

Clinical Pharmacology

We offer the following services on an integrated or standalone basis.

- **Bioavailability / Bioequivalence**

- Dose escalating studies
- Food effect studies
- Multiple dose / Steady state studies
- Urine studies
- Apple-Sauce studies
- Drug-Drug Interaction studies
- Injectables' studies

Our services include, selection of suitable study design, protocol and ICF preparation, interaction with Independent Ethics Committee (IEC), selection of subjects, pharmacokinetic and statistical data evaluation, integrated report preparation and safe archiving of study related documents.

- **Bioanalytical Services**

- Method Development
- Method Validation
- NCE Bioanalysis
- Multiple Metabolites in single assays

With over 200 validated methods, our Bioanalytical laboratory offers, highly selective and sensitive validated methods for assay of drugs, metabolites and endogenous compounds from biological matters using LC/MS/MS and HPLC techniques.

- **PK & Statistical Analysis**
- **Report Writing**

Features

- 1,00,000 sft. of lab space
- Access to >27,000 volunteers, multiple locations
- Seven clinics, 264 beds
- Access to special population volunteers including psychiatry, oncology, elderly, post menopausal women
- Dedicated Analytical facility
- NABL accredited clinical chemistry laboratory
- Watson LIMS for bioanalytical data processing
- eCTD for final reports
- Volunteer Data Management System (VDMS) to avoid cross participation, ensure quality data and better subject care

Accreditation Spectrum

Inspections & Approvals by

- USFDA
- WHO
- ANVISA (Brazil)
- AFSSAPS (France)
- MoH (Turkey)
- ISO

Project Management



Equipment

- Each clinic is equipped with a 2-bedded ICU
- Crash Cart equipped with defibrillator, oxygen cylinder, nebulizer and emergency medications
- Cardiac monitors
- ECG machines
- Mercurial sphygmomanometers
- Glucometers for glucose monitoring
- Refrigerated centrifuges
- 15 LC/MS/MS instruments
- Waters automated HPLCs
- Well equipped state-of-the-art Clinical (Pathology) Lab

Compliance

At GVK BIO, a strong SOP driven culture ensures compliance with all statutory and mandatory requirements.

Good Clinical Practices

- Educated, experienced and trained staff
- Studies conducted in accordance with ethical principles – Declaration of Helsinki
- Protocols as per E6 guidelines
- Protocols and ICFs approved by IEC/IRB
- Medical-care qualified physicians
- Trial information recorded, handled and stored to allow accurate reporting, interpretation and verification of source data

Good Laboratory Practices

- Calibration of analytical instruments at regular intervals
- QA controlled log books and method books
- Method validation as per regulatory guidelines
- Sample analysis as per validated procedures
- Regular QA

About GVK BIO

GVK Biosciences (GVK BIO) is Asia's leading Discovery Research and Development organization. GVK BIO provides a broad spectrum of services, stand-alone and integrated, across the R&D value chain.

Services

- Chemistry Services
- Process R&D and Custom Synthesis
- Biology
- Informatics
- Clinical Research
- Clinical Pharmacology

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