

WELCOME TO AMARA GROUP



AMARA GROUP OF COMPANIES OVERVIEW

AMARA Group of Companies



- ❖ AMARA LABS PVT.LTD, IDA BOLLARAM,
HYDERABAD,TELANGANA

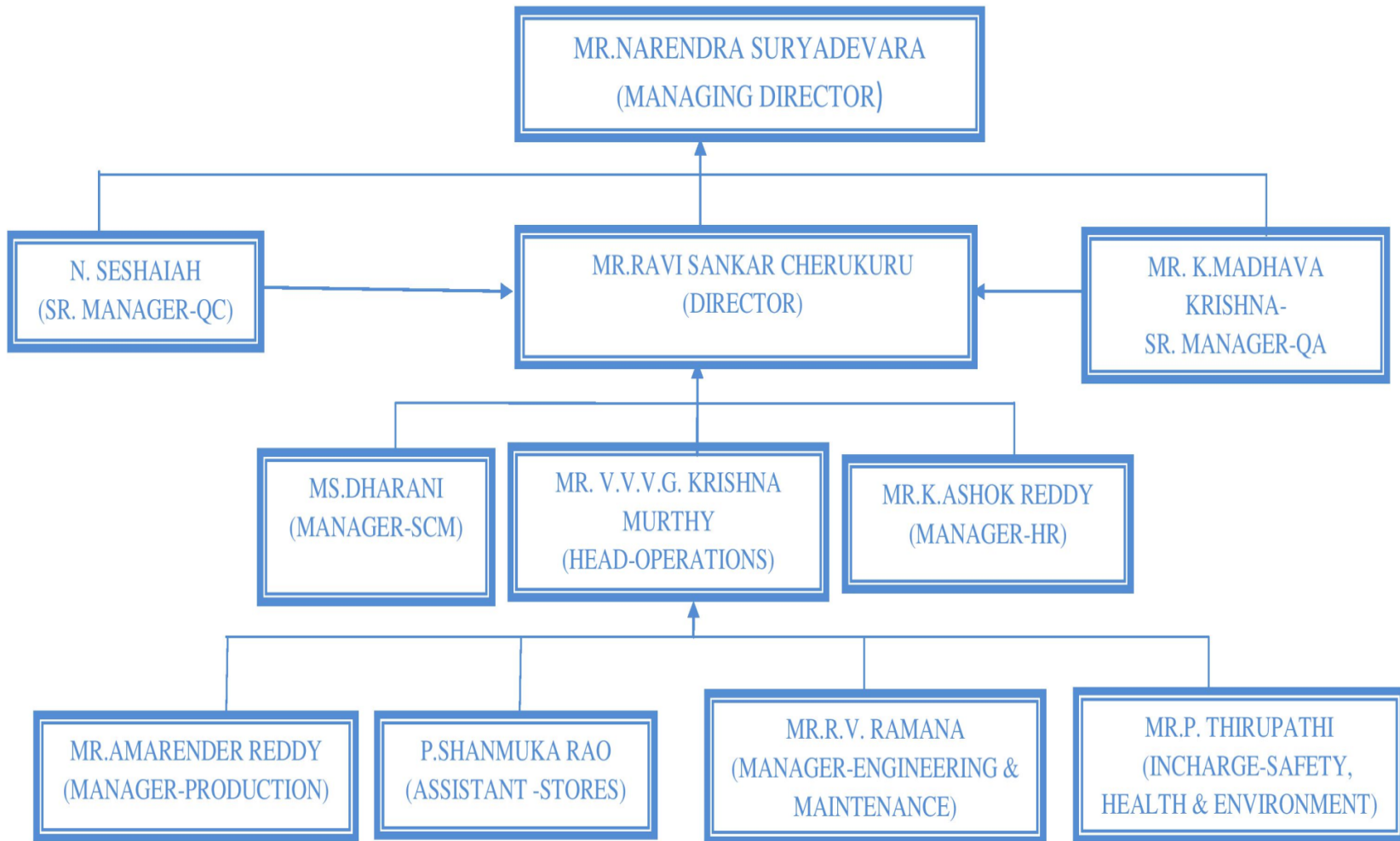
- ❖ AMARA LIFE SCIENCES PRIVATE LIMITED, ATCHUTAPURAM,
VISHAKAPATNAM,ANDHRA PRADESH

