KEMWELL
*Keeping You Competitive*

# STABILITY STUDIES

Kemwell provides complete stability storage and testing standalone services for biologics in all recommended ICH conditions as well as custom temperature, humidity conditions. We can work with your protocol or develop one for you and conduct stability studies at various stages of the product life cycle: development through commercial batches.

Stability programs cover design of the study, generation of stability protocol, execution, statistical data evaluation and preparation of reports.

In addition to routine stability studies as per ICH requirements, various exploratory studies are also executed. These include:

- Comparative/non-comparative force degradation stability studies to evaluate the product degradation pathways under different stress conditions such as high temperature, freeze thaw, pH, oxidation, agitation etc.
- In-use stability
- Hold-time stability

At Kemwell, our cGMP stability storage facilities include 21 CFR part 11 compliant walk–in and reach–in chambers, which are:

1. Qualified as per cGMP conditions
2. Monitored on-line
3. Equipped with multiple sensors
4. Provided with back-up power supply

The following stability chambers are available:

- 2-8°C walk-in chamber & 25°C walk-in chamber
- -80°C chamber & -20°C chamber
- 30±2°C/ 65 ± 5% RH walk-in chamber
- 40±2°C/ 75 ± 5% RH chamber

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