

Stability Studies

< Storage and Testing Programs >



AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

Regardless the type of biopharmaceutical (proteins/peptides, virus, nucleic acid), AppTec can design and implement comprehensive stability testing and storage programs to meet regulatory and client requirements. Our stability studies employ validated storage chambers, complete biosafety and analytical testing services, and dedicated project management oversight.

AppTec's Technical Services department will provide you with technical and regulatory expertise to assure that your product meets the highest expectations of regulatory authorities worldwide.

Validated Storage Conditions

All temperature and humidity conditions needed to comply with ICH guidelines can be provided:

- 75% relative humidity / 40°C
- 60% relative humidity / 25°C
- Ambient humidity / 25°C, 30°C, 40°C, 50°C, 55°C
- Refrigeration at 5°C
- Freezer at -20°C and -60°C
- Liquid nitrogen (LN₂)

Alternate custom conditions can also be created to meet special needs.

Development and Validation of Stability-Indicating Assays

The design of stability programs includes the process of selecting the most appropriate stability-indicating assays and the rationale for those choices. Test articles can be subjected to various conditions to induce product breakdown (e.g., heat, agitation, oxidation or reduction). The analytical assays are then screened for ability to detect various product breakdown components. Stability assays are designed and validated according to ICH standards to meet or exceed the standards demanded by regulatory authorities worldwide. Programs can also include formulation assessment studies to ascertain how various formulations can affect product stability.

Analytical Methods

A variety of methods are available for use in stability studies. These include HPLC (IEX, RP, SEC), ELISA/Immunoassays, SDS-PAGE, IEF, Western Blotting, capillary electrophoresis, flow cytometry, spectroscopic and colorimetric methods for determining concentration, as well as nucleic-acid-based amplification methods (e.g., PCR and qPCR). A range of cell-based, immunoassay or virology potency assays can also be developed on a custom basis.

Other Product Characterization Methods

AppTec offers other characterization or compendial methods that are also a critical part of any stability study product analysis profile. These include sterility, bioburden or bacterial endotoxin testing, pH, visual appearance, particulates determination, Karl Fischer moisture determination and osmolality.



For more information about our wide range of services, contact an AppTec Account Manager at 888.794.0077.

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