

LIST OF SERVICES



1. Bio analytical Part:

Facilities: a. LC-MC/MS systems. {(UP) LC-MS – Waters}

b. HPLC Systems:

- Agilent

- Shimadzu

i. UV detector.

ii. Fluorescence detector. c. Microbalance.

d. All study samples are stored in controlled freezers (-20°C and -70°C).

e. UPS (Uninterrupted Power Supply) and generator back-up.

- Services

i. Method Development.

ii. Method Validation.

iii. Bio-Waiver / Bioequivalence.

2. Data Management Part:

- Non-compartmental pharmacokinetic analysis using validated Kinetica™ software.
- Assessments of Bioequivalence.
- Tabulation, graphical display, analysis and interpretation of study data.
- Study design and development of Protocol and Informed Consent Form (ICF).
- Designing of Case Report Form (CRF) as per protocol requirements.
- Preparation of Bioequivalence Report, Clinical Report, Analytical Report and Statistical Report.
- Sample Size Estimation and Randomization.

3. Clinical Part:

- Screening area for physical examination.
- Sample collection rooms.
- Complete examination of volunteers with close monitoring during two study phase for the expected AE/SE.
- Notify the drop-out volunteers with a copy from his analysis report, and follow them up.
- The BE Center contracted with El-Safwa Hospital for emergency cases.
- First Aid cupboard.
- Dining room.
- Storage freezers (-70 and -20° C).
- Archives for secure document storage.

4. Quality Assurance System:

Quality Assurance Unit ensures that studies are performed in accordance with Good Laboratory Practice (GLP)-Good Clinical Practices (GCP) regulations and through in house procedures. Also, it is responsible for document controlling of study protocols, analysis plans, SOPs & policies; and ensuring the updated versions of these controlled documents are effective and in place or accessible to relevant staff. QA unit is responsible for regular auditing which include:

- Study source documentation, procedures, and reports; and provides regulatory advice and support to the operational staff.
- Facility & system, to check adequacy & eligibility of resources and proper utilization of provisions.