

Information sheet

Stability Chambers: Analytical Sciences

Designated team of highly experienced personnel who control all aspects of sample management and liaise closely with clients throughout the lifecycle of stability studies.

Our aim is to provide robust, sound data on which shelf life and expiration dates for drug substance and drug products can be based. Whatever the phase of development our team can offer support. We also offer a stability protocol creation service if clients prefer not to supply stability protocols themselves. Robust systems are in place to ensure complete tracking of samples from receipt, through stability storage and time-point testing (or shipment if required), to study end.

What Quotient can do for you

We can support a wide range of studies for both drug product and drug substance including packaging stability studies. We can also support studies involving radiolabelled compounds and controlled substances. We can accommodate short duration studies lasting a matter of weeks, to long term studies of months/ years. At some of our facilities, we offer not only 'storage only' studies, where sampling and dispatch is taken care of by our dedicated stability team, but 'storage and test' in which we can store, pull and test on site. Report generation and issue is managed through our Quality Management System, and reports are made available for client review and approval.

Capabilities include

Our global facilities offer purpose built stability suites comprised of 'walk in' chambers to 'stand alone' chambers depending on the site, with ICH conditions of:

- > 5°C,
- > 25°C/60%RH
- > 30°C/65%RH
- > 30°C/75%RH
- > 40°C/75%RH

In addition we have chambers that can be set to accommodate specific storage conditions at the request of the client should this be required. Chambers are continually monitored by the building management system, and alarm notifications are sent to not only the stability team, but also building maintenance if problems are encountered to allow rapid response to issues.

We also have a number of smaller 'reach in' chambers for smaller developmental/investigational studies including a Heraeus Suntest CPS, to allow the conduct of photostability studies.



Stability study testing

For those clients wishing to avail themselves of our extensive testing capabilities we offer a full range of analytical testing to meet the most challenging of needs. We have capabilities to perform a wide range of pharmacopoeial testing, physical characterizations and chemical testing for both drug substances, drug products and radiolabelled compounds. In addition, we can provide method optimization/ qualification services to produce analytical methods tailored to the stability testing of a clients material.

Why choose Quotient?

People and Process

- > Designated stability personnel within Drug Product who control all sample management during stability studies, constantly monitor the stability chambers and can act as a point of contact for clients.
- > Dedicated processes in place to ensure complete tracking of samples from receipt, throughout stability storage to the study termination.

Chamber Maintenance

- > 24 hour maintenance support by facilities personnel.
- > Monthly checks performed by stability personnel to ensure stability chambers are working at optimal conditions.
- > The chambers are monitored by continuum and are mapped annually by external contractors.

Services

- > Can support a wide range of studies, where the storage and testing can all be done onsite if required.
- > We can perform both short term (hours/days) and long term (months/years) studies including radiolabelled compounds, bulk drug substance, controlled drugs and various drug products.
- > Stability chambers support other service lines within the company such as drug product manufacturing, drug substance manufacturing and isotope labelling.
- > We can provide sample storage and shipment for clients who don't require onsite testing.

Your stability study in our hands

- > From development and manufacture of drug substance and drug product, to stability studies, including cytotoxic, radiolabelled and controlled substances, Quotient is your partner of choice.
- > We can fulfil all your needs, from protocol generation through to study end.
- > We work collaboratively with each client to ensure the setdown of their stability samples goes as planned, to fine details such as labelling, pack orientation and storage conditions.
- > Through close consultation, we ensure that the required protocols are clear and concise to match client expectations.
- > Our internal systems are well established to ensure effective sample management, providing a complete chain of custody.
- > We are agile and can quickly respond to changes in sampling requirements and/or ad-hoc client requests.

Who is Quotient Sciences?

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, molecules need to become cures, fast. Because humanity needs solutions, fast.

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Molecule
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