



GLOBAL REGULATORY APPROVALS

- OECD GLP certified
- AAALAC, OLAW accredited
- Two successful USFDA audits
- SEND compliant



GLOBAL SCALE & EXPERTISE

- 140+ room vivarium
- 17 US board / European registered toxicologists
- 300+ IND/NDA packages
- 600+ Reproduction & developmental toxicology studies
- 1000+ Biocompatibility studies



DATA INTEGRITY

- 30+ years of GLP experience
- Provantis for data management
- Dedicated quality assurance team
- Data submitted to US FDA, Health Canada, MHRA- UK, EMA, HSA Singapore, MOH Israel and more

Comprehensive in-house capabilities for bioanalysis, histopathology, immunohistochemistry, clinical biochemistry, biomarker (qPCR, cytokines by FACS/ELISA/MSD-ECL, Western blot, immune-phenotyping using FACS)



Test System

rat, mouse, hamster, guinea pig, rabbit.

In-life testing for non-rodent animals (minipig, beagle dog) in collaboration with our partner laboratory.



ADGYL LIFESCINCES PVT. LTD.

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Contact Us



in cooperation with



ENABLING REGULATORY SUCCESS THROUGH SCIENTIFIC PRECISION AND SAFETY



**Pharmaceutical, Biologics,
Biosimilars, Cell and gene
therapy, Vaccines,
Nutraceuticals**

**Agrochemicals,
Industrial chemicals**

**Medical Device
Testing**

*bullet colours match the above industry testing requirements

Exploratory Discovery Studies

- Mini Ames
- Mini hERG (hERG screening)
- Dose range finding studies
- Screening CVS function in telemetered dogs

Genetic Toxicology (GLP)

In Vitro and In Vivo Mutagenicity

- Ames test & enhanced Ames for nitrosamine & NDSRIs
- Chromosomal aberration test
- Mammalian gene mutation test (HPRT, xPRT, TK6)
- Micronucleus test
- In vivo Comet assay including FISH assay

Safety Pharmacology

- hERG assay
- Pulmonary function (Rats)
- Modified Irwin test/Functional observation battery in rats (FOB-Rats)
- CVS function assessment using telemetered dogs

General Toxicology (Rodents & Non-Rodents)

- Single dose studies
- Repeated dose sub-acute and sub-chronic studies (7, 14, 28 & 90 days)
- Chronic toxicology studies (6, 9, 12 months)
- Combined chronic and carcinogenicity studies
- Carcinogenicity studies in rodents and transgenic mouse models

Development and Reproduction Toxicology

- Segment I fertility studies
- Segment II embryo-fetal studies
- Segment III perinatal and postnatal studies
- Extended one-generation reproduction toxicity studies
- Juvenile toxicity studies
- OECD 414/416/421/422/426/440/441 studies
- Endocrine disruptors studies

Immunotoxicology

- Immunotoxicity assay humoral response
- Immunotoxicity study
- LLNA-skin sensitization

Neurotoxicology

- Neurohistopathology
- Extensive functional observation battery (FOB) tests
- Neurotoxicity study (OECD 424)
- Developmental neurotoxicity study (OECD 426)

Ecotoxicology

- Aquatic toxicology
- Avian toxicology
- Terrestrial toxicology
- Insect toxicology
- Activated sludge
- Bio-degradation

In Vitro Studies/ Alternate to animal studies

- Episkin - skin corrosion and irritation test
- Direct peptide reactivity assay (DPRA)
- KeratinoSens
- Human cell line activation test (h-CLAT)
- Phototox NRU (3T3)
- Epiocular
- The bovine corneal opacity and permeability (BCOP)
- RHCE test

Medical Devices Testing (ISO 17025 & GLP) We offer full scope of testing as per ISO 10993 regulatory guidelines

- Cytotoxicity
- Sensitization test
- Irritation test
- Systemic toxicity test (Acute, Sub-acute/Sub-chronic and Chronic)
- Material mediated pyrogenicity
- Implantation test
- Genotoxicity test
- Ocular biocompatibility test
- Chemical characterization

