Vimta

Driven by Quality. Inspired by Science.

One Stop Solution to accelerate your Integrated Drug Discovery and Development Programs

- Pharmacokinetics & ADME
- Safety Pharmacology
- Safety Assessment Testing (*In vitro* / *invivo*)
- Analytical Product Chemistry
- Biowaiver Studies
- Environmental Safety Testing

450,000	10,000	24+	500+
sq ft State of the Art Vivarium	sq ft Specialized Laboratories	Successful IND Packages	Supported Small & Large molecules (Biosimilars & Vaccines)

WHY VIMTA?

A proficient and highly experienced preclinical partner, facilitating research with dedicated multi-disciplinary teams in Pharmacology, DMPK, Safety Pharmacology, Toxicology, Pathology, Analytical, Bio-analysis and Ecotoxicology which makes Vimta a **One Stop Center** for Integrated Drug Discovery & Development coupled with regulatory testing services for product development.

We are bench marking and redefining quality through a modern GLP certified, AAALAC accredited and FDA audited facility for helping you leverage global data acceptability. Vimta adds value through reliability, quality, time management and cost-effectiveness.

Test Facility

- OECD GLP certified, AAALAC accredited and FDA audited test facility.
- 450,000 sq.ft modern lab space + 10,000 sq.ft specialized laboratories.
- Modular facility with analytical, bioanalytical & pathology labs.
- Barrier controlled rodent facility with pressurized containment.
- Dedicated facilities for Beagle dogs & Mini pigs.
- Multiple flow past nose exposure system for inhalation studies.
- Purpose design facility to offer alternate to animal testing, Efate, ecotoxicology and analytical product chemistry.

Experience

- Fast track discovery services for lead identification/optimization
- IND & NDA enabling studies in rodents & non-rodents
- Post IND/NDA enabling services in rodents & non-rodents
- 505 (b) (2) - Drug repurposing program
- Impurity qualification, excipients qualification & biocompatibility
- Biowaiver studies to support post approval changes
- Complemented numurous successful IND packages
- Supported more than 500 drug molecules, biosimilars & vaccines.

Drug Development Services

- 30+ years of experience in safety evaluation.
- End to end testing solution for product characterization and validation
- Efficacy & kinetic studies on new formulations and new molecule entity.
- Screening of NCEs & NBEs and preformulation.
- In vivo models in rodents, rabbits, beagle dogs through different routes.
- Environmental fate and metabolism studies using radio labelled and nonradio labelled test compound.

Early Drug Development

Screening Platform

Physio-chemical Properties
- Solubility, pka, log P/logD

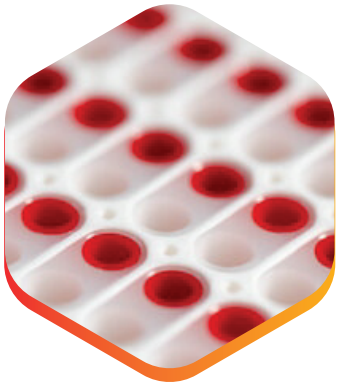
***In vitro* Permeability Assays**
- PAMPA/MDCK/Caco2

***In vitro* Drug-Drug Interaction Assays**
- CYP inhibition (reversible and time dependent)
- CYP induction & CYP phenotyping

Transporter assays

In vitro Protein Binding & Partitioning Assays

- Plasma protein binding all assays
- Tissue protein binding assays
  - Microsomes
  - Brain homogenate
  - Liver homogenate
  - Hepatocyte
- Blood/plasma partitioning



In vitro Stability Assays

- Buffer, simulated intestinal fluid and simulated gastric fluid stability
- Hepatic phase 1/11 metabolic stability (hepatocyte, liver microsomes, liver S9 and cytosol etc.)
- Ex-hepatic metabolic stability (intestinal microsomes, lung microsomes, plasma and blood etc.)

