

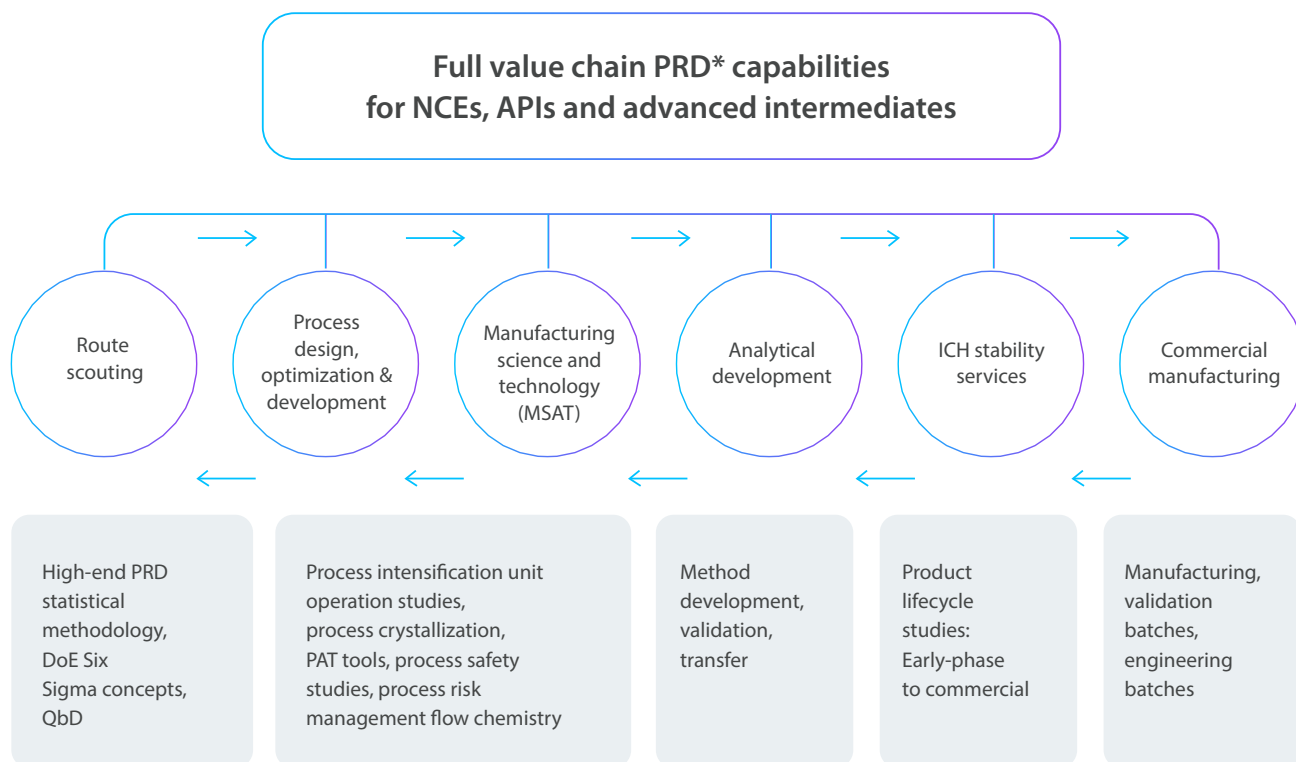
Syngene

Putting Science to Work

Small Molecule Development and Manufacturing



Drug Substance Development & Manufacturing



Syngene offers diverse chemical development facilities, including state-of-the-art laboratories, with advanced technologies such as flow chemistry and HPAPI handling along with cGMP manufacturing sites with reactors for various chemistries and scales. With already existing facilities in Bangalore and Mangalore, and the addition of the new US facility, Syngene is growing its capacity to new scale. Key chemical development infrastructure includes dedicated process engineering and safety labs, specialized equipment like hydrogenators and cryogenic reactors, robust analytical capabilities, and stringent safety and quality management systems compliant with global regulatory standards. benefits human and animal health.



