Srini Group of Companies

Our Business : KSM & INT / API / CRAMS / FDF

Srini Pharmaceuticals Private Limited is a global player in manufacturing and supply of Active Pharmaceutical Ingredients having USFDA, TGA and KFDA approvals. Multiproduct manufacturing facilities are located at Choutuppal near Hyderabad and Parawada, Jawaharlal Nehru Pharma City near Vishakapatanam .

Vision

We envision leveraging state of the art, ever evolving technologies, achieve realistic, attainable set targets within the specific timeline, delight customers, continue to maintain highest standards and become the most valued company for all stake holders.

Mission

To strive towards maintaining work ethics, responsible towards society, become environment friendly company, continuously study, analyze and research in the niche, reduce costs, risks, increase productivity, improve efficiency, invest in resources, and ensure continuous durable business growth, and enduring success.

Brief History & Profile of SRINI

- Srini Pharmaceuticals Pvt. Ltd., was established in the year 1995.
- Flourished to API manufacturing facility.
- Expanded to Finished Dosage Formulations
- Integrated with starting material manufacturing for improved supply chain management and de-risking.
- Two API & Intermediate Manufacturing Facilities, Choutuppal & Vizag
- API facility (Hyderabad) is approved by USFDA, EUGMP, TGA, KFDA and Ecovadis assessed.
- Two Finished Dosage Facilities at Hyderabad.
- One FDF facility is dedicated for ROW market and one facility is dedicated for regulatory market which is approved by TGA, Australia.c

Located Facility

Srini Site1 & Veena Life Sciences
Choutuppal, T.S, India

Cipro Pharma Unit-1 & 2
Hyderabad, T.S, India

Srini Site 2 Visakhapatnam, A.P, India

Corporate Office
Srini Pharmaceuticals Pvt Ltd Plot No:10, Road No: 8, Jubilee Hills, Film Nagar, Hyderabad – 500096 T.S, India

Our Commitment

Manufacture APIs in compliance with CGMP and strictly adhere to the manufacturing process and methods described in our DMFs by maintaining safety / environmental laws and guidelines in all operations.

Notify our customers and regulatory agencies of significant changes that may impact the product quality following all applicable guidelines.

Experienced QA and RA teams maintain the highest global standards of quality and regulatory compliance.

Site Over View - KSM/INT/API

Description	Srini-1	Srini-2	Veena
Built-Up Area	175,000 Sq. ft	95,000 Sq. ft	30,000 Sq. ft
Reactor Volume	352 KL	120 KL	23 KL
No of Blocks	5	1	1
Clean Rooms	6	2	---
Kilo Lab	Kilo Lab with Clean Room	---	---
R&D	R&D with 5 Independent Labs	Site level PD Lab	---
Isolation Equipment	250 – 5000 L	3000 L	Can be upgraded
Site View			

Capabilities KSM/INT/API

S. No	Description	R&D Scale	Kilo Scale	Commercial Scale		
				Srini-1	Srini-2	Veena
1	Reactor Volume	30-40 reactions simultaneously	270 L	320 KL	111 KL	23 KL
2	Crystallization Capacity	---	75 L	32 KL	6 KL	---
3	Manufacturing Capability	Based on Reqmnt	Based on reqmnt	360 T API 200 T Int.	70 T API 50 T Int.	100 T Int.
4	Temperature °C	-50 to 200	-30 to 200	-80 to 200	-60 to 140	-60 to 140
5	Pressure	Up to 15 Kg	---	Up to 25 Kg	---	---
6	Solvent Recovery	---	---	2500 KL / year	1000KL / year	750KL / year
7	Palladium Carbon Handling (kg/year)			~3000	---	---

Capabilities FDF

S. No.	Name of the equipment	Capacity
1.	Vibro Sifter	400kg/hr
2.	Double Cone Blender	500L/80L
3.	Rapid Mixer Granulator	400L
4.	Oscillating Granulator	120kg/hr
5.	Fluid Bed Processor	125L
6.	Compression Machine	1,30,000 Tablets/hr
7.	Neo Cota Machine	50-150kg
8	Tablet Sorting & Inspection Belt	1,50,000 Tablets/hr
9	Metal Detector	3,00,000 Tablets/hr
10	Tablet Deduster	1,00,000 Tablets/hr
11	Blister Packing Machine (BQS)	1,40,000 Tablets/hr
12	Multimill	200kg/hr
13	Fluid Bed Processor	50kg
14	Bottle Packing Line	1,00,000 Tablets/hr

