

We are committed to provide quality central laboratory services for clinical trials, understanding fully that the reliability of clinical laboratory data is crucial for the success of each trial. We maintain the integrity and confidentiality of your research which is critical to the well being of each study subject and overall success of the trial. The lab provides services that meet the required regulatory standards of the pharmaceutical industry.

In last Ten years we have offered our services as central laboratory for Preclinical,clinical trials to most of the leading national and international pharmaceutical companies.

## **ADME (Absorption, Distribution, Metabolism, Excretion)**

In vitro ADME studies help in optimization of pharma cokinetic characteristics of a drug candidate , identify the metabolic pathways and provide valuable inputs for the design of in vivo studies. We offer both standardized as well as customized assays.

- Permeability (Caco2, MDCK and PAMPA)
- Aqueous Solubility
- Metabolic stability and biotransformation
- Test systems (microsomes, hepatocytes, S9, recombinant enzymes)
- Species (rodent, guinea pig, rabbit, canine,non-human primate, human)
- Protein binding (Equilibrium Dialysis and Ultrafiltration)
- CYP Induction
- CYP Isozyme Mapping
- CYP Inhibition
- Metabolite ID and profiling
- Mass balance and drug disposition

### ***In vivo***

In vivo pharmacokinetic (PK) services involve doseranging and bioavailability studies of drug candidates and their metabolites. Compounds are administered at fixed concentrations and biological samples (blood/serum) are collected at fixed time points for UPLC and LC/MS/MS analysis.

- Mouse and rat pharmacokinetics
- Bioequivalence
- Tissue distribution

## **Molecular biology**

### **Gene regulation**

- RNA interference, siRNA, shRNA,
- Micro RNA, miR RNA interference
- Immunoassays
- Gene expression analysis

### **Nucleic acid analysis**

- DNA isolation and purification
- RNA isolation and purification
- cDNA synthesis
- DNA sequencing
- Cloning
- PCR analysis
- Quantitative real time PCR

## **Proteomics**

- **Protein expression profiling (Array based)**
- **SDS-PAGE**
- **Immunoblotting**

## **Clinical & diagnostic applications**

- **Cell cycle analysis**
- **Cell proliferation assays**
- **Apoptosis assays**
- **Mitochondrial membrane potential analysis**
- **Oxidative burst assay**
- **Reactive oxygen species analysis**
- **Autophagy assay**
- **Immunofluorescence (confocal microscopy)**
- **Cell isolation and expansion**
- **Cell immortalization**
- **Cell sorting services**
- **Hematopoietic stem cell analysis**

## **Immunophenotyping**

- **Acute myeloid leukemia characterization**
- **Acute lymphoblastic leukemia characterization**
- **T-ALL diagnosis**
- **B-ALL diagnosis**
- **Chronic lymphoproliferative disorder diagnosis**
- **Hairy cell leukemia**
- **Multiple myeloma**

## **Invitro Pharmacology**

### **Molecular Biology**

DNA sequencing to DNA services have become routine tools in drug discovery research, preclinical and clinical development. Both basic and advanced DNA technologies are used on a daily basis in most research laboratories.

CRC Drug discovery Network offers you a wide range of services has follows,

- **DNA Library Creation**
- **DNA Library Screening**
- **Cloning of target genes into vectors**
- **Gene Amplification and optimization (PCR)**
- **Site directed mutagenesis**
- **DNA Sequencing**
- **Microbial identification**
- **Fragment analysis**
- **DNA Sub-cloning**
- **DNA and RNA Isolation**
- **Northern blotting**
- **Gene expression analysis by Real Time PCR**

## **Cell based assays**

Cell-based assays are a vital early step in the testing of your compounds and drug candidates for activity.

- Proprietary Cell-Based Assays
- High-throughput Fluorescence based assays
- Primary Cells and Proprietary Cell based assays

## **Our Assays include:**

- Angiogenesis
- Apoptosis
- Cell Migration
- Cell Cycle analysis (Flow cytometer)
- Cell Viability (MTT, SRB, CyQuant, 3H)
- Inflammation and Cytokines assays
- Reporter Gene assays (Luciferase)
- Glucose Uptake

## **In vivo Pharmacology**

We offer wide range of preclinical in vivo pharmacology efficacy studies in the therapeutic areas of inflammation, pain, metabolic diseases etc. Inhouse bred and imported animals would be used in the studies.

### **Inflammation and Pyrogen**

- LPS induced sepsis model in mice.
- Adjuvant induced arthritis model in rats
- Collagen induced arthritis model in mice
- Carrageenan induced paw oedema model
- Rat air pouch model

### **Metabolic disorders**

- Diabetic Neuropathy models
- STZ and nSTZ induced Diabetes models | HFD + STZ induced Diabetes Models
- Genetically Modified mice (Lepr db/db mice )

### **Pain**

- Formalin induced pain in rats
- Acetic acid induced writhing model in Swiss albino mice
- Evaluation of analgesic activity by Tail flick
- Apparatus and Eddy's hot plate methods.

### **Oncology**

- Subcutaneous xenograft models
- Orthotopic tumor models
- Metastatic models
- Syngeneic models
- Hollow fibre assay

### **Infective**

- LD50 determination (Systemic infection or Mouse protection model)
- Thigh infection model
- Lung infection model

# Toxicology

CRCDrug discovery Network has facilities and expertise to perform all aspects of health and environmental safety testing with animals. We continue to develop new techniques in line with SOP based system with advances in regulatory requirements and also constantly working towards 3R principle.

