



SUVEN NISHTAA

PHARMA PRIVATE LIMITED

A group company of Suven Life Sciences Ltd

A Complete Pharmaceutical Product Services Organization

Presentation

NCE Product Development & Novel Drug Delivery Systems



SUVEN'S BUSINESS MODEL



Drug Discovery



Drug Product Delivery

Chem lib /
comb chem hits

Lead
identification /
characterization

Lead
Optimization

Pre
Clinical

Clinical
Trials

Process
Research

Custom
Synthesis

Formulation
Development,
Analytical &
regulatory
Services

Clinical
Supplies
Manufacturing
& Packaging

Drug Discovery & Development Support
Services (DDDSS)

Contract Pharma Services



Services offered by Suven Nishtaa

SUVEN NISHTAA – CAPABILITIES OVERVIEW



110,000+ sq.ft of world-class infrastructure comprising:

- Formulation Development Laboratories
- Dedicated and Customized Laboratories for Formulation Development
- Technology Laboratories for New Drug Delivery Systems Development
- Process Development Laboratories
- Packaging Development and Testing Laboratories
- cGMP Scale-up, Manufacturing and Packing of Exhibit and Clinical Supply batches
- Analytical Method Development & Validation Laboratories
- Microbiology Testing Laboratory
- Stability Chambers
- Warehouse

- **Pharmaceutical Product Development Services**
 - NCE Products
 - Generic Products
 - Novel Drug Delivery Systems
- **Pharmaceutical Product Scale-up and Manufacturing Services**
- **Pharmaceutical Analytical Services**
- **Regulatory Management Services**

PHARMACEUTICAL PRODUCT DEVELOPMENT SERVICES

NCE Product Development
Novel Drug Delivery Systems

FORMULATION DEVELOPMENT

- **Pre-clinical Pharmaceutics**
 - **Solubility Studies**
 - Solvent based
 - pH dependent
 - **Hygroscopicity studies**
 - **pH Stability profiling**
 - **Polymorph stability Evaluation**
 - **Dosage form selection**

FORMULATION DEVELOPMENT

- **Preformulation Studies**
 - Solubility
 - Hygroscopicity
 - pH Stability profiling
 - Compactibility / Compressibility
 - Particle Size Distribution
 - Polymorph stability Evaluation
 - Photostability
 - Drug-Excipient Compatibility

PRODUCT DEVELOPMENT

- **Formulation Development for Pre-clinical & Clinical studies**
 - Early Clinical formulation Development
 - Selection of Excipients and Composition
 - Stability testing
- **Process Development & Optimization**
 - Process Selection
 - Process Evaluation & Optimization
 - Scale-up to Laboratory & Pilot Scale

PRODUCT DEVELOPMENT

- **Packaging Development for Clinical supplies**
 - Selection of Packaging materials
 - Container-Closure system selection
 - Selection of Blister foils/films
 - Selection of Packaging configuration
 - Product Labeling - Multilingual
 - Medication Card designing

CLINICAL SUPPLIES

- Clinical Supply Manufacturing including Placebos
- Clinical Supply Packaging
 - Multi Product / Multi strength Blister packing for blind studies
 - Thermo forming
 - Cold forming
 - Child Resistant Packaging (CRP)
 - CRC bottle packing
 - Peel-Push through Blisters
 - Tamper evident Packaging

COMPARATOR PRODUCT

- Comparator Product Characterization
 - Physical Characterization
 - Chemical Characterization
 - Assay
 - Related Substances
 - Dissolution Profiling
- Comparator Product Blinding
 - Over coating
 - Over encapsulation (intact and broken)
- Comparator Product Development and testing

SOLID ORAL DOSAGE FORMS

| Dosage form | Capabilities |
|------------------------------|----------------------------|
| Tablets (coated & uncoated) | √ <input type="checkbox"/> |
| Hard gelatin capsules | √ <input type="checkbox"/> |
| Controlled bead formulations | √ <input type="checkbox"/> |
| Soft gelatin capsules | √ |
| Powders | √ <input type="checkbox"/> |
| Granules | √ <input type="checkbox"/> |

√ **Development Capabilities**

Scale-up and Commercial manufacturing

LIQUID ORAL DOSAGE FORMS

| Dosage form | Capabilities |
|-------------|--------------|
| Solutions | √ |
| Suspensions | √ |
| Drops | √ |
| Emulsions | √ |

TOPICAL PREPARATIONS

| Dosage form | Capabilities |
|---------------------|--------------|
| Ointments | √ |
| Creams | √ |
| Gel preparations | √ |
| Transdermal patches | √ |

√ Development Capabilities

STERILE DOSAGE FORMS

| Dosage form | Capabilities |
|--------------------------|--------------|
| Injections | √ |
| Ophthalmic preparations | √ |
| Lyophilized formulations | √ |

√ **Development Capabilities**

SPECIAL CAPABILITIES

| Dosage form | Development |
|-------------------------------|----------------------------|
| Spray dried formulations | √ |
| Controlled Oral formulations | √ <input type="checkbox"/> |
| High potent Drug formulations | √ |
| Onco / Cytotoxic formulations | √ |
| Steroid formulations | √ |
| Multilayered Tablets | √ <input type="checkbox"/> |
| Compression coated Tablets | √ <input type="checkbox"/> |

