

- Applied for National GLP Compliance Monitoring Authority (NGCMA), Government of India Ministry of Science and Technology Approval.
- Government Approved Drug Testing Laboratory (DTL):(Test Lab/01/2015) under Drug and Cosmetic Act & Rules by the Foodsafety & Drug Administration.
- Approved from National Accreditation Board for Testing and Calibration Laboratory (NABL) - ISO/IEC17025, with DST, Govt. of India,
- CPCSEA Approved Laboratory Animal Facility: (1303/c/09/CPCSEA), Ministry of Environment and Forest, Govt. of India.



Institute for Industrial Research & Toxicology

औद्योगिक अनुसंधान एवं विष विज्ञान संस्थान

Global Preclinical Contract Research Organization
Government Approved Drug Testing Laboratory
Government Approved Chemical & Pesticides Testing Laboratory





INTRODUCTION:

“Institute for Industrial Research & Toxicology (IIRT)” Ghaziabad, Delhi NCR (India) based an emerging Contract Research Organization (CRO), which supports pharmaceutical, biotechnology and Agrochemical companies by providing quality and cost effective Preclinical services. Here we perform various studies like Toxicological Studies or organic chemical, pesticides, insecticide and pharmacological testing of Indigenous and synthetic drug molecule. We have performed the research studies of compound coming from leading industries of India and overseas. IIRT core value is “Integrity of service through Honesty, Responsibility and Uncompromising Devotional Qualities in Generating Unbiased Principal Toxicological and Bio-safety Data”. All the Pharmacological and Toxicological Research Conducted were done as per the National and International guidelines. We are constantly review our research quality for better than the best performance in testing compound. Customer satisfaction through Noble Research is our aim in conducting the studies.



CORE AREA OF RESEARCH

Drug, pharmaceuticals and Cosmetics
Food, Farm and Herbal Product
Chemical, Pesticides and Agro Chemical
Inorganic Chemical and Fertilizers

OUR CORPORATE CULTURE

On time delivery of reports
3R's-highest standards of animal welfare
Focused for Industrial Collaborations
Client service orientation
High quality science with a well defined purpose
Commitment to reliability and punctuality

MISSION AND VISION

To be one stop solution for all preclinical studies for all category of chemical/Drug for all regulatory agencies both National and International.



IIRT SERVICES/CAPABILITIES

PHARMACEUTICAL / HERBALS/ NEUTRACEUTICALS

- ADME PK / IN VIVO AND vitro
- Proof of concept
- Efficacy
- Toxicology
- Phys – chem. Studies
- Batch Release Testing

AGROCHEMICALS/ INDUSTRIAL CHEMICAL

- Phys-chem studies
- Analytical chemistry
- Five Batch Analysis (Impurity profil)
- Toxicology
- Ecotoxicology
- Six Pack Studies
- Bioassays for Bio
- Pesticides
- Identification and quantification of the impurities as well as active ingredients.
- Contact synthesis of organic molecules impurity synthesis Scale up, process optimization, Isolation and purification of impurities.

HORMONES

- Test Batch Production
- Process Development
- Phys-chem
- Potency Assays (HCG, FSH, HMG, Urokinase, Heparin Sodium)
- Stability Studies
- Batch Release Test

ANTI MICROBIALS

- Toxicity
- Production of Test Batch
- Process Development
- Animal Model Development
- Efficacy
- ADME PK/TK

MEDICAL DEVICES

- Phys- chem studies
- Implantation studies
- Irritation and Hypersensitivity
- Systemic Toxicity
- Cytotoxicity and Genotoxicity
- Immunotoxicity
- Toxicokinetics

REACH SERVICES

- Phys-chem Studies
- Analytical Chemistry
- Toxicology
- Ecotoxicology
- Genetic Toxicology



VACCINES

- Test Batch Production
- Process Development
- potency Testing
- Immunogenicity
- Toxicology
- Batch Release Test
- Dose Stability
- Efficacy Test
- Endotoxins
- Abnormal Toxicity

BIOLOGICAL/BIOILARIS BIOPHARMACEUTICALS

- Custom Assay Development Services
- Stability services
- Biologics /Biomilars/Bio Pharma CMC Support Assays
- Bioanalytical Services(PK/TK Immunogenicity /In vitro Assays)
- Final Product Characterization
- Efficacy
- Toxicology
- Antibody product, purification, Labeling and Characterization
- Host Cell Contamination

ACUTE

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalatin Toxicity
- Acute Dermal Irritation/Corrosion
- Acute Eye Irritation /Corrosion
- Skin Sensitization

