

TESTING SERVICES FOR Processed Tissue and Tissue-Based Products

WuXi AppTec, with unequalled experience and expertise, offers the nation's most comprehensive program of testing services for processed tissue and tissue-based products.

All WuXi AppTec facilities are FDA registered. Additional qualifications include ISO certification, AAALAC accreditation, FDA registration for HCT/PS, and accreditation by American Association of Tissue Banks (AATB).

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biologics and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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BACTERIAL AND VIRAL INACTIVATION STUDIES

Customized studies are designed to validate removal, inactivation or other treatments for a variety of bacteria, viruses, yeast and filamentous fungi.

Studies are performed on human and animal tissue, including:

- Bone
- Skin
- Ligaments
- Collagen
- Heart Valves
- Other Tissue

In these studies, the product is inoculated with the chosen organisms. Each step of the client's inactivation/removal process is reproduced in the laboratory so the effectiveness of each step can be analyzed by determining the log reduction of the inoculated organism.

Following are routine inactivation/removal steps that can be analyzed.

- ▶ Heat / Pasteurization
- ▶ Low pH
- ▶ Solvent / Detergent
- ▶ Irradiation / Sterilization
- ▶ Alcohols
- ▶ Filtration
- ▶ Disinfectants / Antibiotic Cocktails
- ▶ Liquid Chemical Sterilization
- ▶ Gas / Plasma / CO₂ Processes

QUALITY TESTING

WuXi AppTec has a wide range of expertise in all areas of quality testing utilized by tissue processors and manufacturers of medical devices with a tissue-based component. Test offerings include:

- **Bioburden** • **Endotoxin (LAL)** • **Sterility** • **Residual Moisture** • **Environmental Monitoring** • **Water Quality**
- **Package Testing** • **Accelerated Aging**

DBM LOT RELEASE ASSAYS (cGMP)

Osteoinductivity (in vitro)

This assay provides in vitro evaluation of demineralized bone matrix (DBM) products for osteoinductivity utilizing alkaline phosphatase as a measure of osteoinductive potential; available as a qualitative or quantitative assay. A second validated assay for the quantitation of BMP-2 in DBM has bone extraction capabilities.

Osteoinductivity (in vivo)

To determine a material's bone-forming potential, an in vivo assay is performed by implanting the material intra-muscularly in nude mice or rats. Histopathology quantifies ectopic bone formation.

Endotoxin (LAL)

The kinetic chromogenic LAL method provides direct quantification of detected endotoxin levels to determine existing level of endotoxin on the product or endotoxin reduction of a production process.

CUSTOM STUDIES

Validation of Sterilization Procedures

All sterilization processes must be validated to ensure achievement of a specified sterility assurance level (SAL).

Validation of Decontamination Procedures

Procedures must be validated to prevent infectious disease contamination or cross-contamination during processing.

Process Change Validations

Process changes or deviations must be validated to prove equivalency or comparable efficacy.

Other Custom Services

WuXi AppTec offers additional customized studies that complement a processed tissue testing program, including biocompatibility testing and cell-based potency assays.

For more information on WuXi AppTec's services please contact:

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