WELCOME TO SYNAPTICS SYNAPTICS LABS PRIVATE LIMITED (SLPL)

Always a step ahead...



DUNS: 565271800 & FEI: 3021487911 Numbers

SYNAPTICS has been incorporated in October 2018, as a Global Research and Innovation driven Integrated Pharmaceutical Company focusing on the Development, Production and Marketing of API's (Active Pharmaceuticals Ingredients) and its Intermediates on an opportunity driven basis.

We at Synaptics, have WHO GMP, ISO Certified and Auditable Facility and are in the Compliance of FDA & WHO Norms located in an area of 4.8 acres at Vizag consists of total 4 Production Blocks & Well-equipped Standalone R&D Lab with entire required facilities.



SYNAPTICS FOUNDERS

The following directors are actively involved in overall day to day operations as below:

Mr. Srinivasa Reddy Goli

Over all performance of the company, as dictated by the board's overall strategy. Formulating and successfully implementing company policy.

Mr. Kishore Reddy Mandapati Corporate affairs and Business development

Mr. Srinivasa Reddy Gaddam Production & Factory Administration

Mr. Sridhar Reddy Chilukuri Quality Control & Quality Assurance

Mr. Jaya BharathaReddy KanamathaReddy PD Lab

VISION

To be one of the leading groups in research, manufacturing and distribution of both Advanced Intermediates and API's Active Pharma Ingredients in those sectors in which it operates.

- > An, innovation strategy
- Broad R&D platform
- Balanced portfolio of specialty and Advanced intermediates
- Global commercial presence, with strength in emerging markets

CORE COMPETENCIES

- **Quality:** Constantly seeking to offer products and service at a high level.
- Agility: Being objective and practical with speed, assertiveness and responsibility.
- **Team Work:** Fundamental to reach our goals.
- **Focus:** Aligning objectives to reach results.
- **Innovation:** Diversify to generate new business opportunities.
- **Pride:** Passion for what we do.
- **Faith:** Believing that anything is possible.

QUALITY POLICY To Provide Accessible High Quality Products.

Quality Policy Statement

It is Synaptic's policy to continuously enhance and challenge our quality systems to produce safe, efficacious and high - calibre products dedicated to improving our customer's quality. It is our irrevocable commitment to adhere to all currently applicable regulatory requirements and to continuously improve while applying a scientifically sound and data driven approach in our decisions.

Geographical Location of Plant:

Longitude : 17°30.339' N Latitude : 82°57.140' E

Our Plant is located in Atchutapuram, Near Visakhatpatnam a historical city which is about 40Km from Visakhapatnam Airport and 610Km from Rajiv Gandhi International Air Port Hyderabad.

Plant Address:

Plot No. 28-B, Industrial Park, Atchuthapuram, APIIC, Lalamkoduru(V), Rambilli(M), Visakhapatnam-531011, Andhra Pradesh, India.

Corporate Office address:

Flat No. S-404, SVSS Nivas, Street No-1, Czech Colony, Sanathnagar, Hyderabad, Telangana – 500 018, India. Phone No: 040-29801835, 29801859 <u>www.synapticslabs.com</u>

KEY HIGHLIGHTS

Strong Pipeline Potential

Consistent Product Launches planning with significant technical, financial backing, Partnerships & Vendors

High Corporate Governance Focused for Delivery Standards

Passion for quality, demonstrated by initiating internal quality audits. facility being established in 4.8 Stringent & Superior global quality and manufacturing standards.

High Operating Values & Ethics

State of the art manufacturing acres with proper alignment of Manufacturing Strategy.

To launch products suitable for the market from its global portfolio and alliance partners, which shall increase the existing product portfolio

