Syngene

Putting Science to Work

Safety Assessment

Syngene offers a full range of *In vivo* and *In vitro* toxicology services for comprehensive nonclinical development of pharmaceuticals

Exploratory studies	GLP studies	Phase I	Phase II	Phase III	Specialty studies
Pharmacokinetics	Analytical and bioanalytical studies to support safety tox program	Repeat dose studies & Genetic toxicology	Sub-chronic toxicity study		Impurity qualification
	Repeat Dose Toxicology (2 Species)				Dermal Tox- Rat & Rabbit
(MTD/Dose Escalation/Short-term repeat dose toxicology)	Genotoxicity *(In vitro/ In vivo)*	Repeat dose studies & Genetic toxicology	Reproductive Toxicology (Male fertility/ Pre and Postnatal development)		Intravenous Infusion - Rat
					Local tolerance/ irritation – Rats & Rabbits
					Guniea Pig skin sensitization/ LLNA Mice
Genotoxicity screening *(In vitro)*	Toxicokinetics				Medical Device Testing – ISO10993
	Core Battery Safety Pharmacology		Chronic Toxicology		*In vitro* Cytotoxicity
					In vitro Skin Irritation
Safety Pharmacology: CNS, Respiratory, CV	Reproductive Toxicology (Seg I, Seg II & Seg IIII)				*In vitro* Phototoxicity
					In vitro skin senstization

Our fully accredited, state-of-the-art vivarium has everything needed for executing PK & toxicology for critical path studies

70,000
Sq. ft. lab

AAALAC
accredited

OECD GLP
certified

CPCSEA
(Govt. of India)
registered

IAEC & IBSC
approval for protocol

Exploratory/ regulatory
toxicology

AAALAC: *Association for Assessment and Accreditation of Laboratory Animal Care* | ***CPCSEA:*** *Committee for the Purpose of Control and Supervision of Experiments on Animals* | ***GLP:*** *Good laboratory practice* | ***IAEC:*** *Institute Animal Ethics Committee* | ***IBSC:*** *Institutional Bio-Safety Committee*

We have a well staffed team with expertise across all essential areas that help drive the highest quality of reports for PK & Tox studies for both small and large molecules

Study Directors

- 14 toxicologists M.Sc./M.VSc and PhDs
- Board Certified Toxicologists, 5 DABT
- 20 PK scientists

Pathologists

- 5 Pathologists DVM, MVSc/PhD
- Board certified Pathologist: 3DABTs

Veterinary Science and Technical staff

- 3 Veterinarians
- 11 technician histopathology work
- 4 technician clinical pathology lab

Biostatistics & Data Management

- 3 biostatisticians and in data management
- 4 in the PK modeling group
- Statistic and report management
- SEND management

GLP Analytical and Bioanalytical

- 70 analysts for small and large molecules
- 20 bioanalysts for non GLP PK
- PK, TK Bioanalysis, immunogenicity, formulation analysis

DABT: *Diplomate American Board of Toxicologists*

We deliver with speed: GLP 28-Day toxicity studies in 11 weeks; best in the industry enabling faster decision making

Pre-study Activities

Day 1-5*
- Consignment arrival
- SEZ clearance initiated
- GLP-TICO
- Verification of documents (CoA, TRIDs) against test items received
- Coding of test item
- Study Allotment

Day 6-50**
- Analytical/bioanalytical method development and validation

Day 1-12
- Animal arrival
- Quarantine
- Acclimatization

28-Day Tox Study Timeline

Day 1-28
- In-life /dosing phase
- 40 tissues /animal (n=10/sex/ main tox group)

Day 29-30
- Clinical Pathology
- Necropsy
- In-life Results

Day 30-38
- Trimming
- Processing
- Embedding + Sectioning
- Staining

Day 35-52
- Slide Evaluation

Day 53-55
- Peer Review
- Target Organ Evaluation
- Pathology Results

Day 52-56
- Draft Pathology Report

Clinical Pathology, Histopathology & Reports

Note: *Pathology Results within 28 days from day of Necropsy*

Acronyms: *TICO: Test Item Control Office | TRIDs: Test or Reference Item Datasheet*

**Cold shipment handled on priority | * *(Timeline varies depending upon method transfer and validation or method development and validation)*

We deliver with speed: IND GLP tox and safety pharmacology in 26 weeks

IND TOX AND SAFETY PHARMACOLOGY PROGRAM																										
Sl.No.	GLP Studies	Timelines (Weeks)																								
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
1	Analytical method development and validation for *In vivo* studies for dose confirmation analysis																									
2	Bioanalytical method validation – rat plasma																									
3	Bio-analytical method validation – nonrodent plasma																									
4	28-day repeat dose tox study with TK and 14-day recovery period in rats																									
5	*In vivo* micronucleus test in rat																									
6	Analytical validation – *In vitro* studies																									
7	*In vitro* Ames test																									
8	*In vitro* chromosomal aberration test																									
9	Analytical transfer validation for dose confirmation analysis-rats/ non-rodent																									
10	28-day repeat dose tox study with TK and 14-day recovery period in non-rodent																									
11	CNS-safety pharmacology – rat																									
12	Respiratory safety pharmacology – rat																									
13	Cardiovascular telemetry study – nonrodent																									
14	*In vitro* hERG Assay																									

