SUVEN PHARMACEUTICALS LIMITED

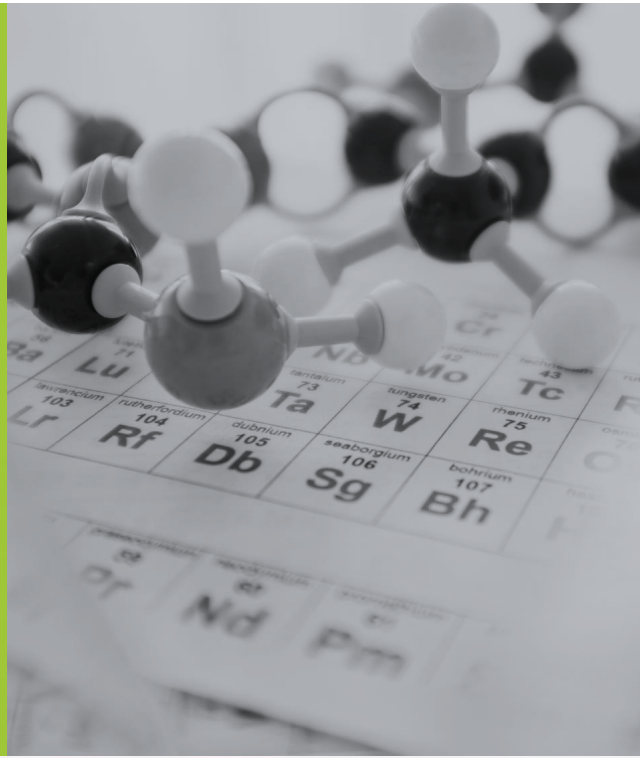
Partnering Drug Development,

Manufacturing

……and beyond!

Vision

To Emerge as a leading player by providing full spectrum services in drug development, manufacturing and support services under collaboration with leading global life science players.



Business Structure

- In operation since 1989 to 2003 as SUVEN PHARMACEUTICAL LTD.
- Profitable for the last decade
- Transformed to SUVEN LIFE SCIENCES LTD from 2003 to 2019.
- Demerged from Suven Life Sciences and in operation as Suven Pharmaceuticals Limited since January, 2020.
- Strong asset base and financial fundamentals
- Pioneering efforts in C-R-A-M-S since 1994
- Relationships with many Global Life Science majors
- IPO in 1995 - Listed on NSE and BSE
- More than 400+ scientific professionals includes 40+ Ph.D Holders.

High growth potential

30 years of Pharmaceutical Relationship

Formulations

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

Relationship with more than 22 global pharmaceutical companies

Strategic Business Segments

- Formulation Development and Manufacturing Centre (FDC)

Full spectrum services in Drug Development and Manufacturing

Facility Capacities Overview

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

- cGMP Scale-up
- Manufacturing and Packing of Exhibit, Commercial and Clinical Supply Batches
- Warehouse
- 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 Pilot / Manufacturing

SUVEN PHARMA

Formulation Development Centre

-a Natural extension to the existing CRAMS Business

Manufacturing

Solid Oral dosage forms
Liquid Oral dosage forms
Topical dosage forms

Analytical Development

Method development
Method Validations
Impurity Profiling
RS Estimation
Microbiology
Stability Management

Formulation Development

NCE's
ANDA's
NDA's (Differentiated Products)
OTC

Manufacturing Support

Dosage Forms

- Solid
- Liquid
- Topical

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

Manufacturing Equipment List

S. No	Description	Capacity
	Solid Dosage Form Module	
1	Multi Mill	25-300 kg/hr
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 (Sejong)	15 Station (1.3 million tabs/day
9	Metal Detection unit	-
10	Autocoater	12-20 kg / 45-75 kg
11	Dedusting M/c	5000 to 200000/hour
12	Tablet printing machine	-
13	Tablet & Capsule visual inspection machine	25-30 kg/Hr
14	Blister Packing machine	25 cycles/min
15	Airjet washing M/c	-
16	Tablet/capsule Counter	-
17	Empty Capsules Elevator (SE-509)	Up to 2,00,000 Capsule/Hr
18	Automatic Capsule Filling Machine (AF25T)	25000 Cap/Hr (0.5 million capsules/ day)

Manufacturing Equipment List

S. No	Description	Capacity
19	Empty Capsule Sorter	Up to 2,00,000 Capsule/Hr
20	Dedusting and Polishing Machine	Up to 1,00,000 Capsule/Hr
21	Auotmatic Capsule Filling Machine (AF25T)	25000 Cap/Hr (0.5 million capsules/ day)
23	Dedusting and Polishing Machine	Up to 1,00,000 Capsule/Hr
24	Semi Automatic self-adhesive labeling machine	50-60 Bottles/min
25	Bottle Cleaning Machine	25-30 Bottles/min
26	Tablet Filling Machine	30 tablets/ min
27	Cotton Inserter	50-60 Bottles/min
28	Capping machine	50-60 Bottles/ min
29	Induction Sealer M/c	60 feet/ min
30	Re-Torquer Machine	50-60 Bottles/ min
31	Semi Automatic self-adhesive labeling machine	50-60 Bottles/min
32	Leaflet In-outserter Machine	120 Bottles/ min
33	Torquer testing Machine	0- 100 Lb -inches

