Pharmaceutical and Biopharmaceutical Testing

At Product Safety Labs (PSL), we understand the FDA’s expectations and regulatory guidelines, so you can be assured our testing will meet all your specific requirements. With more than 40 years of experience, PSL is a leading provider of toxicology, pharmacology and analytical services to the pharmaceutical industry. PSL is GLP compliant, AAALAC accredited and a DEA licensed lab, offering the latest in scientific techniques and instrumentation. Our team of industry experts who specialize pharmaceutical and biopharmaceutical testing can assist with evaluating drug candidates from discovery through early development. PSL’s services include:

Toxicology
As a leader in toxicology research and testing, PSL has developed an outstanding reputation for providing excellent service and superior value. PSL conducts toxicology studies in accordance with national and international regulatory guidelines and GLP standards. PSL’s services include:

General Toxicology
- Single and repeat dose studies in rodents (up to six months in duration)
- Routes of exposure include; Oral, Dietary, Inhalation, Parenteral (including IV infusion)
- Neurotoxicity assessments, including functional observation battery (FOB) and motor activity (MA)
- Immunotoxicology assessments
- Pathology peer reviews

Developmental and Reproductive Toxicology
- Range finding and definitive fertility studies
- Range finding and definitive teratology studies

Genotoxicity
- In vitro gene mutation (Ames) testing
- In vitro tests
  - Micronucleus Assay
  - Chromosome aberration
  - Mouse Lymphoma Assay
- In vivo tests
  - Micronucleus Assay
  - Chromosome aberration
  - Pig-a assay

Additional testing available
Analytical Services
Product Safety Labs (PSL) is a leading GLP laboratory for analytical services to the pharmaceutical industry. At PSL we pride ourselves on using the most sophisticated technology, such as the HPLC, GC, MS, LC/MS, LC/UV, ELISA and ICP.

The majority of the studies we conduct fall into the following categories:

- Formulation characterization
- Analytical support for GLP toxicology, method development, dose analysis, homogeneity and stability
- Bioanlaysis including pharmaco and toxicokinetics

*Custom analytical protocols also available*

Pharmacology
Product Safety Labs (PSL) is a recognized world leader in pharmacology testing with experience in performing a wide range of pharmacology tests using thoroughly validated animal models to help ensure the accuracy of your results. PSL can offer specific pharmacology protocols in multiple therapeutic areas to help identify promising lead compounds. We also welcome the opportunity to develop custom protocols that satisfy your project needs.

- Routes of administration: Oral, intravenous, intramuscular, intraperitoneal subcutaneous, oral film, dermal patch
- Study designs: pharmacokinetic profiling, screening, bioavailability, bioequivalence, tissue collection, metabolite collection, Pathology design and evaluation of animal models of disease for efficacy testing
- Phenotyping of genetically modified animals

**Therapeutic Areas**

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Cardiac Profiling (ECG, Blood Pressure, Arterial gases), Heart Failure, Hypertension, Atherosclerosis</th>
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<tbody>
<tr>
<td>Cardiovascular</td>
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<td>Gastrointestinal</td>
<td>IBD</td>
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<td>Inflammation</td>
<td>Arthritis, Wound Healing</td>
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<td>Metabolic Diseases</td>
<td>Dyslipidemia, Diabetes; Obesity, Metabolic Syndrome</td>
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<tr>
<td>Central Nervous System</td>
<td>Pain (Acute, Visceral, Post-Surgical, Neuropathic, Inflammatory), Parkinsonism</td>
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</tbody>
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Call one of our experts at Product Safety Labs to help you design a study to meet your objectives.

**Product Safety Labs…Superior Service, Reliability and Results.**