BIONEEDS

A Veeda Lifesciences Company

State-of-the-art facilities spanning 250,000 sq. ft with 115 experiment rooms

Specialized offerings on Carcinogenicity, Juvenile, Infusion, Inhalation, EOGRTS with Brain Morphometry

Rich Experience across segments: Pharma, Biotech, Agrochemicals / Industrial Chemicals

27500+ GLP Studies Submitted Globally

Global Submissions: (USFDA, EMA, HC, WHO, ANVISA, REACH, EPA, EEC, SENASA)

Robust HCD, Assured Quality, Compliance, Data Security & Integrity

450+ Scientific Staff: Expert Toxicologists & Analysts

www.bioneeds.in

About Us

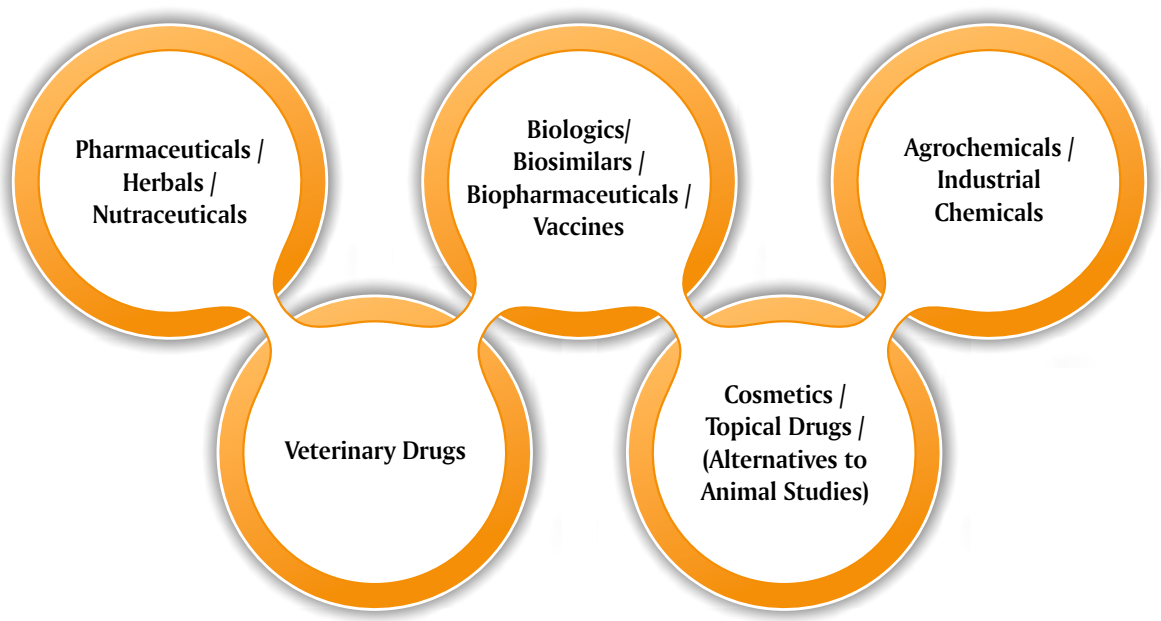
BIONEEDS INDIA PRIVATE LIMITED is a Bangalore based Preclinical CRO providing Integrated Discovery, Development & Regulatory Services to Pharmaceutical, Biopharmaceutical, Agrochemical, Industrial chemical, Herbal & Nutraceutical companies.

- Cutting edge drug discovery & development labs to support pharmacokinetics, toxicology, custom synthesis, process R&D & analytical development services
- Integrated preclinical solutions
- Established track record of successful Regulatory Preclinical submissions
- Multidisciplinary Scientific professionals with rich industry experience
- Customer oriented & collaborative approach with internationally accepted business models

Accreditations / Certifications

- OECD GLP Certified - National GLP Monitoring Authority (NGCMA), Dept. of Science and Technology, Government of India
- CCSEA Registered - The Committee for Control and Supervision of Experiments on Animals (CCSEA), Ministry of Environment, Forests and Climate Change, GOI.
- Drug Testing License (DTL) for tests on Drugs / Cosmetics & Raw Materials used in manufacturing for marketing permission
- AAALAC Accredited - Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- ISO 17025 Accreditation from NABL (National Accreditation Board for Testing and Calibration Laboratories) for Biological and Chemical Testing
- Approved by CIB & RC (Central Insecticides Board & Registration Committee) Government of India
- Approved by Office of Laboratory Animal Welfare (OLAW), Public Health Service, NIH, Dept. of Health & Human Services, Maryland, USA.

