Krish Biotech

Partnering Quality Research

AGRO CHEMICALS / BIOLOGICALS

PHARMACEUTICALS

SPECIALITY / INDUSTRIAL CHEMICALS

MEDICAL DEVICES

VETERINARY DRUGS

Accreditations :

aalac INTERNATIONAL · OECD GLP Certified · CIBRC CENTRAL INSECTICIDES BOARD & REGISTRATION COMMITTEE · CPCSEA · ISO 17025 ACCREDITED LABORATORY · NABL · DSIR RECOGNIZED · senasa · SENAVE

Krish Biotech Research Private Limited (OECD GLP Certified Facility)

ABOUT US

Krish Biotech Research Pvt. Ltd. (KBRPL) is an independent research-based organisation in eastern India. The State-of-the-art laboratory of KBRPL is spread over 13,000 square meters of area, at Kalyani (an educational and industrial hub) near Kolkata. It is well recognised by National & International Regulatory authorities and clients. KBRPL is providing integrated Discovery, Development and Regulatory services, across the Agrochemical, Industrial Chemical, Pharmaceutical and Medical Device Industries. KBRPL is having a pool of well qualified and experienced scientists to carry out the experiments efficiently with precision.

Facility: KBRPL is well equipped to provide **Chemistry, Toxicology and Histopathology Services**. The laboratories of Analytical, Wet and Residue Chemistry, Genetic Toxicology, Eco Toxicology, Inhalation Toxicology, Clinical Chemistry, Histopathology and Pharmacology are adequately spaced and equipped with all advanced instruments. There is also a huge Animal Facility with 65 animal experimental rooms. The Animal Facility is registered under the CCSEA, under the Ministry of Fisheries, Animal Husbandry and Dairying, Govt. of India. Institutional Animal Ethics Committee (IAEC) ensures benevolent & justified use of animals for Research. Cold Room facility of approx. 500 sft., having two chambers of different temperate ranges is also available to accommodate Residue samples and other temperature sensitive items.

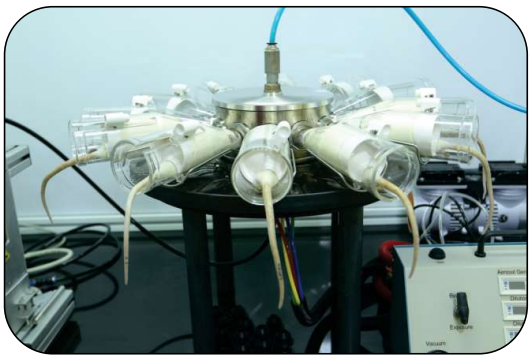
Quality & Commitment: KBRPL has been certified for **ISO-17025:2017** by National Accreditation Board for Testing and Calibration Laboratories and **OECD GLP** by National GLP Compliance Monitoring Authority. The Quality Assurance Team is focussed and committed to ensure that high standards are set and maintained.

Safety & Security: The Company follows high level of safety procedures and provide safe working environment to all its employees and well compliant with National and State Regulations. The facility is under CCTV surveillance along with 24X7 security. The access to the facility is controlled by biometric access control system with data acquisition and archiving. The IT system is secured with Fortinet Firewall and second location backup.

TOXICOLOGY

Toxicology Department of Krish Biotech Research PVT Ltd (KBRPL) offering wide range of pre-clinical safety pharmacology and toxicology studies following various regulatory guideline viz., OECD, EPA, OCSPP, EC, PBM, CIB& RC, etc as per OECD principles of Good Laboratory Practices [C(97)186/ Final].