Pharmacology Models
- Chemical induced models
- Genetic models
- Surgical models

Early Drug Development

Pharmacokinetic & Immunogenicity Studies

Pharmacokinetics /Toxicokinetics & Immunogenicity Studies in Rodents, Rabbits, Dogs & Mini Pigs

Standard / Flexible Study Designs

- Single dose
- Multiple dose
- Cross over
- Cassette dose

Multiple Routes

- Oral
- Parenteral
- Dermal
- Occular
- Inhalation

Pharmacokinetics Study in Disease Models

Bioanalytical & Immunogenicity

- Matrix stability studies
- Bioanalytical method development/method transfer & validation
- Metabolite identification, profiling & structure elucidation
- Matrices: serum, plasma, tissue & milk
- ELISA assay for quantification of large molecule and antibodies

Instruments

- Mass spectrometers- single quadruple, triple quadruple, ion trap
- LC-MS/MS, MALDI/TOF/TOF, GC-MS/TOF, HRGCMS, ICP-MS
- HPLCs with UV, PDA and fluorescence detectors ELISA

Analytical Development Support

- Physicochemical characterization
- Purity assessment
- Stability studies
- Proprietary method development/method transfer & validation
- Impurity identification, profiling & structure elucidation

Instruments

- HPLC (UV and electrochemical detection)
- UV/VIS spectrophotometer
- ICP - MS
- UPLC
- LCMS/MS
- Gas chromatograph (FID, FPD, ECD)
- RT - PCR

Early Drug Development

Genetic Toxicology

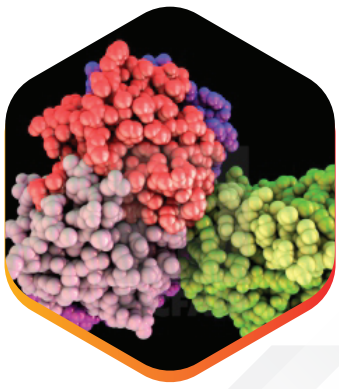
- Bacterial reverse mutation test (*Salmonella typhimurium, Escherichiacoli*)
- Mammalian cell gene mutation test (mouse lymphoma L5178Y tk +/- cells and HPRT)
- Mammalian chromosome aberration test (*In vitro/In vivo*)
- Micronucleus test (*In vitro/In vivo*)
- Comet assay (*In vitro/In vivo*)

Safety Pharmacology

- HERG assay (*In vitro*)
- Cardio Vascular Safety (CVS)
- Central Nervous System (CNS)
- Gastrointestinal safety
- Respiratory safety

Supplementary Tests

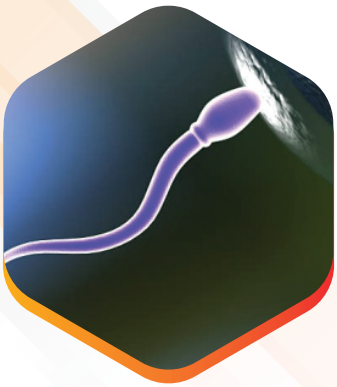
- Analgesic assessments
- Sleeping time
- Tail flick
- Physiological temperature
- Convulsant activity
- Motor in-coordination
- Bleeding time
- Functional observation battery



General Toxicology

- Single dose toxicity studies, dermal irritation/ corrosion, eye irritation/ corrosion and skin sensitization tests
- Maximum tolerable/dose range finding studies
- Sub-acute/sub-chronic toxicity studies
- Chronic toxicity studies
- Combined chronic toxicity and carcinogenicity studies
- Carcinogenicity studies in rats & mice

Special Services

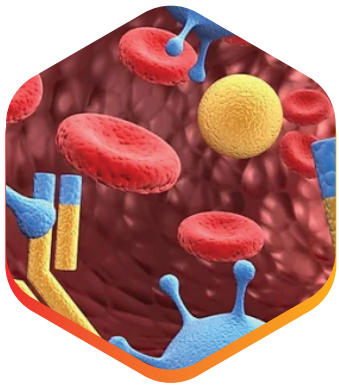


Development & Reproductive Toxicology (DART)

- Pre and Post natal Development study
- Prenatal developmental study (Embryo - fetal development - Teratology)
- Extended one-generation reproductive toxicity studies (All 5 Cohorts)
- Multi generation reproduction toxicity studies
- Reproduction/developmental toxicity screening studies
- Combined repeated dose with reproduction/developmental toxicity screening studies
- Developmental neurotoxicity studies
- Neonatal/Juvenile toxicity studies

Special Studies

- Tissue distribution
- Metabolism
- Ocular toxicity
- Local tolerance
- Pharmacology screening
- Development of *In vivo* model for pharmacology response
- Immunotoxicology
- Neurotoxicology
- Phototoxicology
- Dermal toxicology
- Target organ toxicity using cell line, zebra fish etc.