125+ fume hoods in multiple suites



Automated lab-scale jacketed reactors connected to the sophisticated thermostats (-70- to 180 °C)



Flow chemistry lab for the feasibility studies and synthesis of small-scale proof of concept material



Dedicated process engineering and process safety lab



HPAPI development from lab (up to OEB-5) to manufacturing scale (up to OEB-4)



Therapeutic and diagnostic oligonucleotides – lab to manufacturing scale



Integrated analytical services, analytical method development, validation, transfer, reference standard qualification and regulatory support



Performance and specialty materials laboratory as well as non-GMP manufacturing facility– synthetic organic chemistry, polymer chemistry, and scale-up activities

Process engineering and scale-up

Syngene offers Process Engineering and Scale-up services for pharmaceutical and specialty chemical development, transforming lab-scale processes into robust cGMP-compliant manufacturing for clinical and commercial use over a broad scale (of 0.1 to 100 kg for oral solids). Our process capabilities include direct blending and compression process to produce tablets. We excel in wet, dry and top-spray granulation methods, extrusion and spheronization. We also provide Wurster coating for mini-tablets and pellets. Our experts apply the principles of Quality by Design (QbD) to assess the risk of formulation and process parameters and help identify high-risk factors that could potentially impact the critical quality attributes of a product, using experiments design techniques, our experts then identify and optimize these process parameters to positively impact the quality of products.



Design of experiments (DoE)



Process modeling and simulation



Reaction kinetics studies



Unit operation and processes



Reaction optimization studies



Process crystallization studies



Filtration, distillation, extraction, drying, corrosion studies etc



Mass and energy balances



Flow chemistry feasibility studies & technology development



Technology absorption and transfer



Advanced process analytical technologies (PAT) for process understanding (FBRM, PVM, React-IR etc.)



Quality by design (QbD)

Process safety management

Syngene offers comprehensive Process Safety Management (PSM) capabilities integrated into our Chemical Development process, including our expertise in Risk Assessment (Process Hazard Analysis, Process Control Justification), statistical process control, and systematic hazard evaluation. We employ state-of-the-art tools for qualitative and quantitative risk assessment, incorporating a risk-based process safety (RBPS) philosophy from the initial project stage, and employ safety measures like rupture discs, relief valves and LEL detectors to prevent major accidents. Syngene's facilities are designed to comply with regulatory safety standards and are audited by bodies like the USFDA and EMA, ensuring robust safety practices throughout the product lifecycle.

- Process safety studies (DSC, RC1e, ARC, vent Sizing, etc.)
- Powder safety studies (Fall hammer test, MIE, MIT, ignition test, MEC, LOC, etc.)
- Process safety information
- Process risk assessment (What-if, HAZOP, PHIRA, FMEA, qualitative and quantitative risk assessment, etc.)
- Pre-startup safety reviews
- Asset integrity and reliability studies

High potent APIs

Syngene offers robust HPAPI capabilities, including a dedicated cGMP-compliant facility designed for cytotoxic and cytostatic compounds with occupational exposure limits (OELs) down to 0.01 $\mu\text{g}/\text{m}^3$. Our facility features isolators, a range of reactors and downstream equipment, and a designed batch capacity of up to 30 kg, providing scalability from development to commercial manufacturing. Our HPAPI services cover the entire lifecycle from containment and analysis during development, to safe production and regulatory support for commercial manufacturing.

- Integrated solutions from discovery, process R&D, optimization, scale-up, and clinical supplies to commercial
- OEL determination toxicity studies
- cGMP manufacturing
- Facilities designed to handle cytotoxic, cytostatic, and high potent compounds with OEL values in the range of $>100 \mu\text{g}/\text{m}^3$ to $0.01 \mu\text{g}/\text{m}^3$
- Isolators for full spectrum of unit operations from sampling, dispensing and weighing, reactor charging, filtration, drying, milling & sieving to packing
- A broad range of reactors (stainless steel, glass lined, Hastelloy)
- Dedicated facility for Prep-HPLC and lyophilization of HPAPI molecules
- Development and manufacturing of ADCs, including linker development, optimization, and characterization



Highlights

- Highly experienced process chemists, analytical chemists, process engineers, manufacturing and quality control team
- cGMP facility for lab-scale to commercial-scale manufacturing including registration and validation batches for regulated market
- Integrated with a separate cGMP facility to manufacture non-potent compounds.
- Provision to add reactor and matching downstream equipment to enhance capacity/capability
- PAI inspection for the API registration and validation batches

Oligonucleotides services

Syngene offers comprehensive Oligonucleotide services including Process Development, Synthesis and cGMP manufacturing – from discovery to commercial supply for therapeutic Oligonucleotides. We handle natural, unnatural and modified oligonucleotides along with lipid and cholesterol conjugates, at scales from micro-moles for process development up to tens of millimoles for GMP production. Our expertise extends to analytical services, regulatory support and handling of various oligonucleotide modalities