Long Term Commitment

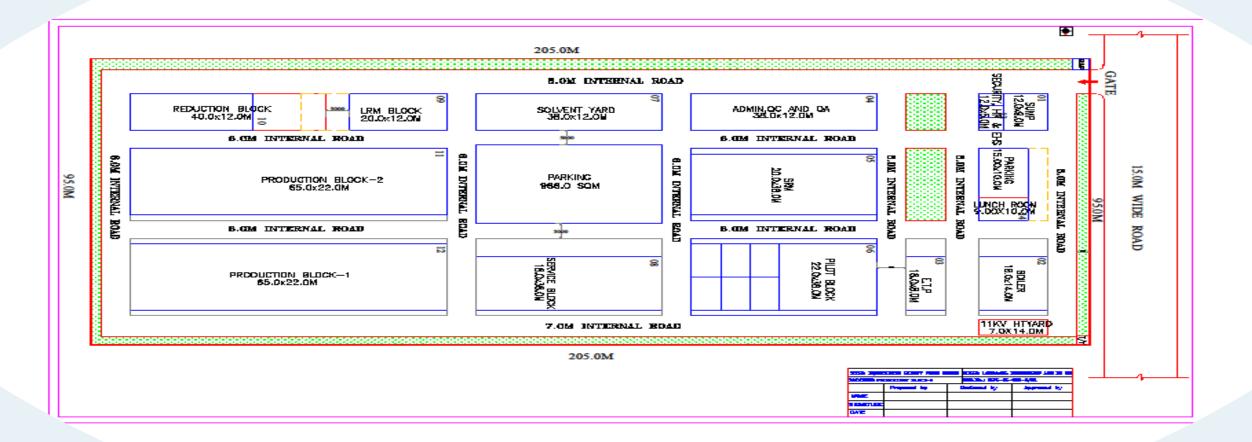
Focus on Win-Win Relationships Everyday.

Execute flawlessly, Think Strategically, Innovate and make things better & Stay connected.

