gap opening between pre-heater platens and the mold.
Incorrect film path	<ul style="list-style-type: none">• Check that formed web does not contact mold surfaces during indexing.• Adjust heights of pre-heaters and mold to correct.
Uneven heating of the forming material	<ul style="list-style-type: none">• Check leveling of heater platens and mold and adjust, if necessary.• Verify temperature of heater platens with pyrometer.
Incorrect timing	<ul style="list-style-type: none">• Follow correct forming sequence: closing of the mold, plugs assist, air pressure, opening of mold, advancing the web.• Minimize the lag time between film index and forming.
Misalignment of heater platens	<ul style="list-style-type: none">• Check functionality and planarity of heater platen.
Heater platen length too short	<ul style="list-style-type: none">• Preferred pre-heater length is 3X the index length. Contact your OEM for retrofit options to increase platen length or to make platens even multiples of the index length.
Misalignment of matched mold	<ul style="list-style-type: none">• Check planarity of upper and lower platens and for evidence of pressure uniformity.• Check for air escaping during the forming cycle.
Forming mold	<ul style="list-style-type: none">• Recommendation is to use only matched mold in barrier blister forming.

For Technical Support or to request a sample of the Honeywell Polarized Film Frame, please visit our website www.aclar.com and select "Contact & Support".

Polarized film may also be ordered from:

Alight
120 Shady Trail
San Antonio Texas 78232

Phone: (210) 545-6867

Fax: (210) 200-8790

sales@polarization.com

Product: PF006, 17" wide roll, Minimum order 2 ft

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December 2010, Printed in USA
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