- **Acute Toxicity**
  - Acute Oral Toxicity
  - Acute Dermal Toxicity
  - Acute Inhalation Toxicity
  - Acute Dermal Irritation
  - Acute Eye Irritation
  - Sensitization Test in Guineapig
  - Local Lymph Node Assay (LLNA)
  - Acute Toxicity (by parenteral routes)



- **Repeated Dose Toxicity**
  - Sub-Acute (28 days) Toxicity
  - Sub-Chronic (90 Days) Toxicity
  - Chronic Toxicity
  - Carcinogenicity
  - Combined Chronic Carcinogenicity
  - Neurotoxicity
  - Inhalation Toxicity

- **DART**
  - Reproduction/ Development Screening
  - Male and Female Fertility
  - Prenatal Developmental Toxicity (Teratology)
  - Two Generation Reproduction Toxicity
  - Extended one Generation Reproduction Toxicology

- **In-vitro Studies**
  - *In-vitro* Skin Corrosion - RhE Test Method
  - *In-vitro* Skin Irritation - RhE Test Method
  - *In-vitro* Eye Irritation/Serious Eye Damage Test
  - *In-vitro* 3T3 NRU Phototoxicity Test

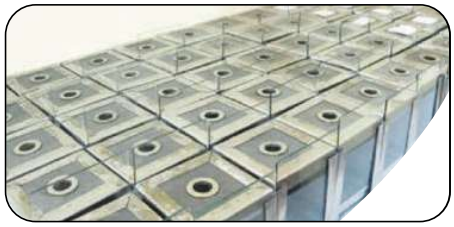
- **Specific Toxicity Study:**
  (CNS studies. Ocular Toxicity)

ENVIRONMENTAL TOXICOLOGY (ECOTOXICOLOGY)

Ecotoxicology section of KBRPL offers Aquatic Toxicology (laboratory and field studies with a focus on marine/freshwater environments) and Terrestrial Ecotoxicology. Our Ecotoxicology facility offers the following studies as per various regulatory guideline viz OECD, OCSPP, CIB & RC etc.

- **Aquatic Studies**
  - Algal Growth Inhibition Test
  - Acute Immobilization test on Daphnia Magna
  - Acute Fish Toxicity (Rainbow trout/Common carp/Zebra fish/Guppy)

- **Terrestrial Studies**
  - Avian Acute Oral Toxicity of Japanese Quail, Chicken, Mallard Duck and Pigeon
  - Avian Acute Dietary Toxicity of Japanese Quail
  - Honey Bee Oral and Contact Toxicity Test
  - Acute Earthworm / Silkworm Toxicity Test
  - Earthworm Repeated Exposure Toxicity under Field Condition.
  - Avian Reproduction Toxicity study



GENOTOXICOLOGY/MUTAGENICITY

Genetic toxicity studies are conducted to assess the mutagenic potential of various chemical/products prior to widespread use in human. Since DNA reactive substance may initiate the carcinogenic process, screening strategies with build in MOA are becoming more useful biologically assessing potential human risk.

At our facility, the following in-vitro & in-vivo genotox studies are being offered as various regulatory guidelines viz. OECD, OCSPP, CIB & RC etc.

• The assays performed at KBRPL are as below

- Ames Test
- In-vivo Micronucleus test
- In-vitro Micronucleus test
- In-vivo Chromosomal Aberration test
- In-vitro Chromosomal Aberration test
- In-vitro Mammalian Cell Gene Mutation Tests
- Mouse Lymphoma Assay
- In Vitro Cytotoxicity

PRODUCT CHEMISTRY

Chemistry Department of Krish Biotech Research Pvt. Ltd. is offering wide range of chemistry studies including Physicochemical, Five Batch Analysis, Residue Analysis, Environmental Fate studies, Packaging Testing of Agrochemicals, Pharmaceuticals, Industrial Chemical and Biocides etc. for worldwide regulatory submission.

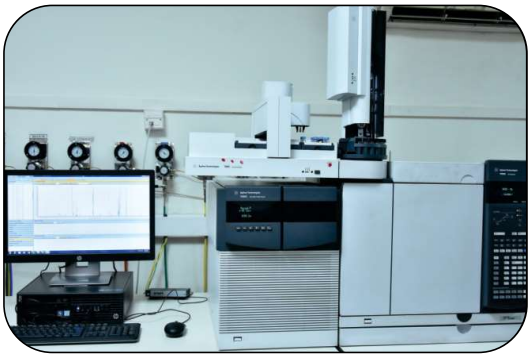
• Department of Product Chemistry offers following studies:

