PharmaPrimes

Pharma Experts House

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.

OUR EXPERTS

Anas Alshishani

PhD Separation Science

R&D and analytical chemistry expert

Mohammad Al Reyahee

BSc Chemistry

QA/QC Expert

Abd Alrahman Mahli

PhD Pharmacy

Biosimilar Expert

Abdulnaser Alsharaa

PhD Bioanalytical Chemistry

Bioanalysis Expert

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.

& VISSION

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 bench-marks 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).
- International standard for testing and calibration laboratories ISO/IEC 17025.
- Medical laboratories standards: ISO 15189:2012.
- 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.

PHARMACEUTICAL SERVICES

Pharmaceutical Formulation Development

At PharmaPrimes Laboratories, we specialize in developing robust pharmaceutical formulations across a wide range of dosage forms, including tablets, capsules, injectables, and topical products. Our comprehensive services are designed to optimize drug delivery and efficacy, ensuring your product stands out in the market.

Dosage Formulation:

Tailored development strategies for optimized drug delivery systems, enhancing bioavailability and patient compliance.

Regulatory Support:

Assistance with regulatory documentation and compliance to meet global standards, including FDA and EMA guidelines.

Drug Master File Initiation.

Analytical Method Development & Validation:

Comprehensive development and validation of analytical methods to ensure accurate and reliable quality control throughout the product lifecycle.

Process Development & Optimization:

From lab-scale prototypes to commercial-scale production, we ensure seamless technology transfer and scalability, optimizing processes for efficiency and cost-effectiveness.

Pharmaceutical Product Testing

We offer an extensive range of testing services to ensure the safety, efficacy, and quality of your pharmaceutical products. Our state-of-the-art facilities are equipped with advanced instrumentation and staffed by experienced professionals committed to excellence.

Stability Testing:

Comprehensive evaluation of the shelf life and optimal storage conditions of drug products under various environmental conditions, following ICH guidelines.

Physicochemical Characterization:

Detailed analysis of physical and chemical properties critical to product performance.

Dissolution & Release Testing:

Assessment of drug release profiles in various dosage forms to ensure consistent performance and bioavailability.

Impurity Profiling & Degradation Studies:

Identification and quantification of impurities and degradation products that may arise during manufacturing or storage, ensuring product safety and compliance.

Regulatory Support:

Assistance with regulatory documentation and compliance to meet global standards, including FDA and EMA guidelines.

Our testing protocols adhere strictly to GMP, GLP, and ISO standards, ensuring data integrity and regulatory compliance.

Nitrosamines Testing Services

Nitrosamines are potential carcinogens that have gained significant regulatory attention due to their presence in various pharmaceutical products. At PharmaPrimes Laboratories, we offer comprehensive Nitrosamines Testing services to ensure your products meet the stringent safety standards set by global regulatory agencies.

Ultra-Sensitive Detection:

Utilizing advanced analytical techniques such as LC-MS/MS and GC-MS/MS, we can detect and quantify nitrosamines at ultra-trace levels, surpassing regulatory requirements.

Regulatory Compliance:

Comprehensive development and validation of analytical methods to ensure accurate and reliable quality control throughout the product lifecycle.

Method Development & Validation:

Customized analytical methods tailored to your specific products, ensuring accurate detection of all relevant nitrosamine impurities.

Risk Assessment & Consultation:

assessments, control strategies, and mitigation plans to proactively address regulatory concerns.

Identification of Unknown Compounds

Identifying unknown compounds, impurities, or degradation products in pharmaceutical substances is critical for ensuring product safety and regulatory compliance. PharmaPrimes Laboratories offers comprehensive identification services using cutting-edge analytical technologies.

- **High-Resolution Mass Spectrometry (HR-MS):**
  For precise molecular weight determination and structural elucidation.
- **Advanced Chromatography Techniques:**
  Including Prep-HPLC, HPLC, UPLC, and GC-MS for efficient separation, isolation, and analysis of complex mixtures.
- **Elemental Analysis:**
  Determination of elemental composition to support structural analysis.
- **Nuclear Magnetic Resonance (NMR) Spectroscopy:**
  Providing detailed molecular structure information to confirm compound identities.
- **Fourier Transform Infrared (FTIR) Spectroscopy:**
  For functional group identification and material characterization.

