



Catalyzing Innovation

## CLINICAL RESEARCH SERVICES

### ● INTERNATIONAL ACCREDITATIONS & APPROVALS

- ▶ Drugs Controller General (India)
  - ▶ UKMHRA (Projects approved)
  - ▶ MOH - Turkey
  - ▶ BPFK - Malaysia
  - ▶ Health Canada (Projects under review)
  - ▶ USFDA (Projects under review)
- More than 40 pivotal studies

### ● ACTIVITIES

#### > Clinical

- ▶ Volunteer Recruitment
  - Mixed Gender- Healthy
  - Biometric Supported Database
- ▶ Crossover /Parallel / Replicate / Proof of Concept design
- ▶ Steady State
- ▶ Food Effect
- ▶ Drug Drug Interaction
- ▶ Patients

#### > Bioanalytical

- ▶ Method Development
- ▶ Method Validation
- ▶ Biological Sample Analysis
- ▶ Pre-Clinical Sample Analysis

#### > Pharmacokinetics & Statistics

- ▶ WinNonlin
- ▶ SAS

### ● INFRASTRUCTURE

- ▶ 72 bedded 3 independent clinics
  - 2 clinics x 18 beds with 2 bed ICU
  - 1 clinic x 36 beds with 2 bed ICU
- ▶ State-of-the-art Bioanalytical Laboratory
- ▶ Documentation Archival

### ● EQUIPMENTS

#### > Clinical

- ▶ All major ICU equipments
- ▶ Humidity Chambers in Pharmacy
- ▶ Deep freezer -30°

#### > Bioanalytical

- ▶ 4 LC-MS/MS
  - ▶ 3 deep freezers -86° with CO<sub>2</sub> backup
  - ▶ Deep freezer -30°
  - ▶ Eurotherm-Data logger for Online Temperature Monitoring
  - ▶ Vibramax (Liquid-Liquid Extraction)
- (This is a representative list)

### ● ANALYTICAL CAPABILITIES

- ▶ More than 50 Methods Developed
- ▶ More than 40 Methods Validated
- ▶ Detection limits upto pg/mL
- ▶ Quantification of Isomeric compounds

### ● QUALITY ASSURANCE

- ▶ Dedicated staff for complete monitoring of the activity
- ▶ Practices as per International Regulatory guidelines



Clinical Research Division Of  
**RA Chem Pharma Ltd**