



Louis
PHARMACEUTICALS PVT. LTD.



Niche API Intermediates



MISSION STATEMENT

- To be a reliable Advanced API intermediate manufacturer





Louis Pharma has an integrated focus from various disciplines including R&D, Quality Control, Quality Assurance, Environment, Human Resource, and Manufacturing teams.

- Established in 2009
 - ISO 9001:2015 & IRCA certified
 - Specialized in Advanced Intermediates Manufacturer
 - Offers custom synthesis chemicals
 - Maintaining cGMP standards and meeting the current US DMF requirements.

CERTIFICATIONS

ISO CERTIFICATE

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1434468**

Certificate Holder:



Louis Pharmaceuticals Pvt. Ltd.
 Sy. No. 262/3 (New), 376/2 (Old),
 Nawabpet (Vill), Shivampet,
 Medak Dist. – 502 313, India.

Scope: **Manufacture and Supply of API Intermediates.**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2018-02-07 until 2021-01-08.
 First certification 2015

Handwritten signature

2018-02-07

TÜV Rheinland Cert GmbH
 Am Grauen Stein · 51105 Köln



GMP CERTIFICATE



SYSGMP
 SYSTEMS & GMP CONSULTANTS
 Hyderabad, Telangana state, India
www.sysgmp.com



Certificate of GMP Compliance of a Manufacturer of Intermediates for Pharmaceutical Use

Manufacturing site address:

Louis Pharmaceuticals Private Limited
 Sy.No.262/3 (New), 376/2 (Old), Nawabpet Village,
 Shivampet Mandal, Medak District, Telangana-India

Systems and GMP consultants auditor (IRCA qualified QMS Auditor), confirms that this manufacturer of intermediates (for pharmaceutical use) has been inspected following ICH Q7 and EU GMP part-II guidelines.

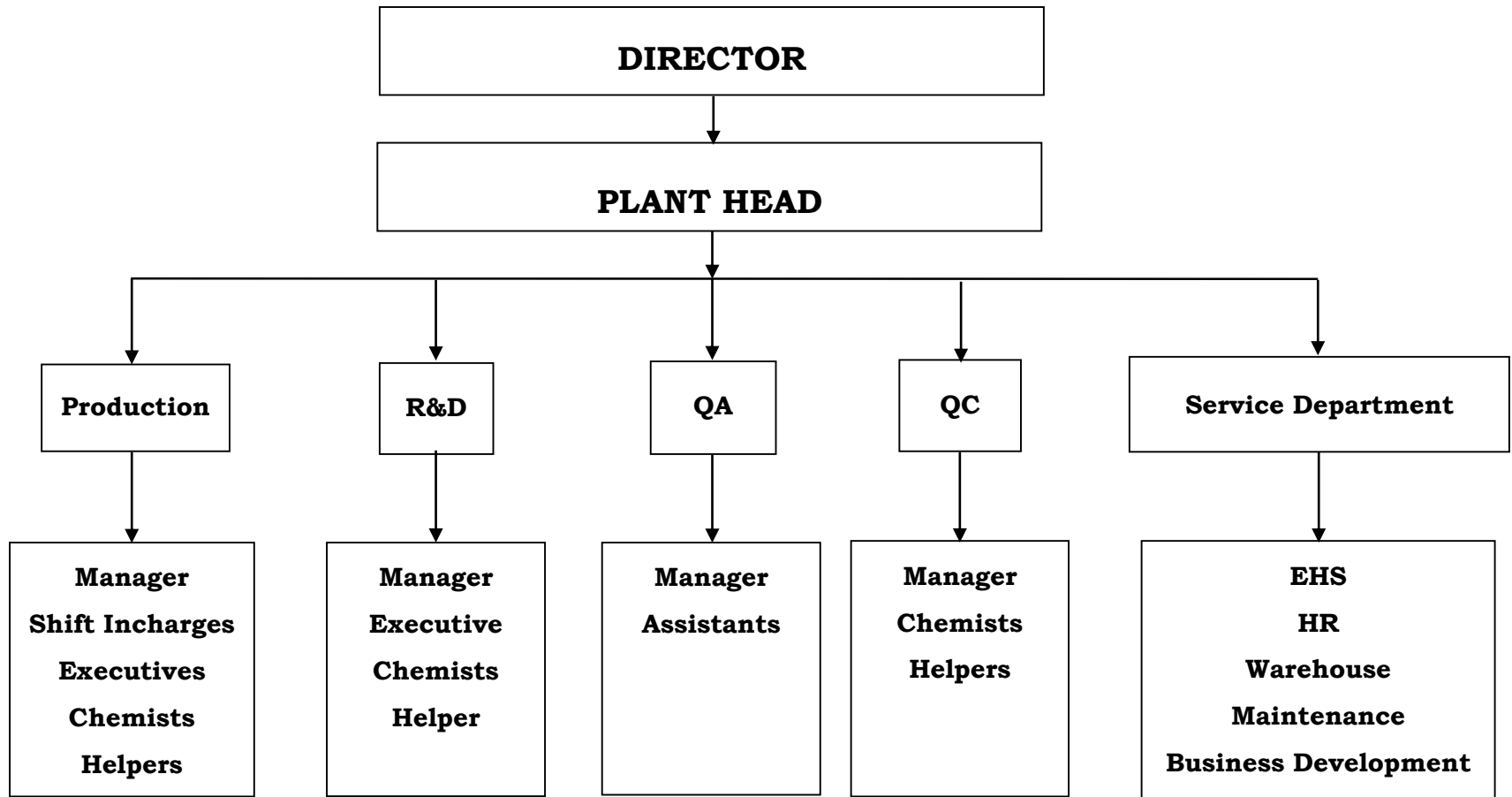
From the knowledge gained during periodical inspection of this site, the latest of which was conducted on 8 and 22 March 2016, it is considered that the manufacturer complies with the Good manufacturing practices requirements of ICH Q7/ EUGMP Part-II (applicable to intermediates).