## GUIDELINES FOLLOWED

OECD, OCSPP (OPPTS), EC, ICH, Schedule Y, ISO and custom design

### *In vivo* TOXICOLOGY STUDIES (5 pack studies for Agro compounds)

- Acute oral Toxicity – Up and Down procedure (UDP)
- Acute oral Toxicity – Toxic Class method
- Acute Dermal Toxicity (Rat/Rabbit)
- Acute Dermal irritation in Rabbit
- Acute Eye irritation in Rabbit
- Skin sensitization in Guinea pig: Buehler test, Magnusson & Kligman
- Repeated Dose 28-Day Toxicity Study in Rodents
- 90-Day Oral Toxicity in Rodents

## ROUTE OF ADMINISTRATION

Oral, Dermal, Intra dermal, Subcutaneous, Intravenous, Intra peritoneal and Intramuscular

## GENO-TOXICITY STUDIES

The impact of any chemical on DNA is genotoxic ability of given test item. Effects of chemicals on the genetic material form an integral part of research and regulatory requirement.

- Ames Test
- Chromosomal aberration test
- In vivo Micronucleus test

## ECO-TOXICOLOGY STUDIES

The impact of chemicals in Eco-system is regulatory requirement. The following studies are conducted to draw the eco-toxic effect of given test item.

- Algae Growth Inhibition Test
- Acute Immobilization Test (Daphnia Sp.,)
- Acute Toxicity in Fish
- Earthworm, Acute Toxicity Test
- Acute Oral Toxicity Test – Japanese Quail

# SAFETY PHARMACOLOGY

## CENTRAL NERVOUS SYSTEM

- Motor activity
- Behavior
- Body Temperature
- Sensory/ Motor reflexes

## CARDIO VASCULAR SYSTEM

- Systolic & Diastolic BP
- Mean Arterial Pressure
- Heart Rate

# Analytical Chemistry

## Analytical Chemistry

CRCDrug discovery Network is equipped with advanced instruments to cater the needs of chemists /researcher in the area of structural elucidation, mass characterization, determination of true elements, separation science etc. The following are the list of equipments completely operational by experts in analytical chemistry. In addition our chemists would offer on need basis, suggestion, help and inputs for any of our client needs / problems etc.

- **High performance Liquid Chromatography (HPLC)**
  - HPLC- Analytical
  - HPLC- Preparative
- **High performance Thin Layer Chromatography (HPTLC)**
- **Nuclear Magnetic Resonance Spectroscopy (NMR)**
- **Gas Chromatography coupled with Mass Spectrometry (GCMS)**
- **Inductive coupled plasma Mass Spectrometry (ICPMS)**

## High performance Liquid Chromatography (HPLC)

- **HPLC Method Development (Analytical/Bioanalytical)**
- **HPLC Method Validation (Analytical / Bioanalytical)**
- **HPLC Qualitative analysis**
- **HPLC Quantitative analysis**
- **HPLC Routine sample analysis or Subject sample analysis**
- **Pharmacokinetics studies using HPLC**

## High performance Thin Layer Chromatography (HPTLC)

- **HPTLC Method Development**
- **HPTLC Method Validation**
- **HPTLC Qualitative analysis (Profiling / finger printing)**
- **HPTLC Quantitative analysis**
- **HPTLC Stability Sample analysis**
- **HPTLC Routine sample analysis or Subject sample analysis**

## Nuclear Magnetic Resonance Spectroscopy (NMR)

- **$^1\text{H}$  -Proton NMR**
- **$^{13}\text{C}$  NMR**
- **Cosy**
- **Nosy**
- **DEBT 135**
- **HMQC**
- **HSQC**
- **HMBC**
- **APT**

### Gas Chromatography coupled with Mass Spectrometry (GCMS)

- **GCMS Method Development (Analytical/Bioanalytical)**
- **GCMS Method Validation (Analytical/Bioanalytical)**
- **GCMS Qualitative analysis**
- **GCMS Quantitative analysis**
- **GCMS Routine sample analysis or Subject sample analysis**
- **Pharmacokinetics studies using GCMS**

### **Inductive coupled plasma Mass Spectrometry (ICPMS)**

ICPMS techniques are robust and suitable methods of trace metals analysis amenable to a wide array of sample types. Metals, plastics, proteins, ceramics many others can be successfully analyzed using ICPMS methods.

- **Total sulfur and sulfur species in hydrocarbon fuels**
- **Organotin species in marine sediments and biota, consumer goods, and drinking water**
- **Mercury species in fish, industrial discharges, and petroleum processing**
- **Arsenic species in marine algae, food products, and drinking water**
- **Brominated and phosphorus-based flame retardants in consumer goods**
- **Phosphorus and sulfur in biological samples**
- **Protein- and peptide-bound metals**
- **Pesticides and herbicides**
- **Chemical warfare agents**
- **Volatile organohalides in air samples**
  
- **Bio-Analytical**
- **Ongoing Projects**
- **Patent Works: New Molecule Identification, Drug Discovery-ADEMT TOX Studies**
- **Medicinal / Phyto Chemistry Lab work Studies**
- **Structural Interpretation, X-ray Crystallography, Structure Identification, Docking Studies**
- **(Our Clients / On going projects)**
- **IPR**
- **Research**