

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



Pharmacokinetics &
Invitro ADME



Safety Assessment Testing
(*In vitro* / *In vivo*)



Biowaiver Studies



Safety Pharmacology



Analytical Product
Chemistry



Environmental Safety
Testing & Efate Studies

600,000

Sq.ft Modern
Lab Space

>80

Successful
Regulatory Audits

24+

Successful IND
Packages

500+

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.
- » 90,000 sq.ft ultra modern lab space & *In vitro* lab
- » Modular facility with analytical, bioanalytical & pathology labs.
- » Barrier controlled rodent facility with pressurized containment.
- » Dedicated facilities for Beagle dogs & Goettingen minipigs.
- » 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 using *in vitro* rodents & non-rodents
- » 505 (b) (2) - Drug repurposing program
- » Impurity qualification, excipients qualification, metabolite qualification & biocompatibility
- » Biowaiver studies to support post approval changes
- » Complemented numerous successful IND & post IND packages
- » Supported more than 500 drug molecules, biosimilars & vaccines development



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 and minipigs 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 Drug-Drug Interaction Assays

- » CYP inhibition (Direct and time dependent)
- » CYP induction
- » CYP phenotyping

In Vitro Metabolite Stability

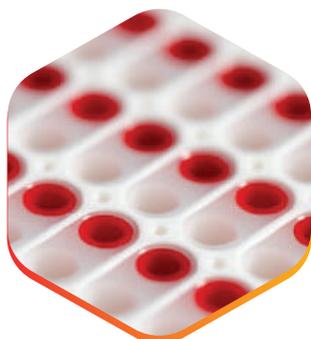
- » Microsome using different species, liver microsomes / S9 / Hepatocytes.

In vitro Permeability Assays

- » PAMPA/MDCK/Caco2

Transporter assays

- » P-GP, Caco2
- » BCRP, MDR, MDCK

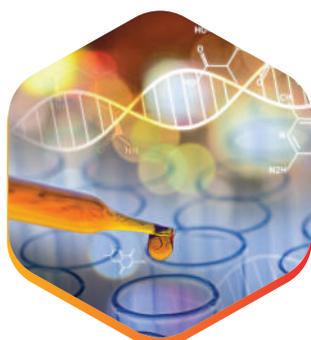


In vitro Protein Binding Assays

- » Plasma protein binding in different species.
- » Tissue protein binding assays
 - » Microsomal binding assay
 - » Liver homogenate
 - » whole blood
 - » Brain homogenate
 - » Hepatocyte
- » Blood/plasma ratio

In vitro Stability Assays

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



Pharmacology Models

Animal Models

- » Chemical induced models
- » Genetic models
- » Surgical models

Therapeutic Areas

- » Oncology
- » Metabolic disorder
- » Pain & Inflammation

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
- » Topical
- » Inhalation

Pharmacokinetics Study in Disease Models



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*) and combination (micronucleus & comet)
- » Pig - A - gene mutation assay.



Safety Pharmacology

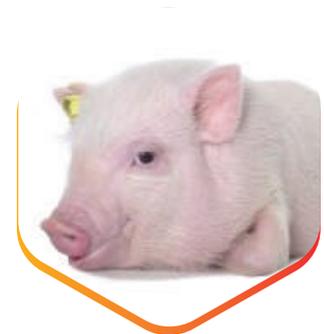
- » hERG assay (*In vitro*)
- » Cardio Vascular Safety (CVS)
- » Central Nervous System (CNS)
- » Gastrointestinal safety
- » Respiratory safety

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 skin sensitization tests, local lymph node assay (LLNA)
- » 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 Studies

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

Safety & Risk Assessment of Impurity/Metabolite/Excipients

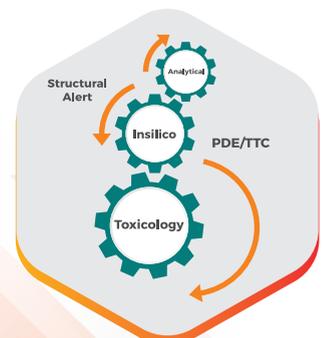
Insilier analysis using rule based algorithm approach

Classification Approach

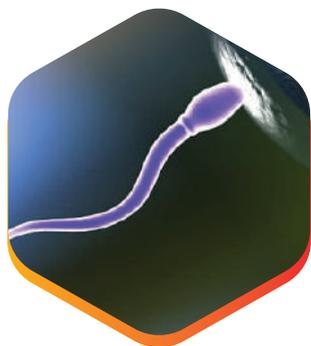
- » Bacterial reverse mutation assay/ mammalian cell gene mutation test
- » *In vitro / In vivo* mammalian chromosomal aberration test
- » *In vitro / In vivo* micronucleus test (MNT)
- » *In vitro / In vivo* Comet assay
- » HPRT
- » Pig - A - gene mutation assay.

Qualification Approach

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



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

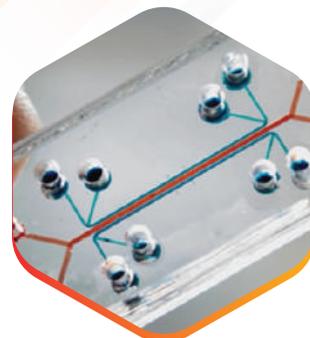
Alternatives to Animal Studies

Genetic Toxicity Studies

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

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

Sensitization Study

- » Direct peptide reactivity assay (DPRA)

Cytotoxicity

- » Cytotoxicity study direct Contact & MEM Elusion Methods

Absorption/Permeability

- » PAMPA/ MDCK/ Caco-2

Permeation and Release Studies

- » *In vitro* permeation testing
- » *In vitro* release testing
- » *In vitro* corneal permeability study



Bioanalytical & Immunogenicity

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

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 Multimode plate reader

Analytical Development

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

Instruments

- » HPLC (UV and electrochemical detection, B.RAM)
- » UV/VIS spectrophotometer
- » ICP - MS
- » Liquid scintillation counter
- » UPLC
- » LCMS/MS
- » Gas chromatograph (FID, FPD, ECD)
- » RT - PCR



Biocompatibility Testing

Chemical Characterization / Toxicological Risk Assessment

In vitro Cytotoxicity

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

Genotoxicity

- » Gene mutations
- » Clastogenicity in mammalian cells
- » Micronucleus test

Implantation

- » Subcutaneous, muscular, bone, ocular

Systemic Toxicity

- » Single and repeat dose
- » In Vitro hemolysis & flocculation



Irritation Studies

- » Eye, skin irritation, intracutaneous reactivity
- » Mucosal irritation (oral, rectal, 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

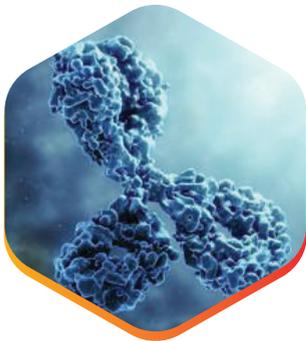
Bioequivalence Studies (IVPT and IVRT Studies)

- » 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 enterocytes *in vivo* with a number of secretory vesicles in apical cytoplasm & form microvilli on the apical surface area
- » 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.



Biosimilar & Vaccine Development

- » Characterization
- » 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
- » Immunogenicity studies

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 aerosol powder or liquid, using
- » 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



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



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