DiTEBA
RESEARCH LABORATORIES INC.

Stability Storage and Testing Capabilities

At DiTEBA, we are committed to your success by providing analytical and bioanalytical chemistry services that accelerate R&D intensive projects.

Through the science of research, let DiTEBA expedite the process of bringing your product to market.

Research Turning Research Into Reality Reality

Stability Storage and Testing

- ◊ Protocol Design
- ◊ Long Term Stability testing
- ◊ Accelerated Stability testing
- ◊ Drug Substance Stability testing
- ◊ IND, NDA, ANDA Stability testing
- ◊ Commercial Product Stability testing
- ◊ Comparator Stability testing
- ◊ Formulation Evaluation Stability testing
- ◊ Forced Degradation studies
- ◊ Photostability (UV and Daylight) and Temperature cycling

Stability Storage Conditions:

- ◊ 25^0C/60% RH
- ◊ 30^0C/65% RH
- ◊ 40^0C/75% RH
- ◊ 5^0C
- ◊ -20˚C, -80˚C
- ◊ Photostability (UV and Daylight)
- ◊ Facility includes available space for expansion to meet any stability storage

Stability Chambers

Our temperature/humidity stability chambers are continuously monitored by the fully Validated Rees Scientific CENTRON Monitoring System® . It provides instant data regarding the individual storage condition while ensuring compliance with FDA 21 CFR 11.

Our natural gas powered roof top generator ensures continuous power during power failures for all stability chambers, fridges and freezers.

Compliance with Regulations

Our services are performed in stringiest compliance with the requirements of:

- ◊ The US Food and Drug Administration (FDA)
- ◊ Health Canada
- ◊ Good Manufacturing Practices (GMP)
- ◊ Good Laboratory Practices (GLP);
- ◊ International Conference on Harmonization (ICH) guidelines.

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