



## Residual Impurities for Bioprocessing

Residual Impurities are typically present at low levels in difficult sample matrices, and development and validation of assays and ongoing testing can be quite challenging. Whether you have impurities that are being introduced in upstream steps from culture growth and harvest or in the downstream processes—we provide expert testing, profiling and consultation for Residual Impurities monitoring.

### Why Choose Lancaster Laboratories?

- With extensive expertise in developing, validating and providing testing support for residual impurities, we can provide you with the best strategy for monitoring residual impurities and accelerating your drug development programs.
- Our 30-year history of cGMP regulatory compliance ensures delivery of the highest quality data.

### Testing Services Available

- Antibiotics
- Degradation Products
- DNA, RNA
- Extractables/Leachables
- Host Cell Protein
- Process-Enhancing Agents
- Solvents
- Surfactants & Antifoams

### Overview of Our Experience

#### Residual DNA (qPCR)

- Validated Assays for CHO, BHK, E. coli, Human and Mouse DNA

#### Host Cell Protein (ELISA)

- Cygnus Kit and Custom Assays

#### Residual Antibiotics

- Kanamycin, ampicillin, tetracycline, penicillin, chloramphenicol, gentamicin sulfate, amphotericin B, hygromycin B, plasmocin

#### Surfactants & Antifoams

- Triton-X, Pluronic, Tween 20 & 80, Antifoam A,B,C

#### Process-Enhancing Agents

- IPTG, DTT, Urea, Guanidine

#### Residual Solvents

- USP <467> and Custom Methods

#### Extractables & Leachables

- Design and execution of forced extraction, controlled extraction and leaching studies

#### Metals

- 34 elemental scans for ICP-OES and 64 elemental scans for ICP-MS, single or multiple element determinations

#### Fraction Collection for Isolation of Impurities and Residuals

#### Instrumentation

##### Mass Spectrometers

- Agilent GC/MS
- Agilent LC-TOF
- Thermo Scientific GC/MS
- Thermo Scientific Accela LC/TSQ Vantage LC/MS/MS
- Thermo Scientific Accela LC/LTQ XL Ion Trap
- Thermo Scientific Accela LC/LTQ Orbitrap XL
- Waters Quattro Micro LC/MS/MS
- Water XEVO-TOF

##### Chromatography Equipment

- Agilent GCs (both headspace & direct injection)
- Agilent/Waters/Thermo Scientific HPLCs
- Dionex ICS-3000 Ion Chromatograph (IC)

##### Detectors

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

Discover our solutions at: [LancasterLabsPharm.com](http://LancasterLabsPharm.com)

#### Global Services:

Biochemistry  
Cell Bank Manufacturing  
Facility & Process Validation  
Method Development & Validation  
Microbiology  
Molecular & Cell Biology

Mycoplasma Services  
Raw Materials Testing  
Release Testing  
Residuals & Impurities Testing  
Stability Testing & Storage  
Viral Clearance & Viral Safety

#### Facilities:

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Portage, MI | 269-323-3366

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Dungarvan Co. Waterford | 00 353 (0) 58 48300