Site-1 : Srini Pharmaceuticals Pvt Ltd Survey No: 247, Choutuppal, T.S, India

Facility – Commercial Scale

- Five production blocks (PB-I to PB-V) with a total capacity of 352 KL.
- Warehouses for Raw Materials, Intermediates, APIs & underground solvent storage tanks.
- QC Laboratories for In process, Raw materials, Intermediates, APIs, Stability and Microbiology).
- Produce Antacids, anti virals, anti bacterials, anti seizure and other category drugs.
- Facility is free from Sartan products.
- Facility is free from betalactams, high potent or any other category drugs.
- Expertise in amination, chlorination etc., reactions
- Expertise in high pressure and low temperature reactions.

Equipment – Commercial Scale

- Reactors-Glass Lined - 33 , ranging from 250 to 6,300 liters.
- SS 316 - 84, ranging from 250 to 10,000 liters.
- Sparkler filter - 24
- Leaf Filter - 29
- Centrifuge - 39
- Tray dryer - 4
- Rotary cone vacuum dryer -16
- Vacuum Tray dryer - 2
- Multi-mill - 11
- Micropulveriser - 2
- Microniser - 1
- Sifter - 11
- Blender - 7

Site-1 : Srini Pharmaceuticals Pvt Ltd Survey No: 247, Choutuppal, T.S, India

Equipment – Spray Drier

- Spray Drier is available with a capacity of 20Kg/Hour.
- Built up in a dedicated facility.
- All the equipments and accessories are made from SS-316.
- Equipped with a dedicate Nitrogen plant.
- Total process is controlled through automation using SCADA (Supervisory Controls and Data Acquisition)

QC Laboratory Capabilities

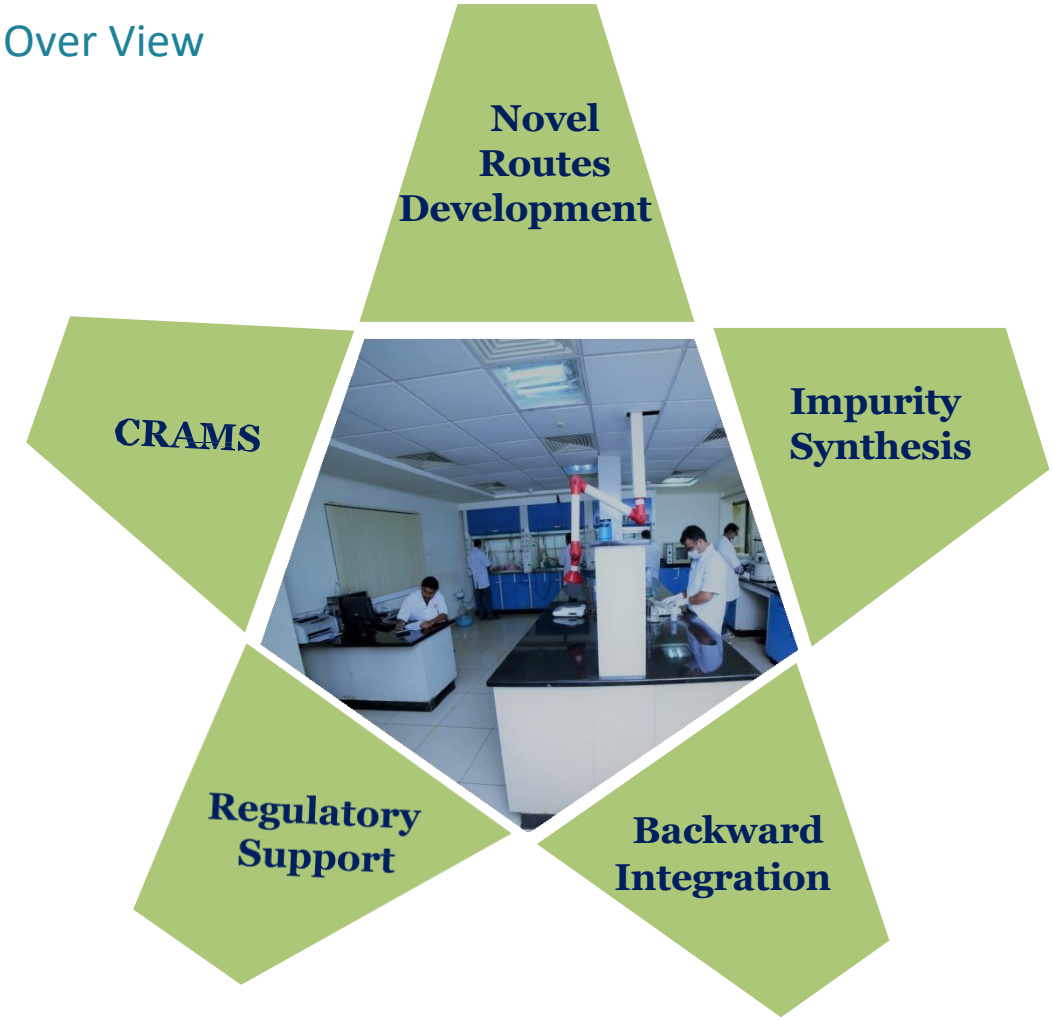
- Spacious Centralized Quality Control Laboratory, located in a separate building from manufacturing activity.
- Separate IPQC laboratory to support in-process samples analysis like pH, MC, LOD
- Separate Microbiology laboratory.
- In-house method development and transfer to the lab.
- Pharmacopoeia metho verifications & In-house method validations if required.
- Separate Empower and Standalone servers.
- 21 CFR Part 11 Compliant
- In-house stability study for all conditions.

