

# STABILITY TESTING

## SERVICES AND CAPABILITIES

As a major independent drug development company, Olon USA works closely with its clients in designing and conducting stability studies that comply with ICH and FDA regulatory requirements.

Olon USA is an FDA registered, DEA licensed cGMP/GLP compliant contract manufacturing facility offering drug substance and drug product stability studies to support R&D, clinical, and commercial activities.



### CORE CHEMISTRY SERVICES

- ANALYTICAL CHEMISTRY
- PROCESS CHEMISTRY
- API MANUFACTURING

### RELATED SERVICES

- Bulk Storage & Distribution
- Solid Form Screening API & Impurity Synthesis
- Standard Purification
- GMP Kilo Labs
- In-Process Support
- Pilot Plant
- Regulatory Support

### RELATED ANALYTICAL SERVICES

- Forced Degradation Studies
- Method Development
- Method Validation
- Release Testing
- Degradant & Impurity Identification
- Reference Standard Characterization
- Preformulation

### STABILITY SERVICES

- Study & protocol design
- Long-term stability testing
- Accelerated stability testing
- Drug substance & Drug Product
- Photostability testing
- Commercial stability testing
- Customized interim & final reports
- Storage & Distribution

### FACILITIES

- Secure, walk-in, & reach-in stability chambers
- Qualified & mapped equipment
- Continuous alarm monitoring
- Emergency back-up power
- Redundant back-up chambers
- LIMS based stability module

### STORAGE CONDITIONS

- -80 °C
- -20 °C
- 5 °C
- 25 °C/60% RH
- 30 °C/65% RH
- 40 °C/75% RH
- ICH Photostability