Process development

- Natural & Modified siRNA | ASOs | Anti-microRNA | Aptamer | CpG
- Conjugated oligos | Molecular beacons | Fluorescent oligos | Probes & Primers
- Backbone modifications | Base modifications | Sugar modifications
- Synthesizer & Scale: ÄKTA oligo pilot 100 | 250 μmol - 6 mmol (100 mg - 5 g / batch (non-GMP))



Analytical support

- Comprehensive analytical support | Method development and validation
- Combination of orthogonal techniques Impurity Analysis | Identification | Sequencing | Characterization
- Release specifications: General | Compendial | Oligo-specific methods
- Forced degradation | Informal stability | ICH stability



Manufacturing

- cGMP facility of 1500 sq. ft. | Fully qualified equipment and area
- Controlled environment to limit endotoxin and bio-burden
- Located in a GMP certified/ USFDA inspected facility
- Synthesizer & Scale: ÄKTA oligo pilot 400 | 4 mmol - 45 mmol (5 g - 135 g / batch (GMP/non-GMP))
- Support for regulatory filing | CMC documentation suitable for Phase 1/2 IND



Formulation

- Drug Substance characterization and method development
- Formulation development and optimization
- Analytical methods development and pre-validation for the drug product
- Supportive stability study
- Component compatibility study and miscellaneous studies

Peptides services

Syngene offers a wide range of custom Peptide Synthesis services to meet your specific research and development needs. Our expertise spans various types of peptides and modifications, ensuring high purity and quality at every scale. From early discovery to clinical supply, Syngene offers a comprehensive, integrated suite of services to navigate through the unique challenges of peptide therapeutics, including synthesis, purification, stability and delivery and offer breakthroughs in modern medicine.



Integrated & Accelerated Program –

Seamless knowledge transfer and significantly reduced timelines through co-location of development workflows for both, Drug Substance (DS) and Drug Product (DP) within a single facility and under one quality system.



Accelerating Peptide supply by Integrating DS and DP –

Knowledge in Peptide API development and manufacture (DS), as well as Clinical / Commercial drug product (DP) development and manufacturing, to create a fully integrated program for clinical / commercial supply.



Centre of Excellence for peptides –

Wealth of experience synthesizing complex peptides and excellence in offering end-to-end services ranging from Discovery to Development and cGMP Manufacturing.



Dedicated Analytical Facility –

Our state-of-the-art analytical lab provides comprehensive structural analysis, characterization, and impurity profiling to ensure product quality.



Flexible Synthesis Scales –

We can accommodate projects from discovery scale to full cGMP manufacturing.



Time and Cost Efficiency –

Our integrated workflows enable rapid and cost-effective development, allowing you to bring your therapeutics to market faster.

Performance and specialty materials (PSM) Capabilities

Syngene's Performance and Specialty Materials (PSM) division develops and synthesizes materials like biopolymers, specialty polymers and performance chemicals for clients across various sectors, including clean energy and consumer goods. Our team leverages expertise in polymerization, chemical synthesis and formulations, from small-scale grams to multi-ton production to provide customized scalable solutions for material design, process development and scale-up. For example, we recently collaborated to develop a specialty polymer membrane that significantly outperformed existing benchmarks for a clean energy client.

Monomers

Acrylates; Schiff bases; Ionic liquids; Radical compounds; Macrocycles; Heterocycles, End functionalization of polymers; Light and air sensitive compounds

Polymers

Supramolecular polymer; conducting polymers; polymer self-assembly; self-healing polymers; hydrogels; silicones; random/block/star/comb copolymers and polymer; polymer membrane rolls for green hydrogen production; polymers- renewable energy (for battery: electrical vehicle)

Materials

Inorganic Materials; Additives; Catalysts; Biomaterials; Nanomaterials- Nanofibers, CarbonNanoTube (CNT)

- Laboratory synthesis and purification of monomers/polymers
- Functionalization chemistry
- Material synthesis and characterization
- Process development and process engineering
- GMP and non-GMP manufacturing of specialty materials and polymer capabilities

Highlights

- Excellent track record of continuous supply of polymers & specialty materials (250-500 kg/batch), Nano materials (1-2 kg) and additives (10-100 kg scale)
- cGMP compliant facilities inspected by USFDA and audited by global customers and quality persons from Europe
- Polymer membrane rolls for green hydrogen
- Polymers for battery technology
- Innovation in specialty materials and polymers – lab-scale to commercial

Formulation Development

Syngene offers end-to-end formulation development services to help clients determine optimal dosage levels for therapeutic formulations across oral solid, liquid, and injectable forms. Our integrated services extend to new chemical entities (NCE) and generics, late-phase product development, and over-the-counter products with a focus on quality, speed, and cost-efficiency. Our services focus on determining optimal dosage forms, improving drug bioavailability, conducting stability studies and assisting with regulatory dossier preparation. Syngene's capabilities include advanced solubilization techniques and technologies such as nanosuspensions and solid dispersions.



