Discovery Research

New Chemical Entities (NCE) Formulations

Discovery Research
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Overview

Suven Life Sciences

Formulation Development

110,000+ sq. ft of World-class Infrastructure comprising

- Formulation Development Laboratories
- Process Development Laboratories
- cGMP Scale-up, Manufacturing and Packing of Exhibit and Clinical Supply Batches
- Packaging Development and Testing Laboratories
- Analytical Method Development & Validation Laboratories
- Dissolution Testing Laboratory
- Wet Chemistry Laboratory
- Microbiology Testing Laboratory
- Stability Chambers (220,000 L)
- Warehouse

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Formulation Development Center









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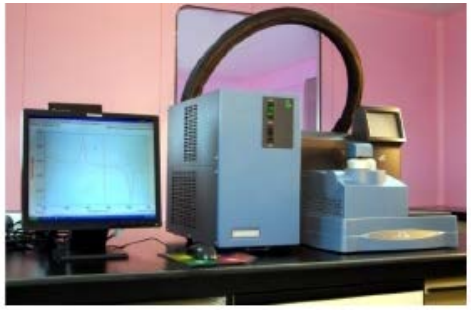
Preformulation



Screening

- Salt and co-crystal screening
- Crystallization screening
- Polymorph screening

Selection

- Hygroscopicity
- Solubility
- Chemical stability
- Physico Chemical Parameters (Log D, Log P, pKa etc.,)
- Hydrates / Solvates

Solid State

- Thermal properties
- Surface morphology, Particle size
- FTIR, Raman, XRD, Cross Polarized Microscopy, DSC, TGA, DVS etc.,
- Compatibility studies

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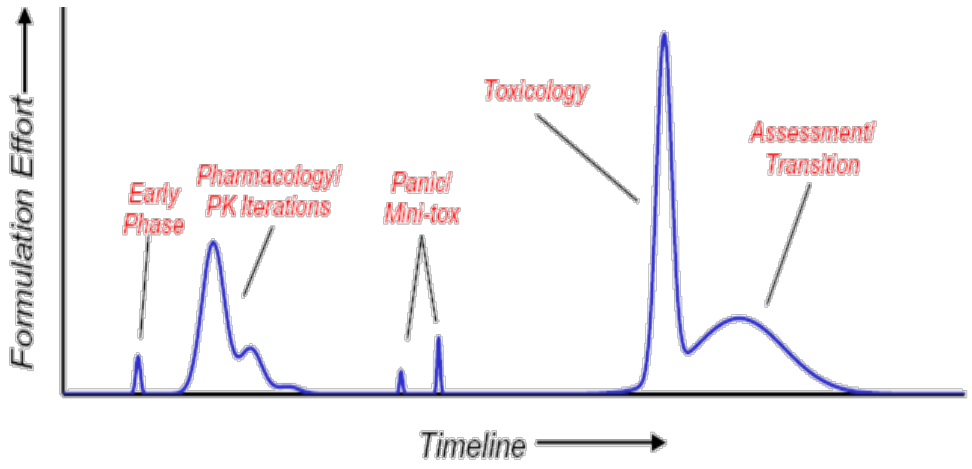
Preclinical Formulations

- Vehicle selection for PK and PD Studies
- High dose formulations for Tox studies
- Solutions and Suspensions formulations for rodents and non-rodents
- Solubilization
- Enabled formulations (SDD, Lyo powders, nanocarriers etc.)
- Dose formulation analysis
- Formulation stability evaluation



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Formulation Development Services

Product Development

- Oral Dosage Forms
- Transdermal Dosage Forms
- Novel Drug Delivery Systems
- Dosage Form Design

Manufacturing

- Solid & Liquid Oral Dosage Forms
- Topical Solutions

Analytical Development

- Method Development and Method Validations
- Impurity Profiling and RS Estimation
- Microbiology
- Stability Management

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Formulation Dosage Forms

Oral Solids

- Tablets, Capsules, Mini Tablets, Pellets, MUPS, ODT and ODF

Oral Liquids

- Solutions, Suspensions and Emulsions

Novel Formulations

- Lipid Formulations, Sprays, SMEDDS, SDD, Nanosuspensions, Liposomes

Topicals

- Creams, Ointments, Gels, Sprays and Transdermal patches

Parenterals & Ophthalmics

- Solutions, Suspension, Nanoemulsions and Implants

Aerosols

- Propellent & Propellent Free Aerosols

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Formulation Technologies

Solid Dosage Forms

- Blending
- Dry / Wet Granulation
- Roller Compaction
- Hot Melt Extrusion
- Fluid Bed Coating / Drying
- Spray Drying / Congealing
- Taste Masking
- Extrusion/Spheronization
- Encapsulation
- Core Compressed Coating
- Pan Coating/Drying

