PharmaPrimes
Pharma Experts House

BIOANALYTICAL SERVICES

www.pharmaprimes.com

WHO WE ARE

PharmaPrimes Laboratories is a leading Contract Research Organization (CRO) dedicated to providing tailored solutions to the pharmaceutical industry. Specializing in pharmaceutical product development, comprehensive testing services, bioanalysis, and biosimilar testing, we drive healthcare innovation through advanced analytics and expert support.

Based in Amman, Jordan, our state-of-the-art facilities and expert team make us your trusted partner in pharmaceutical science and services. We are committed to delivering high-quality, cost-effective solutions that empower our clients to excel in the highly regulated pharmaceutical landscape.

MISSION

Our mission is to provide top-tier pharmaceutical testing and formulation services that enable our clients to advance their drug development programs with confidence. We strive to deliver accurate, timely results while expertly navigating the ever-evolving regulatory landscape.

In the fast-paced world of drug development, every moment and every data point are crucial.

& VISION

Our vision is to revolutionize the future of pharmaceutical research and development by providing services that meet the highest standards of scientific excellence and set new benchmarks in the industry.

PharmaPrimes is committed to fostering continuous learning, collaborative innovation, and industry leadership.

QUALITY SYSTEMS

Quality is at the core of everything we do at PharmaPrimes Laboratories. Our commitment to excellence is demonstrated through our adherence to the highest industry standards:

Accreditations:

- Adherence to Good Clinical Laboratory Practice (GCLP) standards.
- Compliance with international industry guidelines (ICH, FDA, EMA).
- Adherence to the new ICH M10 guideline for Bioanalytical Method Validation and Study Samples Analysis.
- International standard for testing and calibration laboratories ISO/IEC 17025.
- Quality management system ISO 9001:2015.

Quality:

Advanced Quality Management Systems:

eQMS from ZenQMS: electronic Quality Management System ensures compliance, efficiency, and continuous improvement across all operations.

Thermo Scientific Watson LIMS: Laboratory Information Management System streamlines data management, enhancing accuracy and reliability in bioanalytical workflows.

Data Integrity: All our software complies with 21 CFR Part 11 and meets data integrity standards.

BIOANALYTICAL SERVICES

At PharmaPrimes Laboratories, we provide a full range of bioanalytical services that support all stages of drug development, from discovery to clinical trials. Our comprehensive services include:

Simulated Bioequivalence

It is an innovative pre-study service offered by PharmaPrimes, designed to help clients estimate the probability of passing or failing bioequivalence (BE) studies before investing significant resources. Using advanced modeling and simulations based on preliminary data, we generate insights into the likely outcomes of BE studies. This service helps companies make informed decisions about study design, potentially reducing time, cost, and resources associated with failed studies. By leveraging simulated bioequivalence, clients gain a strategic advantage in evaluating study feasibility and optimizing formulation development early in the process.

Drug Dossier Assessment (Due Diligence)

It is a valuable advisory service PharmaPrimes provides to support clients in selecting optimal drug files for acquisition. This service offers a comprehensive analysis of the clinical data, efficacy, safety profiles, and regulatory standing of potential drug candidates. By leveraging our expertise, clients receive a clear understanding of each option's potential value and risks, enabling more informed, strategic decisions in drug file selection. This guidance reduces investment uncertainty and enhances decision-making efficiency in the drug acquisition process.

Why Due Diligence for innovative drugs?

- ✔ Regulatory Compliance
- ✔ Market Readiness
- ✔ Global Adaptability
- ✔ Financial Safeguarding
- ✔ Risk Assessment (technical, regulatory, and business)
- ✔ Uncovers common deficiencies (e.g. incomplete clinical data, outdated standards)

Method Development:

We provide customized bioanalytical methods development all crafted in alignment with international regulatory standards. Our experts specialize in developing challenging methods such as critical metabolic drugs, including **semaglutide, liraglutide, and tirzepatide**. Analyzing these compounds demands sophisticated sample preparation techniques and expert handling of LC-MS/MS analysis to achieve precise, reproducible results. With our advanced expertise and state-of-the-art equipment, we ensure high-quality data and reliable results to support accurate drug development and regulatory submissions.

