Stability Studies

Facilities, analytical expertise and program management to support your global projects

ILLUSTRATION:
Vials of biopharmaceuticals

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WuXi AppTec

WuXi AppTec's Comprehensive Stability Study Programs

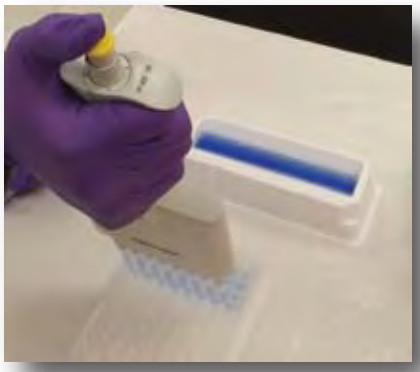
WuXi AppTec provides stability services for biopharmaceuticals, vaccines and bio-medical devices through comprehensive GMP programs designed to evaluate a product's stability over time in the desired temperature, humidity, light, accelerated and/or stressed conditions utilizing the intended container/closure configuration. Our stability studies are designed and implemented to meet testing and storage requirements of both regulatory agencies and clients worldwide. In addition, many of the assays transferred, developed, verified, qualified and validated at WuXi AppTec can also be utilized in product lot release testing or other testing programs (e.g., reference standard characterization).

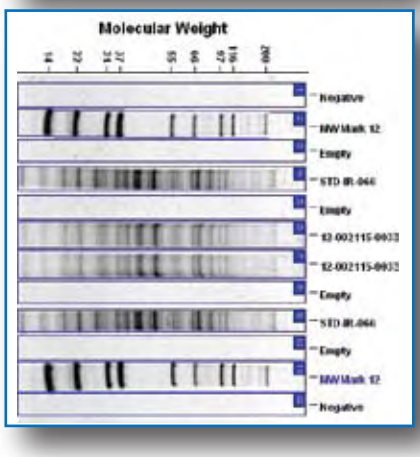
SERVICES FOR A WIDE VARIETY OF BIOLOGICS

Regardless the type of biological product, WuXi AppTec can design and implement comprehensive product stability testing and storage programs to meet regulatory and client requirements.

We have performed or are currently performing product storage and stability analysis for a wide variety of biologics including:

- **Monoclonal Antibodies**
- **Recombinant Proteins**
- **Peptides**
- **Viral Vaccines or VLP Vaccines**
- **Virus or Plasmid-based Gene Therapy Vectors**
- **Cellular Therapeutics or Whole Cell Vaccines**
- **Combination Products (Biologic + Medical Device)**





METHODS

A variety of analytical methods are available including compendial and client-specific/custom assays. WuXi AppTec stability programs are conducted under GMP guidelines. Individual assays can be run under either GMP or GLP conditions with quality oversight. Methods may include:

- General characterization methods *(concentration, visual appearance, particulates, pH, osmolality)*
- Purity methods *(reduced & non-reduced SDS-PAGE, SEC-HPLC, IEX-HPLC, CE-SDS, cIEF)*
- Impurity methods *(ELISAs, qPCR, Western blotting)*
- Identity and potency methods *(cell- and/or virology-based bioassays, ELISAs, IEF-PAGE, cIEF, peptide mapping or sequencing via LC/MS/MS)*
- Safety methods *(endotoxin, bioburden, sterility/CCIT, virology, mycoplasma)*

For virus-based products such as viral vaccines or gene therapy vectors, WuXi AppTec's 25 year history in virology testing can be utilized to support stability studies for these type of products, including methods for virus particle or infectious virus titer, IFA and dynamic light scattering for aggregates. In addition, qPCR or DNA sequencing could be used for identity testing utilizing our molecular biology expertise.