Liquid & Semisolid Dosage Forms

- Mixing
- Homogenization
- Size Reduction
- Lyophillization

Topical Dosage Forms

- Gels
- Sprays
- Foams
- Transdermal Patches

Parenteral Dosage Forms

- SEDDS / SMEDDS
- Liposomes
- Nano Emulsions
- Nanoparticles
- Implants

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Drug Product for Clinic Studies

- Drug Product Manufacturing for Clinical Trials
- COA Generation and Release
- HDPE Packaging and Stability storage as per ICH conditions
- HDPE Bottles Labeling as per IND phase I to phase III studies
- Method Development and Validations
- Stability Studies to submit periodically to IND
- 3.2.P IND documents preparation for e-CTD
- Shipment of clinical supplies to US Drug Product Depot and clinical CRO.

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Formulations for Phase – I, II & III

Capsule Formulations

- API-in-Capsule
- Powders / Blends
- Encapsulation
- Multi Particulates (Granules & Beads)
- Tablet in Capsule
- Liquid Filled Capsules
- MUPS

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Formulations for Phase – I, II & III

Tablet Formulations

- Immediate Release
- Modified Release
- Orally Disintegrating (ODT)
- Multi-Layer Tablets
- Mini / Micro-Tablets
- Multi-API Combination Products
- Press coated

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Formulations for Phase – I, II & III

Coated Formulations

- Coating of Granules
- Coating of Beads
- Functional Coating of Tablets
  - API Coated
  - API + Barrier Coated
  - Taste Masking
- Non Functional Coating of Tablets
  - Barrier Coating
  - Coating for Elegance

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Formulations for Phase – I, II & III

Liquid Formulations

- Solutions
- Suspensions
- Emulsions
- Microemulsions
- Nanoemulsions
- Nanosuspensions
- Lyophilized powders
- Syrups

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Formulations for Phase – I, II & III

Novel Formulations

- Thin Films
- Transdermal Patches
- Potent Formulations
- SMEDDS
- Liposomes
- Sprays
- Aerosols
- 3D Printing

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Analytical Support for Phase – I, II & III

Capabilities Outline

- Analytical Method Development
- Method Transfer & Validations
- Analytical Workforce – HPLC, UPLC, LC-MS/MS
- Preformulation charecterization
- Solid State Charecterization
- Stress Studies
- Degradation Studies
- Tensile Testing
- ICH Stability Studies
- Microbial Testing
- Ultra Micro Weighing
- Powder X-Ray Diffraction
- Hot Stage Microscopy
- Polarized Microscopy
- Particle size – Sympatec
- Size & Zetapotential – Zetasizer
- Texture Analyzer
- Beckman Ultracentrifuge

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Drug Product Packaging for Phase – I, II & III

Solids

- Blister Packing – Manual Line
- Blister Packing – Automated Line
- Bottle Packing – Manual Line
- Bottle Packing – Automated Line

Liquids

- Bottle Packing
- Vials and ampoules
- Sprays

Aerosols

- Propellent and Propellent Free Aerosols

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Drug Product Packaging for Phase – I, II & III

Labeling Services

- Lable Design
- Lable Printing
- Tamper-evident
- Barcoding – 1D, 2D (Worldwide)
- Regulatory compliant
- Booklets
- Randomized and open
- Variable text
- Child-resistant
- Temperature resistant lables -80 to +50°C

Logistics

- Universal Shipments
- Temperature Logger
- Cold chains

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Quality Assurance

- Independent Quality Assurance Team
- SOPs for Operation, Calibration, Maintenance and Quality Systems
- Document and Data Control, Conducting Internal Audits, Study Specific Audits
- Review, Approval, Control and Issue of all documents related to the manufacturing
- Batch records review, OOS & OOT Investigation and resolving
- Dedicated Archive facility for the retention of the records
- Facility audited and approved by many global pharmaceutical companies and majority of Indian Pharma Companies

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Regulatory

- Ensure adherence and compliance with all the applicable cGMP, ICH, GCP, GLP guidelines, regulations and laws
- Preparation of IND documentation in eCTD format
- Experienced in US IND filing
- Acts as a liaison with regulatory agencies and consultants
- Submission of the annual reports for the regulatory agencies
- Qualification of CRO, review and audits

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