Mitigating Risk: The Impact of Extractables and Leachables

Recent regulatory communications and industry publications have created a heightened awareness of the need for testing of devices related to biological products. Of particular note are the risks associated with extractables/leachables for processing aids and disposable components, which have the ability to affect process quality (cell culture growth) and product safety. Among the issues are cytotoxic effects on cells from production materials, such as process disposables and single-use culture bags. These are in addition to the potential impact of the composition of a therapeutic’s own container/closure.

SELECTED READINGS
• J. Wood et al., “Strategy for Selecting Disposable Bags for Cell Culture Media Applications Based on a Root-Cause Investigation,” Biotechnology Progress, 29, No. 6 1535-1549 (November/December 2013).

MATERIALS SCREENING
Preventing costly delays and supporting early- and late-stage applications

Getting accurate materials characterization data that targets a particular process at each stage of the development cycle is critical. With our cutting-edge equipment, highly trained technicians, and sophisticated assay designs, WuXi AppTec can generate the most relevant data possible whether in an early or late-stage program.

We offer comprehensive chemical analysis of materials and products, with R&D and GLP testing programs designed to meet your needs – from process development to release, with many years experience providing testing services for a variety of devices/combination products and biologics.

Our process

Design Product-Specific Program
• Discuss project needs, considering regulatory requirements.
• Perform preliminary risk assessment.

Conduct Testing
• Perform tests per custom program.
• Communicate progress and flag key results.

Provide Results
• Create report packages.
• Generate risk assessments.

Talk to us and find out how our testing services for extractables/leachables can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com
EXTRACTABLES / LEACHABLES TESTING
WuXi AppTec’s extractables/leachables testing services provide you with the data you need to meet regulatory expectations.

Risk Assessments
- Preliminary evaluation
- Program plan
- Risk assessment report

Leachable Profile
- Analyte detection validation
- Analyte ID confirmation
- Analyte quantification

Extractable Profile
- Unknown determination
- Analyte quantification (semi)
- Toxicological potential analysis

Biological Evaluation
- Biocompatibility test plan
- Risk assessment report

CHEMISTRY METHODOLOGIES

**EXTRACTABLES**
Compounds are extracted or “pulled” out of the device

**LEACHABLES**
Compounds are allowed to leach or migrate out of the device

**Wet Chemistry**
- Glutaraldehyde Residues
- Conductivity
- Karl Fischer Moisture
- Osmolality
- USP 381 Physicochemical
- Protein Assay
- TOC
- Hemoglobin
- Carbohydrate

**Analytical Chemistry**
- EO Residual Panels
- EO Exhaustive Analysis
- EO Residuals
- ECH, EG Residuals
- Qualitative Screening
- Targeted Quantitation
- Comprehensive Quantitation
- Materials Characterization
- Extractable Analysis
- Leachable Analysis
- Failure Analysis
- Vendor Comparisons

**Physical Properties**
- SEM-EDS
- TGA
- DSC
- Viscosity
- Specific Gravity
- Melting Point
- Boiling Point
- Flash Point
- Residue on Ignition
- Moisture

PROGRAM FEATURES
- Advanced, high-capacity facilities
- State-of-the-art equipment
- Experienced, expert staff
- Customizable, product-specific testing programs
- Data integration into risk assessments
- Easy access to staff toxicologists
- R&D, GLP and GMP services
- Qualified methods available
- Regulatory and consulting services

Learn more about our comprehensive services for biologics – from concept to commercialization – at wuxiapptec.com