Alternatives to Animal Studies

Genetic Toxicity Studies

- Bacterial reverse mutation test
- Chromosomal aberration test
- Micronucleus Test
- Comet Assay

Irritation Study

- *In vitro* dermal irritation study using reconstructed human epidermal skin (rHES)
- *In vitro* ocular irritation study with reconstructed human cornea-like epithelium (RhCE)

Phototoxicity

- 3T3 NRU phototoxicity study

Sensitizaation Study

- Direct peptide reactivity assay (DPRA)

Cytotoxicity

- Cytotoxicity study
- Direct Contact & MEM Elusion Methods

Permeation and Release Studies

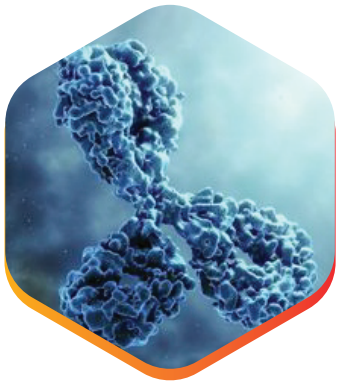
- *In vitro* permeation testing
- *In vitro* release testing

- *In vitro* corneal permeability study

Absorption/Permeability

- PAMPA/MDCK/Caco-2

In Vitro Screening



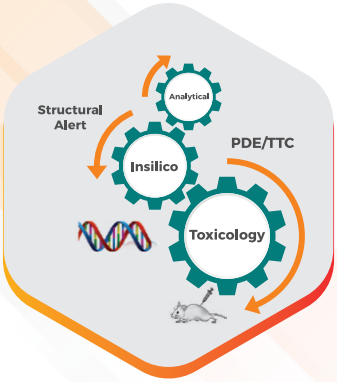
Biosimilar & Vaccine Development

- » Characterization
- » Immunogenicity studies
- » Pharmacokinetic studies in healthy and disease model
- » Proof of Concept (POC) studies (effective dose range; route of administration and dose schedule; putative MOA and biological outcome)
- » Toxicology studies (mimic proposed clinical trial, dose route, dosing schedule, delivery system)
  - Single /repeated dose toxicity
  - Maximum tolerable/dose range studies finding studies
  - Local tolerance
  - Reproductive toxicity
- » Bridging study for change in manufacturing/formulation of product/dosing regimen/schedule, delivery system
- » Adjuvant and excipient testing

Inhalation Testing

- » Testing compliance to OECD/ICH/EMA/EPA
- » Inhalation delivery in rodents accompanied with atmospheric monitoring (airflow rate, temperature, relative humidity oxygen & Co2) and test atmosphere characterization (concentration and particle size distribution)
- » High precision directed flow (flow-past) systems: with online monitoring
  - Nose-only or oronasal exposure
  - Prevents re-breathing
  - Restraint designed to minimize thermal stress
  - Maintains homogeneous breathable atmosphere at all levels of the inhalation tower
- » State-of-the-art technologies to generate powder liquid, or atmospheres
- » Collection and analysis of bronchoalveolar lavage fluid (BALF)
- » Analytical and bioanalytical elimination with HPLC, LC/MS and gas chromatography
- » Specialized histopathology of respiratory tract organs

Special Services



Safety & Risk Assessment of Impurity / Metabolite / Excipients

Classification Approach

- Bacterial reverse mutation assay/mammalian cell gene mutation test
- *In vitro* / *In vivo* mammalian chromosomal aberration test
- *In vitro* / *In vivo* micronucleus test (MEMT)
- *In vitro* / *In vivo* Comet assay

