Dye Penetration vs. Gross Leak Detection (Bubble)

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Outline

• Porous Packaging
• Non-Porous Packaging
• Dye Penetration – ASTM F1929
  – Terminology
  – Procedure
• Gross Leak Detection – ASTM F2096
  – Procedure
• Gross Leak Detection & Dye Penetration
• Conclusions
Porous Packaging

- Tyvek® - spunbonded polyolefin
- Paper
Non-Porous Packaging

- Poly/poly
- Foil/foil
Dye Penetration

- ASTM F1929-12
- Detecting **Seal Leaks (Channel leaks)** in Porous Packaging
- Focus on seals only
- Time duration = 5-20 seconds
• Dye penetrant
• Channel
• Wicking
• What is dye penetrant?

An aqueous solution of a dye and a surfactant designed to penetrate and indicate a defect location in the time prior to the onset of wicking which could mask its presence.
What does dye penetrant consist of?

- Distilled water: 99.45%
- Wetting agent: 0.5%
- Indicator dye: 0.05%
What is a channel?

A small continuous open passage across the width of a package seal through which microorganisms could pass.
• What is wicking?
  Migration of a liquid into the body of a fibrous material
Dye Penetration - Procedure

- Inject dye penetrant into package (0.25 inch)
- Time duration 5 to 20 seconds
- Rotate package to expose each seal edge to dye penetrant
Dye Penetration - Procedure

- 5 to 20 seconds
- > 20 seconds
Gross Leak Detection

- ASTM F2096-11
- Detecting **Gross Leaks** in Medical Packaging
- Porous and nonporous packaging
- Whole packaging
- Time duration = varies
Gross Leak Detection - Procedure

• Create a hole (known failure/defect) less than or equal to 250 microns
• Insert air source
• Submerge under 1 inch of water
• Inflate to a pressure where the air bubbles are observed emanating from the defect

MINIMUM TEST PRESSURE
Gross Leak Detection - Procedure

- 200 Mm
- Known Failure

[Images of testing equipment and results]
Gross Leak Detection & Dye Penetration

- Tyvek® separation
- Abnormal breathing from seal
- Follow up with dye penetration test
Gross Leak Detection & Dye Penetration
Conclusions

Dye Penetration
- Channel leaks
- Porous packaging
- Time duration: 5-20 seconds
- Focus only on seals

Gross Leak Detection
- Leaks
- Porous and nonporous packaging
- Time duration: varies
- Focus on the whole package (pouch or tray)