

# Suven Life Sciences

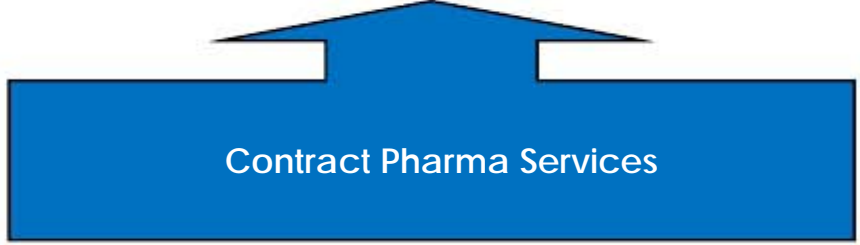


**A Treasure House of  
Innovations and  
Excellence**

# Company Overview

- Established in 1989
- Profitable and dividend paying since listing in 1995 on the NSE and BSE
- Established presence across Contract Research and Manufacturing Services (CRAMS) - Leader and Innovator for NCE based Intermediates
- Drug Discovery – Focused on CNS segment
- World-class infrastructure, equipment and models with over 800 employees
- Robust financials and a healthy balance sheet
- Formulation Development and Manufacturing Services
- USFDA inspected facilities

# SUVEN'S BUSINESS MODEL



 Services offered by FDC





## Of Pharmaceutical Relationship

### DDDSS

- Leader in CNS based internal discovery in India
- State of the art facility, models
- Multiple big Pharma relationships

### CRAMS

- Leader and Innovator for many NCE based intermediates
- 600+ projects
- 380+ R&D professionals
- Generic API's

### FORMULATIONS

- Pharmaceutical product development
- Product scale up and manufacturing services
- Pharmaceutical Analytical services
- Regulatory management services

*Relationship with more than 22 global pharmaceutical companies*

# Financials

Year Ending March '31	2015	2014
	Million (Rs)	Million (Rs)
Income	5,188.73	5,294.36
Pre-R&D EBITDA	2,055.55	2,250.02
Pre-R&D EBITDA Margin	39.62%	42.50%
EBITDA	1,426.04	1,680.40
EBITDA Margin	27.48%	31.74%
EBIT	1,258.83	1,562.64
EBIT Margin	24.26%	29.52%
Financing Costs	54.17	47.09
Taxes	254.98	428.04
Net Profit after tax	949.69	1,087.50
NP Margin	18.30%	20.54%
EPS (basic & diluted not annualised)	7.46	9.04
Paid up Share Capital (One Rupee Share)	127.28	127.28
Depreciation	167.20	117.76
R&D expenses	629.51	569.63

# Formulation Development Centre

# CAPABILITIES OVERVIEW

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

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

# FDC Services

## Formulation Development Centre

*-a Natural extension to the existing CRAMS Business*

### Formulation Development

NCE's

ANDA's

NDA's (Differentiated Products)

OTC

### Analytical Development

Method development

Method Validations

Impurity Profiling

RS Estimation

Microbiology

Stability Management

### Manufacturing

Solid & Liquid Oral dosage forms

Topical Solutions



# Generic/Branded Generic/OTC Product Development

- Literature Survey
- Identification of API Supplier
- Patent Review
- Quality and Characterization of API
- Analytical Development – API
- Product Development Strategy Evaluation
- Procurement of API / RM / PM / RLD
- Lab Scale Development
- Analytical Method Development
- Prototype Development
- Packaging Development
- Stability Studies
- Pilot BE supplies
- Development Report (QbD)

# Generic/Branded Generic/OTC Product Manufacturing

- Technology Transfer Verification, Modifications & Adoption
- Scale up Batch Production /Modifications (Short Term Stability)
- Exhibit Batches Production
- Exhibit Batches Stability (Short Term & Long Term)
- Pivotal BE Supplies
- Compilation of Data for Regulatory Submission
- Satisfactory replies to Drug Agency w.r.t queries additional data generation/submission
- Validation, Commercial Production on Regulatory Approval
- Post Approval Stability Studies

