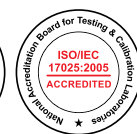


# BIONEEDS

Integrated Discovery, Development & Regulatory Services



## CHEMISTRY SERVICES



### Medicinal Chemistry

- Building blocks, scaffold based library synthesis
- Structure Activity Relationship (SAR) generation with drugability parameters
- Lead generation and optimization

### Custom Synthesis

- Small molecules involving multi step synthesis
- Impurities and metabolites
- Key/advanced intermediates

### Process Research

- Process development & optimization to achieve cost reduction/green process/effluent reduction for intermediates (Pharma and Agro)
- Non infringing process development for APIs and AIs
- Tech transfer for commercialization
- GMP packages for APIs with material generation

### Drug Development Services

- Process development & supply of material for IND enabling studies
- GMP material generation for FIH studies
- Complete CMC package as a part of IND
  - Process and analytical method development
  - Impurities profiling and quantification
  - Phys-chem studies
  - Process and analytical method validations
  - IMPD dossier preparation
  - Tech transfer

### Analytical Services

- Method development, validation and transfer
- Raw material characterization as per latest pharmacopoeia (USP/BP/EP/IP/JP)
- Qualification of standards: Characterization & establishing assay by mass balance (potency determination)
- Quantification of organic volatile impurities & residual solvents as per latest pharmacopoeia/ICH
- Impurity profiling: Method development, identification, isolation & characterization
- Batch release testing
- Forced degradation as per ICH: Acid, Base, Oxidation, Thermal & UV exposure conditions
- Stability studies as per ICH guidelines
- Dossier preparation & support in regulatory submissions

#### GLP Accredited Preclinical Development Center

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