

# Residuals Testing for Bioprocess Validation

Process-related impurities are introduced into the manufacturing process of biopharmaceuticals at a variety of stages. These impurities may originate from upstream steps such as cell and culture growth or harvest, during downstream processes, or from the use of single-use technologies. This can impact critical quality parameters and product safety by adversely modifying proteinaceous materials. Process-related impurities may include cell-derived impurities, buffer components, antibiotics, surfactants, anti-foaming agents, process enhancing agents, catalysts, or compounds that leach from contact materials.

Process-related impurities are typically present at low concentrations in complex matrices, making their detection and quantitation quite challenging. Demonstration of their effective removal is a key to validating the manufacturing process. Therefore, process validation studies require a broad set of testing capabilities and expertise.

## Why Choose Eurofins BioPharma Product Testing?

Our experienced staff has developed and qualified thousands of highly selective and sensitive methods. Our experience with these methods can help shorten your process validation and method establishment timelines and minimize costs.

We have a range of instrumentation dedicated to testing samples for process-related impurities.

Our 30-year history of cGMP regulatory compliance ensures delivery of the highest quality data.

Our expertise in biochemistry, molecular and cell biology, virology, and chemistry provides you with a single source for all of your validation testing needs.



## Instrumentation

### qPCR

- Applied Biosystem 7500 and Via7

### Plate Readers

- Multiple vendor plate readers with ability to read fluorescence, absorbance, and electrochemical luminescence

### Mass Spectrometers

- Thermo TSQ Vantage LC/MS/MS
- Thermo ICP-MS
- Sciex 4500 LC/MS/MS
- Agilent GC/MS
- Sciex 6500

### Chromatography Equipment

- Agilent/Waters HPLC/UPLC
- Agilent GC with Headspace Autosampler

### Detectors - Associated with Chromatography Equipment

- Corona Charged Aerosol (CAD)
- Evaporative Light Scattering (ELSD)
- Fluorescence (FL)
- Photodiode Array (PDA)
- Refractive Index (RI)
- Ultraviolet (UV)
- Electrochemical (ECD)
- Flame Ionization Detector (FID)
- Thermal Conductivity Detector (TCD)

Sample Category	Compound Name	Method	Sensitivity
Upstream & Downstream	Benzonase	ELISA	mid ppm
	Bovine Serum Albumin (BSA)	ELISA	high ppt- low ppb
	Host Cell Protein (HCP)	ELISA	low ppm
	Insulin	ELISA	mid ppm
	Long-IGF3	ELISA	mid ppm
	Protein A	ELISA	low ppm
	rDNA	qPCR	low ppt
Buffer Components	Acetate	LCMSMS or LC/UV	low ppm
	Ammonium	LC/CAD or CE	low ppb
	Arginine	LCMSMS	mid ppb
	Citraconic Acid	LC/RI	low ppm
	Citrate	LC/UV	low ppb
	Citric Acid	LC/RI	low ppm
	Cyanide	LCMSMS	low ppm
	Cysteine	LCMSMS	mid ppb
	Cystine	LCMSMS	mid ppb
	Glucose	LC/CAD	mid ppb
	Glycine	LC/RI	low ppm
	HEPES	LC/UV or LC/CAD	low ppm
	Histidine	LC/UV	low ppm
	Imidazole	LC/UV	low ppm
	Iodate	LC/UV	low ppm
	Mannitol	LC/RI	high ppm
	Periodate	LC/UV	low ppm
	Phenol Red	LC/UV	low ppm
	Phosphate	LC/CAD or CE	low ppm
	Sorbitol	LC/RI	low ppm
	Sucrose	LC/RI	high ppm
	Sulfate	LC/CAD or CE	low ppm
	Triazole	LC/UV	low ppm
	TRIS	LC/CAD	low ppm
	Tropolone	LCMSMS	low ppb
	Urea	LC/CAD	low ppm

Sample Category	Compound Name	Method	Sensitivity
Antibiotics	Carbenicillin	LCMSMS	low ppb
	Chloramphenicol	LCMSMS	high ppt-low ppb
	Colistin (Polymyxin E)	LCMSMS	low ppm
	Geneticin	LCMSMS	low ppb
	Gentamicin	LCMSMS	low ppb
	Kanamycin	LCMSMS	mid ppb
	Meropenem	LCMSMS	low ppb
	Methotrexate	LCMSMS	low ppb
	Penicillin	LCMSMS	mid ppb
	Puromycin	LCMSMS	low ppb
	Streptomycin	LCMSMS	low ppb
	Tetracycline	LCMSMS	low ppb
	Thiamphenicol	LCMSMS	low ppb
	Tobramycin	LCMSMS	mid ppb
	Vancomycin	LCMSMS	mid ppb
Surfactants and Anti-foaming Agents	Alcohol Ethoxylate	LC/CAD	low-mid ppm
	Antifoam B	LCMSMS or CAD	low ppm
	Antifoam C	LC/CAD	low ppm
	Antifoam DF204	LCMSMS	low ppb
	Hexylene Glycol	GC/FID	low ppm
	Octyl-b-Glucopyrano-side	LC/ELSD	low ppm
	Polyglycol P2000	LCMSMS	low ppb
	Polypropylene Glycol	LCMSMS or LC/ELSD	low ppb - mid ppm
	Polysorbate (Tween) 20	LCMSMS or LC/CAD	low ppm
	Polysorbate (Tween) 80	LCMSMS or FLD	low-mid ppm
	Pluronic F68	LCMSMS or LC/CAD	mid ppb - low ppm
	Pluronic L61	LCMSMS	low ppm
	Sarkosyl	LCMSMS	low ppb
	Simethicone	ICP-OES or ICP-MS	low ppb - low ppm
	Sodium Deoxycholate	LC/CAD	low ppm
	Triton X-100	LCMSMS or LC/UV	low ppb - low ppm

Sample Category	Compound Name	Method	Sensitivity
Process Enhancing Agents and Catalysts	AEBSF (4,(2-aminoethyl)benzene Sulfonyl Fluoride Hydrochloride)	LCMSMS	low ppb
	Arabinose	LC/CAD	low ppm
	Cystamine	LCMSMS	mid ppb
	Dithiothreitol (DTT)	LCMSMS	mid ppb
	EDC (N-ethyl-N', (3-dimethylaminopropyl) carbodiimide)	LC/UV	low ppm
	EDTA	LC/UV	low ppm
	Guanidine	LCMSMS	mid ppb
	IPTG	LCMSMS or LC/CAD	low ppb - low ppm
	Leupeptin	LCMSMS	low ppb
	Methionine Sufoximine	LCMSMS	low ppb
	Phenol/m-Cresol	LC/UV	mid ppb
	Polyethylene Glycol	LCMS or LC/CAD	low ppb - low ppm
	TCEP	LC/ELSD	low ppm
	TEMPO	GC/FID	high ppb
	Tri-n-butyl Phosphate (TnBP)	GC/FID	low ppm
	Tropolone	LCMSMS	low ppb
	Urea	LC/CAD or UV/Vis	low ppm
Residual Solvents	Residual solvents can be monitored using USP <467> or by custom methods		
Extractables and Leachables	Design and execution of controlled extractions, simulations and leaching studies		

#### Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing  
 Cell Banking Services • Virology Services • Facility & Process Validation  
 Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
 Stability Testing & Storage • Primary & Secondary Package Testing

#### Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com  
 Europe: Information@BPT.EurofinsEU.com  
 APAC: easl.cserv@BPJP.EurofinsAsia.com  
[www.Eurofins.com/BPT](http://www.Eurofins.com/BPT)



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