Formulation development – oral solids, liquids, semisolids (OEL up to $1 \mu\text{g}/\text{m}^3$), injectables (OEL up to $0.1 \mu\text{g}/\text{m}^3$)



Conventional and complex injectable product development (nanosuspensions, nano-emulsions, polymeric nanoparticles, and liposomes) – small molecules, large molecules (proteins, peptides, oligonucleotides), and biologics (mAb, ADC, m-RNA vaccines)



Pre-formulation pro ling, including salt and polymorph screening



Preclinical formulation development (conventional and enabling techniques)



Enabling formulation approaches: spray-dried dispersion (SDD), hot melt extrusion (HME), lipid-based, complexation-based, self-micro emulsifying drug delivery system (SMEDDS), and nanosuspensions



Development of palatable dosage forms for companion animals (hard chews and soft chews), spot-on formulations



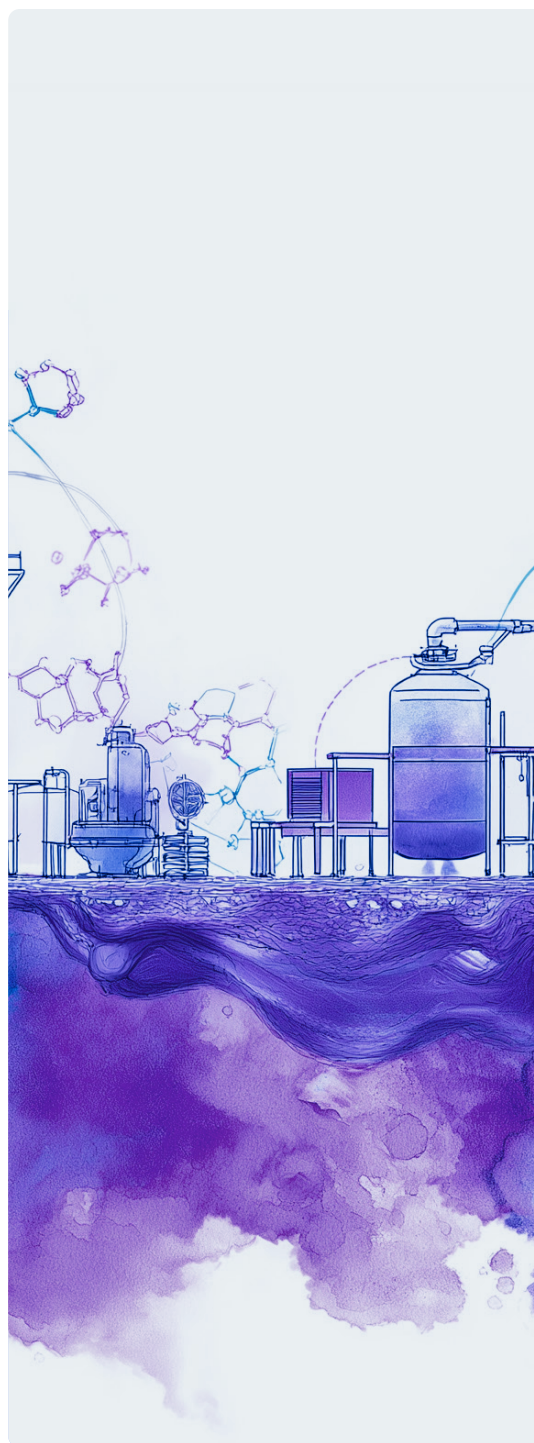
Formulation development of oral solids (immediate release, modified-release, controlled-release, timed-release, delayed-release)



Novel drug delivery systems (liposomes, nano-emulsions, biodegradable polymers-based microspheres, nanoparticles, and in situ depots)



Analytical method development and validation



Drug product manufacturing

Syngene offers end-to-end drug product manufacturing services as a CDMO, supporting the entire drug lifecycle from clinical supplies to commercial manufacturing for both small molecules and biologics. Our services encompass formulation development, Process development, GMP-compliant manufacturing for clinical and registration batches, packaging, and support for regulatory filings, serving our clients from pre-clinical stages through global commercial supply.