SUB ACUTE

- 7/14 Day Dose Rangefinding study
- 14/28Days Repeated Dose Toxicity Studies

GENETIC TOX

- *Bacterial Reverse Mutation Test (AMES) Salmonella typhimurium and Eschrichiacoli
- Invitro Chromosome Aberration Test
- InvivoBone Marrow Chromosome Aberration Test
- Invitro Mammalian Cell Micronucleus Test
- Mammalian Gene Mutation Test



EFFICACY MODELS

- In vivo and Invitro Efficacy Model
- Urinary System
- Respiratory System
- Psychotropic and Neurotrophic Activity
- Pain and Inflammation
- Antipyretic Activity
- Immune System
- Gastrointestinal system
- Metabolic Diseases
- Ophthalmology
- Dermatology
- Cardiovascular System

INFECTION MODELS

- Thigh Infection Model
- Systemic Infection Model
- Skin Infection Model
- Sepsis Model
- Aerosol Model /Lung Infection Model
- Germ Free Mice Model
- wound Healing Model
- Sucking Mice Model

ROUTES OF ADMINISTRATION

- Oral
- Inhalation
- Intravenous
- Ocular
- Dermal
- Subcutaneous
- Intradermal
- Intramuscular

SUBCHRONIC AND CHRONIC

- 90/180 Days Repeated Dose toxicity Studies
- Carcinogenicity Studies
- Chronic Toxicity Studies
- Combined chronic Toxicity / carcinogenicity Studies
- Neuro Toxicity Studies

REPRODUCTIVE AND DEVELOPMENT TOXICITY

- Prenatal Developmental Toxicity
- One Generation Reproduction Toxicity
- Two Generation Reproduction Toxicity
- Combined Reproduction/ Development Toxicity
- Seg 1,2 and 3 studies
- Developmental Neuro Toxicity
- Hershberger Bioassay
- Uterotrophic Bioassay

IMMUNO TOXICOLOGY

- Guinea Pig Maximization Test
- Local Lymph Node Assay
- Cytotoxicity
- Immuno Histochemistry
- Vaccine Potency Test
- Closed Patch Test

ECOTOXICITY

- Alga, Growth Inhibition Test (Pseudokircheriella subcapitata)
- Lemna, Growth Inhibition Test (Lemna gibba and Lemna minor)
- Daphnia magna, Acute Immobilisation Test and Reproduction Test
- Fish Acute Toxicity Test (Common Carp Rainbow Trout, Guppy etc.)
- Honeybees, Acute Oral and Toxicity Test (Eisenia Fetida Fetida)
- Avian Dietary Toxicity Test (Coturnix coturnix japonica)
- Avian Oral Toxicity Test (Coturnix Coturnix japonica)
- Some Alternative model to Animal studies
- Class 8 Corrosivity (Corrositex) Simulated Skin Corrosivity test

PHYSICAL CHEMISTRY

- Color
- Physical state
- Odor
- Flash Point
- Storage Stability
- Miscibility
- Corrosion Test
- Determination OFPH
- Viscosity
- Melting Point
- Boiling point
- Density
- Partition CO- efficient
- Particle Size
- Hydrolysis
- Dissociation Constant
- Thermal Stability
- Surface Tensions
- Molecular wt Det.
- Gel Permeability
- Absorption

BIOLOGICAL TESTS

- Biological Activity / Potency (In vivo /Invitro/ Exvivo)
- Quantification (Colorimetric/UV280)
- Process Related Contaminants/Impurity carryover Determination
- Endotoxin (Qualitative and Quantitative)
- Sterility
- Identity, Purity, Copy number / Gene Integration
- Mycoplasma Detection /Quantification
- Antibody Production, Purification,
- Labelling and characterization
- Biologics /Biosimilars / Bio PharmaCMC support Assays
- Final product Characterization
- Bioanalytical Services (PK/TK/ Immunogenicity/Invitro Assays for Biologics /Biosimilars and bio pharma product)
- Custom Assay Development Services
- Stability Services
- Clinical Trial Sample Analysis
- Host Cell Protein Analysis



ANIMAL FACILITY

TEST SPECIES :

RAT	: Wister and Suprgue Daweley	Freshwater Fish	: Common Carp ,Guppies
Mice	: Swiss albino,BALB/C and C57Bl/6		Rainbow Trout , Zebra Fish
Hamster	: Golden(Syrian)	Honeybees	: Apis mellifera
Guinea Pig	: Dunkin Hartley	Earthworms	: Eisenia fetida fetida
Rabbit	: New Zealand White	Chicken	: White Leghorn (Gallus gallus)
Alga	: Pseudokircheriella subcapitata	Pigeon	: Cotumba Livia
Daphnia	: Daphnia magna	Japnese Quail	: Cotumix COturnix Japonica