Our team of scientists is adept at tackling even the most challenging identification tasks, ensuring that all potential impurities or degradation products are accurately detected and characterized. We provide detailed reports and support for regulatory submissions, helping you maintain compliance and product integrity.

BIOSIMILAR SERVICES

At PharmaPrimes Laboratories, we offer a comprehensive suite of specialized services tailored to meet the unique challenges of biosimilar development. Our expert team and state-of-the-art facilities enable us to support clients in the pharmaceutical and biotechnology sectors, ensuring quality, compliance, and efficiency at every stage of the biosimilar lifecycle.

01 Biosimilarity Assessment

We provide thorough and detailed biosimilarity assessments focused on critical quality attributes essential for regulatory approval. Our expertise includes:

Purity and Impurity Profiling:

- **Charged Variant Analysis:** Utilizing techniques like capillary isoelectric focusing and ion-exchange chromatography to identify and quantify charged variants, ensuring consistency with the reference product.
- **Impurity Detection:** Sensitive methods to detect and quantify process-related impurities and degradation products.

Glycosylation Analysis:

- **Detailed Glycan Profiling:** Employing high-resolution mass spectrometry and HPLC to characterize glycosylation patterns, crucial for protein stability and efficacy.
- **Site-Specific Glycosylation Analysis:** Determining glycosylation at specific sites to ensure structural and functional similarity.

Potency and Functional Assays:

- **Bioassays:** Customized cell-based and binding assays to evaluate the biological activity and potency relative to the reference product.
- **Mechanism of Action Studies:** Assessing the functional attributes that contribute to therapeutic effects.

Primary Structure Analysis:

- **Amino Acid Sequencing:** Using advanced mass spectrometry to confirm the primary structure matches the reference molecule.
- **Peptide Mapping:** Detailed analysis to detect any differences in the amino acid sequence or post-translational modifications.

Higher-Order Structure Analysis:

- **Secondary and Tertiary Structure Characterization:** Techniques like circular dichroism (CD), Fourier-transform infrared spectroscopy (FTIR), and nuclear magnetic resonance (NMR) to compare folding patterns.
- **Aggregation Studies:** Dynamic light scattering (DLS) and size-exclusion chromatography (SEC) to assess aggregation profiles.

Protein Modifications:

- **Post-Translational Modifications (PTMs):** Identification and quantification of PTMs such as oxidation, deamidation, and phosphorylation.
- **Disulfide Bridge Mapping:** Ensuring correct disulfide bond formation essential for protein function.

Our comprehensive biosimilarity assessments help you demonstrate equivalence to the reference product, a critical step for regulatory approval.

02

Batch Testing for Fill & Finish Products

Our batch release services ensure that your fill and finish products meet all necessary quality and regulatory requirements before market release. We provide:

Method Development & Validation:

We specialize in the customized development and rigorous validation of analytical methods, ensuring robustness and compliance with international guidelines.

Stability Studies:

extensive stability studies to determine the shelf life and optimal storage conditions for your biosimilar products.

- Long-Term and Accelerated Stability Testing.
- Forced Degradation Studies.
- Data Analysis and Reporting.

Quality Control Testing:

Comprehensive physicochemical and biological tests to verify product specifications.

Regulatory Compliance:

Documentation and certification in accordance with GMP guidelines and regulatory agencies' standards.

03 Biosimilar Testing in Clinical Samples

Our bioanalytical services support both pre-clinical and clinical development phases, offering precise quantification and analysis of biological samples. Capabilities include:

LC-MS/MS Analysis:

- **Quantitative Bioanalysis:** Sensitive detection of therapeutic proteins, peptides, and small molecules.
- **Pharmacokinetic (PK) Studies:** Supporting dose selection and exposure-response evaluations.

Flow Cytometry:

- **Cell Phenotyping:** Identifying and quantifying cell populations in immunological studies.
- **Receptor Occupancy Assays:** Measuring drug binding to target receptors on cells.

Immunogenicity Testing:

- **Anti-Drug Antibody (ADA) Assays:** Detecting and characterizing immune responses against therapeutic proteins.
- **Neutralizing Antibody (NAb) Assays:** Assessing the impact of antibodies on drug efficacy.

Biomarker Analysis:

- **Exploratory Biomarkers:** dentifying biomarkers for safety and efficacy monitoring.
- **Validated Assays:** Developing and validating assays for regulatory submissions.

Our GLP-compliant laboratories ensure high-quality data essential for informed decision-making and regulatory compliance.