PRECLINICAL CRO



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Innovators

- **DMPK Services – towards Lead Optimization & Preclinical Development**
  - *In vitro* Assays
  - Caco-2 Permeability
  - Plasma Protein Binding
  - Solubility
  - Microsomal Stability
  - Blood / Plasma Ratio
  - CYP Assays
  - TK / PK
  - Bioanalysis
- **Safety Assessment - IND Enabling Studies**
  - Customized NGLP Tox / Exploratory PK / Tox
  - Regulatory Tox
    - MTD + 28 Day Rat
    - MTD + 28 Day Dog
    - Genotox studies (*in vitro* / *in vivo*)
  - Safety Pharmacology
    - hERG
    - Telemetry
    - CNS
    - Respiratory

GLP Toxicology / Safety Assessment

- Single Dose Studies
- Repeat Dose, Short term & Long Term Studies with Toxicokinetics & Immunogenicity Assessment
- Biodistribution Studies
- Chronic Toxicity / Carcinogenicity Studies
- Developmental & Reproductive Toxicity - DART Studies
- Immunotoxicity / Neurotoxicity
- Acute & Repeat Dose **Inhalation Studies**
- Genotoxicity (*In vitro* & *In vivo*)
- Juvenile Tox Studies
- *In vitro* Bioassays
- Ocular toxicity

Generics / Complex Injectables

- **Impurity Qualification Studies**
  - Chemistry Support (Isolation, Characterization, Identification & Synthesis of Impurities)
  - Battery of Genotoxicity & *in vivo* Tox Studies
    - Ames Test & **Enhanced Ames Test (NDSRI)**
    - *In vitro* Chromosomal Aberration Test
    - 14 Day, 28 Day, 90 Day, 180 Day Tox Studies
    - Bridging Studies for 505 b(2)
- **PK / TK / Tissue Distribution**
- **Method Dev & Validation**
- **Analytical - MD, MV, DFA (HPLC, LC-MS/MS, GC-MS / MS, ICP-MS / MS)**
- **Bioanalytical – MD, MV, sample analysis in various matrices** – Small / Large Molecules
- *In vitro* Batch Release Analysis
- **Environmental Risk Assessment Studies (ERA)**
  - Phase I
  - Phase II: Tier A & Tier B
- *In vitro* toxicity studies for Skin, Eye etc.

Biopharma

- Preclinical Toxicology - Global Submissions
- DCGI / RCGM Submission Studies
- Bioassays (*in vitro* / *in vivo*) Batch Release Assays
- PK / TK Analysis
- Product Release Testing - IP, EP / BP, JP, USP compliant methods
- Immunogenicity Testing - Screening & Confirmatory ELISA
- Cell Based Potency & Functional Assays
- Custom HCP Assay Development
- Highly Sensitive ELISA Method Development, Validation & Sample Analysis
- Polyclonal & Monoclonal Antibody Development & Purification

Vaccine

- Conducting Long-Term Toxicity Studies Safety Assessment DART Studies, etc.
- Adjuvant Toxicity
- Specificity & Reactivity Assays

Critical Reagent Generation & Validation

- Polyclonal, Monoclonal Antibody Generation (Positive Controls for Several Assays)
- Custom HCP Assay Development
- Hyper-immune sera

Rich Experience with

- **GLP-1 analogues, Insulin and its analogues, Hormones, Co-factors, mAbs based biosimilars etc.**
- **Vaccine development for “Pneumococcal (23 strains)”, “Hexavalent”, “Typhoid conjugate”, “Malaria”, “Hepatitis A”, “Hepatitis B”, “Rubella”, “Influenza”, “Rabies”, “Measles” and “COVID-19” programs**

Analytical Methods

- Determination of active substance content
- Validation of analytical method
- 5 Batch analysis

Physico-chemical Testing*

- Spectral data (MS, NMR, IR, UV/ Vis)
- Melting point/ Boiling point
- Relative density
- Vapour pressure
- Storage stability
- Partition coefficient n-octanol
- Explosive properties
- Solubility in water & organic solvents
- Viscosity

Complete Battery of over 120 types of Phys-chem Tests are Performed

Biopesticides / Biostimulants Toxicity Testing

- Acute oral toxicity / pathogenicity
- Acute dermal toxicity / pathogenicity
- Acute pulmonary toxicity/ pathogenicity
- Avian oral, Tier I
- Freshwater fish testing, Tier I
- Freshwater aquatic invertebrate testing, Tier I
- Non target insect testing, Tier I
- Non target plant studies, Tier I