Method validation:

We adhere to the ICH M10 guidelines for method validation, ensuring specificity, accuracy, precision, and robustness in our processes. This guarantees reliable data for preclinical and clinical studies.

Preclinical Studies

Our preclinical bioanalytical services provide critical insights during the early stages of drug development. We offer:

- **Pharmacokinetic (PK) Studies:** Determining ADME profiles of drug candidates.
- **Toxicokinetic (TK) Studies:** Supporting safety assessments by quantifying drug levels in animal studies.
- **Drug Metabolism Studies:** Identifying metabolites and assessing their pharmacological or toxicological impact.

Clinical Trials (Phase I - IV)

PharmaPrimes Laboratories offers bioanalytical support across all phases of clinical trials:

- **Phase I:** First-in-human studies focusing on safety, dosage, and pharmacokinetics.
- **Phase II-III:** Expanding studies to assess drug efficacy and side effects.
- **Phase IV:** Post-marketing studies to monitor long-term safety and effectiveness.

Bioequivalence & Bioavailability

We provide expert support for bioequivalence (BE) and bioavailability (BA) studies, which are essential for generic drug approval and new drug development. Our services include:

- Quantitative analysis of drugs and metabolites in biological matrices.
- High-quality data generation to meet regulatory requirements and ensure drug safety and efficacy.
- Support for both single-dose and steady-state studies.

Biomarker Analysis

Biomarkers play a critical role in drug development, allowing for the assessment of drug response, disease progression, and therapeutic outcomes. Our biomarker analysis services include:

- **Pharmacodynamic (PD) Biomarkers:** Assessing drug efficacy and mechanism of action.
- **Safety Biomarkers:** Monitoring potential adverse effects and toxicity during treatment.

Therapeutic Drug Monitoring (TDM)

Our TDM services measure drug concentrations in patients to ensure optimal therapeutic levels. TDM helps to:

- Adjust dosages based on individual pharmacokinetics and pharmacodynamics.
- Minimize adverse effects while maintaining efficacy.
- Ensure compliance with treatment regimens for chronic conditions.

Areas can be covered at PharmaPrimes Laboratories:

- ✔ Antiepileptic drugs (AEDs)
- ✔ Cardiac drugs
- ✔ Psychiatric Medications
- ✔ Anti-HIV drugs
- ✔ Anti-Tuberculosis
- ✔ Immunosuppressant
- ✔ Antibiotics
- ✔ Anticancer drugs
- ✔ Anticoagulants
- ✔ And more ...

Our Facility:

PharmaPrimes has a completely new laboratory adhering to GLP regulations, equipped with state-of-the-art technology.

Our comprehensive offerings include:

- Liquid Chromatography-Mass Spectrometry (LC-MS/MS)
- Quadrupole Time-of-Flight Mass Spectrometry (QToF-MS)
- Gas Chromatography-Mass Spectrometry (GC-MS/MS)
- Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
- Immunochemistry (ELISA based assays)

WHY CHOOSE PHARMAPRIMES LABORATORIES FOR BIOANALYTICAL SERVICE

PharmaPrimes provides industry-leading bioanalytical support with state-of-the-art technology and an expert team of scientists. Our commitment to quality, regulatory compliance, and fast turnaround times makes us your ideal partner in drug development. We offer customized solutions tailored to your project's unique needs, ensuring you achieve timely and reliable results for all stages of pharmaceutical research.

CORE VALUES

On-Time Delivery:

We optimize methodologies to enhance efficiency, ensuring that project timelines are consistently met.

High-Quality Science:

Committed to data integrity and scientific excellence, we provide our clients with the highest level of service.

Client-Centric Approach:

We prioritize our clients' needs, offering customized solutions tailored to their specific goals.

Competitive Pricing:

Transparent and competitive pricing structures offer clients clear, accessible information about costs, fostering trust and enabling informed decision-making.

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PharmaPrimes excel in healthcare innovation with advanced analytics

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