Oral solids

- cGMP manufacturing and clinical supplies for solid orals (OEL up to 1 µg/m³)
- Unit operations such as dry and wet (top spray and high shear) granulation, Wurster coating, blending, spray drying, tablet compression, tablet coating, powder in capsule encapsulation, lipid in capsule encapsulation, extrusion, and spheronization.
- Automatic capsule filling machine for pellets, powders, and mini tablets.
- Blister packing machine; ALU- ALU, PVC-ALU, PVC/PVDC-ALU, and automatic bottle packing machine for tablets and capsules
- Phase 1/Phase 2, and Phase 3 clinical supplies/registration batches/process validation batches
- Small-scale drug product commercial supply for niche and orphan drug products scaling up to 400kg.

Sterile fill-finish facility

Syngene operates sterile fill-finish facilities to develop and manufacture sterile drug products for both small molecules and biologics, serving the clinical and commercial needs of pharmaceutical and biotech companies. We provide a variety of sterile fill-finish products such as formulations (sterile liquid and lyophilized products), container formats (pre-sterilized vials and pre-filled syringes) and handle various aseptic filling processes under our Isolator technology to ensure sterility. Intermediates, and APIs), semi-large molecules (polymers, oligonucleotides), and biologics using a variety of spectroscopic, chromatographic, and physiochemical techniques.

Sterile Fill Finish

- Capability to manufacture ready-to-use solutions, enabled formulations (liposome, LNPs, micelles, drug-polymer conjugates, PLGA microparticles, and nano pharmaceuticals) and lyophilized products (pre-sterilized vials and pre-filled syringes) OEL: $\geq 1 \mu\text{g} / \text{m}^3$ – ready-to-use format for vials (2R to 50R) & PFS (1cc – 10cc)
- Aseptic filtration and filling and terminal sterilization
- Batch size of 500 to 25,000 vials, volume: 5L- 100L
- Lyophilization capability for vials (3500 vials of 10R size)
- Capability to handle clinical batch manufacturing and small volume commercial of small molecules and biologic products

Isolator technology

- Isolator-based robotic arm-enabled filling line reduces time to first-in-human trials
- Ensures sterility of drug substance and drug products
- An isolator system in place as early as phase I and II, ensures seamless execution of batches across the entire drug life cycle
- The robotics arm in manufacturing de-risks the process for high-value molecules

Animal healthcare manufacturing facility

We provide extensive contract research and manufacturing services for animal health products, including small molecules and biologics-based therapies. Syngene has manufactured drug substances for leading animal health clients, including the first-in-class monoclonal antibody for canine osteoarthritis – Librela (bedinvetmab) – in partnership with Zoetis.

Our animal healthcare manufacturing capabilities include dedicated cleanrooms for Drug Substance (DS) API and services for API and drug product development for both small molecules and biologics. Our Bengaluru facility and the newly acquired US facility in Baltimore are both designed for large molecules and strive to meet customer demand for regional production of the biologics requirements of our clients in the Animal Healthcare sector.

- Dedicated GMP facility for animal health products (up to OEL $1\mu\text{g}/\text{m}^3$). Batch size of up to 60kg
- Manufacturing and packing of conventional and bolus tablets
- Capability to manufacture hard chews and soft chews tablets
- Blister packaging capability for small and bolus tablets; PVC-ALU, PVC-PVDC/ALU, Alu-Alu, and Aclar, and bottle packaging

Highlights

- Quick-to-clinic approaches for Phase-1 Clinical studies (first-in-human)
- Expertise in animal healthcare formulation development (complex palatable formulation development and long-acting injectable formulations)
- Skilled in developing and manufacturing niche technologies like polymeric biodegradable nanoparticles for sustained release, depot formulations, chronotherapeutic drug delivery systems, and sustained/modified/delayed release formulations
- Delivered numerous Phase 1/2/3 clinical supplies for customers across the globe.
- Delivered successfully 505(b)(2)/Hybrid application programs as early as the ideation process, repurposing of molecules and identifying the unmet medical need
- Clean regulatory track record with different regulatory bodies across the globe (USFDA and Russian regulatory agency-approved, oral solid manufacturing facility)
- Drug product supplier for commercial products in the US
- Accelerating orphan drug development to clinics and beyond
- Flexible formulation strategies for rapid dose adjustment during phase I clinical supplies
- Tailor-made formulation approaches to enhance drug bioavailability to de-risk early drug development

Analytical Development

Syngene offers comprehensive analytical development services, specializing in method development, validation and transfer for drug substances and products across various formulations and molecules, including small molecules, semi-large molecules and biologics. We provide expertise in stability studies, impurity analysis and routine testing using advanced chromatographic, spectroscopic and physicochemical techniques to support the entire drug development lifecycle and ensure product quality and safety.

