testing for processed tissue and tissue-based products

WuXi AppTec offers the industry's most comprehensive program of testing services for processed tissue and tissue-based products – built on our unequalled experience and expertise.

Our tissue testing facilities are FDA registered, with additional qualifications that include ISO certification, AAALAC accreditation, FDA registration for HCT/Ps, and accreditation by the American Association of Tissue Banks (AATB).

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

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 / CO_2 Processes

Quality Testing

WuXi AppTec has a wide range of expertise in all areas of quality testing used for processed tissue processors and tissue-based products. 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*)

In-vitro assays can be used to estimate the potential osteo-inductivity of demineralized bone matrix (DBM) as an alternative to animal testing or as a screening tool for raw materials and final product. Two platforms are available: the alkaline phosphatase assay and the BMP (bone morphogenic protein, -2, -4 or-7) ELISA assays.

Osteoinductivity (*in vivo*)

In-vivo assays in nude mice or rats are used to definitively prove the ability of a DBM product to induce ectopic bone formation. The study is performed either by intra- or inter-muscular implantation of the product followed by histopathology.

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 Assays

Validation of Sterilization Procedures

Validation of Decontamination Procedures

Process Change Validations

Other Custom Services

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

Talk to us and find out how our tissue testing services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

药明康德
WuXi AppTec
Expert Solutions for Product Development