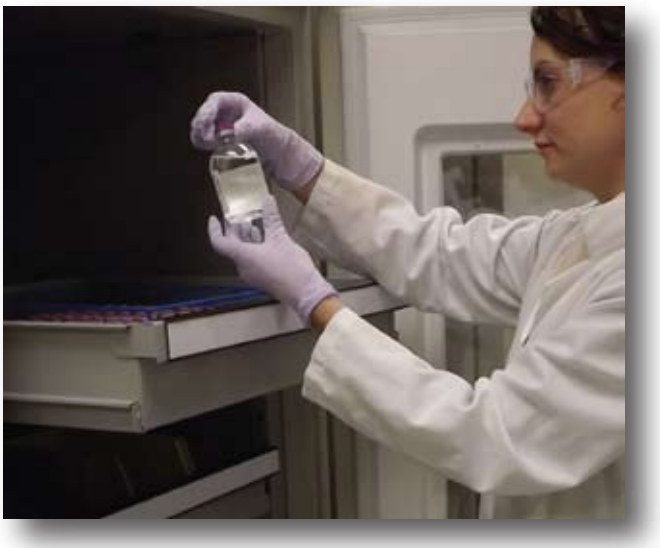
VALIDATED STORAGE CONDITIONS

For biological products, data to support intended storage conditions for a requested storage period or for expiration date determination should be based on real-time, real-condition, long-term stability studies.

The following temperature and humidity conditions are available to support stability programs:

- 2-8 °C
- 25 ± 2 °C / 60 ± 5%RH
- 30 ± 2 °C / 65 ± 5%RH
- 30 ± 2 °C / 70 ± 5%RH
- 40 ± 2°C / 75 ± 5%RH
- -20 ± 5 °C
- -40 ± 10 °C
- -80 ± 10 °C
- Liquid Nitrogen
- Photostability

Additional storage conditions may be evaluated to assess accelerated and/or stressed product conditions, as well as container/closure interactions that could impact product quality, such as studies using horizontal or inverted positions. Integrity testing of container/closure configurations or packaging integrity, strength and shelf-life can also be addressed or provided prior to initiation of stability studies.



DEVELOPMENT AND VALIDATION OF STABILITY-INDICATING ASSAYS

Methods that comprise the stability-indicating profile of a product will need to be justified as stability-indicating and validated for use. WuXi AppTec offers evaluation of drug substances and/or products under:

- Forced degradation conditions *(heat, agitation, pH, oxidation, light exposure, metals, and freeze-thaw)*
- Various formulations on product stability

The stability-indicating methods, which generally include methods to assess identity, purity, and potency, must be validated to demonstrate that they are suitable for their intended purpose. WuXi AppTec offers methods validation according to ICH guidelines for the assessment of assay characteristics, parameters, acceptance criteria and system suitability to assess assay accuracy, precision, linearity, range, specificity, LOQ/LOD, and robustness, as appropriate.

ADHERENCE TO ICH / REGULATORY GUIDELINES

WuXi AppTec's stability programs conform to the guidelines provided in the International Conference on Harmonization Guidelines (Federal Register Volume 60 (40) 11260): ICH Guideline Q1A(R2) Stability Testing of New Drug Substances and Products , ICH Guideline Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products, ICH Guideline Q1B Stability Testing: Photostability Testing of New Drug Substances and Products, as well as USP Section 1049 Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products and 21CFR Part 211.166, Federal Code of Regulations, Title 21 Volume 4, Stability Testing.

FACILITIES AND EQUIPMENT

Appropriate temperature and humidity settings are supported by REES temperature monitoring equipment.

REES system data is collected and maintained at WuXi AppTec and all equipment is supplemented with both emergency electrical power and secondary data recording devices. Mapping of chambers is performed every three years and calibration performed every year. Chambers are physically inspected once a day for temperature and humidity verification. All equipment utilized for stability programs is also maintained under well-controlled metrology and calibration quality progams.

Stability Studies

WuXi AppTec provides services of exceptional quality, utilizing more than 20 years of experience in the analysis and testing of biological products

STABILITY STUDY PROGRAM FEATURES

- Worldwide facilities utilizing state-of-the-art equipment designed to meet ICH stability guidelines and other regulatory standards.
- Cumulative stability summary tables for client reports and program updates.
- On-line 24/7 client portal sample tracking and testing status updates.
- Project Management to oversee every step of your project – from technical transfer of assays and program initiation to final report delivery.
- Mapped and monitored chambers to ensure stable, uniform storage conditions utilizing a wide variety of temperature and humidity settings.
- Studies for all development and clinical phases of drug substances and drug products, including commercial products.
- Wide array of analytical, molecular biology, cell-based and biosafety assays available to provide a single-source for our global clients.

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Contact WuXi AppTec for your stability studies:

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