# Product Development

# Solid Dosages

- Tablets: Immediate Release, Sustained Release, Delayed Release, Chewable, Orally Disintegrating (ODT) and Multilayered
- Capsules: Multi-particulates, Powders, Tablet in Capsule, Enteric Coating and Modified Release
- Powders: Immediate Release, Sustained Release, Delayed Release, Powders for Sachet or Suspension, Taste Masking and Effervescent Powders
- Multi particulates: Mini-tablets for Encapsulation, Pellets, Drug Layering, Immediate Release, Sustained Release, Delayed Release and Sachet or Capsule Filling



# Oral Liquids

- Oral solutions, Syrups and Elixirs,...
- Oral suspensions
- Immediate Release and  
Powders for Suspensions
- Emulsions



# Topicals

- Topical Liquids: Rx, OTC and Personal Care Products for Topical Administration
- Topical (Semisolids): Rx, OTC and Personal Care Creams, Gels and Ointments for Topical or Oral Administration (dentifrice)
- Ear Drops
- Sterile Ophthalmic Preparations



# Injectables

- Terminal Sterilization
- Filtration
- Lyophilization
- Powder Filling



# Process Development Capabilities – R&D

- High Shear Mixer Granulation (RMG)
- Fluid Bed Granulation (Top Spray)
- Roller Compaction & Slugging
- Tableting (Conventional, **Bilayer & Tablet in Tablet**)
- Encapsulation (**Powder, Pellet & Tablets or combination thereof**)
- MUPS (Wurster & Extrusion-Spheronization)
- Solid Drug Layering
- Tablet coating – Film, Drug Layering, Functional & Sugar
- ODT/Chewable Tablets, Gastro Retentive Floating Tablets
- Microencapsulation in Gels
- Dry Powder/Mouth Melt Sachets
- Dry Powder Inhalers/ Multiple Dose DPIs
- Transdermal Patches
- Medicated Chewing Gum/ Lozenges
- High Potent and Oncology Formulations



# Packaging Development

- Blister Packing
- Strip Packing
- Bottle Packing
- Bulk Packing
- Liquids Packing
- Ointments

# List of Equipments – R&D

S. No.	Description	Capacity	S. No.	Description	Capacity
1	Vibro Mechanical Sifter	12 inch	13	Core Coated Tablet Press	20 STN
2	Double Cone Blender	2/5/20 lts	14	Homogeniser (Silent Crusher)	0.8 to 2000 ml
3	Rapid Mixer Granulator	3/5/10 lts	15	Autocoater	500gm -1 kg & 3 kg -5 kg
4	Fluid Bed Coater	3Lt	16	Automatic Mini Capsule Filling Machine	3000 Cap/Hr
5	Tray Dryers	200/325 lts	17	Blister Packing Machine	20 blisters/Min
6	Fluid Bed Processor	3 lit.	18	Lyophilizer	2 lit
7	Fluid Bed Drier	5 lit	19	Horizontal Laminar Air Flow Station	
8	Spray Drier	5 lit	20	Semiautomatic Vial, Ampoule and syringe Filling M/C	
9	Oscillating Granulator	2Kg	21	Flexi Mil cum Micronizer	5-15 kg
10	Bilayer Compression M/C	5D / 5B	22	Air Steam Class-ii Bio Hazard Safety Cabinet	1340*774*1360
11	Octagonal Blender	5/20 lts	23	Air Steam class-III Bio Hazard Safety Cabinet	1340*850*2250
12	Mini Rotary Tablet Presses	8Station/10 Station			

# cGMP Pilot / Manufacturing

# Manufacturing Support

## Dosage Forms

- Solid
- Liquid

## Support

- Scale up Batches
- Exhibit Batches
- Validation & Commercial Batches
- Clinical Supplies
- BE/BA Supplies

# Solid Dosages

- Tablets: Immediate Release, Sustained Release, Delayed Release, Chewable and Orally Dissolving
- Capsules: Powders, Multi-particulates and Tablets in Capsules
- Powders: Immediate Release, Sustained Release, Delayed Release, Powders for Sachet or Suspension & Taste Masking
- Multi particulates: Pellets & Mini-tablets for encapsulation
- Immediate release, Sustained Release, Delayed Release, Sachet or Capsule Filling

