

# Structural Chemistry Services

The proven source to help expedite your regulatory submissions and to bring your product to market faster

Catalent Pharma Solutions provides clients with comprehensive analytical chemistry and spectroscopy services that combine state-of-the-art instrumentation with the unparalleled techniques, expertise, and problem-solving ability of our staff—all delivered in a timely manner to keep your project on track.

Catalent offers contract research services, including superior oral, inhalation, biopharmaceutical, and sterile product support. Through leading-edge technologies and processes, our facilities in North America and Europe provide extensive capabilities, including discovery support, pharmaceuticals, analytical chemistry, structural chemistry, microbiology, clinical manufacturing, and clinical supply services.

## Extractables and leachables studies

Over the years, we have built a team of high-level scientists second to none. Our scientists have added to their experience and expertise through a commitment to cutting-edge technology and new and improved techniques. As leaders in the field, Catalent scientists have knowledge of the most up-to-date expectations from regulatory bodies. Our knowledge allows Catalent services to be efficient, accurate, and timely for designing and executing extractables/leachables studies to meet your important milestones. Whether you are looking for the characterization of pharmaceutical entities, structural elucidation of drug-related impurities and degradation products, analysis of extractables/leachables, or other services, you will find our team ready to help solve your problem—with an attention to detail and accuracy, a focus on your schedule, and a dedication to quality science that will make a major contribution to your product's success.



## Our services include:

### Materials characterization

- Extractables characterization
  - Controlled extraction studies per PQRI and all FDA guidances
  - Polymer additive identification
  - Toxicological assessments including USP <87>
- Residual and casting solvent identification
  - USP <467> and related methods
  - Headspace GC-MS
- Identification and purity of polymers
  - Thermal analysis
  - FT-IR

### Trace organic analysis

- Extractables routine control methods
  - Metered dose inhaler valve components and canisters
  - Dry powder inhaler devices
  - Blister-packs
  - Elastomeric closures including USP <381>
  - Blow/Fill/Seal packaging
  - Containers including USP <661>
- Leachables
  - Stability protocols
  - "In-use" study designs
  - Targeted profiling using GC-MS and LC-MS
- Migration studies
- Trace level impurity control
- N-nitrosamines
- Polynuclear Aromatic Hydrocarbons (PNAs)
  - Single-Ion-Monitoring GC-MS
- Residual solvents
  - API
  - Packaging

## Our services include (continued):

### Impurities and degradation chemistry

- Forced (stressed) API and drug product degradation
- Impurity profiling
  - LC-MS, LC-MS<sup>n</sup>, GC-MS
  - High-resolution accurate mass LC-MS
  - LC-NMR
- Degradant and impurity isolation and characterization
- Semi-preparative chromatography (LC and GC)
- Reference standard synthesis/qualification
- Mechanistic evaluation of impurity formation
- Microscopy and FT-IR microscopy

### NMR and organic spectroscopy

- Purity assays for release testing by NMR
  - Purity assay by USP <761>
  - USP and EP poloxamer testing
- FT-IR method development/validation
  - Quantitative analysis of the composition of polymers
  - Method development and analysis using multivariate techniques
- Structure determinations
  - Proof-of-structure for small molecules (cGMP)
  - Proteins
- Analysis of metabolites of pharmaceutical ingredients
  - Metabonomics

### Atomic spectroscopy

- Elemental analysis from boron to uranium
  - Percent level to ppb
- Toxicological and animal study support
- Raw materials
  - USP, EP, JP, BP
- Leachables/extractables including silicone oil lubricants
- Inorganic-based API
  - Specifications
  - Cleaning validations
- Investigations
  - Off-color
  - Specks
  - Precipitates



### Biopharmaceutical characterization

- Amino acid analysis
- Peptide/protein sequencing
- Proteolytic mapping
- Disulfide bond mapping
- High-order structure characterization (including MMR studies)
- Identification/characterization of post-translational modifications

### Call Catalent when you need our:

- Breadth and depth of capabilities and expertise that is unparalleled in the industry
- Access to proprietary delivery technologies to help better differentiate your product in market
- Solutions to accelerate your product's development

### Catalent Pharma Solutions

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