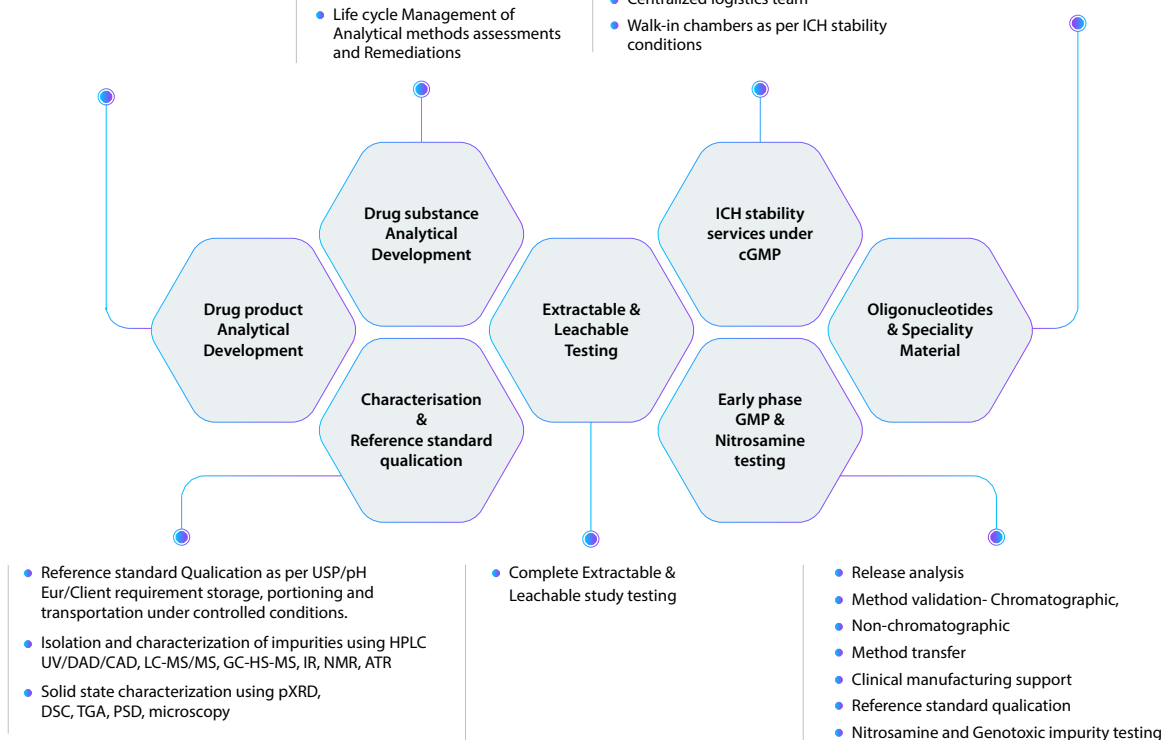
Analytical Development

- Assay, RS method development
- pH- solubility and stability prole
- pKa determination, Partition coecient
- Intrinsic dissolution
- Melting point
- Hygroscopicity

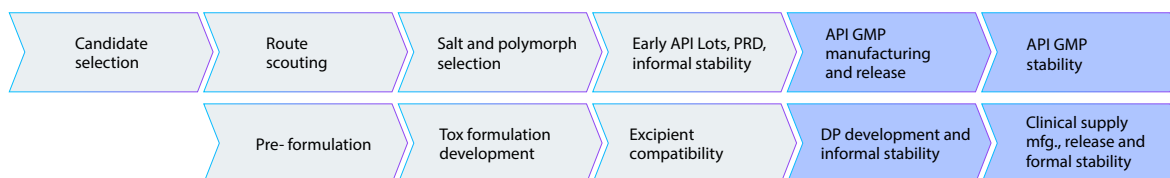
- Assay, RS, Dissolution method development
- Stability studies
- Forced degradation studies
- Excipient Compatibility
- Polymers, Peptides & Small molecules
- Life cycle Management of Analytical methods assessments and Remediations

