

# 

Laboratories India Pvt Ltd

Corporate Profile

### Introduction

# FULLY INTEGRATED SOLUTIONS FOR INTERMEDIATES

### Contact Us

#### -: Orch Laboratories India Pvt Ltd :-



Website www.orchlabs.com

#### **Corporate Office**

Plot No: 44. Palampally Villas Opp: Karur Vysya Bank Nizampet Road, Kukatpally Hyderabad, Telangana – 500090 INDIA

**Tel:** +91(40)23899403

email: info@orchlabs.com

#### **Manufacturing Facility**

Plot No: 51A, D, E, F, G & H IDA, Kondapalli, Ibrahimpatnam Mandal Krishna Dist, Andhra Pradesh – 521228 INDIA

**Tel:** +91(866)2871112

# Location Map



#### Vision & Mission

#### Vision

Our vision is to be a leading manufacturer of intermediates and Active pharmaceutical ingredient (API) company in India and to become a significant player by providing high-quality cost-effective, affordable and innovative solutions for products

#### Mission

We shall provide total customer satisfaction and achieve leadership in chosen markets, products and services in domestic and overseas markets through innovative technology.

We Respect for our customers, partners, investors and competitors forms our awfully essence.

We are responsible to the society. We shall be good corporate citizens and will be driven by high ethical standards in our practices

# Values

#### Values

- > Reliable
- > Transparent
- Accountable

#### Team Work

Our Culture is built on quality and trust. The way we work together and with our partners embodies trust, transparency and close collaboration.

# Leadership

The Company is promoted by

Mr. P. Butchinayudamma

Incorporated in the Year 2011.



Orch Laboratories business philosophy is to deliver value added services to its customers by supplying the Quality products with cost competitive price

### Certification



#### Certificate of Registration

This is to certify that the

#### **QUALITY MANAGEMENT SYSTEM**

of

#### ORCH LABORATORIES INDIA PVT. LTD.

Administration Office: Plot No 44, Palampally Constructions, Opp: Karur Vysyabank, Nizampet, Kukatpally, Ranga Reddy Disrict, Telangana, 500072, INDIA
Factory: Plot No. 51A, D,E,F, G&H, IDA Kondapally, Ibrahimpatnam (M), Krishna (Dist), Andhra Pradesh, 521228, INDIA

for

#### Manufacture & Supply of Intermediates for Active Pharmaceutical Ingredients (API)

has been assessed and registered against the provisions of

#### ISO 9001:2008

International Standard

With

Registration Number:

11Q17826

Project:

43-17826-1-Q

Certification Date:

8 July 2016

Code: DG 24.66

Recertification Due Date: 14 September 2018

Exclusions: 7.3, 7.5.4

Mahmut Sogukpinar

Certification Approved By:

Technical Manager

tegistration is subject to the management system being continually maintained to the above standard und regular surveillance. Should surveillance not take place when required, registration shall be removed. This certificate is the property of GlobalGROUP of Companies Limited 21 Lansdowne Crescent, Edinburgh, Midlothian, EH12 SEH, Scotland, United Kingdom





# Organisation Values Chain Feedback After Sales Production Development Service Sales Marketing Production Materials Creation

### Work Force

#### Work Force

Production

Ware House

Maintenance

Safety

HR

QC

QA

R&D

Purchase

Marketing

Accounts

-15 No's

- 3 No's

- 7 No's

- 1 No

- 1 No

- 6 No's

- 3 No's

- 5 No's

- 2 No's

- 2 No's

- 1 No

Total - 46 Nos

# Our Expertise

### Reaction Specializations

- Friedal Craft's Reaction's
- Halogenations Reaction's
- Wittig Reaction's
- Cyanation's
- > High Pressure Reaction's (pd and Ni catalyzed Reaction's)
- Acid Catalyzed Reaction's
- Chiral Separation (Asymmetric synthesis)
- Butyl lithium, Diborane, LDA Reaction's
- > All types of Reduction Reaction
- > All types of Oxidation Reaction's
- > Grignard Reaction's
- Peptide synthesis
- Cryogenic Reaction's
- All types of protection's and Deprotection's