√ **Development Capabilities**

Scale-up and Low volume commercial manufacturing





- Efficient Drug Delivery
- Life Cycle Management

TECHNOLOGIES

- Aqueous Solubilization
- Topical Drug Delivery
- Pulmonary Drug Delivery
- Orally Disintegrating Tablets
- Oral Controlled Release Systems

AQUEOUS SOLUBILIZATION

- Aqueous Solubility enhancement
- Alternative dosage form development
- Improve drug release & Bioavailability

TOPICAL DRUG DELIVERY

- Drug Formulations for Cutaneous & percutaneous delivery
- High Drug loaded topical Formulations
- Controlled / Sustained release topical formulations
- Matrix / Reservoir based Patch formulations
- Lipid based penetration enhanced systems

ORAL CONTROLLED RELEASE SYSTEMS

- Matrix based formulations
- Reservoir based formulations
- MUPs
- Biphasic release systems
- Target organ release systems

PULMONARY DRUG DELIVERY

- Formulation for Localized action
- Formulation for Systemic action
- Protein/Peptide delivery
- Porous & Low density Micro/Nanoparticulate systems

ORALLY DISINTEGRATING TABLETS

- Drug encapsulated solid porous Microcapsules
- Formulations for faster action
- Formulations for improving bioavailability

PRODUCT DEVELOPMENT

INFRASTRUCTURE


Suven Nishta



A World class and state-of-the-art infrastructure with 18000 sq ft area comprising:

Formulation Development Laboratories – 6 Nos

- Equipped for conducting Preformulation and Prototype development studies
- Provided with access controls

Process Development Laboratories – 2 Nos

- Automated equipment with PLC controls
- Flexible batches ranging from 0.5 kg to 3 kg

Technology Development Laboratories – 8 Nos

- Dedicated laboratories for Platform technology development

Packaging Development Laboratory

- Equipped with blister and bottle packaging facilities

Storage areas

- Raw material Stores
- Packaging Material Stores
- Product Stores

Stability Testing Area

- Walk-in Stability chambers
- Accelerated, Intermediate, Long term and various temperature Zones

Equipment Wash & Cleaned Equipment Storage Area

- Dedicated area for washing and cleaned equipment storage

Laboratory to Pilot Plant – Equipments of Similar Design and Work Mechanism



Rapid Mixer Granulator (RMG)

- Inter changeable bowls of 3, 5 & 10 L capacity
- Hydraulic lifting arrangement for bowls
- Flexible batch sizes ranging from 0.5 to 3 kg

Blenders

(Double Cone & Octagonal)



- Replaceable bowls of 5 & 20 L capacity
- Flexible batch sizes ranging from 0.5 to 7 kg





Automated Tablet Press

- 10 station Rotary Tablet compression machine
- Precompression facility
- Both manual and force feeding options

Automated Capsule Filling Machine

- Automated, Mini capsule filling machine
- capability to fill pellets, pellets and powders
- Tablets in capsule and pellets and tablets in capsule





Fluid Bed Processor (FBC)

- PLC based equipment
- Particle/pellet coating
- Top spray granulations
- Batch sizes 0.5 - 2 kg

Fluid Bed Dryer

- PLC based equipment
- Granule drying
- Top spray granulation
- Batch sizes up to 2 kg





Automated Coating Pan

- PLC based, Automated equipment
- Replaceable pans
- Flexible batch sizes ranging from 0.5 kg to 5 kg

Blister Packaging Machine

- Laboratory Blister packing machine
- Alu/Alu Blisters
- PVC blisters



Roll Compactor, Granulator and Sizer:

- Single equipment for Compaction, milling and sizing
- 2-3 kg/hr capacity
- Jacketed roller chamber
- Variable speed controls

Microniser:

- 5-15 kg/hr capacity for size reduction
- Jacketed milling chamber
- Variable speed controls



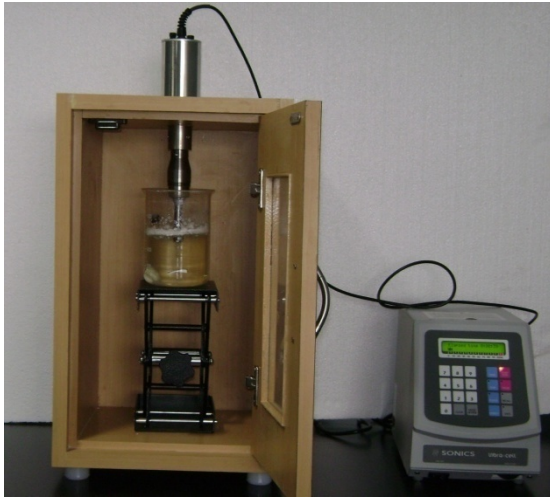
Lyophilizer

- Bench top Lyophilizer
- Programming in both manual and auto mode
- 6L capacity : Accommodates 400 vials of 2 ml size
- Stoppering facility