- Small molecules, generics, animal health, consumer health
- Experience to handle any phase form FIH, NDA/ANDA and commercial
- In house microbiology testing, photostability testing
- Centralized logistics team
- Walk-in chambers as per ICH stability conditions

- End to End analytical capability and service for
 - Therapeutic Oligonucleotides
 - Polymer & specialty materials



Integrated analytical support: Non-GMP and GMP activities

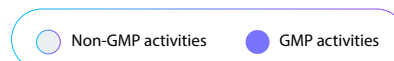


Non GMP activities

- 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
- Pre-formulation, excipient compatibility and salt 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



Analytical Capabilities for Drug Products

Syngene offers comprehensive analytical capabilities for drug products including method development, validation, transfer, and stability studies for small molecules, large molecules as well as biologics – supporting all phases of drug development from discovery to commercial manufacturing. Our services include characterization, in-process testing, lot release analysis and impurity testing (including nitrosamines) using advanced spectroscopic, chromatographic, and physicochemical techniques in our large-scale analytics center. Our integrated services ensure the quality, safety and efficacy of drug products, supporting regulatory submissions.

Analytical Capabilities for Drug Substances



Tablets capsules

- Assay and content uniformity
- Related substances and water content
- Drug excipient and filter compatibility and degradation studies
- Solubility, antioxidant and preservatives
- Dissolutions
- PSD, pXRD and residual solvents.



Powder for injection (lyophilized, microspheres, liposomes)

- Assay of encapsulated and free drug, and antioxidants / preservatives.
- Polymer and lipid characterization,
- Related substances and residual solvents,
- impurity profiling
- Reconstitution stability study, diluent/ component stability compatibility studies



Suspensions, solutions

- pH, viscosity, light transmission, Density, solubility, AET, 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
- In vitro comparative nasogastric feeding tube studies for vial suspension



Liquid injections (ampoules, prefilled syringes, vials)

- Assay
- Related substances, residual solvents, diluent and component stability compatibility studies



Semisolid dosage forms

- pH, viscosity, physical appearance, density, AET, CU
- degradation studies, drug excipient compatibility studies
- Related substances antioxidant & preservatives, IVRT, texture analysis

Analytical Capabilities for drug substances



Solid state characterization

Syngene offers salt and polymorph screening to identify optimal physical forms, and Particle size and morphology analysis using tools such as X-ray diffraction (XRD), Differential Scanning Calorimetry (DSC), Scanning Electron Microscopy (SEM), Optical Microscopy, Particle Analyzers and Atomic Force Microscopy (AFM) to ensure product stability and bioavailability.



Structural characterization

Syngene provides structural characterization services for drug product using techniques like NMR, Mass Spectrometry and UV Spectrometry for compound elucidation and impurity identification, supporting both small molecules and biologics.



Method development / validation

Syngene offers Quantitative NMR, wet chemistry and HPLC method development and validation for drug product, as well as forced degradation studies to identify and quantify genotoxic impurities (GTIs) and other degradants under stress conditions



Extraction and Purification

Syngene employs chromatography (semi prep HPLC, HPLC, GC), column and flash chromatography, spectroscopy (NMR, IR, MS) and advanced Mass Spectrometry (LC-MS/MS, GC-MS/MS) for impurity identification, profiling and quantification. We offer our expertise in impurity characterization, high-throughput purification and stability studies using state-of-the-art instruments and validation methods to support regulatory requirements and accelerate drug development.



Analytical Capabilities for Complex Injectables

We offer analytical capabilities for complex injectables through our integrated platform of method development, validation and characterization for both, small and large molecules including biologics, oligonucleotides and antibody drug conjugates (ADCs). Our comprehensive services support the entire drug lifecycle – from early development through commercialization – with state-of-the-art facilities and experience in handling various drug products including parenteral formulations. Our expertise encompasses a wide range of analytical techniques and regulatory compliances to ensure quality, safety and efficacy of complex injectable formulations.



Pre-formulation studies

Syngene offers pre-formulation services to include characterizing complex injectables by evaluating their physicochemical properties, stability and potential for interactions to support Formulation Development and process design. Our capabilities involve determining parameters like solubility, particle size, polymorphism and stability under various conditions such as pH, light and temperature. We use techniques such as DSC, X-Ray diffraction and chromatography to ensure stable, effective drug formulations.