Instruments Overview

S.No	Instrument	Make	Number
1	HPLC	Waters	13
2	UPLC	Waters	2
3	GC	Agilent	5
4	UV	Perklin	2
5	FTIR	Perklin	1
6	Malvern Mastersizer	Malvern	1
7	Auto Titrator	Metrohm	3
8	Polarimeter	Rudolph	1
9	Moisture Analyser	Metrohm	1
10	Alpine Air Jet	Alpine	1

Site-1 : Srini Pharmaceuticals Pvt Ltd Survey No: 247, Choutuppal, T.S, India

R&D Over View



Site-1 : Srini Pharmaceuticals Pvt Ltd Survey No: 247, Choutuppal, T.S, India

R&D Capabilities

- 5 independent labs with a total of 15 fume hoods.
- 30 – 40 reactions can be run at a time.
- Oxidation, Reduction, Cyanations & Halogenation reactions.
- Catalytic reductions using Palladium, Raney-Nickel, Platinum and Hydrogen, NaBH4, BF3-THF/etherate etc.
- Reactions involving n-butyl lithium, DIBAL, Vitride, NaH, BDMS etc.
- Palladium mediated cross couplings like Suzuki, Heck and Negishi reactions.
- Heterocyclic synthesis
- Cryogenic reactions up to -50 degrees.
- High temperature reactions up to 200°C.
- High pressure reactions up to 15 Kg pressure and 120°C temperature.
- Asymmetric synthesis.
- Chiral resolutions & Racemizations.
- Friedel-Crafts reactions & Grignard reactions
- Custom Synthesis

R&D Capabilities

- Asymmetric synthesis.
- Synthesis of Novel Polymorphic Forms.
- Cyanations.
- Azide formation by using Sodium azide
- Halogenation reactions using SOCl2, POCl3, PCl5, Liquid bromine, NBS etc Oxidation reactions like Swern, Jones, Bayer-Villiger, oxidations using KMnO4, OsO4, Hydrogen peroxide, Titanium isoproxide and Cumin Hydroperoxide.
- Reductions-Catalytic reductions Palladium, Raney-Nickel, Platinum and
- Hydrogen, hydride transfer reductions using NaBH4, BF3-THF/etherate etc.

