

Product Development Services

Flexible solutions for your most difficult analytical challenges

When you work with Catalent, you gain access to the strongest set of analytical chemistry resources available to the pharmaceutical and biotechnology industries. Our scale, infrastructure and scientific expertise allow us to solve your most difficult analytical challenges—and deliver unique value to your product.



Catalent's Pharmaceutical Services Team Offers:

	Preclinical	Phase I	Phase II	Phase III	Launch	Commercial/Phase IV
Analytical Services	GLP toxicology study support; MD/MV for Phase I clinical supplies	Clinical supply release/stability for clinical supplies	MD/MV for Phase III clinical supplies; support scale-up	Tech transfer to commercial site; support process validation; registration specifications	Validation batch release and stability	Troubleshooting/method remediation
Structural Chemistry	Isolate active; structural proof of active for IND; polymorph screening/selection	Impurity profiling	Reference standard characterization; structural proofs for NDA	Extractables and leachables		Counterfeit analysis; litigation support; impurity/contaminant ID/characterization; process improvement
Stability Services	Toxicology study support	Formulation support; clinical batch stability	Formulation support; clinical batch stability	NDA stability; expiration dating; CMC documents	First 3 post-approval lots	Post-approval changes; annual lot(s)
Microbiology	Toxicology study and preservative formulation support	Clinical supply release/stability	Method qualification; clinical supply testing; support scale-up	Process validation support; registration specifications	Validation batches release and stability	Sterility release

Capabilities

- Complete analytical services from discovery support to commercial product
- Capacity for large projects
- Dedicated project management
- Global regulatory consultation and support, including dossier preparation

Our ability to solve your analytical challenges is backed by product development services that extend from preformulation to commercial manufacturing. To shorten your time to market and maximize your return on investment, partner with Catalent.

Specialized services

- DEA license: schedules I-V
- Potent compound handling
- Penicillins, cephalosporins and other beta-lactams
- Light-sensitive compounds
- Low-humidity environment requirements

Analytical services— from discovery support to the commercial product

Methods development and validation

- All HPLC chromatography detection modes
UV, RI, ELSD, EC, MS, fluorescence, diode array
- Raw materials, API, in-process, finished products, cleaning methods
- Methods remediation

Compendial analysis

- Full testing services per USP/NF, PhEur/PharmEuropa, JP/JPE, FCC, ACS, AOAC, DAB and ACS methodologies
- Method development and validation for noncompendial APIs and excipients
- Release specifications development

Trace metals analysis

- State-of-the-art GMP/GLP atomic spectroscopy facility
- Inductively coupled plasma mass spectrometry
- Method development and validation

Structural chemistry—problem-solving skills, specialized equipment and full spectroscopy services

Instrumentation capability

- GC-MS and LC-MS
- GC-NMR, LC-NMR
- Nanoprobe NMR
- Headspace GC-MS
- FT-IR

Service offerings

- Extractables and leachables characterization for MDI components and canisters, elastomeric closures and packaging materials
- Residual and casting solvent identification
- Identification and purification of polymers
- Degradant/impurity isolation and characterization
- Structural determination
- Identification and analysis of metabolites
- Mechanistic determination of impurity formation

Stability services— for preclinical and clinical studies, drug registration and commercial products

- Over 20,000 sq. ft. of chamber capacity
- Statistical analysis and data trending
- On-time sets and pulls assured by validated LIMS system
- All ICH and regional storage conditions for pharmaceutical and biotech products
- Photostability ICH (Option II)
- Redundant critical systems for power and humidity
- Validated primary and secondary monitoring systems for zero-gaps chamber monitoring

Microbiology—quality testing services with rapid data turnaround

- Barrier isolator technology for sterility testing
- Ribotyping (genotypic) bacterial identification
- Compendial testing: USP, EP, JP, BP
- Environmental monitoring
- Container-closure integrity evaluation
- Cleaning/disinfection validation
- USP water testing and system validation
- Preservative system formulation support



Catalent offers analytical support for your manufacturing operation:

- Vendor qualification
- Remediation of problem methods
- Isolate/ID unknowns in raw materials and finished products
- QC release
- Commercial product stability
- Troubleshooting

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