ABOUT MANAGEMENT

- ❖ Mr. Narendra Suryadevara, Managing Director of the company is a young and dynamic having expertise in multiple knowledge in pharma industry with global perspective and entrepreneurial drive. He is the key architect in shaping the company.
- ❖ He had a successful stint at Cipla Ltd as a senior executive position handled contract manufacturing with cost effective process and DMF site transfer activity. His expertise had resulted in establishing Amara Labs along with some of his associates who are experts in Quality and regulatory resulted to WHO GMP approval.
- ❖ With an experience of 20 years in the pharma industry in Cipla and Mylan, he brings together his experience with a futuristic approach in bringing the vision of the establishment into reality.

AMARA LABS OVERVIEW

Organization Structure



Site Information

- Total Site Area – 4000 Sq. Meters
- Built Area – 2200.7 Sq. Meters

Manufacturing Site address:

AMARA LABS PRIVATE LIMITED

Plot No. 73C/4

Anrinch Industrial Estate

IDA Bollaram

Hyderabad 502325

Telangana, INDIA

Tel: 08458295166

www.amaralabs.in

marketing@amaralabs.in

DUNS: 86-048-0315



Longitude: 78°23'55.9"E

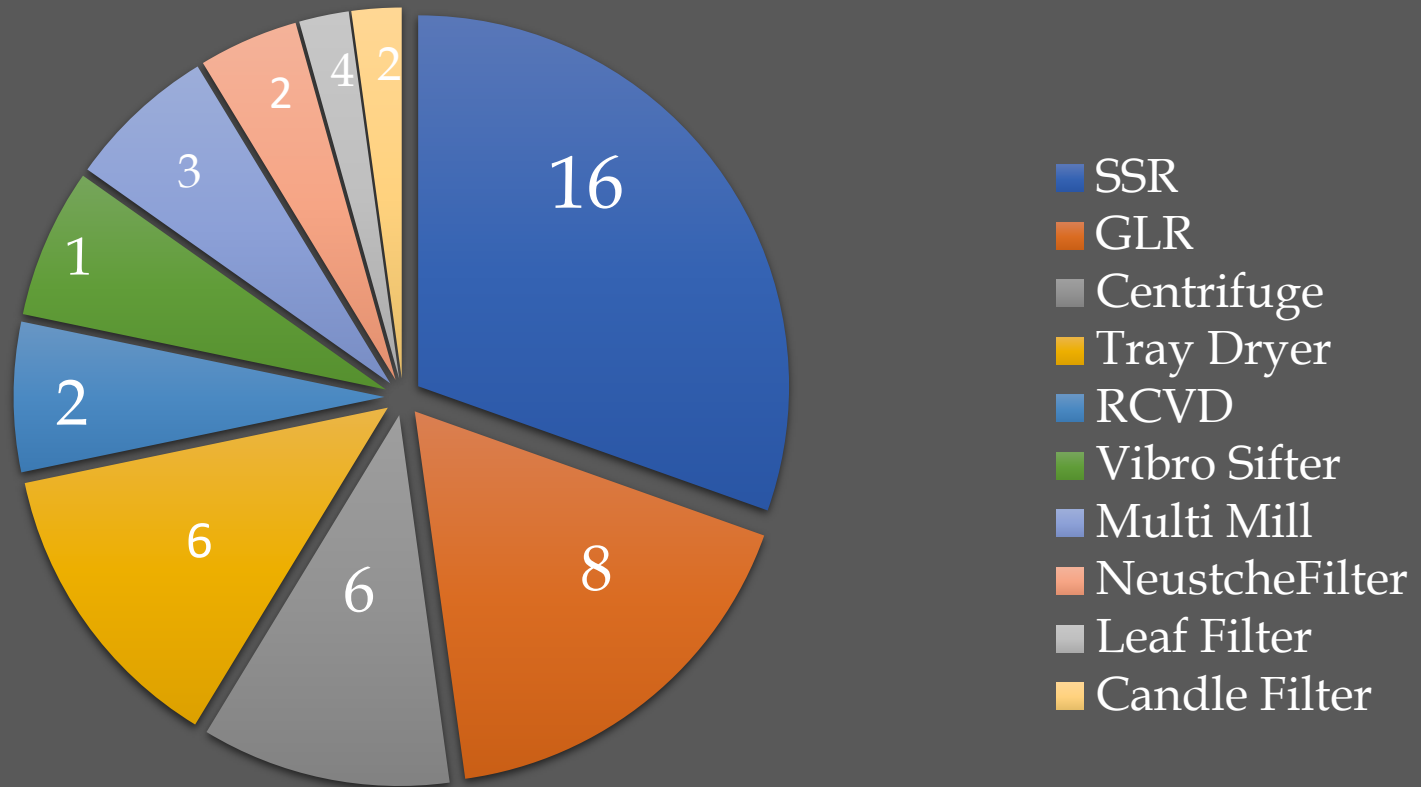
Latitude: 17°31'58.80"N

Employees

S. NO.	DEPARTMENT	NO.OF EMPLOYEES
1.	PRODUCTION	18
2.	QUALITY ASSURANCE	06
3.	QUALITY CONTROL	08
4.	WAREHOUSE	04
5.	ENG. & MAINT.	16
6	ACCOUNTS	03
7	SAFETY	01
8.	HUMAN RESOURCE	02
9.	INFORMATION & TECHNOLOGY	01
10.	SCM	02
TOTAL NO.OF EMPLOYEES		61