BIOANALYSIS 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:

Method Development & Validation

We offer customized development and rigorous validation of bioanalytical methods for small molecules, peptides, proteins, and complex biologics. Our methods are developed in compliance with international regulatory standards (ICH, FDA, EMA) and are validated to ensure specificity, accuracy, precision, and robustness. 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 absorption, distribution, metabolism, and excretion (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)

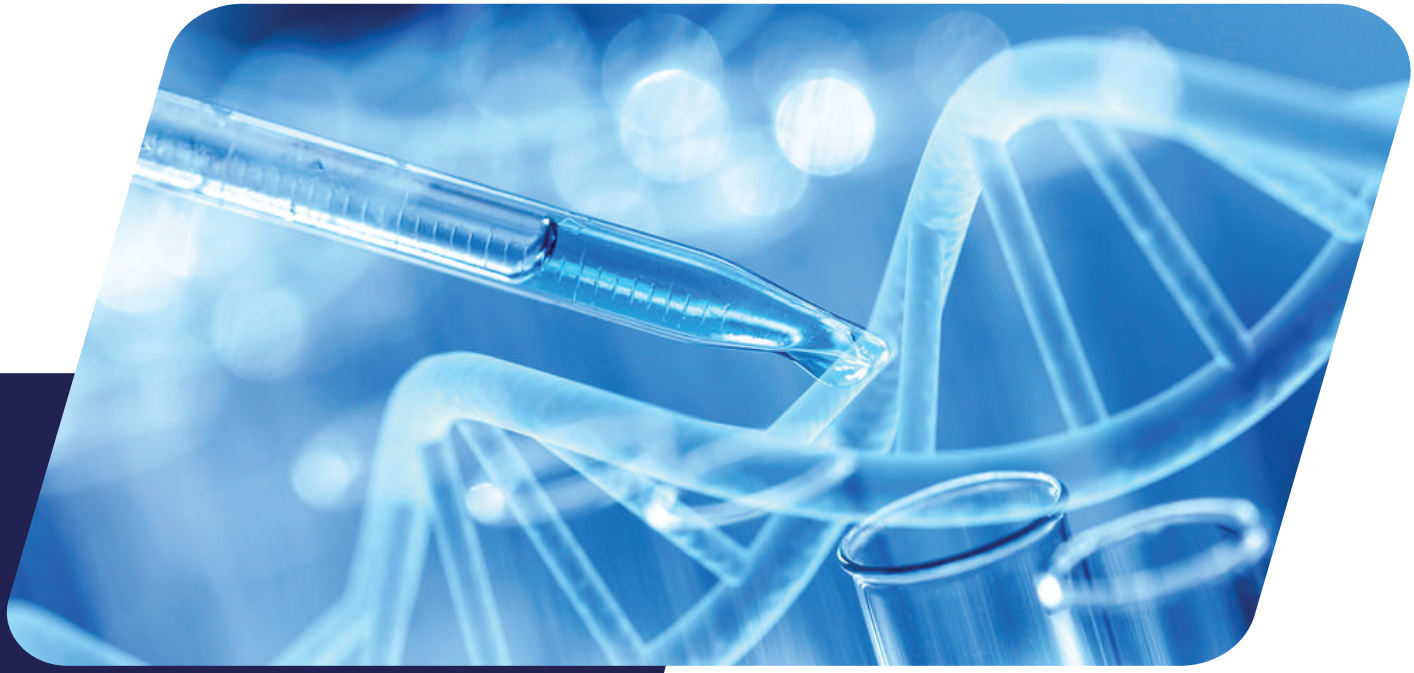
PharmaPrimes Laboratories offers bioanalytical support across all phases of clinical trials:

- **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. Our high-throughput laboratories and advanced technologies allow us to process large volumes of clinical trial samples with precision and speed.

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 such as epilepsy, cancer, and cardiovascular diseases.



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 (plasma, serum, urine, etc.).
- High-quality data generation to meet regulatory requirements and ensure drug safety and efficacy.
- Support for both single-dose and steady-state studies.

Biomarkers 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.

WHY CHOOSE PHARMAPRIMES LABORATORIES FOR BIOANALYSIS 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 turn-around 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:

Leveraging our strategic location in Jordan and our team's extensive experience, we offer exceptional services at competitive rates.

PharmaPrimes
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PharmaPrimes excel in healthcare innovation with advanced analytics

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