# Process Capabilities - Solids

- Blending
- Sizing/Milling
- High Shear and Fluid Bed Granulation (aqueous or organic solvents)
- Tableting
- Encapsulation
- Vacuum homogenization
- Tablet coating (aqueous and solvent)
- Multi-particulate and Powder Coating
- Controlled Release
- Solubility Enhancement
- High and Low Dose Potency
- Taste-Masking
- Orally Disintegrating and Chewable Tablets
- Packaging
  - Blisters, Strips, bottles,
  - Seamless collaboration with packaging partners for larger volumes, blinding
- Supply of clinical materials to domestic and international markets

# Process Capabilities - Liquids

- Topical liquids:  
Rx, OTC, and Personal care products for topical administration
- Oral solutions
- Oral suspensions: Immediate Release and Powders for Suspension

# Manufacturing Equipment List

S. No	Description	Capacity
<b>Solid Dosage Form Module</b>		
1	Multi Mill	-
2	Vibro Mechanical sifter	600 mm dia
3	Rapid Mixer Granulator	75 & 150 L
4	Fluid Bed Processor	35 & 125 L
5	Double Cone Blender	50, 100 & 200 L
6	Octagonal Blenders	100, 250 & 1000 L
7	Roller Compactor with OG	2 & 3 kg
8	Tablet Compression Machine	15 Station
9	Metal Detection unit	
10	Autocoater	12-20 kg / 45-75 kg
11	Dedusting M/c	
12	Tablet printing machine	
13	Tablet & Capsule visual inspection machine	
14	Blister Packing machine	25 cycles/min
15	Airjet washing M/c	
16	Tablet/capsule Counter	
17	Semi Automatic Capping Machine	
18	Induction Sealer	

S. No	Description	Capacity
19	Semi Automatic self-adhesive labeling machine	
20	Automatic Capsule Filling Machine	25000 Cap/Hr
21	Empty Capsule Sorter	
22	Dedusting and Polishing Machine	NA
<b>Liquid Dosage Form Module</b>		
23	Premixing Tank	1000 L
24	Mixing Tank	2000 L
25	Holding Tank	2000 L
26	Filtration Unit	0.2 Micron
27	Bottle Cleaning M/C	
28	Caps Cleaning M/C	
29	Bottle Filling M/C	
30	Screw Capping m/C	
31	Induction Sealer	
32	Purified Water Generation System	250 L/Hr



# LIQUID ORAL FACILITY



Premixing Tank 1000L



2000L Mixing Tank and 2000L Holding Tank

# Analytical Services/ Stability

# Analytical Method Development, Validation and Testing

- Our fully equipped GLP Analytical Laboratory is well suited for Drug Product Analytical Method Development, Validation and Analysis to support R&D, Exhibit, Clinical, Validation and Commercial activities.
- Our Microbiology Lab is equipped to carry out Method Development and Validations/Verifications of Preservative Efficacy, Sterility, Microbial Limit and Bacterial Endotoxins

# Pre-formulation Studies

- Excipient Compatibility Studies
- Calorimetry by DSC
- Forced-Degradation Studies
- Solubility Determination
- Bulk Powder Characterization

# Method Development and Validations

- Assay
- Related Substances
- Chiral Purity

## Dissolution

- USP Apparatus I
- USP Apparatus II

## Cleaning Verification

- Compound Specific Method
- Total Organic Carbon (TOC)



# ANALYTICAL SERVICES

## MICROBIOLOGY LABORATORY INSTRUMENTS

- Horizontal Laminar Air Flow Benches (2 No's)
- Incubators (2000 liters)
- Cooling Incubator 2-8 °C (400 liters)
- Autoclave
- Colony Counter
- Carl Zeiss Microscope



# ANALYTICAL SERVICES

# INFRASTRUCTURE



Walk-in Stability Chambers

- Walk-in Stability Chambers of 2,20,000 liters Capacity (10 numbers)
- Centralized data acquisition for monitoring and trending Temperature and Humidity 24/7.
- Stability Studies meeting the ICH Guidelines and any customer specific requirements.