# Our Products

S.No	Name of the Product	Code	CAS Number	Usage for
1	4-Sulphanamido Phenyl Hydrazine Hydrochloride	CLI-II	17852-52-7	Celecoxib Intermediate
2	1-(4-Methylphenyl)-4,4,4-Trifluoro-Butane-1,3- Dione	CLI-I	720-94-5	Celecoxib Intermediate
3	2,2-Dihydroxyacetic acid (-)-menthyl ester	CHE-I	111969-64-3	Lamivudine Intermediate
4	(2R,5R)-(1R,2S,5R)-2-isopropyl-5- Methylcyclohexyl 5-hydroxy-1,3-oxathiolane-2- carboxylate	CHE-II	147126-62-3	Lamivudine Intermediate
5	4-Amino-2-oxo-pyrimidinyl-oxathiolane-2-carboxylic acid-isopropyl-methyl-cyclohexylester	CHE-III	147126-73-6	Lamivudine Intermediate
6	Sucralfate	SCF-I	54182-58-0	Sucralfate
7	Cytosine	CHE-IIA	71-30-7	Lamivudine Intermediate
8	N-(Triphenyl methyl)-5-(4-Methyl biphenyl-2-yl) Tetrazole	OSI-I	124750-53-4	Olmisartan Intermediate
9	1-(Mercapto methyl)Cyclopropane acetic acid	MKI	162515-68-6	Montelukast Intermediate

# Our Products

S.No.	Name of the Product	Code	CAS Number	Usage for
10	6-Chloro Hexan-2-One	PFI-I	10226-30-9	Pentoxifylline Intermediate
11	5-Hydroxy metylthiazole	RTI-I	38585-74-9	Ritonavir Inermediate
12	2-[2-(4-Fluorophenyl)-2-oxo-1-phenylethyl]-4-methyl-3-oxo-N-phenyl pentanamide	DKT-III	125971-58-6	Atorvastatin Intermediate
13	1-(Mercapto methyl)Cyclopropane acetic acid	MKI	162515-68-6	Montelukast Intermediate
14	2,4-Difluoro-2-(1H-1,2,4,-Triazole-1yl) Acetophenone	FZI-I	86404-63-9	Fluconazole Intermediate
15	2-n-Propyl-4-methyl-6-(1-methylbenzimidazole-2-yl) benzimidazole	TSI-I	152628-02-9	Telmisartan Intermediate
16	Tert-Butyl 4'-(bromomethyl)biphenyl-2-carboxylate	TSI-II	114772-40-6	Telmisartan Intermediate
17	Ethyl 3-[[[2-[[(4-Cyanophenyl) amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]pyridin-2-yl amino] propionate	DGI-I	211915-84-3	Dabigatran
18	P-tert-Butylbenzenesulfonamide	BSI-I	6292-59-7	Bosentan Intermediate

## Our Clients

Impressive Clients

☐ M/s. Mylan Laboratories Limited



☐ M/s. Laurus Labs Private Limited



☐ M/s. Granules India Limited



# Plant Capacity

### Plant Capacities

Description	Capacities (Volumes)
Reaction Volume in KL	63 KL
Range In Reactors Size	1KL to 10.0KL
Total Number of Reactors	14
Facility	Glass Line Reactors and Stainless Steel Reactors

### Future Business Strategies

- Manufacturing and marketing at Global scale
- Low Cost and quality conscious approach
- Focus on high volume products
- Process / Reaction based specialization
- Dedicated facilities to selected product and customer requirement
- Product Selection process to be strengthened
- Assessment of customer requirement to be strengthened

#### Our Business Strength

### Our Business Strength



# Quality Policy

#### Quality Policy

We Orch laboratories manufacturing and supplying quality intermediates of API's for domestic/overseas market to consistently meet the needs of esteemed clients and the organization is committed to continually improve the Quality management system

