VerGo Pharma Research

A leading Contract Development, Manufacturing & Clinical Research Organization

VerGo Clinicals
Spirit of Health

VerGo Pharma Research
Spirit of Innovation

VerGo Organics
Spirit of Synthesis

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Formulation Development

- **Formulation Development of Oral Solids:**
  Tablets (IR, SR, ER, DR (Enteric)
  ODT (including MUPS)
  Sublingual & Effervescent Tablets
  Capsules (IR, SR, ER, DR (Enteric)
  Powders & Pellets
  Oral powders & Granules in sachets or bottles

- **Formulation Development of Oral Liquids:**
  Solutions, Suspensions, Syrups & Drops

- Development of FTF & Para IV products
- Platform drug delivery technology development
- Development of feasibility & POC for NCEs

Special Product Development

- Dedicated laboratory for solid & liquid dosage forms of Cytotoxic drugs, Hormones, Steroids, Immuno-suppressants

Analytical Development

- Method development & Method validation
- Pre-formulation studies
- Dissolution USP - Type I, II & III
- Equipped with GC, HPLC, FTIR, UV-VIS, AAS, UPLC, DSC, Prep-HPLC
- Dedicated Cytotoxic product testing laboratory
- Impurity isolation & characterization

cGMP Manufacturing

- MHRA, TGA Australia & WHO approved cGMP facility
- Capability to manufacture pilot, submission & commercial batches of solid oral dosage products
- Capability to manufacture micro dosage products
- Current annual capacity - 400 million tablets/capsules with significant scope for expansion
- EU-FMD compliant facility integrated with ACG TracknTrace serialization
- Batch size flexibility (2-200kg)
- Batch scale-up capacity (5kg-200kg)
- RMG (25L, 50L, 100L & 250L)
- Roll compaction with water jacket to maintain 7-8°C
- Coating machine (Neocota 40D/50D)
- Blender (25L, 50L, 75L, 150L, 300L, 600L, 1000L)
- Bi-layer compression machine (40 RH)
- FBE-125 top spray (60L & 125L)
- FBE-125 bottom spray (40L & 84L)
- Capsule filling machine (Pam AF 25T) with pellet & tablet filling attachment
- El Mach 3010 high speed blister packing machine - cold and thermos packing

Stability Studies

- ICH stability testing (All IV zones including zone IVB) with a qualified standby stability chamber
- Stability chamber capacity of 100,000L expandable up to 250,000L
- 21 CFR Part 11 compliant Yokogawa data acquisition software
- Freeze thaw studies (-18°C stability chamber)
- Photo stability studies
- Semi-permeable container testing
- Stress testing (50°C)

Clinical BA/BE Studies

- Approved by CDSCO (India), MHRA (UK), NPRA Malaysia (PIC/s), WHO-Geneva, & USFDA
- GCP/GLP compliant facility
- BA/BE, Steady state, Pk studies on healthy volunteers & special populations for multiple dosage forms
- 166 bed facility across 4 clinical units
- Bio-analytical laboratory with 9 LC-MS/MS
- NABL approved Pathology laboratory (ISO 15189)
- Fully equipped 2 bed ICU
- Integrated data management & regulatory support
- Protocol preparation to reporting in e-CTD format
- VIMS & OVIS software for volunteer registration & prevention of cross-participation
- SAS® software for pharmacokinetic & statistical evaluation

Custom Synthesis Laboratory

- Chemical testing & organic synthesis laboratory for the development of novel & established compounds
- Custom synthesis of organic compounds including medical chemistry scaffolds & API impurities
- 120 ft. linear fume hoods
- API process development, scale-up to kilogram level
- Expertise in NCE and nucleic acid intermediates
- In-house stock and synthesis processes available for ~1000 molecules