QUALITY ASSURANCE

Quality Assurance Unit (QAU) at IIRT follows GLP principles. The internal Audits conducted by QAU ensures that the studies are performed as per the study plan which are designed in compliance with required guidelines. The Standard Operating Procedure are reviewed by the Quality Assurance Unit to ensure that the studies are conducted as per the GLP guidelines. The QAU is involved in reviewing the study plans, conducting in-life phase inspections and report reviews during studies. The Quality Assurance Unit performs regular in-house training programs for the staff to ensure highest quality and compliance to OECD GLP Standards.

LABORATORIES





ANALYTICAL

Determination of phys –chem properties
Determination of Active Ingredient content (purity)
Five Batch Analysis (Impurity profile)
Storage Stability Studies
Analytical services to support Toxicological Studies
(eg. Dose certification, stability Determination)
Production Purification

HISTOPATHOLOGY

Gross Pathology
Organ Collection and Preservation
Tissue Processing
Embedding
Sectioning
Slide Preparation
Slide Evaluation
Histomorphometry

CLINICAL PATHOLOGY

Hematological Parameters
(Whole blood)
Clinical Chemistry Parameters
(Serum, plasma and body-fluids)
Urine Analysis

MICROBIOLOGY

*Total Microbial Count *Pathogen Detection *Preservative Efficacy Testing *In vitro Antibacterial Test *Anti Dandruff Assay
*Anti Sanitizer Efficacy Test *Hand Sensitizer Efficacy Test *Anti –Acne Assay *AMES Test

APPROVAL FOR CARRYING OUT TESTS ON DRUG/COSMETICS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENCEES FOR MANUFACTURE FOR SALE OF DRUG/COSMETICS

PHYSICOCHEMICAL TESTINGS

- (a) Identification by Chemical and UV Spectrophotometer (b) Determination of PH. (c) Moisture Content Analysis (LOD) (d) Disintegration and Friability
(e) Analytical Method Development and Validation (f) Microbiology Culture Preparation and Identifications (g) Stability Studies (Real time and Accelerated Stability Studies) (h) Color Measurements and Identification
(i) Bulk Density and Tap Density (j) Viscosity Measurements (k) Ash Value Determination (l) Weight Variation
(m) Sieve Analysis (n) Related Substances (o) Content Uniformity (p) Refractive Index (q) Impurity Profile (r) Particle Size Evaluation
(s) Assay (t) Distillation (u) Thickness (v) Limit Tests (w) Titration (x) Melting point (y) Dissolution (z) Hardness

CATEGORIES

- a) Drug other than those specified in schedule c and c (I) and also excluding Homeopathic Drugs.
b) Drug Specified in Schedule c and c (I) (c) Cosmetics

Laboratory Facility

HAEMATO-BIOCHEMICAL LAB	HISTOPATHOLOGY LAB	MICROBIOLOGY LAB	ANALYTICAL LAB
Complete hematology kit	Distillation Unit	All the basic requirements for the microbial study	High Performance Liquid Chromatography (HPLC)
UV Spectrophotometer	Microtome, Automatic stainer	Laminar Air Flow	Thin Layer Chromatography (TLC)
Auto analyzer	Homogenizer	Biological incubator	Gas Liquid Chromatography
Deep freezer	Hot Plate	Hot Air Oven	FTIR, UV Spectrometer, Calorimeter
Binocular Microscope with attached camera	Tissue Processor	Autoclave	Water Bath
Centrifuge Machine	Cryostat Microtome	Elisa	Refrigerated Centrifuge
Digital pH meter, Digital weighing balance	Trinocular Research Microscope	Gel electrophoresis	Magnetic Stirrer With Hot Plate
Hematology Auto Analyzer	Automatic Slide Staining Machine	Colony counter	Atomic Absorption Spectrophotometer

SERVICES FOR RESEARCH LABORATORIES PHARMACODYNAMIC, PHARMACOKINETIC AND TOXICITY TESTING

- * Testing of pharmacodynamic effect using in vivo or based assays
- * Pharmacokinetics studies in animal with HPLC OR ELISA-based analysis
- * Toxicology studies as per regulatory guidelines
- * Immunogenicity and Neutralization studies for vaccine candidates.