# ICH Stability Storage and Testing

- 40°C/75% RH
- 30°C/65% RH
- 30°C/75% RH
- 25°C/60% RH
- 5°C
- Photo Stability
- Flexible Conditions



# Analytical Instrumentation

**Inductively coupled plasma mass spectroscopy (ICP-MS)**

**HPLCs (DAD, UV & RI)**

**UPLC (DAD & UV)**

**RRLC (DAD)**

**GC-HS**

**LCMS**

**Polarimeter**

**FTIR**

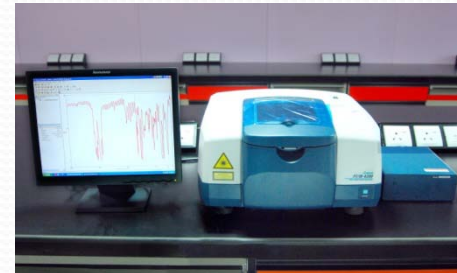
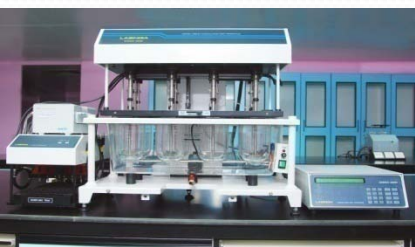
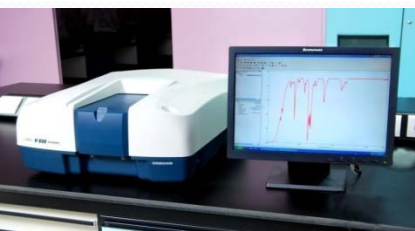
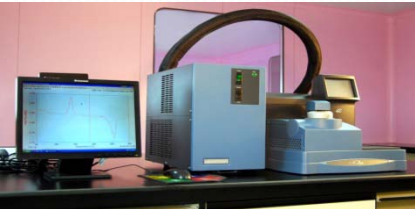
**Particle Size Analyzer (Sympatec)**

**Dissolution Tester - Auto Sampler**

**UV-Vis Spectrophotometer**

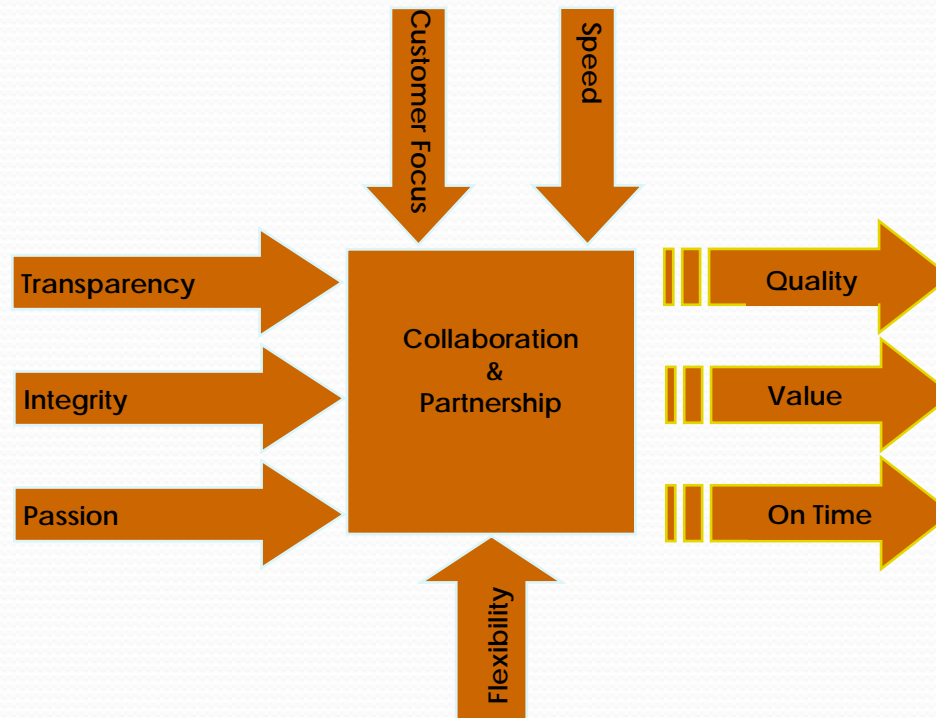
**Disintegration Tester**

**BIO-DIS Dissolution Apparatus  
(USP Type III / Reciprocating Cylinders)**



# Collaboration - Partnership

WE BUILD



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**Thank You**