Production Equipment's

Total Equipment's



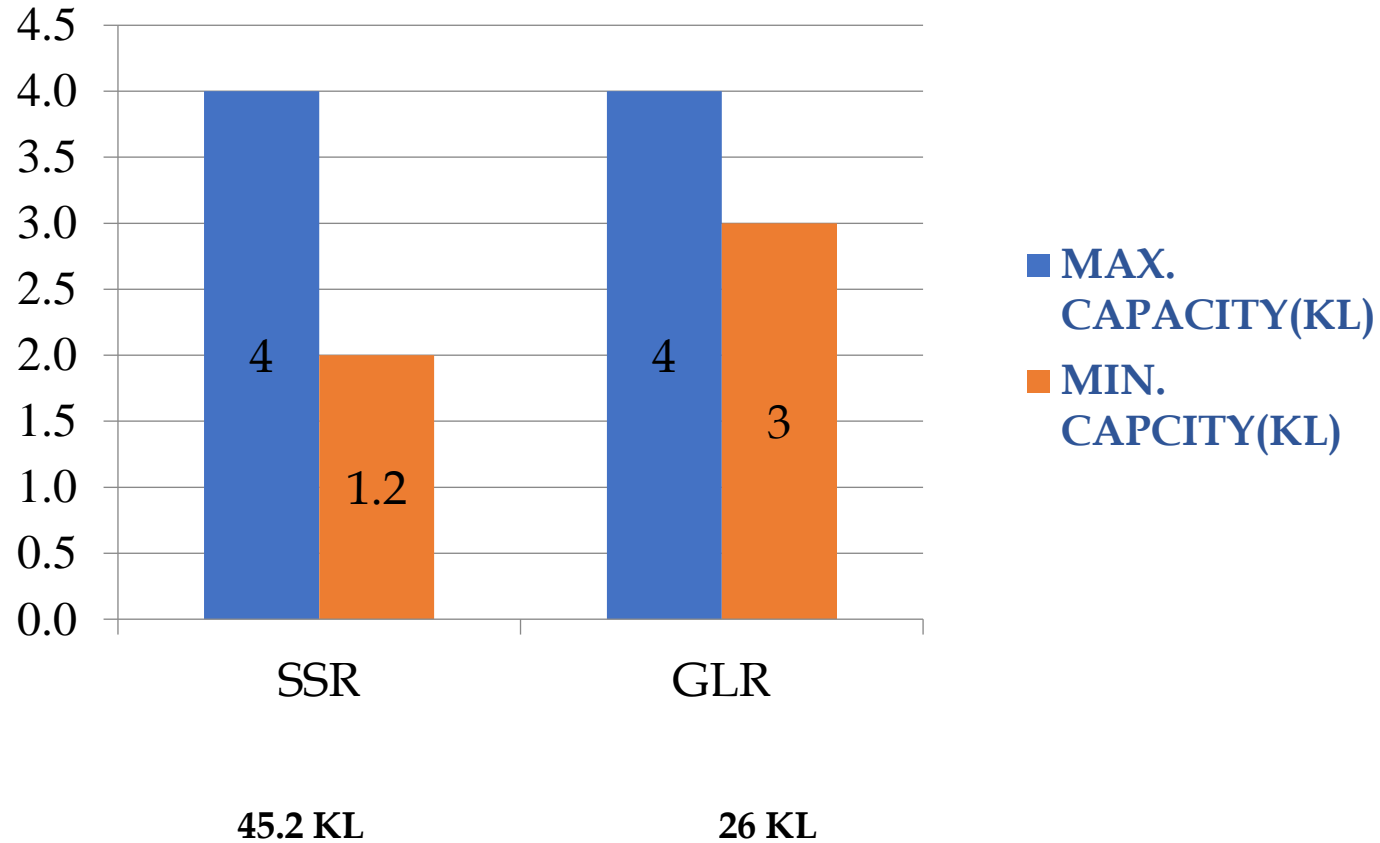
MANUFACTURING AREA



INTERMEDIATE PROCESSING AREA



REACTOR CAPACITY



TOTAL REACTOR VOLUME CAPACITY: 71.2 KL

Utilities

Boiler	2.0 Ton/hr (135°C)
Generator	225 KVA (100% Power backup)
Chilling Plant	60 TR (02 no.) at -20°C
Purified Water System	1 KL/hr
Vacuum System	High/General Vacuum
Hot Water System	20 m ³ /hr
Cooling Tower	300 TR, 200 TR, 200 TR
Air Compressor	115 CFM

Reaction Capabilities

REACTION CARRIED OUT AT SITE:

