

Building Blocks Available To Help You With Your Risk Assessments

Assessment Topics*

Supporting Documentation

Package Design Validation

- Packaging Performance
- Packaging Stability

- Mechanical property comparison pre- and post-sterilization, after accelerated aging and real-time aging for [1073B](#) and [1059B](#)
- Sheet stability testing (including sterilization) for [1073B](#) and [1059B](#)
- MPTP stability testing over 60 + 18 cells for [Pre- and Post-Sterilization, 1-, 3- and 5-year accelerated aging and 1-year real-time aging](#)
- [CFDA Jinan sheet function equivalence confirmation](#)

Material Characteristics

- Biological Safety
- Food Contact & Pharmacopeia
- Particulate Matter

- [Biocompatibility, Food Contact and Pharmacopeia Testing](#)
- [Particle generation properties](#)
- Regulatory letter available on request
- [Differential Scanning Calorimetry](#)
- [Infrared Spectrum "Fingerprinting" via ATR-FTIR](#)

Sterilization Process Validation

- Specification and miscellaneous property comparison [English](#) and [Metric](#) data sheets
- Key point: Gurley porosity specification is not changing [English](#) and [Metric](#) data sheets
- MPTP U.S. FDA Protocol and Phantom Protocol: no issues reported

Packaging Process Validation

- [Sealing fingerprints](#)
- [MPTP U.S. FDA Protocol and Phantom Protocol, cell selector tool](#)
- Various reports by SPMs participating in the protocol

* Specific assessment topics and required supporting documentation depend on packaging applications and specific required design features to be determined by the manufacturer.