Piramal Clinical Research
knowledge action care

GLP Bio-analytical Services

Piramal Clinical Research (PCR) is dedicated to helping our clients meet today's demands for regulatory compliance. We offer analytical method development and validation, and sample analysis services to support to the Clinical Pharmacokinetic and BA/BE studies conducting under GCP and GLP guidelines.

Bio analytical Services (GLP)

- ❑ Method development, validation, and transfer
- ❑ Early discovery bio-analysis.
- ❑ GLP sample analysis.
- ❑ Clinical sample analysis.

Techniques Used:

- ❑ LC/MS/MS.

Types of studies supported:

Clinical Studies:

- ❑ Phase I-IV.
- ❑ Clinical pharmacology.
- ❑ Drug-drug interaction.
- ❑ BA/BE studies.

Experience with a variety of matrices including:

- ❑ Whole blood.
- ❑ Plasma.
- ❑ Serum.
- ❑ Urine.

Method development & Validation

PCR specializes in developing and validating robust methods for the analysis of a wide array of compounds, including small molecules and metabolites.

We perform method validations, method transfer, method verifications, cross matrix validations, full GLP validations, or any combination.

Parameters evaluated during method validation:

Bio-analytical Methods

- ❑ Sensitivity, Specificity.
- ❑ Carryover.
- ❑ Matrix effect.
- ❑ LLOQ accuracy and precision.
- ❑ Intraday accuracy and precision.
- ❑ Inter-day accuracy and precision.
- ❑ Extraction recovery.
- ❑ Dilution integrity.
- ❑ Standard solution stability. (bench-top and long-term)
- ❑ Freeze-thaw sample stability.
- ❑ Long-term sample stability.
- ❑ Incurred sample reproducibility during sample analysis. (10%)

Experts in Regulatory Compliance:

PCR's instrument is fully validated to include IQ/OQ/PQ. Our in-house instrument services. Staffs perform regularly scheduled preventive maintenance and performance qualification on all project instruments. Instrument software is installed and validated to confirm to 21 CFR part 11 regulations.

We offer with full compliance with regulations and guidelines of DCGI, USFDA, EU, ANVISA, CHILE – ANAMED, THAI FDA and WHO.

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Please Contact us to discuss your specific projects and how we can help with your drug development Challenges Reach us at +91-897 8000 331 or mail us at *Maddela.rambabu@piramal.com*

Facilities:

- Equipped with **6 LC-MS/MS** (1Waters xevo tq-s, 2API 4000, 2 API 3000, 1API 2000) for highly sensitive assays in biological fluids.
- Sample storage area with 24 x 7 monitoring.
- Refrigerators with 21 CFR compliant data loggers.
- Alarm system for detecting temperature deviations.
- Sodium vapours lamps and fume hoods.

Capabilities:

- Team of qualified, trained and experienced employees.
- More than 200 validated methods including methods for premium molecules.
- New Method development and validation is continuous process.
- Method validations as US-FDA guidelines and all processes as per GLP.
- Employ stable isotope internal standards for precise and accurate quantization.
- Use of advanced sample cleanup techniques for rapid sample analysis.
- Routine performance of incurred sample reanalysis for establishing the method reproducibility.
- Determination of two or more analytes / active metabolites in a single run.

Piramal Clinical Research

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