- Method Development & Validation (CIPAC / APVMA / SANCO / OCSPP / ANVISA)
- A.I Content analysis of pesticide formulation
- Five Representative Batch Analysis (TGAI)
- Spectral Analysis (UV/VIS, IR& Mass)
- Storage stability (Stability at 54 ± 2°C & 0 ± 2°C)
- Determination of Physicochemical Properties
  - ✓ Colour, Odour & Physical State
  - ✓ Density/Relative density/Specific gravity
  - ✓ Acidity/Alkalinity/pH
  - ✓ Boiling point/Melting Range
  - ✓ Dissociation constant
  - ✓ Solvent Solubility
  - ✓ Water Solubility
  - ✓ Vapour Pressure
  - ✓ Surface Tension
  - ✓ Viscosity
  - ✓ Suspensibility
  - ✓ Wettability
  - ✓ Wet Sieve test
  - ✓ Dispersibility/ Dispersion Stability
  - ✓ Spontaneity of Dispersion
  - ✓ Flowability
  - ✓ Particle Size Distribution
  - ✓ Attrition Resistance
  - ✓ Persistent Foaming
  - ✓ Dilution Stability
  - ✓ Emulsion Stability
  - ✓ Explodability
  - ✓ Corrosion Characteristics
  - ✓ Flash Point
  - ✓ Miscibility
  - ✓ Moisture Content (KFT)
  - ✓ Oxidation/ Reduction
  - ✓ Oxidizing Properties (Solid)
  - ✓ Partition Co-efficient (Shake Flask Method)
  - ✓ Flammability
  - ✓ Shelf-Life Storage Stability (30 Months, 3 Locations)

RESIDUE CHEMISTRY

- **Method Development & Validation of Residue Studies (SANCO/BIS)**

- **Determination of Pesticide Residue in**
  - Crops/Plants (Harvest)
  - Rotational Crops
  - Stored Commodities
  - Processed Commodities
  - Soil
  - Water



- **Determination of**
  - Dissipation Kinetics & Half Life in Soil/Water/Plant
  - Multi Residue in Export Commodities (ET)
  - Antibiotics in Export Commodities (ET)
  - Dose Formulation Analysis for Toxicology and Safety Pharmacology Studies.

DRUG METABOLISM AND PHARMACOKINETICS (DMPK)

- **Department of DMPK offers following studies:**

  - Bioanalytical method development and validation
  - Method Development and Transfer
  - Pharmacokinetic/Toxicokinetic Study
  - Comparative Bioavailability Study
  - Stability of Drug in Different Biological Fluid and Buffer at Different Condition
  - In-vivo and in-vitro Metabolite Identification
  - GLP chromatographic and Mass Spectrometric Bioanalysis
  - Genotoxic Impurity Quantification in API

PACKAGING TESTING

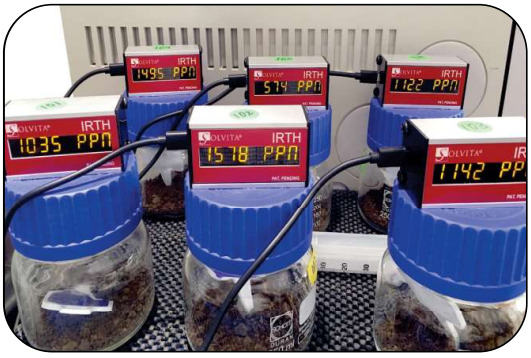
We undertake Packaging material Compatibility and Transport worthiness test as per CIB & RC Guidelines.

- **Container Content Combability**
  - 54 ± 2°C and 65% ± 5 RH
  - 54 ± 2°C and 85% ± 5 RH

- **Transport Worthiness Test**
  - Drop Test
  - Compaction /Compression Test
  - Vibration Test

ENVIRONMENTAL FATE STUDIES

- Ready Biodegradability
- Inherent Biodegradability
- Carbon Transformation
- Nitrogen Transformation
- Hydrolysis as a function of pH
- Photolysis (Aqueous/Surface)
- Adsorption /Desorption (KoC)



CUSTOMISED RESEARCH AND DEVELOPMENT SERVICE IN AGRICULTURE

- Customized R & D Field Trial for Insecticide, Fungicides & Herbicides.
- New Formulation Development (Pesticides) and Bio-efficiency Testing

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