AR&D Capabilities

- Dedicated Analytical Research & Development Laboratory.
- In-house method development & fullscale method validation.
- Pharmacopoeia method verifications.
- Impurities characterization.
- Regulatory support to address deficiencies & customer queries.
- 21 CFR Part 11 Compliant.

Instrument	Make	Number
HPLC	Waters	6
GC	Agilent	2
UV	Perkin	1
FTIR	Perkin	1
Auto Titrator	LabIndia	3
Polarimeter	Rudolph	1

Site-2 : Srini Pharmaceuticals Pvt. Ltd Plot No: 47, Parwada, Visakhapatnam, A.P, India

Facility

- Total capacity available for production is 117 KL.
- Warehouses (Raw Materials, Intermediates, tanks.
- QC Laboratories (Raw materials, In process, Intermediates , APIs, Stability and Microbiology).
- R&D laboratories to support the ongoing production and our central R&D is located in Hyderabad facility.
- Utilities include Process Water, Steam, Chilled water, Cooling water, Vacuum Nitrogen and Compressed air.
- All the equipment's are qualified as per the GMP requirements

Equipment's Overview

- Reactors-Glass Lined – 14, ranging from 0.25 KL to 6.3 KL
- SS 316 - 15, ranging from 1.0 KL to 8.0 KL.
- Sparkler filter - 04
- Leaf Filter - 04
- Centrifuge - 06
- Tray dryer - 05
- Rotary cone vacuum dryer -03
- Vacuum Tray dryer - 01
- Multi-mill – 03
- Sifter - 03
- Blender – 02

Instruments Overview

- HPLC - 02
- GC - 02
- FT-IR - 01
- UV - 01
- Karl fisher Auto titrator – 01
- pH meter- 03
- Conductivity meter - 0 1
- Muffle furnace – 01
- Stability chambers – 03
- MR Apparatus - 01
- Analytical balance – 04
- Ovens – 05
- Auto clave – 02
- Incubator-04

Site-3 : Veena Life Sciences India Private Limited, Survey No 271to 273, S. Lingotam, Choutuppal, T.S, India

Facility

- It intermediates manufacturing facility.
- Total capacity available for production is 23.2 KL.
- Warehouse (Raw Materials and Intermediates) Above ground solvent storage tanks.
- QC Laboratories (Raw materials, In process and Intermediates,).
- R&D laboratories to support the ongoing production and our central
- R&D is located in Choutuppal facility.
- Utilities include Process Water, Steam, Chilled water, Cooling water, Vacuum, Nitrogen and Compressed air.
- All the equipment are qualified as per the GMP requirements.

Equipment/Instruments

- Reactors-Glass Lined - 05
- SS 316 - 04
- Centrifuge - 02.
- Tray dryer - 01
- Rotary cone vacuum dryer -01
- Multi-mill – 01
- Sifter -01
- HPLC – 02
- UV - 2
- Melting point apparatus -01
- KF Autotitrator-01
- Sonicator-02
- UV Chamber-02
- pH Meter-01
- Analytical Balance- 01

Cipro – 1 &2 : Cipro Pharma, Mallapur, Hyderabad, T.S, India

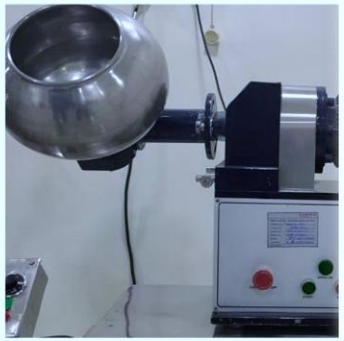
Capabilities – R&D Scale

- Development and scale-up of Generic formulations for different dosage forms (Tablets/Capsules/Pellets/Liquids)
- Product development is done right from the literature search & patent evaluation
- Preparation of the strategy sheet of the product
- Innovator samples evaluation & compatibility study
- Lab scale batches execution and validation
- Tablets/Capsules by Direct compression /wet granulation
- Develop Immediate Release and Extended-Release tablets, capsules & pellets
- Pellets by Extruder & Spherodizer/ FBP
- Batch size upto considered as 6000 Tablets can be executed in R&D for tech transfer with six months stability data.