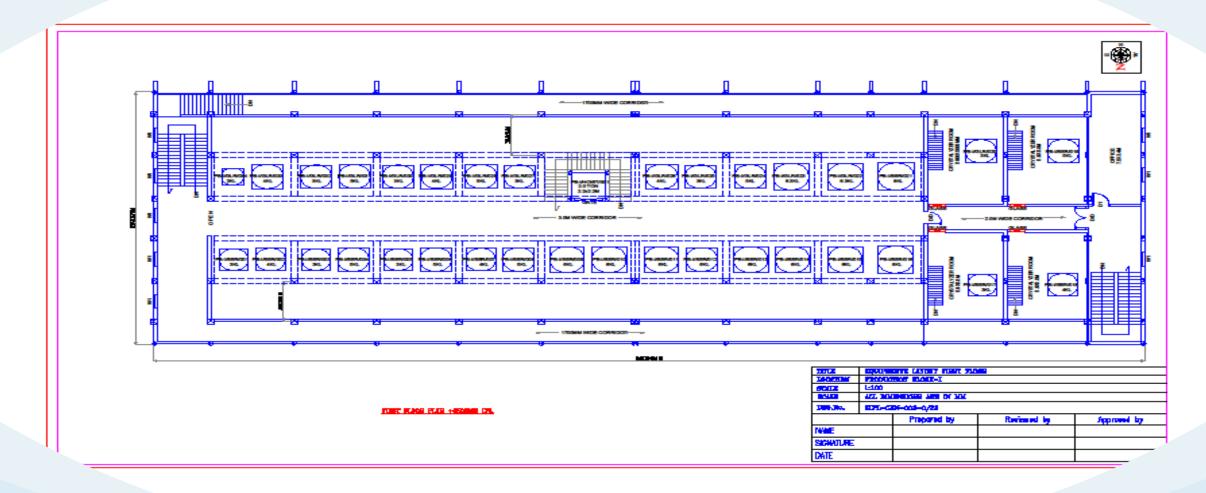
CERTIFICATIONS

- ✓ ISO 9001:2015;ISO 14001:2015;ISO 45001:2018
- ✓ GMP
- ✓ WHO GMP

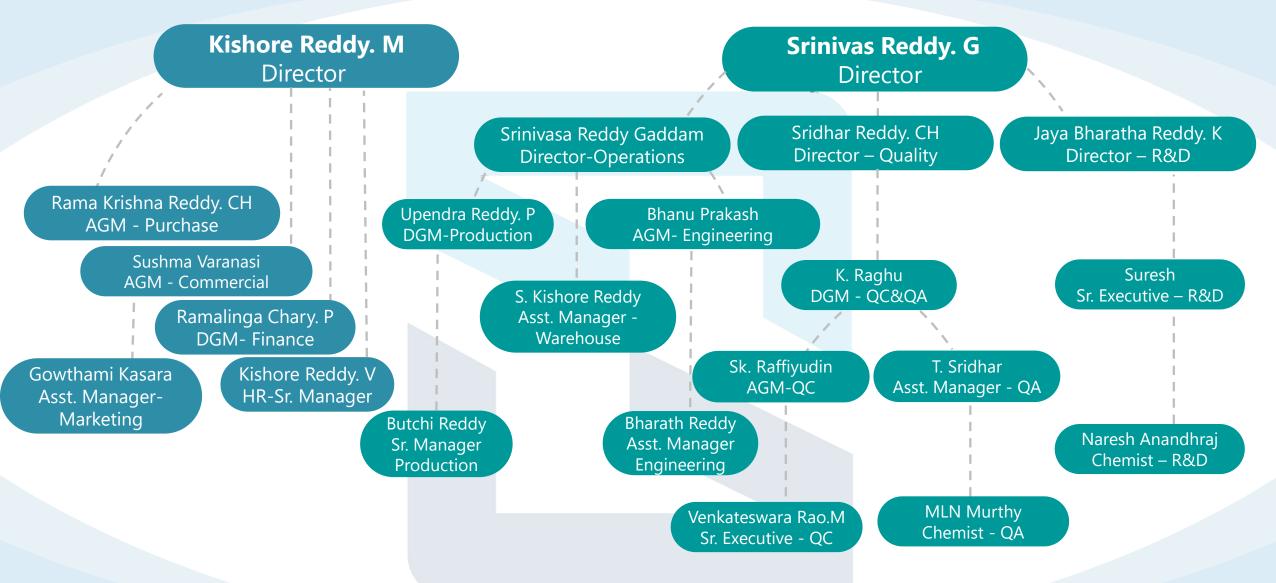
PLANT LAYOUT



PRODUCTION BLOCK - I



ORGANOGRAM



LIST OF APIS --- COMMERCIAL SCALE

ΑΡΙ	Pharmacopoeia		API	Pharmacopoeia	
ARIPIPRAZOLE	IP/USP/IHS	ANTI - PSYCHOTIC	VALSARTAN	IHS	ANTI-COAGULANT
QUETIAPINE FUMARATE	IP/USP/IHS	ANTI - PSYCHOTIC	IMEGLIMIN HCL	IHS	ANTI-DIABETIC
RABEPRAZOLE SODIUM	IP/USP/IHS	ANTI - ULCERATIVE	VILDAGLIPTIN	IHS	ANTI-DIABETIC
2-DEOXY-D-GLUCOSE	IHS	ANTI - COVID	SITAGLIPTIN	IHS	ANTI-DIABETIC
MOLNUPIRAVIR	IHS	ANTI - VIRAL	TAFAMIDIS MEGLUMINE	IHS	To TREAT CARDIOMYOPATHY
NIRMATRELVIR	IHS	ANTI - VIRAL			
CARIPRAZINE HYDROCHLORIDE	IHS	ANTI-DEPRESSANT			
DABIGATRAN MESILATE ETEXILATE	IHS	ANTI-COAGULANT			
RIVAROXABAN	IHS	ANTI-COAGULANT			

LIST OF APIS - UNDER DEVELOPMENT

ΑΡΙ	Pharmacopoeia	
ΑΡΙΧΑΒΑΝ	IHS	ANTI-COAGULANT
FIMASARTAN	IHS	ANTI-HYPERTENSIVE
BEMPEDOIC ACID	IHS	ANTI- HYPERCHOLESTEROLEMIA
VALSARTAN	IHS	ANTI-COAGULANT
DABIGATRAN MESILATE ETEXILATE	IHS	ANTI-COAGULANT
VARDENAFIL	IHS	

ANTI - PSYCHOTIC	
ARIPIPRAZOLE	
3,4-Dihydro-7-hydroxy-2(1H)-quinolinone	22246-18-0
7-(4-Chlorobutoxy)-3,4-dihydro-2(1H)-quinolinone	120004-79-7
1-(2,3-Dichlorophenyl)piperazine Hydrochloride	119532-26-2
QUETIAPINE FUMARATE	
Dibenzo[b,f][1,4]thiazepin-11(10H)-one	3159-07-7
11-(1-Piperazinyl)-dibenzo[b,f][1,4]thiazepine dihydrochloride	11974-74-4
ANTI-ULCERATIVE	
RABEPRAZOLE SODIUM	
2-Hydroxymethyl-4-(3-methoxypropoxy)- 3-methylpyridine hydrochloride	675198-19-3
2-Chloromethyl-3-methyl-4-(3-methoxypropoxy)pyridine hydrochloride	153259-31-5
2-{{[4-(3-Methoxypropoxy)-3-methyl-2-pyridyl]methyl}thio}-1H-benzimidazole	117977-21-6
2-[[4-(3-methoxypropoxy)-3-methyl-pyridin-2-yl]methylsulfinyl]-1H-benzoimidazole	117976-89-3