Syngene offers *In vivo* toxicology studies across all common safety species

Syngene in-house

Rats
Sprague Dawley/ Wistar

Mice
Swiss Albino, BALB/c, ICR

Guinea Pigs
Dunkin Hartley

Hamster
Golden Syrian

Rabbits
New Zealand White

Syngene's partner sites (EU & US CROs)

Monkey

Dog

Minipig

Our GLP analytical services support analytical method development and validation for dose formulation analysis

Analytical Services

- Characterization
- Physical Chemical Testing
- Method Development
- Method Validation
- Stability and Homogeneity Testing
- Dose Confirmation Analysis

Bioanalytical Services

- Method Development
- Method Validation
- Bioanalysis
- PK Analysis - Phoenix WinNonlin®
- Immunogenicity Testing
- Neutralizing Antibody Assays

We understand what drives and enables a successful strategic partnership – this is what differentiates us

Innovation focus
- Process
- Technology

World class talent
- Competency
- Continuity of resources

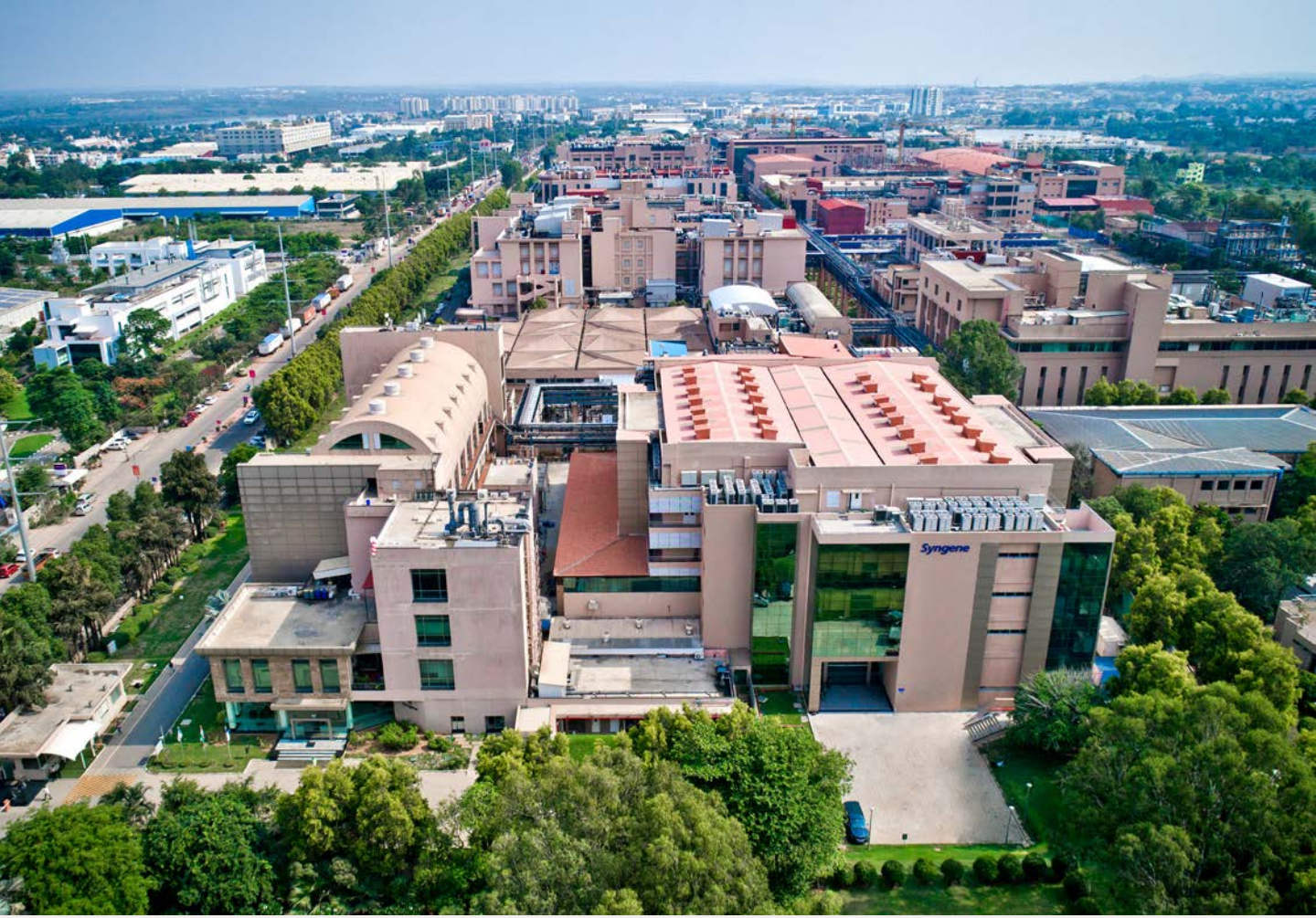
Operational excellence
- Speed
- Cycle time

Enhanced productivity
- Process excellence
- Optimizing operating costs

Commitment to quality
- The best Infrastructure
- Compliance to global regulations and standards

Ability to scale
- Financial stability
- Commitment to invest in new technologies and capacity

Communication and governance
- Project level
- Collaboration level



For more information, contact bdc@syngeneintl.com

Syngene
Putting Science to Work

www.syngeneintl.com

Stay Connected