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
Liquid Dosage Form Module		
1	Premixing Tank	60L, 1000 L
2	Mixing Tank	75L, 2000 L
3	Holding Tank	2000 L
4	Filtration Unit	0.2 Micron, 0.45 Micron
5	Bottle Cleaning M/C	50 - 80 bottles/min (30 ml - 500 mL)
6	Caps Cleaning M/C	80 caps/min
7	Bottle Filling M/C	50 - 80 bottles/min (30mL -500 mL)
8	Screw Capping m/C	50 - 80 bottles/min (20 mm - 50 mm)
9	Induction Sealer	50 - 80 bottles/min (30mL -500 mL)
10	Purified Water Generation System	250 L/Hr
Topical Solutions Module		
1	Mixing Tank	500 L
2	Holding Tank	500 L
3	Horizontal Pouch machine	70 pouches/ min
Otic Products (Solutions/Emulsions/Suspensions) & Semi solid dosage forms		
1	Automatic Liquid filling, Plugging and Sealing Machine	30-45 Bottles/min
2.	Automatic Tube Filling Machine	25-40 Tubes/min

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

Method Development and Validations

- Assay
- Related Substances
- Chiral Purity
- Elemental Impurities
- Extractable and Leachable Study

Dissolution

- USP Apparatus I
- USP Apparatus II
- USP Apparatus III

Cleaning Verification

- Compound Specific Method
- Total Organic Carbon (TOC)

ANALYTICAL SERVICES

MICROBIOLOGY LABORATORY INSTRUMENTS

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

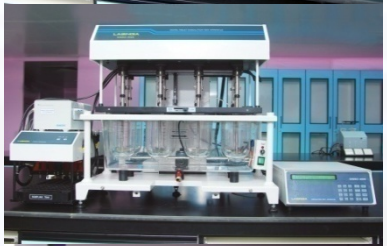
INFRASTRUCTURE

- 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±2°C / 75±5% RH
- 30±2°C / 65±5% RH
- 30±2°C / 75±5% RH
- 25±2°C / 60±5% RH
- 5±3°C (2-8°C)
- Photo Stability
- Flexible Conditions

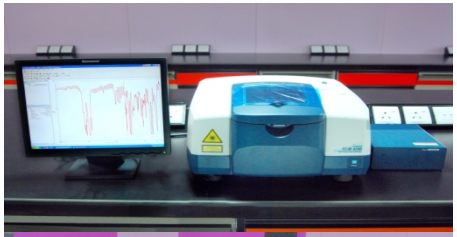



Analytical Instrumentation

SUVEN PHARMA

Ion Chromatography (IC)
Inductively coupled plasma mass spectroscopy (ICP-MS)
HPLCs (DAD, UV & RI)
UPLC (DAD & UV)
RRLC (DAD)
GC-HS & GCMSMS
LCMSMS
Polari meter
FTIR
Particle Size Analyzer (Sympatec)
Differential Scanning Caloriemetry (DSC)
Dissolution Tester - Auto Sampler
UV-Vis Spectrophotometer
Disintegration Tester
BIO-DIS Dissolution Apparatus (USP Type III / Reciprocating Cylinders)




Formulation Development Centre

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 Development

- 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

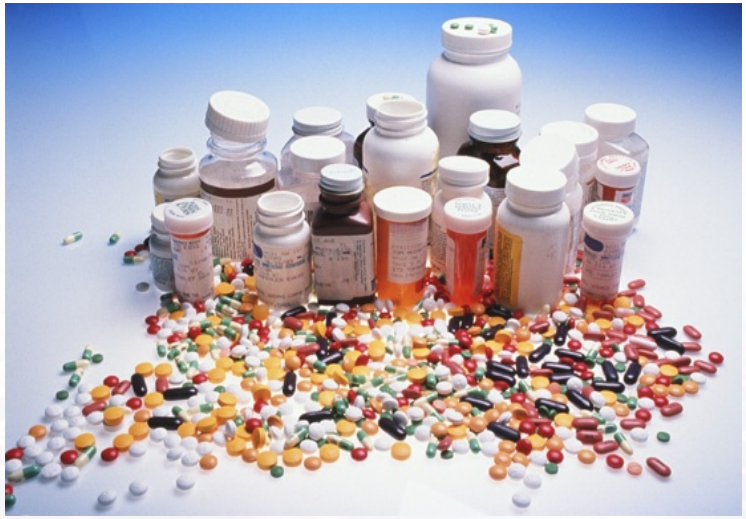
Product Development

Pre-formulation Studies

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

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
- OTIC Products (Solutions & Emulsions)

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
- Tabletting (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
- Tube Packing
- Pouch Packing

