Syngene

Putting Science to Work

Analytical Development Services

IND Filing to Commercialization

Complete drug life cycle support – IND filing to commercialization

Syngene has one of Asia's largest Analytical centers spread across 72,000 sq. ft, dedicated to global clients. With world-class scientists and state-of-the-art laboratories, our Analytical services are designed to offer deep insights into the quality, safety, and efficacy of your drug products, thereby increasing the success rate of your regulatory submissions. The facility supports small and large molecules programs from early development to CMC filing and commercialization.

Key features

- Diverse experience in handling generic, animal health, consumer packed goods (CPG), nutrition, and OTC products
- Facility audited and approved by USFDA, PMDA, Russian Regulatory Agency, and ISO 9001: 2015 accredited
- Well-equipped state-of-the-art analytical laboratories – all analysis done in-house.
- Modular labs that can be customized to client needs
- Comprehensive Analytical support for drug substances across small molecules, oligonucleotides, and polymer specialty materials (PSM)
- Supports a broad spectrum of molecules across multiple therapeutic categories
- ICH Stability services which are cGMP compliant; multiple walk-in and reach-in chambers compliant with ICH Q1 A(R2), Q1B, Q1C for new dosage forms, and Q1 F guidelines

Our comprehensive Analytical offerings

- Method development
- Method verification/validation
- Structural characterization and elucidation
- Reference and working standards qualification
- Identification and characterization of impurities
- Prep HPLC/chiral purification
- Residual Solvent Analysis
- Elemental impurities analysis
- Impurity analysis
- Method transfer
- Stability studies
- Phys-Chem studies/5-batch analysis

Analytical capabilities for Drug Products

Tablets capsules:
Assay & content uniformity, related substances, water content, drug excipient compatibility studies, filter compatibility, solubility, degradation studies, antioxidant and preservatives, DT, dissolutions (release media, multimedia & bio-relevant media), PSD, pXRD and residual solvents.

Powder for Injection (lyophilized / dry powder, microspheres, liposomes):
Assay, related substances, residual solvents, reconstitution stability study, diluent/component stability compatibility, assay of encapsulated/free drug, polymer characterization, lipid characterization, assay of antioxidant/preservatives, dissolution, particle size distribution.

Suspensions, Solutions:
pH, viscosity, light transmission matter/color, Density (Wt/mL), solubility, AET, assay & CU, degradation studies, drug excipient compatibility studies, related substances, antioxidant and preservatives, dissolutions and PSD.

Suspensions (ophthalmic suspensions, vial suspension for injection):
Assay, related substances, residual solvents, component stability compatibility, assay antioxidant and preservatives, dissolution, particle size distribution, *Invitro* comparative nasogastric feeding tube studies for vial suspension.

Liquid Injections (ampoules, prefilled syringes, vials):
Assay, related substances, residual solvents, diluent and component stability compatibility, particulate matter.

Semisolid dosage forms:
pH, viscosity, physical appearance, density (Wt/mL), AET, assay & CU, degradation studies, drug excipient compatibility studies, related substances antioxidant & preservatives, IVRT, texture analysis.

Analytical capabilities for complex injectables

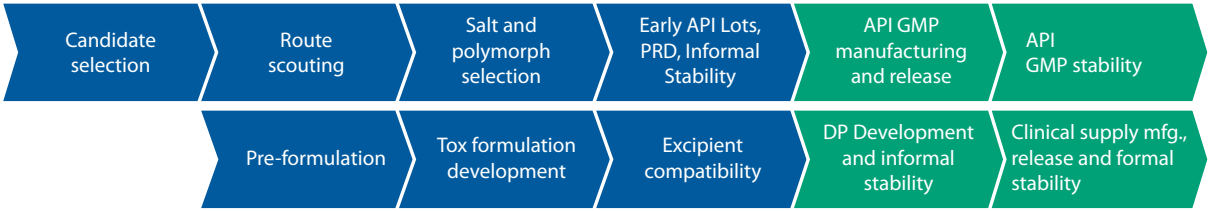
Pre-formulation studies	Liposomal injection	Injectable nanosuspension	Extended release injectable microspheres
• API characterization • API solubility • Excipient's evaluation • pH solubility and impact on stability • Impact of various parameters on API stability • Aggregate evaluation	• Assay; free/entrapped drug; other critical excipient • Related substances Phospholipid content (lyso forms) • Size and zeta potential • Internal environment (volume, pH, and ionic concentration): • State of encapsulated drug • *In vitro* drug release dissolution method using USP Type IV • Lipid degradation	• Dissolution method • Development – USP yype IV Assay • Related substances • Free fatty acid content • Phospholipid content • Drug partitioning • Globule size and zeta potential • Redispersibility	• Dissolution method development using Incubator orbital shaker or bottle rotating • Assay of free drug and encapsulated drug • Particle morphology size, shape • Molecular weight determi nation by GPC for polymer • Related substances • Polymer degradation

Analytical capabilities for Drug Substances

One-stop solution for all Analytical needs: Small molecules, oligonucleotides & performance and specialty materials (PSM)

Solid state characterization	Structural characterization	Method development/ validation	Extraction and purification
• Optical microscopy • XRPD • DSC/ TGA • DVS • Particle size analyzer	• NMR • LC/MS • LC/MS-MS • HRMS • GC/MS	• HPLC, GC, IC • Quantitative NMR • Wet chemistry • LC/MS, GC/MS • Genotoxic impurity methods • Forced degradation studies	• Semi prep HPLC • SFC • Column chromatography • Flash chromatography

Integrated Analytical support: Non-GMP and GMP activities



Non GMP Activities

- Phase-appropriate API, intermediate, DP analytical method development
- Support to chemists/process scientists / formulators for:
    - Route scouting, PRD activities
    - Tox/clinical formulation development
- Salt and polymorph screening
- Preformulation and excipient -- compatibility support
- Development stability of DS and DP (in use, accelerated, follow-up)
- Processing and packaging component compatibility

GMP Activities

- Phase-appropriate method qualification/ validation
- Release of RMs/ Intermediates/ DS/ excipients/ DPs
- DS and DP GMP stability
- Use time study for injectable DP

Non- GMP activities

GMP activities

Stability services: Salient features

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

- Tablets
- Capsules
- Soft gels
- Injectables
- Creams
- Ointments
- Eye drops
- Parentrals
- 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
- Chromatography data systems
- 24*7 Online Temp/RH monitoring with backup facility
- Data managed electronically with systems 21CFR, Part 11 compliant

Our key differentiators

Scientific expertise, comprehensive services

- Strong scientific team; SMEs available in all the areas of Analytical development, e.g., method development, method validation, method transfer, instrumentation, chemistry manufacturing control (CMC) development, life cycle management
- Comprehensive Analytical services across small molecules and large molecules (drug substance and drug product)
- Integrated Analytical support across non-GMP and GMP activities
- Adding value to deliverables through cutting-edge innovative solutions

Quality systems and global compliance

- World-class infrastructure and systems
- Phase-appropriate quality systems
- Environment health and safety (EHS) as per international standards
- Data protection and confidentiality
- Intellectual property (IP) assurance, client-owned IP
- Widely audited/accredited at national/regional and global levels

To know more about our Analytical services or to contact our experts, click here

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About Syngene

Syngene Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2.2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA.

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

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