



Impurities Testing for Pharmaceutical Products and APIs

From residual solvents and process-related impurities to extractables/leachables and degradant-related impurities, Lancaster Laboratories offers a broad range of services in support of impurities testing. We are able to identify and quantify very low levels of impurities in the most difficult of sample matrices.



Why Choose Lancaster Laboratories?

- You can easily identify extractable compounds detected by LC/MS analysis, using our non-volatile compound database consisting of more than 120 compounds.
- If you have a short-term or infrequent need for testing, our self-validating method approach for residual solvents testing is a faster and more cost-effective option.
- For unknown impurity identification, we offer the most extensive range of mass spectrometric approaches, including accurate mass.
- Our 30-year history of cGMP regulatory compliance ensures that you get the highest quality data.
- With extensive expertise in developing, validating and providing testing support for impurities, we can provide you with the best strategy for monitoring impurities and accelerating your drug development programs.

Testing Available

Residual Solvents/Impurities

- USP <467> (all classes of residual solvents in current chapter)
 - Customized method development/validation
 - Extractables/Leachables
 - Forced extraction studies
 - Controlled extraction studies
 - Validation of disposables for use in Biomanufacturing
 - Customized method development/validation
- Specific example of methods include:*
- Phthalate esters by GC/MS in tablets
 - Benzo(a)pyrene by HPLC and GC/MS in final finished product
 - Nitrosamines in metered dose inhaler O-ring components
 - Trace metals by Inductively Coupled Plasma in drug products

Process Impurities/Related Compounds

- Customized method development/validation
- HPLC product and API specific methodology
- Qualitative/Quantitative analysis
- Tracking/trending of resulting stability studies

Degradation Products

- Customized method development/validation
- Forced degradation studies
- HPLC product and API specific methodology
- Qualitative/Quantitative analysis
- Tracking/trending of resulting stability studies

Heavy Metals

- Qualitative/Quantitative limits testing (using ICP and ICP/MS approaches)

Elemental Analysis

- Qualitative/Quantitative limits testing (using AA and CHN approaches)



Major Instrumentation

Mass Spectrometers

- Agilent GC/MS
- Agilent LC-Iontrap
- Agilent LC-TOF
- Applied Biosystems Voyager DE PRO MALDI-TOF
- Perkin Elmer Inductively Coupled Plasma ICP/MS
- Thermo Scientific Accela LC/LTQ XL Ion Trap
- Thermo Scientific Accela LC/LTQ Orbitrap XL
- Thermo Scientific Accela LC/TSQ Vantage LC/MS/MS
- Thermo Scientific ISQ GC/MS
- Waters Quattro Micro LC/MS/MS

Chromatography Equipment

- Agilent GCs
- Agilent/Waters/Thermo Scientific HPLCs
- Dionex ICS-3000 Ion Chromatograph (IC)
- Direct Injection (GC)
- Headspace (GC)

Detectors

- Corona Charged Aerosol (CAD⁺)
- Electrochemical (ECD)
- Evaporative Light Scattering (ELSD)
- Fluorescence (FL)
- Laser-Induced Fluorescence (LIF)
- Refractive Index (RI)
- Ultraviolet (UV)
- Photodiode Array (PDA)

Spectrophotometers

- PE Analyst 800 Flame Atomic Absorption Spectrometer
- PE CHN Analyzer
- PE Graphite Furnace Atomic Absorption Spectrometer

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