Qualification Approach

- Repeated dose toxicity studies in rodents (rats/mice) & non-rodents
- Stand-alone / integrated TK studies
- Follow up studies for risk assessment

Biocompatibility Testing

Chemical Characterization / Toxicological Risk Assessment

***In vitro* Cytotoxicity**

- MEM elusion
- MTT assay
- Neutral red uptake
- Agar diffusion
- CFU assay
- Growth inhibition assay

Implantation

- Subcutaneous, muscular, bone, ocular

Systemic Toxicity

- Single and repeat dose

Genotoxicity

- Gene mutations
- Clastogenicity in mammalian cells
- Micronucleus test

Irritation Studies

- Eye, skin irritation (dermal, intracutaneous reactivity
- Mucosal irritation (oral, erectile, penile, vaginal)

Skin Sensitization

- GPMT
  Buehler's test

DART & Hemocompatibility

Data Presentation for Global Submissions

- SEND modules compilation
- Validated data files
- nSDRG template
- Safe and secure storage
- Online data recording
- Controlled terminology in line with SEND
- A complete two-step validation
- Generation of define.XML
- Validation of XML

Special Services

Bioequivalence Studies *(IVPT and IVRT Studies)*

- Logans Franz Diffusion Chamber equipped with water jacketed bubble Free cell and controlled temperature autosamplers are available to perform multiple studies in parallel.
- Human Skin/ Artificial membrane mounted on the respective receiver chambers and occluded for IVRT and unoccluded for IVPT Studies.
- Adopted different Dosing technique methods using Syringe, HPLC Vial, Glass Rod or capillary based on study specific requirement.
- Method development and Validation for the IVRT/IVPT, Analytical method integrated as per the FDA and EMA and ICH guidelines.
- Key attention provided to demonstrate Selectivity, Sensitivity, Reproducibility, Robustness, Recovery, Mass Balance and Dose depletion for the IVRT/IVPT.
- Comprehensive statistical programs adopted for sample size, several study endpoints along with Bioequivalence etc.

Caco-2 Permeability Assay

- Trans well plates patented and designed to support cell growth and differentiation of endothelial and epithelial cell lines in different configurations like 24, 48 and 96 well capability are available to perform the Caco-2 permeability studies.
- Caco-2 cells derived from a Human colon adenocarcinoma are seeded in respective plates and differentiate for 21 to 28 days to form confluent monolayer of polarized cells structurally and functionally resembling the small intestinal epithelium.
- Analytical method development and validation integrated as per regulatory guidelines.
- Adopted different stages of the experiment which accommodates the combination of the test product along with High, Low and other required permeability markers.
- Demonstration of the nonspecific binding, sensitivity, reproducibility, recovery and pre and post membrane integrity evaluation with TEER's and florescent permeability markers for the adopted Caco-2 permeability assay.
- Sample analysis performed using validated LC-MS/MS methods allows a rapid and accurate determination to classify the products per the Biopharmaceutical Classification System.

About Vimta

Founded in 1984 with headquarters in Hyderabad, India, Vimta Labs Limited., is a leading contract research and testing organization, providing bio/pharmaceutical companies an integrated scientific, technical and regulatory expertise to support all stages of drug development and manufacturing process.

Vimta has been serving several companies across the globe for almost 4 decades, for their third party testing, research and outsourcing needs. VIMTA has been able to grow and also expand its services across biopharmaceutical, food, consumer goods, electronic, electrical, agrochemical, healthcare, medical device, power, cement, oil & gas, ores & minerals, infrastructure and many other industries.

Accreditations & Certifications

VIMTA LABS LIMITED ★★★★★ GLP CERTIFIED

VIMTA LABS LIMITED ★★★★★ FDA INSPECTED

VIMTA LABS LIMITED ★★★★★ AAALAC ACCREDITED

VIMTA LABS LIMITED ★★★★★ DSIR RECOGNIZED

VIMTA LABS LIMITED ★★★★★ WHO PREQUALIFIED

VIMTA LABS LIMITED ★★★★★ CPCSEA REGISTERED

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