Recipharm

Stability studies

Global excellence for pharma and consumer health products

Recipharm's state-of-the-art analytical facilities can provide comprehensive support to meet the needs of any global stability study programme. With experienced scientists, the cGMP-approved facilities can handle every aspect of a stability studies project, from logistics to regulatory compliance, with precision and efficiency.

Stability is a critical quality attribute (CQA) for pharmaceuticals. An effective stability study is essential to help companies ensure that they have evidence to justify process, formulation, packaging, and storage condition changes to maintain optimum product stability. A study can also provide justification for extending or extrapolating use/review periods. Testing should be carried out in accordance with proper scientific principles, and with comprehensive understanding of current regulatory requirements and relevant climatic zones.

ICH stability zones

Zone	Type of climate	Mean kinetic temperature (Deg C)	Yearly average relative humidity (% Rh)	Example countries
Zone-I	Temperate	21	45	USA, Canada
Zone-II	Subtropical with high humidity	25	60	Southern Europe, Japan
Zone-III	Hot and dry	30	35	Iraq, Jordan
Zone-IVa	Hot and humidity	30	65	Egypt, Uganda
Zone-IVb	Hot and high humidity	30	75	India, Brazil

Support for a range of project needs

From sample receipts to shipment and reporting, the Recipharm team can provide a seamless experience for customers through-out the process.

Our stability study services

- Real or room temperature
- Accelerated
- Intermediate
- Temperature excursion or freeze/thaw
- Static thermal/humidity stress
- Photostability
- Bulk hold stability
- Shipping
- Period after opening (PAO) stability
- In-use

Our facility services

- Logistics including sample transportation and import requirements
- Shelf-life assessment
- Forced degradation and photostability studies for method development and molecule identification
- Stability chambers for all climatic zones per ICH guidelines (ICH Q5C and ICH Q1B)
- Support for schedules II, IIIN and IV controlled substances
- State-of-the-art analytical
- capabilities including microbiology testing
- Impurity identification and qualification
- Execution of protocol, data analysis and final report

Chambers with a range of capacities

Technique	Make
25°C/60% RH	124,000
30°C/65% RH	43,800
30°C/75% RH	124,000
40°C/75% RH	43,800
50°C/75% RH	500
2°C–8°C	10,000 & 200
15°C	4,200
Deep freezer (-20°C)	400 & 200
Photostability	200 (2)
50°C, 60°C	600 (2)
25°C/40% RH	4,200 & 1,000
30°C/35% RH	1,000
40°C/25% RH	500
21°C/40% RH	600
40°C/90% RH	600
Freeze thaw stability chamber (temp cycler) -60°C to 120°C (ramp and programmable)	300

About us

Established in 1995, Recipharm's manufacturing, fill & finish, and delivery-device services encompass a wide variety of drug dosage forms and modalities. Recipharm is an industry leading CDMO with over 30 facilities and 9,000 employees globally – supporting companies that are developing small molecules, biologics, and drug-device combinations. The company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US.

Introducing ReciBioPharm, Recipharm's biologics business combining the capabilities of recently acquired CDMOs Arranta Bio, GenIbet and Vibalogics. Our expanded biologics drug development and manufacturing services encompass technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, recombinant proteins, nucleic acid-based mRNA and plasmid DNA production.