Spray Dryer

- Table-top Spray dryer
- Aqueous & non-aqueous applications
- 1000ml of water evaporation/hour





Probe Sonicator

- Suitable for Nanoparticles / Liposomes
- 0.2ml - 5 L capacity

Silent crusher

- Suitable for emulsions/Suspensions
- Particle size reduction
- 2 ml- 2 L capacity



PHARMACEUTICAL PRODUCT SCALE-UP AND MANUFACTURING SERVICES

Capabilities for the manufacture of:

- Tablets
- Capsules
- Pellets
- Granules
- Powders



Facilities, Systems, Procedures & Practices meeting cGMP requirements of any regulatory agency

PRODUCT SCALE-UP & MANUFACTURING

SERVICES



A State-of-art, world class clean room manufacturing facility for manufacturing Exhibit/Submission batches & commercial supplies



| Capabilities | Dosage forms |
|----------------------------|---|
| Scale-up & Exhibit batches | Tablets Plain Coated Capsules Pellets Powders Granules |
| Low Volume Manufacturing | Tablets – 500,000 / shift Capsules – 200,000 /shift Pellets – 50 kg / shift |



- Raw Material Stores
- Packing Material Stores
- Printed packing Material Stores
- Secondary Packing Material Stores
- Finished Product Stores
- Sampling & Dispensing Area

Temperature and RH controlled

- IND / NDA Support Documentation
- Preparation of Regulatory Responses
- Post Approval Regulatory Changes
- Compliance Audits
- Submission of Annual Reports

- Supports the management of Intellectual Property
- Committed to maintaining and Managing the Confidentiality of the information, data and transactions
- Committed to Functional & Transactional Integrity



The Quality Assurance Management system delivers and assures the defined Quality Product(s), through well structured process of designing, defining, documenting, training and facilitating all the Quality Delivery resources. The process runs through, but not limited to, Systems and Procedures connected with Procurement, Ware-Housing, Production, Analytical, Engineering and Facilities.

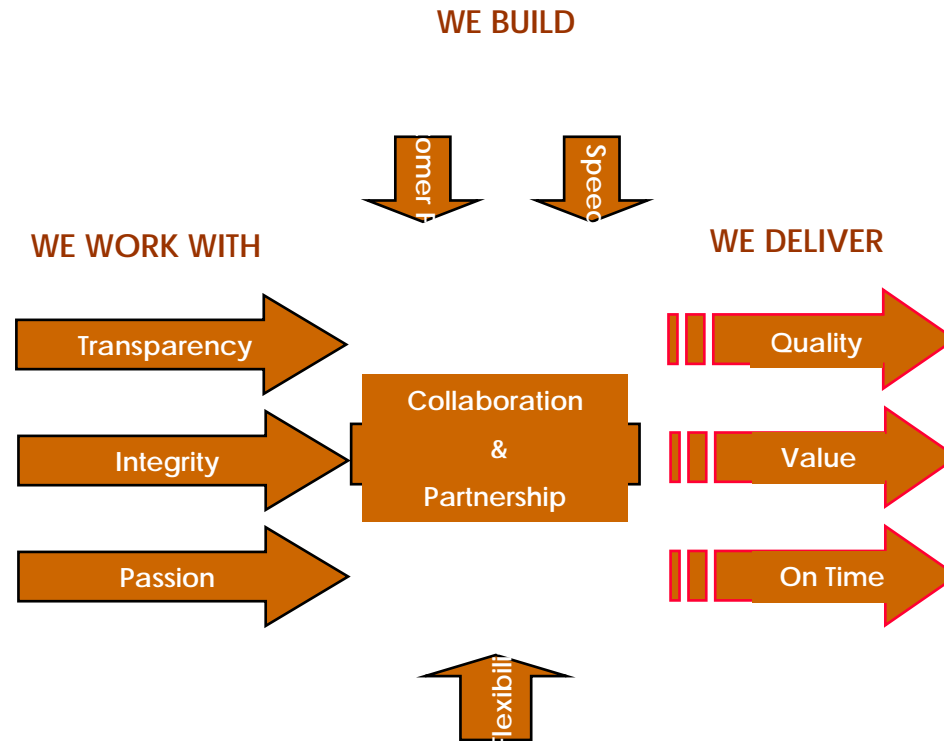


- **Self, Internal and Compliance Audits** will ensure that the Quality is managed in the way it is defined to be delivered.
- **Deviations/incidents are detected on line and handled appropriately** to ensure that they do not impact the assured Quality. Changes, if any will be handled through a defined and controlled process.
- **Manufacturing and Analytical Assurance** to ensure Identity, Strength, Purity and Quality of Drug Product manufactured.
- Structured process for **issuance, control and archival** of all approved documents



- **An Organization Structure to support the organizational goals and functional deliverables**
- **Well qualified and highly experienced Functional Heads**
- **Personnel recruited with predefined Qualifications**
- **Structured induction process and training program**

COLLABORATION - PARTNERSHIP



CONTACT DETAILS



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THANK YOU