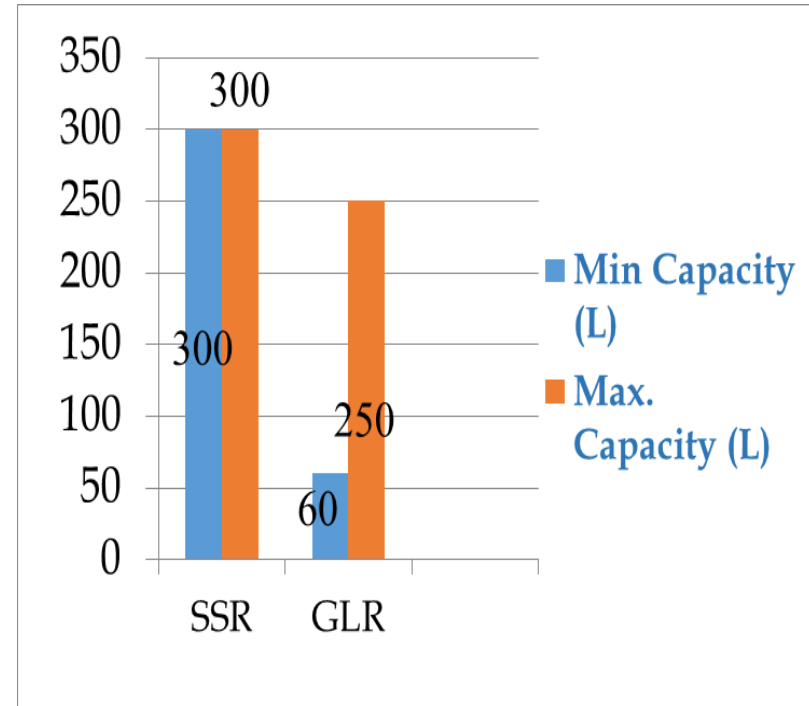
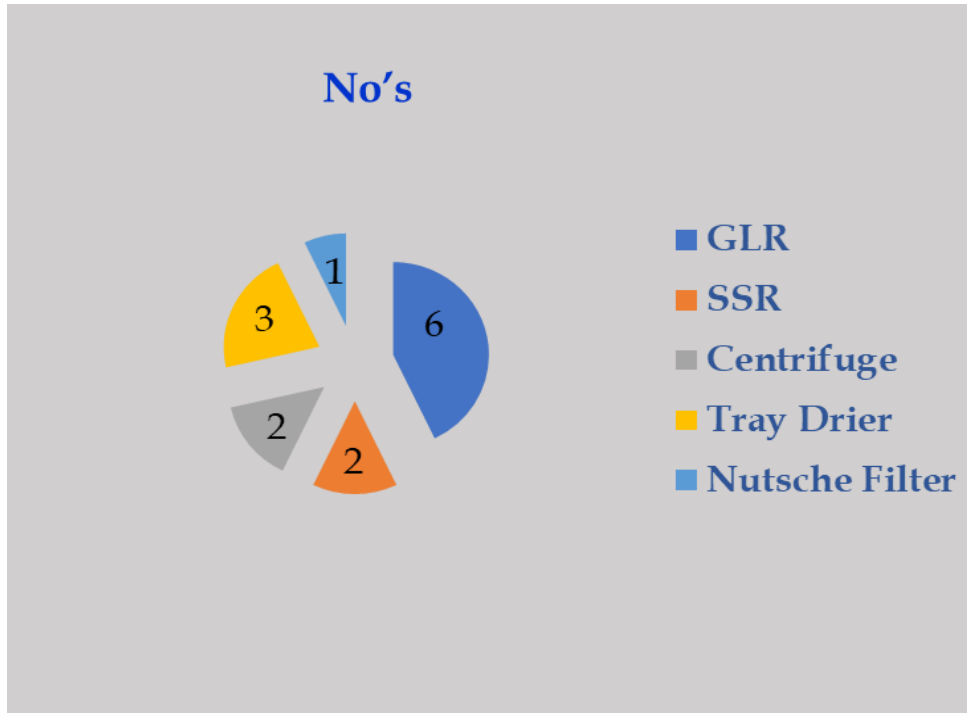
- CHLORINATION
- BROMINATION
- HYDROGINATION
- EPOXIDATION
- HYDROLYSIS
- REDUCTION
- CONDENSATION
- METHYLATION
- FRIEDEL CRAFT REACTION

TEMP. MAX.: 200°C +
TEMP. MIN.: -15°C

Clean Room

- Site having 3 air handling unit i.e. AHU-101, AHU-102 and AHU-103 respectively.
- AHU-101 is for Pharma crystalliser area.
- AHU-102 is for Pharma powder processing area.
- AHU-103 is for Pharma pilot plant.
- AHU pre-filters are 10 μ , 5 μ and terminally HEPA filter.
- AHU system is validated.
- Area classified as class 1,00,000

Pilot Plant – Equipment Details



600 L 760

Total reactor volume capacity is 1360 L.