ANTI-COAGULANT		
DABIGATRAN ETEXILATE MESILATE		
2-[(4-cyanophenyl)amino]acetic acid	42288-26-6	
Ethyl 3-(2-(((4-carbamimidoylphenyl)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5- carboxamido)propanoate	429658-95-7	
Ethyl 3-[3-Amino-4-(methylamino)-N-(2-pyridyl)benzamido]propionate	212322-56-0	
Ethyl 3-[{[4-(methylamino)-3-Nitrophenyl]carbonyl} (pyridine-2-yl) amino] propanoate	429659-01-8	
RIVAROXABAN		
4-(4-Aminophenyl)morpholin-3-one	438056-69-0	
(S)-(+)-N-(2,3-Epoxypropyl) Phthalimide	161596-47-0	
5-Chlorothiophene-2-Carboxylic acid	24065-33-6	
(S)-4-(4-(5-(Aminomethyl)-2-oxooxazolidin-3-yl)phenyl)morpholin-3-one hydrochloride	898543-06-1	
APIXABAN		
3-Morpholino-1-(4-(2-oxopiperidin-1-yl)phenyl)-5,6-dihydro pyridin-2(1H)-one	545445-44-1	
(Z)-Ethyl 2-Chloro-2-(2-(4-methoxyphenyl)hydrazono)acetate	27143-07-3	

ANTI VIRAL	
FAVIPIRAVIR	
6-Bromo-3-hydroxypyrazine-2-carboxamide	259793-88-9
MOLNUPIRAVIR	
(((3aR,4R,6R,6aR)-6-((E)-4-(hydroxyimino)-2-oxo-3,4-dihydropyrimidin-1(2H)-yl)-2,2-dimethyltetrahydrofuro[3,4- d][1,3]dioxol-4-yl)methyl isobutyrate)	2346620-55-9
NIRMATRELVIR	
(1R,2S,5S)-methyl 6,6-dimethyl-3-aza-bicyclo[3.1.0]hexane-2- carboxylate hydrochloride	565456-77-1
α-amino-2-oxo-3-Pyrrolidinepropanamide Hcl	2628280-48-6
3-methyl-n-(trifluoroacetyl)-L-valine	666832-71-9
ANTI-COAGULANT	
VALSARTAN	
L-Valine, methyl ester, hydrochloride (1:1)	6306-52-1
5-[4'-(Bromomethyl)[1,1'-biphenyl]-2-yl]-1-(triphenylmethyl)-1H-tetrazole	124750-51-2

ANTI-HYPERCHOLESTEROLEMIA	
BEMPEDOIC ACID	
Ethyl 7-Bromoheptanoate	29823-18-5
P-toulenesulfonylmethyl isocyanide	36635-61-7
ANTI-HYPERTENSIVE	
FIMASARTAN	
2-Butyl-1,6-dihydro-N,N,4-trimethyl-6-oxo-1-[[2'-[1-(triphenylmethyl)-1H-tetrazol-5-yl][1,1'-biphenyl]-4-yl]methyl]-5- pyrimidineacetamide	503155-67-7
5-(4'-(BROMOMETHYL)(1,1'-BIPHENYL)-2-YL)-1-TRITYL-1H-TETRAAZOLE	124750-51-2
TAFAMIDIS MEGLUMINE	
4-amino-3-Hydroxy benzoic acid	2374-03-0
3,5 dichloro benzoyl chloride	2905-62-6
3,5-Dichlorobenzoic Acid	51-36-5

ANTI-DEPRESSANT	
CARIPRAZINE HYDROCHLORIDE	
Ethyl trans-2-(4-Aminocyclohexyl)acetate Hydrochloride	76308-26-4
CarbaMic acid, N-[trans-4-(2-hydroxyethyl)cyclohexyl]-, 1,1-diMethylethyl	917342-29-1
Trans N-tert-butoxycarbonyl-4-[2-[4-(2,3-dichlorophenyl)-piperazine-1-yl]- ethyl]-cyclohexylamine	506427-91-4
ANTI-DIABETIC	
VILDAGLIPTIN	
3-Amino-1-adamantanol	702-82-9
(S)-1-(2-Chloro-acetyl)-pyrrolidine-2-carbonitrile	207557-35-5
SITAGLIPTIN	
3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine hydrochloride	762240-92-6
Boc-(R)-3-Amino-4-(2,4,5-trifluorophenyl) butanoic acid	486460-00-8

MAN POWER

WARE HOUSE	10
PRODUCTION	49
QUALITY CONTROL	27
SAFETY HEALTH & ENVIRONMENT	
QUALITY ASSURANCE	
R&D	
ENGINEERING SERVICES	23
HR	
TOTAL	123

FACILITY OVERVIEW



WARE HOUSE

- Material Management system is in place.
- Dedicated areas for de-dusting, quarantine, sampling and dispensing, approval of raw materials and rejected materials.
- Separate rooms for sampling and dispensing.
- Separate storage areas for intermediate and finished products.