### Buildings & Facilities

# Buildings & Facilities

Description	Area
Total Site Area	5,400 Sq.Yd
Total Build Up Area	777 Sq.Yd
Production	286 Sq.Yd
Maintenance & Utilities	122 Sq.Yd
Raw Materials Storage	245 Sq.Yd
Bulk Storage	183 Sq.Yd
Effluent handling	32 Sq.Yd
QC/QA & Admin	167 Sq.Yd
Green belt	4,839 Sq.Yd

#### **Production Facilities**

#### Production Facilities

Total Reactors (2KL, 3KL, 4KL, 5KL)

- No. of reactors : 14

-Total volume : 63 KL

SS reactors- (3KL, 4KL, 5KL, 8KL, 10KL)

- No. of reactors : 8

- Total volume : 41 KL

GLR reactors- (1KL, 2KL, 3KL, 5 KL)

- No. of reactors : 6

- Total volume : 22 KL

• Graphite heat exchangers : 2

• Tray drier :3

• Agitated Nutch filter cum drier : 1

• Centrifuges (48") : 4

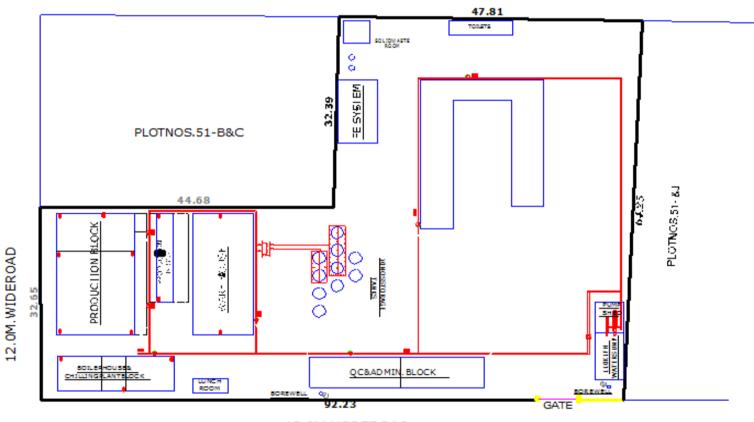
• Dual stage Scrubbers : 1

#### Site Layout



INNERIDAROAD

#### 12.0M.WIDEROAD



12.0M.WIDEROAD

INNERIDAROAD

### Utilities

#### **Utilities**

■Coal fired boiler - 1.5 MT/hr

■Softener water system - 4 KL/hr

■Chilling Plant up to -10°C - 54 TR

■Cooling water circulation - 350 TR

■Power (SPDCTL) - 225 KVA

■ Diesel Generator - 125 KVA

### **Laboratory Facilities**

### Laboratory Facilities

•	HPLC	- 1 No
•	GC	- 2 Nos
•	FTIR	- 1 No
•	Polari Meter	- 1 No
•	Karl Fischer Titrator	- 1 No

Melting point apparatus - 1 No
 Chemical Analysis

UV Cabinet -1 No
 Conductivity meter -1 No
 pH meter -1 No

• Tied-up with external agencies to get NMR, XRD, Mass and LCMS reports instantly.





#### QMS Status General

#### QMS Status General

- Provides a high level assurance that intermediates are manufactured in a way that ensures their safety,
   efficacy and quality
- Consistently provide product that meets customer and applicable statutory and regulatory requirements
- Facility up-gradation
- Personnel training and assessment
- Periodical Self inspections and Quality audits
- Specifications and testing procedure for starting and packaging materials, for intermediate and bulk products and for finished products
- Control of starting materials and intermediate, bulk and finished products
- Prevention of cross-contamination and contamination during production

#### QMS Status General

#### QMS Status General

- Deviations are reported, investigated and recorded
- Regular evaluation of product quality to verify consistency and continued improvement
- System for change control is applied
- Comprehensively designed and well implemented quality system
- Clearly defined and systematically reviewed processes
- Qualification and validation are performed
- Clear, written instructions and procedures are in place
- "All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures and corrective action should be taken."