Accreditations

✓ WHO-GMP CERTIFIED BY CDSCO



✓ CEP APPROVED



✓ GMP CERTIFIED BY DCA TELANGANA




✓ ISO 9001: 2015




Regulatory Status

OWN PRODUCT FILING STATUS

Name of Product	Filing	Status
Deferiprone		<i>DMF Filing activity is completed with EDQM and waiting for Approvals.</i>
Deferasirox		
Acetyl cysteine		
Gliclazide		
Olmesartan medoxomil		

FILING STATUS OF JOINT VENTURE

Name of Product	Filing	Status
Irbesartan		<i>CEP's Approved</i>
Torseamide		
Darunavir Ethanolate		
Dorzolamide HCl		

Quality Management System

- Quality Management System is as per ICH guideline.
- All changes are routed through change control procedure.
- Deviation procedure is in place.
- Annual product quality review is in place.
- Batch release procedure is in place.
- Vendor qualification procedure is in place.
- Market complaint procedure is in place.
- Corrective and Preventive Action procedure is in place.

Quality Control Laboratory



HPLC



GC



STABILITY CHAMBER

Equipment in Wet Lab:

- Muffle Furnace
- Melting Point Apparatus
- Hot Air Oven
- Sonicator
- KF Titrator
- Potentiometer
- pH Meter
- TLC Chamber and UV cabinet
- Weighing Balance

Instruments

HPLC

Total number – 03 no.

Agilent with EZ chrome software - 01 no.

Waters with Empower 2 software- 01 no.

Shimadzu with Lab Solutions Software-01 no.

GC

Total number – 02 no.

GC auto-injector (Agilent) with EZ chrome elite- 01 no.

GC-HS (Shimadzu) with lab solution software- 01 no.

STABILITY CHAMBER

Total number – 02 no.

Make- Thermolab

Long term storage condition: $25 \pm 2^{\circ}\text{c}$ & $60\% \pm 5\%\text{Rh}$

Accelerated storage condition : $40 \pm 2^{\circ}\text{c}$ & $75\% \pm 5\%\text{Rh}$

OTHER INSTRUMENTS

FT-IR spectrophotometer - 01 no.

UV visible spectrophotometer- 01 no.

Quality Control

- ❖ Quality Control is equipped with sophisticated equipments like HPLC, GC & GC Head Space with latest software.
- ❖ Quality control instruments are enabled Audit trails to comply 21 -CFR-PART-11.
- ❖ Server is connected to instruments to handle the electronic data for back up and retrieval.
- ❖ All employees are trained with respective to Data integrity as per the Data integrity policy.

AMARA LIFE SCIENCES OVERVIEW

AMARA Life Sciences

Amara Life Sciences is a green field project located in Pharma Zone at Atchutapuram, Visakhapatnam, Andhra Pradesh. This zone offers viable eco-system with features like common effluent treatment facility, good manpower, well-organized Industrial policies and supporting infra suitable for Pharmaceutical Industry.

This Project is planned to accommodate huge production capacity aligning with International and National regulatory norms. The products which are developed, scaled and filed at Amara labs will be transferred here for further commercial viability.

Site Information

- Total Site Area – 20000 m²
- Built Area – 11000 m²

Manufacturing Site address:

Amara Life Sciences Pvt. Limited

Plot No. 5G, Gurajapalem(v),

Rambilli(M), Atchutapuram,

Visakhapatnam 531011

Andhra Pradesh, INDIA

www.amaralifesciences.com

marketing@amaralifesciences.com



AMARA Life Sciences – Project Details

PROJECT DETAILS		
Land Area	5.5 acres	
Manufacturing blocks	Production Block	Total
Capacity (KL) Installed	230	230KL
No of reactors Planned	28	28 nos
Expected Output (TPA)	600	600MT/annum

Current Status: Equipment qualification is completed and commercial operations are started in December 2022

Major Customers



