Syngene
Putting Science to Work

ICH Stability Services

Complete drug life cycle support – from IND filing to commercialization

Syngene is one of Asia's largest ICH Stability centers. Spread across 72,000 sq. ft, it offers shared and dedicated storage facilities for a global clientele. The facility supports both small and large molecules from early development to CMC filing and commercialization. Its internationally accredited Analytical labs and highly skilled scientists ensure all the data generated is compliant with regulatory requirements.

Key Features

- Diverse experience in handling Generic, Animal Health, CPG, Nutrition and OTC products
- Multiple walk-in and reach-in chambers compliant with ICH Q1 A(R2), Q1B, Q1C for new dosage forms and Q1 F guidelines
- State-of-the-art and internationally accredited analytical laboratories
- Comprehensive analytical solutions including method development, validation and in-house microbiology testing
- Fully cGMP compliant to meet Drug Substance and Drug Product development and commercial lifecycle

Why Syngene for Stability Services

Highly experienced in setting up dedicated centres customized to client requirements

Separate infrastructure for handling steroids, hormones, narcotics and other special categories

Dedicated logistics and regulatory teams for handling shipments and license requirements

SEZ enabling speedy clearance of shipment

Our Study expertise

- Complete Product lifecycle studies: Early phase till commercial
- Developmental stability
- Follow-up stability
- Forced degradation
- Freeze-Thaw stability
- In-Use stability
- Photo stability
- Registration stability
- RLD stability
- Commercial stability
- Transport assessment studies

Formulation types we deal in

Drug substances, drug intermediates including HPAPIs

- Tablet
- Capsules
- Soft gels
- Injectables
- Creams
- Ointments
- Eye drops
- Parenterals
- Lotions
- Emulsions
- Gels
- Suspensions
- Patches
- Liquid Spray
- Aerosols
- Powders

Our State-of-the-art facilities

- Biometric chamber access
- Multi-client ICH stability facility with long-term and intermediate testing conditions
- Uniquely coded and appropriately labelled samples for client confidentiality
- Chromatography data systems connected to server
- 24*7 Online Temp/RH monitoring of Stability chambers with backup facility
- Data managed electronically with systems 21CFR, Part 11 compliant

USFDA Approved | PMDA Approved | RUSSIAN REGULATORY AGENCY Approved | ISO 9001: 2015 Accredited

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com

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