Liposomal injection

Liposomal formulations focus on method development, validation, characterization and stability studies to ensure quality, safety and efficacy. Our state-of-the-art facilities employ techniques like Dynamic light scattering (DLS) for particle size, electron microscopy for morphology, zeta potential measurements for surface charge and encapsulation efficiency assays to understand various parameters like lipid degradation, phospholipid content (lysoforms), internal environment (pH and ionic concentration) and the state of encapsulated drug.



Injectable nanosuspension

We conduct phase-appropriate method development, validation and transfer for drug substances and products. Our expertise lies in characterization of nanosuspensions for particle size, stability and drug release, ensuring product quality through sophisticated analysis through parameters such as free fatty acid content, phospholipid content, drug partitioning, globule size and zeta potential and re-dispersibility – supporting early development as well as commercialization, while focusing on enhancing drug solubility, bioavailability and achieving controlled release



Extended-release injectable microspheres

Syngene creates extended-release microspheres by developing and validating phase-appropriate analytical methods to ensure drug quality, safety and stability through every stage. We offer an array of services covering microsphere characterization to assess release profiles, particle size, drug content and degradation. Our state-of-the-art facility supports the development of complex parenteral drug products, including long-acting formulations through processes like dissolution method development using Incubator orbital shaker or bottle rotating, assays of free and encapsulated drug, particle morphology size and shape, molecular weight determination by GPC for polymers, and polymer degradation.

ICH Stability Services

In accordance with the International Council for Harmonization (ICH), Syngene provides a comprehensive battery of services for drug substances and products, including storage in walk-in chambers for various climatic zones, photostability testing, freeze-thaw and in-use stability studies – all within cGMP-compliant facilities that have robust monitoring and back-up systems. Our ICH services include analytical method development and validation supported by experienced scientists and a large state-of-the-art facility to help our clients meet their regulatory requirements for product shelf-life and quality changes over time.

ICH Stability services

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
- Parenterals
- Lotions
- Emulsions
- Gels
- Suspensions
- Patches
- Liquid Spray
- Aerosols
- Powders

Our state-of-the-art facilities

- One of Asia's largest stability chambers
- 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

Clinical and Commercial Manufacturing

Syngene has the capabilities to provide integrated clinical and commercial drug manufacturing for a varied client demand. We cater to both small molecules and biologics with capacities for scaling up from pre-clinical volumes to full commercial supply across various industries such as pharmaceuticals, animal health and specialty chemicals. Our facilities have been consistently cGMP regulations compliant and approved by major regulatory agencies such as the USFDA, PMDA and EMA – offering flexible solutions including HPAPI manufacturing, biologics production using bioreactors and the clinical supply for oral solid dosage forms.

Capabilities

Manufacturing of Regulatory starting materials, APIs, HPAPI, NCEs and novel advanced intermediates

| Mfg. facility | nGMP | Kilo Lab-1 | Kilo Lab-2 | HPAPI | Banglore | Mangalore |
|--|----------------|-------------|-------------|--------------|-------------------------|-------------------|
| Range | 160 L - 5000 L | 10 L - 20 L | 10 L - 50 L | 60 L - 630 L | 60 L - 8,000 L | 2000 L - 12,500 L |
| Total Capacity | 26,640 L | 120 L | 90 L | 2010 L | 63,600 L | 69,600 L |
| Largest reactor | 5,000 L | 20 L | 50 L | 630 L | 8,000 L | 12,500 L |
| # Reactors | 15 | 3 | 4 | 5 | 32 | 11 |
| Total number of reactors and manufacturing volumes | | | | | 70 reactors & >161,000L | |

Salient features

- 24/7 operations to ensure optimal utilization of resources
- A broad range of reactors (stainless steel, glass lined, Hastelloy)
- A broad range of chemistries (Asymmetry catalysis, halogenation, etc.)
- High potency expertise (Cytotoxic, Cytostatic compounds up to 0.1 µg/m³ - 8h OEL)
- High vacuum (< 10 Torr) & high temperature (140°C) distillations
- Hydrogenator for highly acidic/basic reactions with capacity up to 4 KL and 26 bar pressure rating
- 12 KL cryogenic reactor operating within a temperature range of -90°C to 140°C
- Particle size reduction to < 10 microns with nitrogen and air in class 100,000 area
- Batch sizes range between 100kg (Bangalore) to 40 MT per annum (Mangalore)
- PMDA (commercial) and USFDA (RSM) approved Bangalore S14 manufacturing facilities
- USFDA-approved Mangalore manufacturing facility



Syngene
Putting Science to Work

About 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 5000+ 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 Baxter, and Bristol-Myers Squibb, as well as 2.2 million 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