List of Equipments – R&D

SUVEN PHARMA

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	1 -5 Lt rs	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			
10	Bilayer Compression M/C	5D / 5B	21	Flexi Mill cum Micronizer	5-15 kg
11	Octagonal Blender	2, 5, 10, 20 ltrs	22	Air Steam Class-ii Bio Hazard Safety Cabinet	1340*774*1360
12	Mini Rotary Tablet Presses	8Station/10 Station	23	Air Steam class-III Bio Hazard Safety Cabinet	1340*850*2250

Regulatory Information
(DMF/Product Dossier/Technical Information Submitted)

Regulatory Authorities / Country(ies)	Active Pharmaceutical Ingredients (API)		Intermediates		Drug Product / Formulation		
	Suven	Customer Specific	Suven	Customer Specific	Suven	Customer Specific	
					ANDA	ANDA	ANADA
FDA, USA	16	04	02	--	04	12	03
Health Canada	02	--	--	--	--	--	--
EDQM	02	--	--	--	--	--	--
MHRA, UK	01	--	--	--	--	--	--
Netherlands	01	--	--	--	--	--	--
France	01	--	--	--	--	--	--
17 EU Countries	01	--	--	--	--	--	--
PMDA, Japan	--	--	02	--	--	--	--
Registration at China	04	--	--	--	--	--	--
Registration at Korea	02	--	--	--	--	--	--
ANVISA, Brazil	01	--	--	--	--	--	--

Regulatory Inspection History

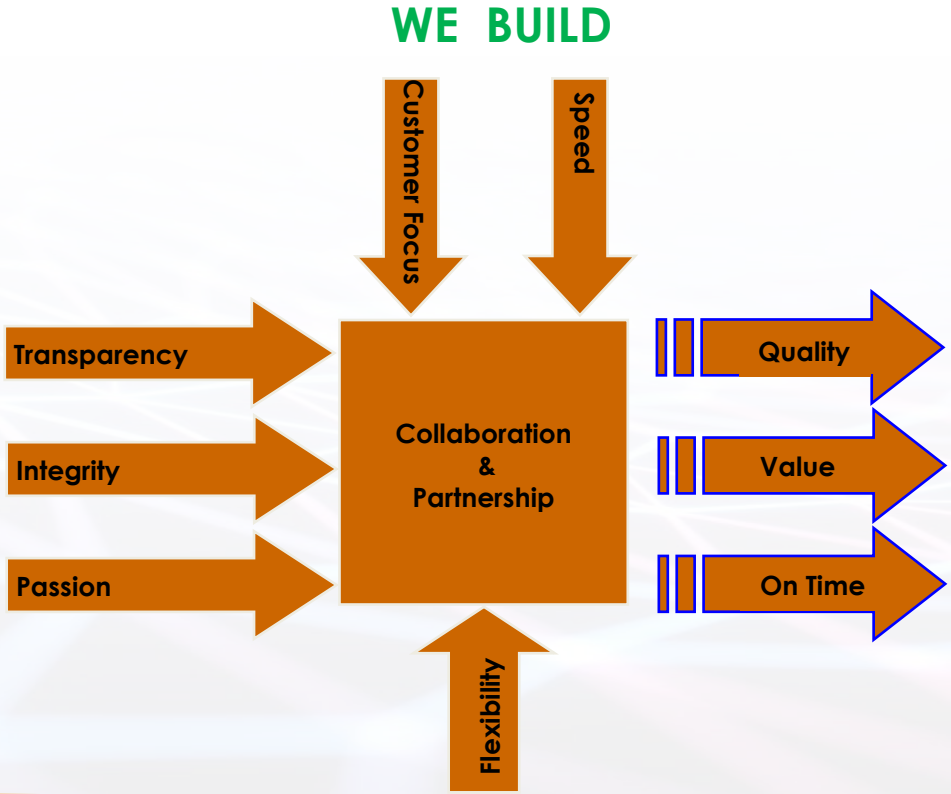
Name of the Regulatory Authority	Month & Year
United States Food & Drug Administration (USFDA)	April 9 -12, 2007 / November 1 - 4, 2010 February 04 - 08, 2013 / April 04 - 14, 2016 February 05 - 15, 2018 October 21 - November 01, 2019
The European Directorate for the Quality of Medicines & HealthCare (EDQM)	May 15-17, 2019
Korean Food & Drug Administration (KFDA)	October 15 - 16, 2012
Behörde für Gesundheit und Verbraucherschutz (BGV), Hamburg.	December 10 - 12, 2012
The National Health Surveillance Agency of Brazil (ANVISA)	April 07 - 11, 2014
Drugs Control Administration, Government of Andhra Pradesh, India.	May 23, 2006 #, July 10, 2008 #, Dec 02, 2008*, Aug 12, 2010 # Nov 03, 2012 #, Aug 01, 2013 *, Oct 26,2018 [Periodical Inspection]
Drugs Control Administration, Government of Telangana & CDSCO , India.	January, 7 – 8, 2015 # February, 3-4, 2017 # February, 21-22, 2019 # / June 7-8,2016**

Issue / Renewal of WHO GMP certificate

* Renewal of Manufacturing License

** Renewal of EU-Written Confirmation

Collaboration - Partnership



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Thank You