# Manufacturing Reactors



# Raw Material Vendors

S. No.	Name of the Material	Approved Vendor
1	Sulfanilamide	Zhejiang Chemsyn Pharma Co Ltd, China
		Suzhou Wugan Pharmaceutical Co. Ltd, China
		Wujiang Bolin Industry Co Ltd, China
	Hydrochloric acid	SG Chemicals, Hyderabad
		Sri Rayalaseema Alkalies and Allied
2		Andhra Sugars Ltd, Saggonda
		Durga Industries Ltd
	Sodium Nitrate  Rashtriya  Radiant In  Panjab Ch	Indian Oxalate Ltd, L Parshuram, MH
		Rashtriya Chem & fertilizers, Mumbai.
3		Radiant Induschem Pvt. Ltd, Auranga
		Panjab Chemicals and corp Protection Ltd
		Deepak Nitrate Ltd, Gujarat
4	Sodium Sulfate	Magna Chem. Mnfrs. Pvt. Ltd, Pondy
4		Aditya Birla Chemicals (Thailand) Ltd

#### **Product Packing**

#### Product Packing

- The product packing will be carried out at identified & designated area
- The Product packing followed by primary packing in transparent LDPE bag and twist tied.
- Secondary packing in black LLDPE bag and twist tied.
- Final packing in HDPE drums with metallic ring having pilfer seal.
- The product standard packing capacity is 50 Kg
- Paste the product label on each drum for identification and traceability.
- Store at designated Finished product area to keep away from heat sources.

Note: Based on the customer requirement packing will be carried out.

### Transportation

### Transportation of Product

- We follow our consignment to ensure safe and timely delivery.
- We follow all labeling, packing circumstances as per customer requirements and applicable Guidelines.



#### Product Label

#### 4-(SULFAMOYL PHENYL) HYDRAZINE HCL (CCI)

Batch No. : Gross wt :

CAS Number : 27918-19-0 Tare wt :

Mfg Date : Net wt :

Exp/Re-Test Date: Container No.:

Storage: Store in well closed containers at ambient temperature.

#### Manufactured by:



#### ORCH LABORATORIES INDIA PVT.LTD

#### Admin. Office:

Plot No. 44, Palampally Villas, Opp. Karur Vysya Bank Nizampet Road, Kukatpally, Hyderabad-500 090 Telangana, India. Ph: +91 40 2389 9403

#### **Factory:**

Plot No. 51A, D,E,F,G,&H, IDA Kondapalli, Ibrahimpatnam (M) Krishna (Dist). 521228, A.P., India Ph: +91 866-287112

Format No. QA-027-L03-00

**Effective date: 01-10-2016** 

#### **Customer Service**

#### Customer Service

- We will respond immediately to customer inquiries, guide customers through purchasing process, make product or service recommendations and resolve complaints or technical concerns.
- We are active in adopting and follows the customers STP and their requirement.
- We can develop the quality parameters as per customers' requirement if desired.

#### Customer Feedback

#### Customer Feedback



We get customer feedback once in a year from our valuable customers on our services during last year, same will be filed in our records.

Suggestions made by the customers will be effectively implemented.

Safety Protocol

**Safety Protocol** 

# Safety Protocol

### Safety Protocol

Visitors shall be allowed up on prior permission from the consent authority.

Visitors are allowed with visitor's pass.

Wear Goggles while handling of materials and process operations.





Wear helmet while visiting plant and warehouse.

Photography is restricted inside the factory premises. Electronic goods shall be deposited in security while entering.



# Safety Protocol

#### Safety Protocol



Usages of mobile phones, pager etc will not be permitted in premises.

Smoking is strictly prohibited inside the factory premises. Cigarettes, lighters, match box and alcoholic related substances etc... should be deposited with security while entering into the premises.