Signed:

Handwritten signature

Dr. Madhusudhan Thota
 IRCA qualified QMS Auditor (Pharma)
 Date: 24 March 2016

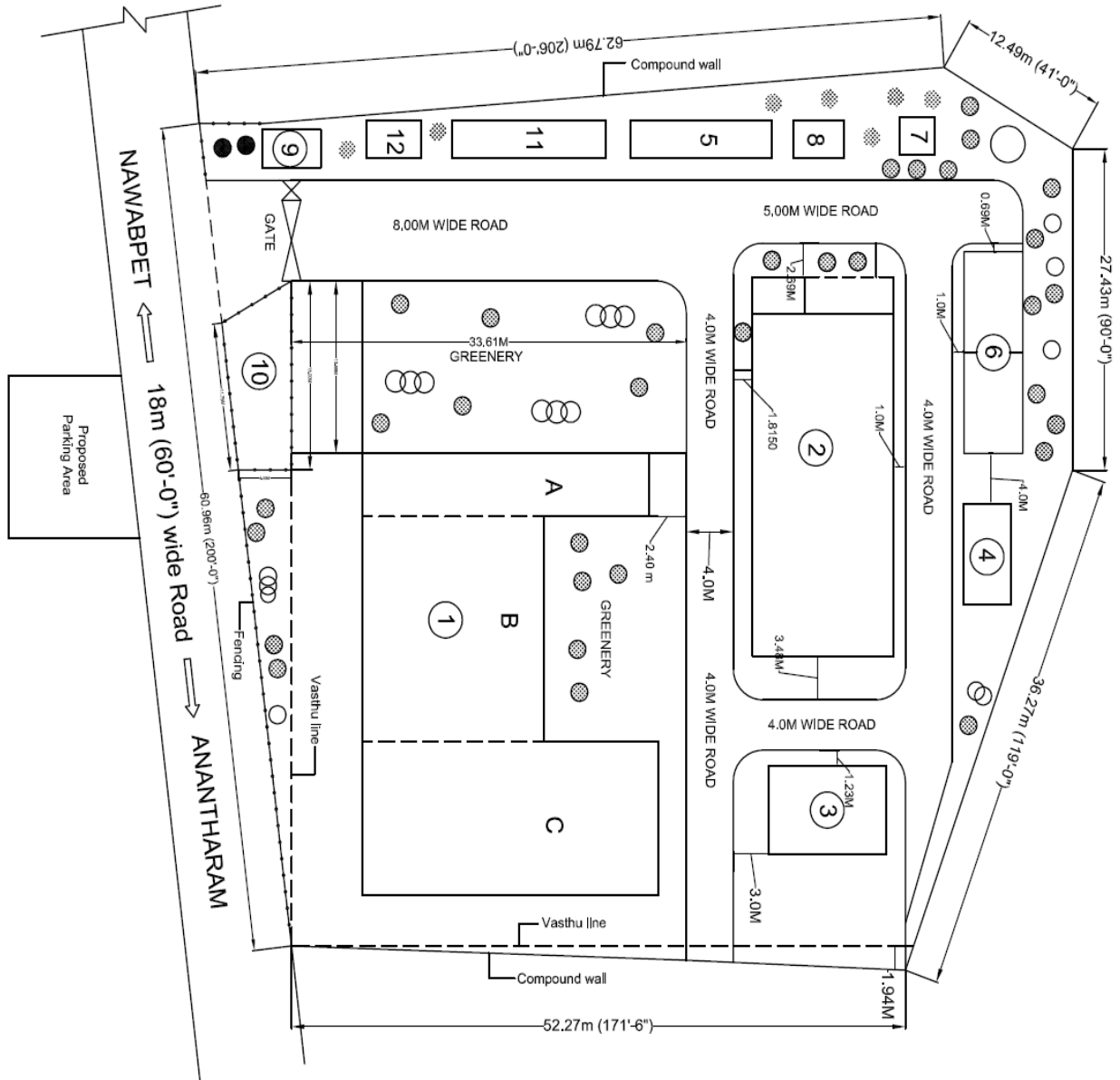
Organogram



Highly qualified people and rich experience in manufacturing and other key areas across the organization.

Total Strength- 60

Plant Layout





Well cleaned and ventilated process equipment for manufacturing the intermediates



PURIFICATION AREA



Purification Area (Mezzanine floor)



Purification Area (Ground floor)

Clean room facility to take up the manufacturing of advance intermediates up to N-1 stage

Purification area conforms to ISO-8 classification.

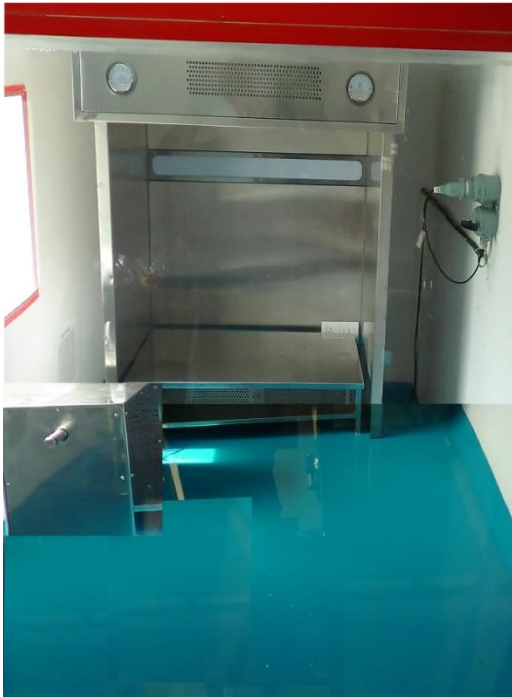
Technical Information:

AHU System- 10,000 CFM & 2,500 CFM with 0.3 micron Hepa filter

Brine Compressors- 20 TR & 10 TR

Contd...

BLENDING & PACKING



Packing Area

Blending & Packing area conforms to ISO-8 classification.

Technical information:
RLAF- 0.5 micron Hepa filter



WAREHOUSE



Key features:

Segregated areas for Sampling, Quarantine, Approved and Rejected materials to meet the regulatory requirements.



QUALITY CONTROL



Instrumentation



Wet lab

Instrument Details:

HPLC	3
GC	2
UV	1
IR	1

Key features:

Well equipped Wet lab system
Quality Control Lab is well maintained
as per GLP standards



R&D



Pilot Plant

R&D Expertise:

- ❖ Develop API Intermediates with multi step synthesis
- ❖ Can handle reactions such as Esterification, Grignard reaction, Hydrogenation etc.,
- ❖ Expertise in characterisation of organic compounds
- ❖ Impurity synthesis and characterisation.

