VerGo Pharma Research Pvt. Ltd

Division of VerGo Clinicals

A private limited company registered in September 2010 under "Companies Act 1956"

Commenced operations in February 2013

Regulatory Inspections and Approval history

CDSCO (India)	• Approval-Feb 2013, • Subsequent approval in July 2016, Nov-2017, Dec-2020 (Validity : 5 years) • Approval of additional 66 beds – June 2023
NPRA (Malaysia)	• Audit 03-Oct-2016 to 07-Oct-2016. • Approval granted in Feb 2017 • Surveillance Audit:23-Sep-2019 to 27-Sep-2019 • Re-approval granted in Feb 2020 (Valid up to 07-Feb-2025) • NPRA Inspection (*Ongoing) – 24th till 28th June 2024
MHRA (UK)	• Inspection from 06-Mar-2017 to 10-Mar-2017 • Closeout Letter issued on 11-May-2017 • Inspection from 09-Aug-2021-13-Aug-2021 • Closeout Letter issued on 15-Nov-2021
WHO	• Inspection from 16-Apr-2018 to 19-Apr-2018 • Closeout Letter issued on 20-Jul-2018 • Inspection held from 24-May-2022 to 27-May-2022 • Closeout Letter issued on 07-Sep-2022 • Inspection from 22-Jan-2024 to 26-Jan-2024 • Closeout Letter issued on 03-Apr-2024
USFDA	• Remote Record Review Inspection from 18-Apr-2022 to 21-Apr-2022 • Closeout Letter issued on 21-Apr-2022 (No observations) • Onsite Inspection from 04-Jul-2022 to 08-Jul-2022 (EIR dated 09-Jan-2023) • Onsite Inspection from 06-May-2024 to10-May-2024 (Bioanalytical review - No observations – No form 483) • Onsite Inspection from 29-May-2024 to 04-Jun-2024 (Clinical review - No observations – No form 483)

Facility Layout

Floor	AREA (Sq. Mt.)	Particulars
Basement	140.32	Pathology laboratory (VerGo Pathology)
Ground Floor	1473.04	• Screening and registration • **Clinical Unit I (17 beds)** • Pharmacy • ICU • Archive II • Walk in cold room (-20^{o}C) • Data Mangement • Project Management • Administration area
First Floor	1251.39	• **Clinical Unit II (48 beds)** • Bioanalytical Laboratory • Quality Assurance • Server Room
Second Floor	851.30	• **Clinical Unit III (48 beds)** • Archive-I
Third Floor	323.30	• **Clinic IV (53 Beds)** • Kitchen

Clinical Facility

- Dedicated Pharmacy for Storage and Dispensing of Investigationals Products
- Dedicated Screening and Volunteer Registration Area
- Clinical Units

- Facilities in Clinical units
- Spacious wards
- Phlebotomy Room
- Nursing Station
- Emergency bell- each bed side
- Dinning Area
- Entertainment with Audio Visual Amenities
- Sample Separation and Storage Area

Volunteer Registration and Screening

Volunteer Database

- A pool of 18000+ volunteers (male, female and Post menopausal female volunteers)

Process & Procedures

- Photo ID & Biometrics
- Medical examination
- ECG
- Lab Investigations (VerGo Pathology)
- X-ray (out sourced)

Emergency Handling

EMERGENCY EQUIPMENTS

- Well, equipped two bedded ICU
- Defibrillator, Cardiac Monitors, Oxygen cylinder, Ambu Bag, Suction machine, Nebulizer and Emergency Medications

EMERGENCY HANDLING FACILITY

- Medical and Para-medical staff available round the clock Collaboration with hospital for emergency handling Ambulance on Standby

Human Safety & Human Rights

Approval Obtained from Independent/Institutional Ethics Committee for

Informed Consent Documents & Forms

Protocols

Subject compensation plans

No repeat testing of volunteers in less than 90 days

Clinical Trial Liability Insurance

Type of Studies & Dosage Form Handled

Type of Studies

- Fasting Studies
- Fed Studies
- Steady State (Multiple Dose Studies)
- Pharmacokinetic Studies

Type of Dosage Forms

- Solid Oral (Tablet, Capsules)
- Suspension
- Liquids
- Suppositories
- Oral Thin Films

Bioanalytical Facility

Sample storage and handling facilities

- Freezers for sample storage (6 Nos)- (-20oC, -30oC and -70oC)
- Walk in Cold Room (-20oC)
- Refrigerator for storage of working standard and Stock solution (2 Nos) (* All freezers & refrigerators are continuously monitored)

Well equipped sample processing laboratory

- Centrifuge, Vibramax Shaker (LL extraction) & SPE extractors

Detection methodologies

- AB Sciex LC/MS/MS instruments – 9 Nos
- (1 API 3200 , 2 API 4000 Q trap, 4 API 4000 and 2 API 4500) coupled with Shimadzu HPLC as a frontend system)

Quality Assurance System (QA)

Independently monitors Clinical, Bioanalytical, PK & Stat activities to ensure compliance to Protocol, SOPs, GCP, GLP and other regulations

- Control revision of Standard Operating Procedures and applicable forms
- Conduct annual internal System audits and Vendor audits
- Monitor study for Protocol and SOP compliance
- Audit data to ensure that it accurately reflects the source data

Information Technology

Hardware

- HP Prolient Tower and Rack Servers
- Lenovo/Dell/HP Client PCs

Access control

- Selective departmental access for authorized personnel

Backup

- Daily backup using Veeam Backup and replication software
- Daily, weekly, monthly and yearly backup on LTO-8 Magnetic tapes

Human Resource

Qualified, Experienced & Skilled manpower

Clinical Team

- Principal Investigator
- Clinical investigators
- Qualified Medical Doctors
- Research Scientist
- Medical assistants
- Nurses
- Phlebotomists

Bioanalytical Team

- Bio-analysts (M.Pharm, B. Pharm, M. Sc)

Medical Writing Team

- M. Pharma

PK & Biostatistics Team

- Biostatistician (M.Sc)

Pathology Lab

ISO 15189:2012 Approved Pathology Lab

- Fully automated 5 part differential Hematology analyzer from Horiba (Pentra ES 60)
- i-smart 30 pro Electrolyte Analyzer
- Fully automated Biochemistry analyzer from Siemens Xpand plus
- Urine Analyzer from Roche

Accreditations (NABL):

- First grant: 21-Jul-2015 in accordance with ISO 15189:2012 (2 yrs)
- 1st Renewal audit : 21-Jul-2017 to 20-Jul-2019
- 2nd Renewal audit : 21-Jul-2019 to 20-Jul-2021 (Extended to 1 year)
- 3rd Renewal audit : 16-Jul-2022 to 17-Jul-2024

Thank You