eurofins | BioPharma Product Testing

Product Stability Testing and Storage

Eurofins BioPharma Product Testing provides secure storage and experienced testing of your samples according to your specified procedures and timetables. We also offer testing for samples stored at your facility in addition to any project management and consulting you might need.

Our capabilities include **biochemistry, chemistry, molecular and cell biology and microbiology testing services** to support your bio/pharmaceutical product. We can use your procedures or those found in any compendium to support your stability needs. Our Stability staff can also design studies specific to your project needs, and our experienced Method Development and Validation team is available for any additional services you may require.

Why Choose Eurofins BioPharma Product Testing?

We offer the largest Stability Testing and Storage facilities with more than **400 chambers** and more than **322,000 cubic feet of storage space** including ATEX chambers**.** Our chambers are housed in secured areas, continuously monitored by our validated monitoring systems and supported by a fully validated computerized stability laboratory information management system (LIMS) to manage and ensure proper execution of your studies.

Our facilities can meet the specific requirements of any project with the ability to provide alternate temperature and humidity conditions.

Our online data access portal, LabAccess.com℠, features a stability calendar that displays the progress of your stability studies with detailed links to information posted, allowing you to link to a sample number and see live data. You can also link to your overall protocol plan in our document control system, ensuring complete alignment between your requirements and scientific procedures.

Support Services Available

- Marketed & Clinical Stability & Release Testing
- Support of Method Development/Validation
- Comparator Product Testing
- Protocol Writing
- Storage Testing & Distribution of Reference Materials
- Sample Retain Program Management
- Capability to Store and Analyze Controlled Substances
- Photostability Studies
- Storage only

Support Systems and Capacity

- More than 25 different set points for the stability chambers including all ICH conditions
- Full redundancy on critical systems

Storage and Distribution of Reference Materials

We provide full-service support for the storage, testing and distribution of your critical biologic reagents and reference standards, including:

- Aseptic aliquoting of bulk biological reagents and reference materials
- Storage, including vapor phase liquid nitrogen and **-20°C, -30, -40, -70°C, 5°C** and ambient (dedicated and undedicated chambers)
- Cold-chain management and secure monitored shipping for your materials
- A full complement of biopharmaceutical services to support the stability testing of your materials

Stability Program Management

Upon arrival at our lab, stability samples are documented as to date and time of receipt and taken directly to our sample storage area.

We take inventory, compare the inventory with protocols and then log these samples into our LIMS. A quality check is performed as required for samples received from third-party manufacturers. This check can include but is not limited to: **label quality, lot number, print quality, container quality and container closure.** The inspection can be tailored to meet your in-house standard.

The LIMS, client input, and stability quotation are used to build stability protocols for clients. Quality reviews of the protocol entry (client provided protocol), along with Eurofins written protocol documents, are conducted. The LIMS tracks inventory, storage locations, pull dates, and time point testing as defined in the stability protocol. Inventory is verified every time we access samples.

We generate “pull reports” from our scheduling database for each workday, pull the samples as scheduled and log the samples due for testing and/or shipment into our LIMS.

You will then receive an acknowledgment letting you know that the appropriate samples have been pulled and are scheduled for the required testing. All steps of the storage and testing process are tightly controlled and accurately documented.

Reserve Program Management

Sample receipt of cGMP reserve samples are the same as stability samples. Samples are stored per client requirements. If requested, annual physical observations can be performed often within chamber space, depending on the condition. We use the pull interface from our LIMS each work day, pull the samples as scheduled and log the samples due for testing into our LIMS.

You will then receive an acknowledgment letting you know that the appropriate samples have been pulled and are scheduled for the required testing. All steps of the storage and testing process are tightly controlled and accurately documented.

Contact Us

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