

DATA SHEET

Stability Analytical Services



AVAILABLE AT:



Center for
Breakthrough
Medicines



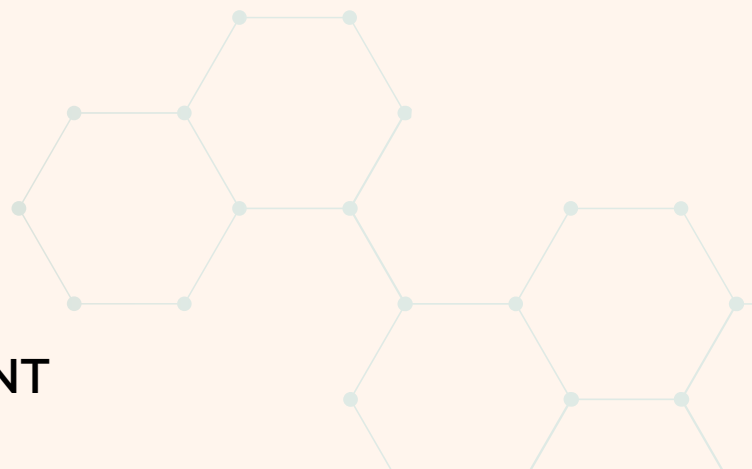
www.breakthroughmedicines.com
www.skpharmteco.com

CURRENT OFFERINGS

- ICH Stability Programs & Storage
- Phase-appropriate stability study guidance
- Submission support
- Forced Degradation
- 24/7 monitoring and alarms
- Electronic QMS
- Validated Laboratory Information Management System (LIMS)
- Method Development, Transfers, Qualification and Validation
- Microbiology
- Sequencing
- Compendial Testing
- Safety/Virology
- Cell Banking
- Bioanalytical
- Flow Cytometry
- Molecular
- Immunoassays

KEY DIFFERENTIATORS

- Dedicated Program Director with Full Regulatory Oversight
- Dedicated Sample Management team
- Trending and Custom Timepoint Reporting of Results
- CCIT can be offered in place of Sterility Testing on site to minimize sample volumes for testing
- Testing on site allows for samples to be shared across testing laboratories
- Storage and testing of multiple modalities including AAV, lentivirus, plasmids, and cell therapies



STATE-OF-THE-ART EQUIPMENT

Type	Manufacturer	Model
Cryogenic Liquid Nitrogen Freezers	Chart Biomedical	MVE 818P-190
-80 °C	Thermo Fisher Scientific	TSX50086D
-20 °C	Thermo Fisher Scientific	TSX2320FA
2-8 °C	Thermo Fisher Scientific	TSX5005CA
Stability Chambers*	Thermo Fisher Scientific	FORMA 3940
LIMS	LabWare, Inc.	PSv6.4 Version 8.0.0e