Ecotoxicology Studies

- Acute toxicity for fish
- Acute immobilization & reproduction test - Daphnia
- Growth inhibition test - Algae & Lemna sp.
- Acute oral & dietary toxicity to birds
- Sub-chronic & reproductive toxicity to birds
- Honeybees - Acute oral & contact toxicity
- Earthworm - Acute & reproduction test
- Collembolan reproduction test in soil
- Predatory mite reproduction test
- Seedling emergence & seedling growth test
- Vegetative vigour test

CIPAC
OECD
EPA
EEC

Efate Studies

- Hydrolysis as a function of pH
- Adsorption-desorption in soil (kd or koc)
- Biodegradability studies
- Photolysis

Residue Analysis & Field Studies

Synthetic Chemistry Services

- Process Chemistry
- Custom Synthesis (mg to kg) - Intermediates, Metabolites & Impurities

Toxicological Studies

Acute Toxicity

- Oral toxicity
- Dermal toxicity
- Inhalation toxicity
- Skin irritation / corrosion
- Eye irritation / corrosion
- Skin Sensitization

Skin Irritation / Corrosion

- *In vitro* Reconstructed human epidermis test method

Eye Irritation / Corrosion

- *In vitro* Bovine corneal opacity & permeability test
- *In vitro* Isolated chicken eye test method

Endocrine Disruptor Screening

Skin Sensitisation

- Local lymph node assay
- Direct Peptide Reactivity Assay (DPRA)

Phototoxicity - *In vitro* 3T3 NRU phototoxicity test

Repeated Dose Toxicity Studies

- Repeated dose oral toxicity: 28 / 90 / 180 days
- Repeated dose dermal toxicity: 28 / 90 / 180 days
- Inhalation toxicity: 28 / 90 days
- Neurotoxicity: Acute & Delayed

Long Term Toxicity & Carcinogenicity

- Chronic toxicity test
- Carcinogenicity studies
- Combined chronic toxicity / carcinogenicity study

Genotoxicity Studies

- Bacterial Reverse.Mutation Test (Ames Test)
- *In vitro* / *In vivo* Mammalian micronucleus tests
- *In vitro* / *In vivo* chromosome aberration test
- *In vitro* Gene mutation assay mammalian cells
- Mouse lymphoma assay
- Comet assay

Reproduction & Generational Studies (DART)

- Prenatal developmental toxicity
- Combined reproduction / developmental toxicity
- Two generation reproduction toxicity
- Extended one-generation reproduction toxicity (EOGRTS)
- Segment I, II & III studies

REACH testing represents Registration, Evaluation, Authorization & Restriction of Chemicals which came into effect on 1st June 2007.

Rich Experience in conducting EU REACH testing services for a wide range of products- Industrial / Specialty chemicals, Plant Protection Products, Biocides, Additives, Paints and Dyes, Polymers etc.,

- Industrial Chemicals (REACH Regulation 1907/2006) Annexure VII to X
- Plant Protection Products (EU Regulation 1107/2009)
- Biocides (Biocidal Products Regulation 528/2012)

Analytical Methods

- Determination of AI content
- Validation of analytical method
- Analysis of five batches

Physico-chemical testing

- Spectral data (MS, NMR, IR, UV / Vis)
- Melting point / freezing, boiling point
- Relative density
- Vapor pressure
- Solubility in water & organic solvents
- Auto / self-ignition temperature
- Partition coefficient n-octanol
- Flash point
- Explosive properties
- Flammability
- Surface tension
- Granulometry
- Oxidizing properties
- Dissociation constant
- Viscosity & others

Ecotoxicology Studies

- Acute toxicity for fish
- Acute immobilisation & reproduction test-Daphnia
- Growth inhibition test –Algae & Lemna sp.
- Acute oral, dietary, sub-chronic & reproductive toxicity to birds
- Honeybees - Acute oral & contact toxicity
- Activated sludge, respiration inhibition
- Earthworm - Acute & reproduction test
- Collembolan reproduction test in soil
- Predatory mite (hypoaspis (geolaelaps) aculeifer) reproduction test
- Seedling emergence & seedling growth test
- Vegetative vigour test & others…

