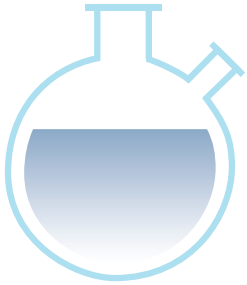
Catalent development



STABILITY TESTING & STORAGE

World class stability services to ease your critical path

Experts in reliability and service With thousands of stability studies successfully completed, Catalent is sought after for our expert analytical and stability support team to manage this critical milestone for preclinical, clinical and commercial products. From our reliable support and service to our industry leading capabilities and capacities, we have the tools to keep your product on the fast-track to market.

Global support for your products Globally, Catalent leads the industry in laboratory and chamber capacity. Whether your product is designed for the US, the EU or the global market; Catalent can provide unique partnering efficiencies to ensure advancement of a product candidate through development and registration as well as providing complete commercial product support.

- Over 70,000 cubic feet of qualified stability storage capacity
- Complete sample traceability and perpetual inventory systems
- Environmentally controlled and monitored chambers
- Computerized primary monitoring systems for temperature and humidity
- Automated out-of-range alarms and notifications 24/7/365
- Secondary chamber monitoring systems
- Backup power, air handlers and water systems to assure study continuity
- Chamber access controls and hardwired security systems

Superior capabilities generating quality results Catalent's 20 years of experience serving the pharmaceutical, biotechnology, consumer health and medical device industries has placed emphasis on operational excellence, generating on-time delivery of reports, and providing effective regulatory assessment for all your stability challenges.

We offer support for:

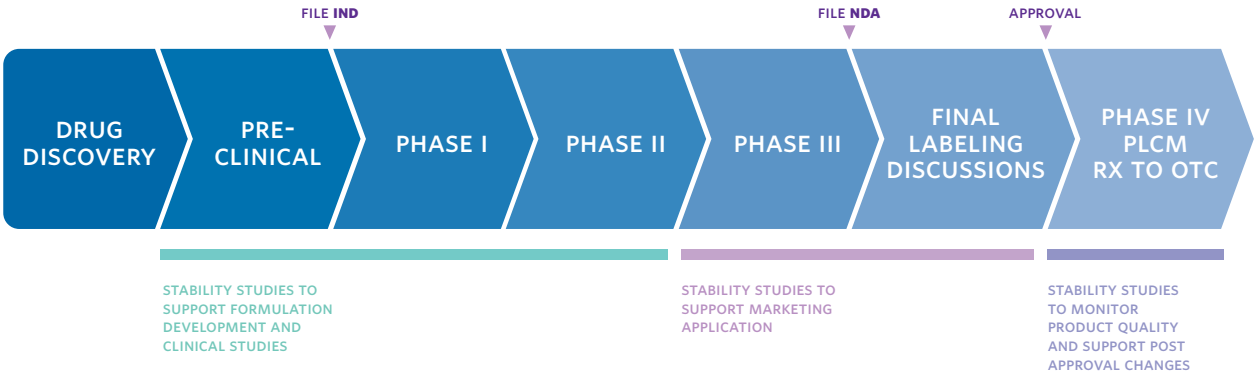
- All dosage forms and API
- Specialty products (Controlled substances, cytotoxics, radio-labeled materials)
- Drug-device combination products
- Transfers of on-going studies
- All global ICH and WHO conditions plus specialized conditions
- Photostability ICH (option II)—light exposure/temperature control

DEVELOPMENT DELIVERY SUPPLY

The stability study process More than just physical, chemical, biological and microbiological testing, Catalent's successful protocol is built around transforming these tests into a timely and quality deliverable that is matched to our clients' needs. From designing a protocol appropriate to the stage of the product life cycle to the incorporation of global and regional regulatory requirements, we start with your success in mind.

We offer our clients:

- Physical Testing, Chemical Testing, Biological Testing, Microbiological Testing, Dissolution testing, and Drug-Excipient Compatibility Studies
- Extractables/leachables
- Packaging component interactions
- Temperature excursion studies
- Shipping studies
- Method development and validation
- Protocol design appropriate to stage of product life cycle; per ICH for NDA or ANDA (API, Drug Product, and Combination Products) including bracket and/or matrix designs
- Determination of shelf life with statistical analysis and data trending
- Metrics driven performance
- On-time delivery
- first-pass acceptance
- Robust quality systems
- Comprehensive global regulatory knowledge and exemplary inspection record
- On-time set downs and pulls assured by a validated LIMS system
- Validated primary and secondary monitoring systems for zero-gap chamber monitoring
- Sample storage under ICH conditions



Let us help design a stability program that delivers more than just data for you.

more products.
better treatments.
reliably supplied.™

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