Cambridge Polymer Group

Packaging for Medical Devices and Pharmaceuticals

Summary

Packaging design for medical devices and pharmaceuticals extends far beyond appearance. As materials science experts with extensive product development experience, Cambridge Polymer Group understands the importance of careful material selection and thorough characterization and testing of medical device and pharmaceutical packaging.

Packaging Materials

Packaging selection must consider the desired performance properties and compatibility with the product and processing methods.

Barrier Properties

Due to differences in physical and chemical properties, materials range in their ability to protect against contaminants.

Barrier to:	Common Packaging Materials:
Oxygen	Ethylene vinyl alcohol (EVOH) Nylon
Moisture	Polyethylene Polypropylene
Light	Aluminum
Biologics	Polymer films Tyvek®

Sterilization Compatibility

Sterilization processes place additional constraints on packaging materials. Ethylene oxide (EtO) and autoclaving, for example, require gas permeability, while gamma and e-beam processes require stability against ionizing radiation.

Biocompatibility

The risk associated with transfer of packaging materials (and potentially harmful additives) through contact, extraction (into a liquid product), or particulate generation, for example, must be evaluated through a chemical risk assessment per ISO 10993-18.

Testing

Packaging design must also consider the end user interface. Packaging that cannot be opened or that opens prematurely is ineffective and can compromise the product shelf life. Peel or tear testing can be used to evaluate seal quality and optimize manufacturing conditions.

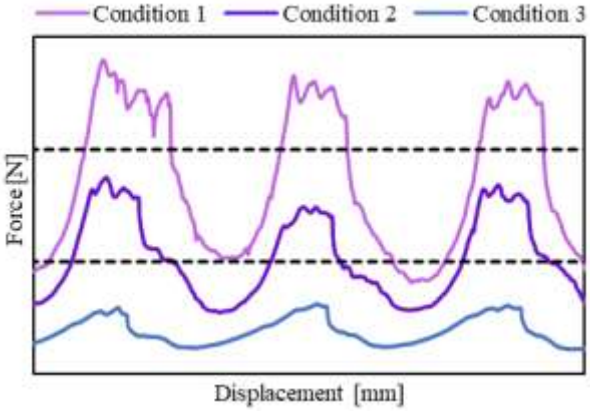

Figure 1: Peel force measurements for three consecutive seal segments manufactured with various welding conditions. Condition 2 met the minimum and maximum peel force requirements and was selected for continued manufacture.

The ability of packaging materials to meet performance requirements is evaluated as-manufactured and after shelf aging. To accelerate testing timelines, standard aging methods such as ASTM F1980 are employed. Accelerated aging typically involves storage at elevated temperatures, though other accelerating factors, such as humidity, light, pH, etc., must also be considered.

Conclusions

Improper selection of packaging materials for medical devices and pharmaceuticals could lead to costly circumstances resulting from reduced shelf life or sub-optimal product performance. Therefore, a deep understanding of materials science is critical when selecting packaging materials.

Cambridge Polymer Group, Inc. is a contract research laboratory specializing in materials. We partner with our clients to solve problems utilizing our multi-disciplinary research team and full service laboratory.

Contact Cambridge Polymer Group for help with your packaging selection or characterization needs.

- **Material selection**
- **Deformulation/identification**
- **Chemical characterization/ISO 10993-18**
- **Oxygen content**
- **Water vapor transmission rate (WVTR)**
- **Fourier transform infrared spectroscopy (FTIR)**
- **Raman spectroscopy**
- **Differential scanning calorimetry (DSC)**
- **Accelerated aging**
- **Optical microscopy**
- **Scanning electron microscopy (SEM)**
- **Energy dispersive spectroscopy (EDS)**
- **Tensile strength**
- **Peel force**
- **Tear strength**

Cambridge Polymer Group, Inc. was founded in 1996 to provide a cost-effective resource for testing, research and development to clients who need periodic access to Ph.D.-level scientists and their support structure. We have developed a host of testing methods and materials for our clients, which number more than 600.

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