Fate & Behaviour in the Environment

- Hydrolysis as a function of pH
- Adsorption-desorption
- Biodegradability test

Toxicological Studies

Acute Toxicity

- Acute oral toxicity
- Acute dermal toxicity
- Acute inhalation toxicity

Skin Irritation / Corrosion

- *IIn vitro* Reconstructed human epidermis test method
- Acute toxicity: skin irritation / corrosion

Eye Irritation / Corrosion

- *In vitro* bovine corneal opacity and permeability test
- *In vitro* isolated chicken eye test method
- Acute toxicity: irritation / corrosion

Skin Sensitisation

- Guinea pig maximisation test
- Skin sensitisation – Local Lymph Node Assay

Phototoxicity

- *In vitro* 3T3 NRU phototoxicity test

Repeated Dose Toxicity

- Repeated dose 28 / 90 -day oral toxicity studies
- Repeated dose dermal toxicity: 21/28-day studies
- Dermal toxicity: 28 / 90-day study
- Inhalation toxicity: 28 / 90 day studies

Long Term Toxicity & Carcinogenicity

- Chronic toxicity test
- Carcinogenicity studies
- Combined chronic toxicity / carcinogenicity study

Genotoxicity Studies

- Bacterial Reverse.Mutation Test (Ames Test)
- *In vitro* / *In vivo* Mammalian micronucleus tests
- *In vitro* / *In vivo* chromosome aberration test
- *In vitro* Gene mutation assay mammalian cells
- Mouse lymphoma assay
- Comet assay

DART Studies

- Prenatal developmental toxicity study
- Two generation reproduction toxicity
- Extended one-generation reproduction toxicity (EOGRTS)

Process Research

Bioneeds has collective experience & expertise in demonstrating high quality process research especially for advanced intermediates, NCE's, APIs & specialty chemicals involving.

- Route Scouting
- Process Development, Optimization, Validation & Technology Transfer
- Preparation of Required Quantity In-house for Preclinical Studies
- Phys-chem Studies & Qualification of Standards
- Impurities & Stable Metabolites
- Scale up - upto 5 Kg

Custom Synthesis

- New Chemical Entities (NCEs)
- Heterocyclic Building Blocks & Scaffolds
- Carbohydrate Chemistry, Organophosphorus Compounds, Specialized Boronic Acids / Esters
- Key / Exotic Raw Materials, Intermediates / Advanced Intermediates
- Drug Substances & Pro-drugs
- Impurities, Stable Metabolites & Intermediates
- Support in Identification, Isolation, Characterization & Synthesis of Impurities
- Intermediates available for Oxybutynin, Paliperidone & Silodosin

Analytical Services

- Method Development / Validation & Transfer
- Forced Degradation: Chemical (Acid, Base, Oxidation conditions) Thermal & UV exposure
- Raw Material Characterization as per latest Pharmacopoeia (USP / BP / EP / IP / JP)
- Impurity Profiling: Method Development, Identification, Isolation / Synthesis & Characterization
- Qualification of Standards: Preparation, Characterization & Establishing Assay (Potency Determination)
- Qualification of Organic Volatile Impurities & Residual Solvents as per USP / EP / ICH
- Stability Studies as per ICH Guidelines

Flexible Engagement Models

FTE, FFS, Hybrid & Integrated Models as per client requirements

ERA (Environmental Risk Assessment) Studies

Phase I – Risk Assessment

- **Log P_{ow} Evaluation (OECD 107/123)** : If Log P_{ow} < 4.5, proceed to the predicted calculation of PECsw. If PECsw < 0.01 μg/L, no further risk assessment is required. However, if PECsw ≥ 0.01 μg/L, proceed to refined PECs calculation. If refined PECs remain < 0.01 μg/L, no further risk assessment is needed; if refined PECs ≥ 0.01 μg/L, conduct a tailored risk assessment
- **Specific Toxicity Profile Evaluation** : If the active substance exhibits a specific toxicity profile, proceed with the appropriate environmental ecotoxicity studies
- **Comprehensive Environmental Fate and Effects Analysis** : Assess environmental fate, exposure pathways, and potential effects to ensure a thorough understanding of the active substance's impact on ecosystems.

