Top Failures Observed During Gross Leak Detection and Seal Strength Testing of Medical Device Packaging
WHAT WE WILL COVER

• Sterile Barrier Packaging System (SBS)
• Gross Leak Detection (Bubble Test)
• Seal Strength (Peel Test)
STERILE BARRIER PACKAGING SYSTEM

Protective Packaging
- Shipper (i.e. corrugated fiberboard box)
- Secondary, tertiary package, etc. (i.e. folding carton)

Sterile Barrier System (SBS)
- Primary package – Sterile Barrier System (i.e. pouch or tray)
GROSS LEAK DETECTION (BUBBLE TEST)

ASTM F2096 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

- Detects substrate holes and channel leaks
  - Puncture with needle
  - Inflate with low pressure air
  - Submerge under 1” of water
  - Finds leaks as small as 125 – 250 µm
GROSS LEAK DETECTION (BUBBLE TEST) (cont’d.)

WESTPAK test video:
https://youtu.be/isK9m08YJHU

ASTM F2096 - Standard Test
Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
FA I L U R E  M O D E  # 1  S T R E S S  C R A C K I N G

Possible Causes
• Compound folding
• Excessive pouch length
• Universal package configurations

Recommendations
• Aim to use the proper pouch size
• Use a stronger / more flexible laminate material (i.e. nylon)
FAILURE MODE #2 PUNCTURED SURFACES

Pouch Punctures Caused by Protruding Objects

Possible Causes
• Protruding objects
• Abrasion

Recommendations
• Use a device card
• Apply plastic covers
• Use a thermoformed tray (not pouch)
FA I L U R E  M O D E  # 3  T R A Y  C R A C K I N G

Possible Causes
• Impact testing
• Tray bend radius too tight
• Extreme aging temperatures

Recommendations
• Tray redesign
  • Tray geometry
  • Use less brittle / more ductile material
• Use lower accelerated aging temperature (e.g. < 60°C)
Failure Mode #4 Sealing Issues

Possible Causes
- Equipment setup issues
- Bad sealing parameters
- Protruding package contents

Recommendations
- Check sealing equipment
- Ensure proper sealing parameters prior to conducting your full package validation
SEAL STRENGTH (PEEL TEST)

SEAL STRENGTH (PEEL TEST) (cont’d.)

Technique A – Unsupported
- Commonly used
- Consistent data

Technique B – 90° Supported
- Least requested
- Human factor involved

Technique C – Supported 180°
- Commonly used
- Vendor suggested
- Higher values than Method A
SEAL STRENGTH (PEEL TEST) (cont’d.)

ASTM F88 – Medical Device Package Seal Strength (Peel Test)

Common Problem: Using 1lbf peel strength without conducting pre-validation to determine minimum acceptable peel values.

Result: False failures.

Solution: Determine sealing process parameters and minimum peel values using IQ, OQ, PQ.
RECAP: TOP FAILURES OBSERVED DURING GROSS LEAK DETECTION AND SEAL STRENGTH TESTING

# 1 Stress Cracking
# 2 Punctured Surfaces
# 3 Tray Cracking
# 4 Sealing Issues
# 5 Selection of minimum 1lbf peel requirement
QUESTIONS
REFERENCES

• ASTM F1980 – 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
• ASTM F2096 – 11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
• ASTM F88 / F88M -15 Standard Test Method for Seal Strength of Flexible Barrier Materials
HAVE QUESTIONS? NEED A QUOTE?

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• Useful Resources
  www.westpak.com/page/resources/
  - Webinars, White Papers, Accelerated Aging Calculator
ABOUT WESTPAK

• Independent test laboratory specializing in mechanical and environmental testing
  • Medical device
  • Pharmaceutical
  • Electronics, technology
  • Consumer goods
• Established 1986
• Accreditations: ISO 17025, ISTA Certified Lab
• 100% Employee Owned
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