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Formulation development

of various dosage forms for preclinical and clinical use

- Laboratory spread across 9000 Sq.ft.
- ICH compatible stability testing for small and large molecules
- Advanced analytical facility
- Seamless tech transfer

Capabilities

Preformulation

- Physiochemical properties, Solubility, solid state compatibility & stability studies

Early formulations for preclinical dosing

- Formulation development including analytical support

Formulation Development and Scale up/ Technology transfer for clinical trials

- Oral dosage forms like oral solutions and suspensions, uncoated and coated tablets, capsules, Modified Release formulations etc.
- Parenteral dosage forms
- Development based on QbD principles
- Glatt fluid bed processor, Rapid Mixer Granulator (RMG), Compression machine, Capsule filling machine, Lyostar III, Coating machine, Roll Compactor

Analytical method development and validation as per ICH guidelines

- Chromatography, Modulated DSC 8000, KF Coulometer, UV assay, compendial methods, HIAC particulate counter, Osmometer

Stability study of drug product

- Multiple storage conditions as per ICH recommendation
- Photo stability studies

Parenteral Development Capabilities

Type of Molecules:

- Small molecules
- Large molecules - peptides & proteins

Liquids

- Aqueous and Non-aqueous solutions
- Suspension and Emulsions

Powders

- Dry fill and Lyophilized

Type of sterilization processes:

- Terminal Sterilization
- Aseptic processing

Type of packaging configurations:

- Vials
- Pre-filled syringes
- Cartridges

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