Equipment – R&D Scale

Equipment & Instrument	Capacity
Fluid Bed processor	5 L
Compression Machine	8 Station
Hand Coating Pan	8 inches & 12 Inches
Double Cone Blender	5 L
Spherodizer	-
Twin Cone Extruder	-
Tray Dryer	-
Stirrer	10 L
Rapid Mixer Granulator	12 L

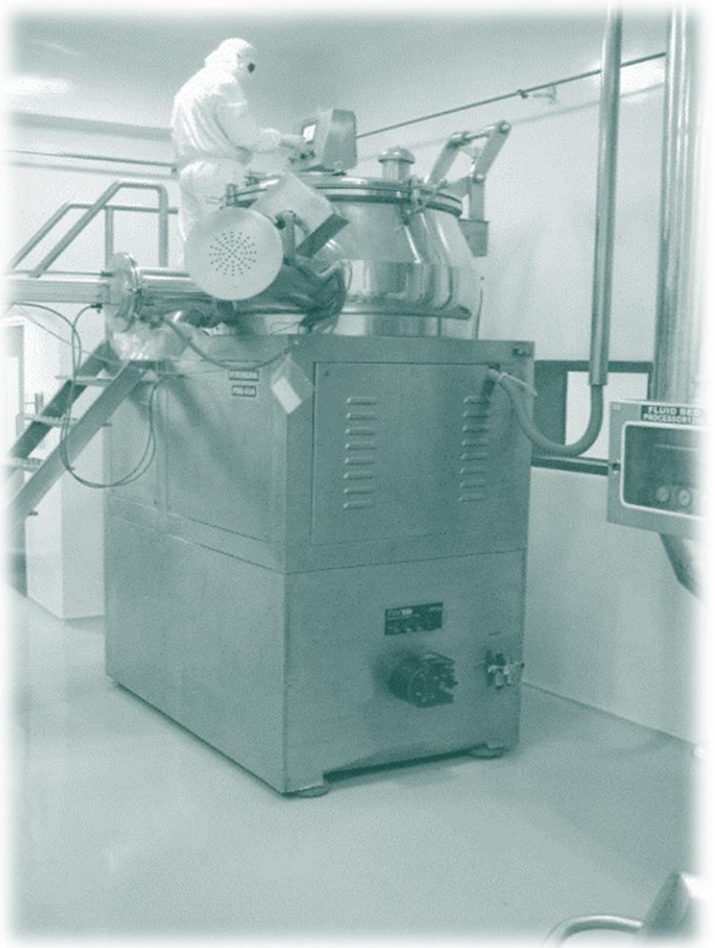



Cipro – 1 &2 : Cipro Pharma, Mallapur, Hyderabad, T.S, India

Equipment – Commercial Scale

- Separate production lines are available for Tablets & Capsules
- Separate packing lines are available for blister & bottle packing.
- Independent Tablets section, wet & dry granulation.
- Independent Capsules/pellets section.
- Automatic compression and coating.
- Metal detector with automatic rejection system
- Automated Bristol packing with camera system for defects automatic detection and rejection.
- Bottled packing line with automatic counting and sealing.
- Purified Water System meeting USP/Ph.Eur specs



Quality

- Quality is everyone's responsibility at Srini group.
- Key component of our Quality system is management's responsibility from
- functional area to executive level.
- Quality system is established based on ICHQ7 / PIC guideline requirements .
- Internal Audits are conducted periodically to ensure GMP compliance and for any betterment opportunities.
- Spot checks are carried out by IPQA.
- Each batch is released by Quality Assurance after thorough verification of
- batch records including raw data in the chromatography systems.
- Full documentation of each batch is archived.
- Product performance is reviewed through Annual Product Reviews.

Quality Policy

Srini Group is committed to provide quality drugs and intermediates to the customer satisfaction and also committed to ensure cGMP and regulatory compliance to industry standards and ICHQ7 for Active Pharmaceutical Ingredients.

Regulatory Inspections

USFDA

EU GMP

TGA, Australia

Korean FDA

WHO GMP

EU 'WC"

ISO 9001:2015

ISO 14001:2015

ISO 45001:2018

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Thank You