Phase II Risk Assessment Tier A - Environmental Fate Exposure And Effects Analysis

- **Water Solubility Testing (OECD 105)** : Assess the water solubility of substances to determine their potential mobility in aquatic environments
- **Dissociation Constant Calculation (OECD 112)** : Calculate the dissociation constant to evaluate the chemical behavior of compounds in different pH environments, impacting PECs (Predicted Environmental Concentrations) for water (PECsW), groundwater (GW), sediment (PECSED) & soil (PEC soil)
- **Non-Biodegradability Evaluation :** Analyze the biodegradability of substances, identifying them as non-biodegradable, which influences environmental persistence and risk assessments
- **Aerobic & Anaerobic Transformation Studies (OECD 308)** : Conduct transformation studies in aquatic sediment systems to calculate PECow (Predicted Environmental Concentration in overlying water)
- **Sludge Adsorption Insights** : Evaluate KFOC (organic carbon partition coefficient) values between 1000 to 10,000 L/kg, predicting PECs of 2 to 3 pg/L and assessing non-readily biodegradable characteristics.
- **Soil Transformation Assessment (OECD 307)** : Determine the transformation rate in soil over 120 days to calculate PEC soil and its potential impact on soil ecosystems
- **Nitrogen Transformation Analysis (OECD 216)** : Analyze nitrogen transformation within a 28-day period to accurately calculate PEC soil and assess ecological implications.

Ecotoxicity Studies

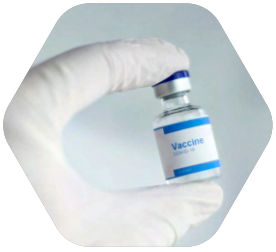
- Algae, Growth Inhibition Test (OECD 201)
- Fish, Early Life Stage Toxicity Test (OECD 210)
- Daphnia Sp. Reproduction Test (OECD 211)
- Activated Sludge, Respiration Inhibition Test (OECD 209)
- Chironomid Studies: Spiked Water/Sediment Test (OECD 218/219), Life-Cycle Study (OECD 233)
- Lumbriculus sp. Sediment Water Toxicity Test (OECD 225)
- Terrestrial Plants Testing (OECD 208)
- Earthworm/Enchytraeid Studies (OECD 222/220)
- Collembola Testing (OECD 232)
- Bioconcentration Factor (BCF) Evaluation

Alternate Studies	Animal Studies
• Isolated chicken eye test - OECD 438	Eye irritation studies
• *In Vitro* ocular irritation test (EpiOcular™) - OECD 492	Eye irritation studies
• Direct peptide reactivity assay (DPRA) - OECD 442C	Sensitization studies
• *In Vitro* skin irritation test (Episkin™ / Epiderm™) - OECD 439	Skin irritation
• *In Vitro* dermal absorption (Episkin™ / Epiderm™) / Human cadaver skin / porcine skin / cornea - OECD 428	Dermal absorption
• *In Vitro* 3T3 NRU phototoxicity - OECD 432	*In vivo* acute phototox. Studies
• Local Lymph Node Assay (LLNA): BrdU-ELISA* - OECD 442B	Sensitization studies
• *In vitro* skin corrosion: reconstructed human epidermis (RHE) test method - OECD 431	Skin corrosion studies
• *In vitro* skin sensitization study (hCLAT method) - OECD 442E	Skin sensitization studies

**** In vivo Assay - Reduction of animals***

Preclinical

- ADME / Biodistribution
- Toxicity Studies
  - Single / Repeat Dose
  - Developmental and Reproductive Toxicity (DART) (Segment I, II and III Studies)
  - Long-term Studies
  - Inhalation Toxicity
  - Ocular Toxicity
  - Adjuvant Toxicity
- RoA (Oral (Dietary / Gavage), SC, IM, IP, Inhalation, Intranasal)
- Batch Release (Specific activity / reactivity / safety)



Experience with Vaccine Programs

- Pneumococcal (23 strains)
- Hexavalent
- Typhoid Conjugate
- Malaria
- Hepatitis A & B
- Rubella
- Influenza
- Rabies
- Measles
- COVID-19
- Chikungunya
- GBS
- EV-D68
- HFMD

Bioanalytical

- Cytokine Analysis
- Surface Marker Assessment
- Immunogenicity (ADA / NAb / Positive control generation)
- Response against multiple serotypes / multivalent vaccines
- Critical reagent generation & validation (pAbs, mAbs, Hyperimmune sera, positive control generation for ADA / NAb)

Vaccine Modalities

- Multivalent Vaccines
- Inactivated Vaccines
- Live-Attenuated Vaccines
- mRNA Vaccines
- Subunit, Recombinant, Polysaccharide, and Conjugate
- Vaccines Viral Vector Vaccines

Bioneeds India Private Limited

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