LIST OF EQUIPMENT

SS Reactors - 11 No's	Capacities from 50 Ltrs to 5 KL 50 L - 1 No, 100 L - 1 No, 250 L - 1 No, 1 KL - 1 No, 2 KL - 2 No's, 3 KL - 2 No's, 4 KL - 1 No, 5 KL - 1 No
Glass Lined Reactors - 05 No's	Capacities from 630 Ltrs to 3 KL 630 L - 1 No, 1 KL - 1 No, 1.6 KL - 1 No's, 3 KL - 2 No's
PP VAT - 1 No	5 KL Capacity
Tray driers - 02 No's	48 trays Driers
All Glass Unit - 03 No's	50 L - 1 No & 100 L - 2 No's
Vacuum Tray drier - 03 No's	4 Trays - 1 No, 15 Trays - 1 No & 45 Trays - 1 No
Nutsche Filters - 11 No's	In both SS and PP/FRP of different capacities (630 mm Dia, 650 mm Dia, 800 mm Dia, 850 mm Dia & 950 mm Dia)
Agitated Nutche Filters - 03	800 mm Dia - 1 No & 1.5 Mtr Dia - 2 No's
Centrifuges - 05 No's	12" - 1 No, 36" - 1 No & 48" - 3 No's
and other Process equipment	

“We at Louis Pharmaceuticals Pvt. Ltd aiming to achieve Quality excellence of active pharmaceutical ingredient intermediates.

To achieve this we shall follow

- Customer satisfaction through effective implementation of quality management system.
- Current good manufacturing practices by statutory & regulatory requirements.
- Strive to continual improvement of the organization”.

QUALITY ASSURANCE

Documentation Control	SOP Control
Market Complaints	Deviation Control
CAPA	Batch record review and Batch release
Internal Audit	Employee Trainings
Change Control	GMP, SOP

GMP and Quality aspects:

- All time readiness for audits
- GMP trainings and current regulatory requirements
- Online monitoring to implement GMP standard
- GMP as per ICHQ7 and EUGMP requirements
- Customer support



Authority	
Emcure Pharmaceuticals Pvt Ltd	Hetero Labs Limited
Gland Pharma Ltd (DUNDIGAL)	Fresenius-kabi Oncology
Gland Pharma Ltd (JNPC)	MSN Laboratories Ltd
Natco Pharma Ltd	Alembic Pharmaceuticals Ltd
Themis Medicare Ltd	Mac-Chem Products (I) Pvt. Ltd
Bal Pharma Ltd	Optimus Drugs Private Limited
Aurobindo Pharma Limited	

Customer Name

Fresenius Kabi Oncology

Emcure Pharmaceuticals Pvt. Limited

Hetero Group

Gland Pharma Limited

MSN Laboratories Pvt. Limited

Balpharma Limited

Natco Pharma

Aurore Life Sciences Pvt Limited

Mac-Chem Products (India) Pvt. Limited

Loba Chemie Pvt. Limited

Alembic Pharmaceuticals Ltimited

Macleods Pharma

Granules India Limited

Unichem Laboratories ltd

- **Dr. Madhusudhan T- GMP Consultant**
(Having 20+ years of experience in various MNC companies in CQA)
- **Dr G Nadamuni- Technical Consultant**
(Having 40+ years of experience in Organic Synthesis)
- **Dr. Chidhambaram VS - Technical Consultant**
(Having 25+ years of experience in Organic Synthesis)
- **Mr. Venkateswara Sastry K- Electrical Consultant**
(Having 40+ years of experience in Electrical and Safety)
- **Mr. Srinivas Reddy V- EHS Consultant**
(Having 20+ years of experience in EHS)

PRODUCT LIST

Commercial Products:

CODE	NAME OF THE INTERMEDIATE	CAS NO.	USED FOR API
L/AZ/01	1-O-acetyl-2,3,5-tri-O-benzoyl-beta D –Ribofuranose	6974-32-9	Azacitidine/ Decitabine
L/AZ/02	5-Aza Cytosine	931-86-2	
L/EL/01	2-Chloro-4,6-dimethoxy-1,3,5-triazine (CDMT)	3140-73-6	Eluxadoline/Ledipasvir/ Pemetrexed/ Peptide coupling agent
L/PL/01	Cyclam (1,4,8,11-Tetraazacyclotetradecane)	295-37-4	Plerixafor
L/PL/02	Alfa,alfa-Dibromo para Xylene	623-24-5	
L/RE/01	2,6-Dichloropurine	5451-40-1	Regadenoson/ Ribavirin/ Clofarbine
L/RI/01	β -D-Ribofuranose-1,2,3,5-Tetraacetate	13035-61-5	Ribavirin
L/TO/01	2,3:4,5 Bis-O-(1-Methyl ethylidene)-Fructopyranose azido sulphate	106881-35-0	Topiramate
L/VA/01	L-Valine methyl ester hydrochloride	6306-52-1	Valsartan/ Ritonavir

Onorder Products:

CODE	NAME OF THE INTERMEDIATE	CAS NO.	USED FOR API
L/AB/01	1, 5-Pentane diol diacrylate	36840-85-4	Atracurium Besylate
L/AB/02	Atracurium oxalate crude	64228-78-0	
L/BE/01	1,4-Butane sultone	1633-83-6	Betadex
L/CB/01	Cis- Atracurium oxalate crude	96687-52-4	Cis Atracurium Besylate
L/DE/01	(S)-(-)-1,2-Diaminopropane dihydrochloride	19777-66-3	Dexrazoxane
L/GE/01	2-Deoxy-2,2-difluoro-D-erythro-pentofuranose-3,5-dibenzoate-1-methanesulfonate	122111-11-9	Gemcitabine
L/LS/02	3,5-Diiodo-L-tyrosine	18835-59-1	Levothyroxine Sodium
L/LS/03	Bis(4-Methoxy Phenyl)Iodonium Bromide	19231-06-2	
L/MI/01	4-(5-(4-(pentyloxy) phenyl) isoxazol-3yl))) benzoic acid	179162-55-1	Micafungin
L/PE/01	2,4,Diamino-6-Hydroxy-Pyrimidine	56-06-4	Pemetrexed
L/PE/02	Methyl 4-Bromo Benzoate	619-42-1	

Onorder Products:

CODE	NAME OF THE INTERMEDIATE	CAS NO.	USED FOR API
L/PR/01	Methyl 4-(2-methoxy-2-oxoethyl) benzoate (Homoterephthalic acid dimethyl ester)	52787-14-1	Pralatrexate
L/PR/02	2, 4-diamino-alpha-[4-(methoxycarbonyl) phenyl]-alpha-2-propynyl-6-pteridinepropanoic acid methyl ester	146464-91-7	
L/PR/03	4-[1-[(2,4-Diamino-6-pteridiny)methyl]-3-butynyl]benzoic acid	146464-93-9	
L/RS/01	3-Acetylpyridine	350-03-8	Risedronate sodium
L/RS/02	3-Pyridylacetic acid	501-81-5	
L/RS/03	3-Pyridyl acetic acid Hydrochloride	6419-36-9	
L/RB/01	(2β, 3α, 5α, 16β, 17β)-2-(4-Morpholinyl)-16(1-Pyrrolidinyl)androstane-3, 17-Diol	119302-20-4	Rocuronium bromide
L/TH/01	N-(n-Butanesulfonyl)-O-[4-(4-pyridinyl)-butyl]-(S)-tyrosine	149490-61-9	Tirofiban Hcl
L/TH/02	N-(Butanesulfonyl)-O-(4-(4-pyridinyl)butyl)-(L)-Tyrosine methyl ester (TFE)	--	
L/TH/03	N-Trityl-L-Tyrosin methyl ester	--	
L/TH/04	4-(4-Chloro butyl) pyridine Hydrochloride	149463-65-0	
L/ZL/01	3-Chloro-1,2-benzisothiazole	7716-66-7	Ziprasidone/ Lurasidone



Thank you

Customers Demand and Warrant a High Quality Product, Louis will take Responsibility to Give them What they Need.

