Syngene

Putting Science to Work

Integrated Animal Health Solutions

From Molecule to Market, for Every Animal Everywhere

Power your Progress with End-to-End Expertise

Reduce time to market, de-risk scale up, and accelerate global launch with a single partner offering end to end Discovery, Development and Manufacture of Drug Substance and Drug Product, and Analytical services for both small and large molecules.

Why Syngene

A strategic CDMO partner purpose built for Animal Health

Faster progression

Integrated workflows across Discovery, Development & Manufacturing, and QC. eliminate hand offs, reduce re-learning, and shorten development timelines

Lower risk

Dedicated animal health development and manufacturing facilities for oral solids, complex injectables, biologics, and sterile fill finish ensure predictable scale up

Regulatory confidence

VICH aligned manufacturing for clinical, registration, and commercial batches across both small molecules and biologics

Proven partner

Broad experience in chewable, palatable multi API tablets, injectables, topicals, nano systems, and biologics development, with successful deliveries for leading global animal health companies

The Integrated CDMO Model

One team.
One data backbone.
One accountable owner.

Small Molecules: Drug Substance (DS)

Value

Commercial thinking from the start ensures robust, scalable, and regulatory aligned DS processes.

What you gain

- Fewer iterations through process engineering, QbD principles, and risk based design
- Predictable technology transfer supported by strong analytical packages and VICH aligned stability
- Reliable scale up from tox to commercial manufacturing

Technical capabilities

- Route scouting, salt/polymorph screening, process design and optimization
- Process safety and hazard assessments
- Analytical method development and validation
- VICH stability studies and regulatory documentation

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Small Molecules: Drug Product (DP)

Value

Formulations that meet species specific needs, achieve palatability and stability targets, and scale reliably.`

Veterinary specific strengths

- Chewable tablets (soft and hard), including multi API combinations, low dose bitter actives, and high weight formats up to 5 g
- Liquids and semisolids including spot on, pour on, gels, and pastes
- Injectables: ready to use, lyophilized, nano emulsion and nano suspension systems, long acting depot and microsphere formulations

Facility advantages

- Dedicated pilot and GMP oral solids facilities
- Batch sizes up to 50 kg
- High shear and top spray granulation up to 20 kg per lot
- Bolus tablet compression up to 14 mm
- Engineered for safety: controlled differentials, zoning, OEL ≥ 1 µg/m^3, and compatibility with animal origin materials and ectoparasiticides
- Packaging capabilities include Alu Alu, PVDC Alu blisters, and bottles

Bangalore (B-SEZ) & Mangalore (M-SEZ)

	Bangalore (B-SEZ)				Mangalore (M-SEZ)
Mfg. Facility	S1 Kilo Lab (non-GMP)	U-2 Kilo Lab (non-GMP)	HPAPI GMP (OEB-4 & 5) USFDA, PMDA	S14 Semi-commercial GMP USFDA, PMDA	Mangalore Including high potent Intermediate Block Commercial GMP USFDA (OEB-4)
Range	10-20 L	10-50 L	60 L to 630 L	60 L to 8,000 L	1000 L to 12,500 L
Total Capacity	120 L	90 L	2,010 L	63,600 L	71,000 L
Largest reactor	20 L	50 L	630 L	8,000 L	12,500 L
# Reactors	3	4	5	32	12
Total number of reactors (Manufacturing Volumes)					**56 reactors (~135,000 L) & expanding** SEZ = Special Economic Zone

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Biologics: Drug Substance (DS)

Value
Scalable, compliant biologics enabled by end to end DS capabilities.

Core strengths
- Cell line and strain development
- Upstream and downstream process development supported by detailed characterization
- Virus clearance studies and advanced protein analytics in-house
- Manufacturing at 100 L, 500 L, 2000 L, and 4000 L suitable for clinical and commercial supply
- Demonstrated process enhancements including multi fold yield improvements
- Experience across monoclonal antibodies, recombinant proteins, biosimilars, hormones and conjugates

Biologics: Drug Product (DP)

- Sterile fill finish capabilities include RTU vials, RTU PFS, robotic isolator based filling, and lyophilization suitable for early stage through commercial supply
- Fill volumes: vials (1–50 mL), PFS (0.1–10 mL)
- Lyophilization capacity of approximately 3500 10R vials
- Batch sizes ranging from 500 to 25,000 vials (3–100 L)
- Facilities include low RH GMP environments, single use mixing and transfer systems, and cold storage at 2–8°C and –30°C
- Specialized capabilities for nano emulsions and nano suspensions in both solution and lyophilized formats

Experience That Accelerates Your Programs

Discovery programs for parasiticides and CMVD candidates

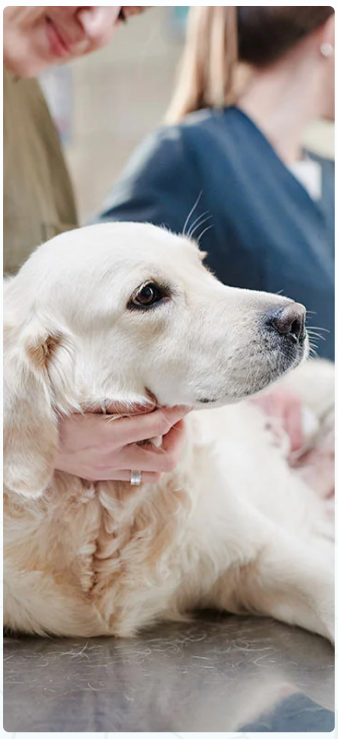
Development of multi API chewable tablets delivered through clinical, registration, and technology transfer stages

Long acting injectable systems including microspheres and depot technologies

Topical formulations including pour on systems for farm animals

Commercial manufacturing experience for biologics used in chronic veterinary conditions

Cell line development for multiple veterinary biosimilars



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Analytical, Bioanalytical, and Stability Services

Value
Regulatory ready data packages that support global submissions and reduce agency queries.

Analytical
- Nitrosamine impurity testing, multi API dissolution, impurity isolation, identification, qualification, and synthesis
- Analytical methods development for complex veterinary formulations

Bioanalytical
- Immunoassays for PK, PD, biomarkers, immunogenicity, and potency
- Cell based potency and neutralizing antibody assays
- GLP/GCLP environments aligned with global regulatory expectations

Stability
- Development, ICH, and commercial stability studies
- Controlled stability storage and analysis for both APIs and drug products

Global Footprint

Bengaluru


Mangalore


Hyderabad


Maryland, USA


Let's accelerate your path to veterinary registration and commercial success

Syngene provides flexible engagement models including feasibility assessments, FTE based collaboration, milestone based programs, and turnkey VICH ready packages.

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Scan the QR code
to learn more

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 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 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

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