

BIOPROCESS LABORATORY AND APPLICATION TESTING SERVICES



Our comprehensive laboratory and application testing services offer a full spectrum of advanced testing and analytical solutions tailored for single-use bioprocessing systems. We focus on ensuring compliance, safety, and integrity across all aspects of single-use technology in biomanufacturing, with services designed to meet rigorous industry standards.



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TESTING SERVICES

STERILIZATION AND DEPYROGENATION SERVICE

Our steam sterilization and depyrogenation services are meticulously conducted to achieve and verify sterility, ensuring safety and regulatory compliance for your single-use products.

- ◆ Validated processes for complete sterility assurance
- ◆ Customized sterilization protocols for diverse materials
- ◆ Comprehensive documentation and certification of result

LAB CODE	SERVICE
CCG-STER-100	Autoclave Steam Sterilization
CCG-STER-200	Depyrogenation

PARTICULATE TESTING

Our particulate testing identifies and quantifies foreign particles, safeguarding product quality and preventing contamination.

- ◆ Microscopic and spectroscopic analysis for precise particle ID
- ◆ Quantitative assessment for regulatory adherence
- ◆ Traceability through particle origin analysis

LAB CODE	SERVICE
CCG-PART-100	USP <788>, Particulate Testing for Injectables (Light Obscuration)
CCG-PART-200	USP <789>, Particulate Testing in Ophthalmic Solutions
CCG-PART-300	USP <790>, Visible Particulate Testing
CCG-PART-400	Visible Particulate Identification (ID)
CCG-PART-500	SLS Particulate Analysis (0.2nm - 2000µm)
CCG-PART-600	Raman ID, Chemical ID/Finger-printing
CCG-PART-700	UV Absorbance
CCG-PART-800	Particulate Removal Service
CCG-PART-010	Particulate Recovery/Efficiency for Quantification

PHYSIO-MECHANICAL TESTING

Our physio-mechanical testing ensures single-use components meet durability and performance standards.

- ◆ Tensile, compression, and burst strength testing
- ◆ Compatibility assessments under operational conditions
- ◆ In-depth data for product lifecycle insights

FILTERABILITY STUDIES

Our filterability studies optimize filtration processes and validate membrane performance under operational conditions.

- ◆ Membrane selection and process optimization
- ◆ Verification of flow rates and pressure stability
- ◆ Integrity testing to confirm filtration efficacy

TESTING SERVICES

BIOBURDEN AND ENDOTOXIN TESTING

Our bioburden and endotoxin testing confirms the absence of microbial contaminants, crucial for biopharmaceutical safety.

- ◆ Quantification of microbial load to assess cleanliness
- ◆ Endotoxin testing for critical contamination control
- ◆ GMP-compliant methods for reliable results

LAB CODE	SERVICE
CCG-IMPU-100	USP <85>, Bacterial Endotoxin
CCG-IMPU-200	USP <61>/<62>, Bioburden Testing
CCG-IMPU-210	Microbial ID (Gram Stain and Cell Type)
CCG-IMPU-220	Microbial ID (Genus and Species)
CCG-IMPU-010	Endotoxin Recovery Efficiency Testing
CCG-IMPU-300	USP <63>, Mycoplasma Testing

CONTAINER CLOSURE INTEGRITY TESTING (CCIT)

Our CCIT confirms the security and integrity of product containers to prevent leaks and contamination.

- ◆ Leak detection using advanced analytical techniques
- ◆ Seal strength testing for robust containment
- ◆ Environmental conditioning to simulate real-world scenarios

LAB CODE	SERVICE
CCG-CCIT-100	ASTM F2391, Helium Leak Testing
CCG-CCIT-200	USP <1207>, Container Closure Integrity Testing
CCG-CCIT-300	VHP Ingress Testing

NUCLEIC ACID TESTING

Our nucleic acid testing is conducted to detect contamination at the molecular level, enhancing product safety.

- ◆ Rapid detection of nucleic acid contaminants
- ◆ High-sensitivity testing for assured purity
- ◆ Compatible with DNA, RNA, and other biomolecules

LAB CODE	SERVICE
CCG-NUCL-100	Nuclease Testing (RNase and DNase)
CCG-NUCL-110	RNase Testing
CCG-NUCL-120	DNase Testing

TESTING SERVICES

TOC AND CONDUCTIVITY TESTING

Our TOC and conductivity testing ensure minimal organic and ionic contaminants, crucial for ultrapure processes.

- ◆ Sensitive detection of organic impurities (TOC)
- ◆ Accurate conductivity analysis for ionic purity
- ◆ Compliance with global pharmacopeia standards

LAB CODE	SERVICE
CCG-SOLN-100	TOC Testing
CCG-SOLN-200	Conductivity Testing
CCG-SOLN-300	pH Testing

EXTRACTABLES & LEACHABLES TESTING

Our extractables and leachables testing assesses chemical safety and material compatibility, essential for drug integrity.

- ◆ Comprehensive profile of potential extractables
- ◆ Leachable studies under real-use conditions
- ◆ Risk assessment for regulatory compliance

LAB CODE	SERVICE
CCG-EXTR-100	USP <665>, E&L
CCG-EXTR-200	USP <1663>, Extractables Analysis

CHEMICAL COMPATIBILITY TESTING

Our chemical compatibility testing provides insights into material interactions and ensures materials resist degradation, preserving safety and performance.

- ◆ Assessment of chemical interaction with product components
- ◆ Stability testing under various chemical exposures
- ◆ Detailed reporting for informed material selection

LAB CODE	SERVICE
CCG-CHEM-100	ASTM D543, Chemical Resistance