WARE HOUSE IMAGES





PRODUCTION

- Production Block-I is our intermediate and API manufacturing Facility.
- Dedicated AHU's in the clean room for corridor, Crystallizer room and powder processing areas

Production Block





PRODUCTION IMAGES



MANUFACTURING CAPACITIES (PB-I)

REACTORS

Equipment	Capacity	Nos
SS Reactor	8KL	2
SS Reactor	6KL	6
SS Reactor	5KL	4
SS Reactor	4KL	2
SS Reactor	3KL	3
GL Reactor	6.3KL	2
GL Reactor	5KL	3
GL Reactor	4KL	3
GL Reactor	3KL	4
GL Reactor	2KL	1

EQUIPMENT DETAILS

Equipment

Capacity Nos

SS Centrifuge -	48″7
Tray Dryer	
Tray Dryer	
Multi Miller	50-500kgs 3
ANFD	5KL 3
Filter Press	1.5 Tones 1
SS Centrifuge	60" 2

MANUFACTURING EQUIPMENTS - CRYSTALLIZER (PB-I)

REACTORS			EQUIPM
Equipment	Capacity	Nos	Equipment
	3KL		SS Centrifuge
	4KL		FBD
	5KL 3KL		Sifter Multi Miller
GL Reactor	SNL	I	

QUIPMENT DETAILS

Equipment	Capacity	No
SS Centrifuge	48″	4
BD	500Kg	1
Sifter	30″	
Multi Miller	50-500kg	s 1

MANUFACTURING CAPACITIES (PB-III)

REACTORS

Equipment	Capacity	Nos
SS Reactor	6KL	2
SS Reactor	5KL	1
SS Reactor	4KL	3+2
SS Reactor		
SS Reactor	2KL	1+1+1
SS Reactor	0.63KL	1+1
GL Reactor	6.3KL	1
GL Reactor	5KL	1
GL Reactor	4KL	1
GL Reactor	2KL	1

EQUIPMENT DETAILSEquipmentCapacityNosSS Centrifuge48"7Tray Dryer964Tray Dryer1921Multi Miller50-500kgs3ANFD5KL3Filter Press1.5 Tones1SC Centrifuge60"2

MANUFACTURING CAPACITIES (PB-IV)

REACTORS

Equipment	Capacity	Nos
SS Reactor	3KL	2
SS Reactor	2KL	2
SS Reactor	1.6KL	1
SS Reactor		
SS Reactor	0.75KL	2
SS Reactor	0.5KL	2
GL Reactor	2KL	2
GL Reactor	1.6KL	1
GL Reactor	1KL	······ 1
GL Reactor	0.63KL	2

EQUIPMENT DETAILS

Equipment

Capacity Nos

SS Centrifuge	48″7
Tray Dryer	96 4
Tray Dryer	1921
Multi Miller	50-500kgs 3
ANFD	5KL 3
Filter Press	1.5 Tones 1
SS Centrifuge	60" 2

QUALITY CONTROL INSTRUMENTS

SL. No	INSTRUMENT NAME	No's
01	HPLC	3
02	GC	3
03	Analytical balance	2
04	UV Spetrometer	1
05	FTIR	1
06	Hot Air Oven	
07	Vaccum Oven	1
08	Muffle Furnance	1
09	Melting Range Apparatus	1
10	Stability Chambers	4
11	Conductivity Meter	1
12	UV-Cabinet for TLC	1
13	KF & Auto Titrator	2
14	pH Meter	2

KEY UTILITIES

EQ. NAME

BOILER 5.0T/Hr APSEB TRANSFORMER ------ 1250KVA COOLING TOWER 650 TR *2 , at +25°C PROCESS WATER SYSTEM 5 m³/Hr HIGH VACUUM SYSTEM 0.1 Torr*2 NITROGEN PLANT ----- 50 nm³/Hr

CAPACITY

CHILLING PLANT 182TR at +5°C, 92TR at -20°C UPS FOR QC LABS 30 KVA-2nos, 10 KVA-1 no











QUALITY CONTROL







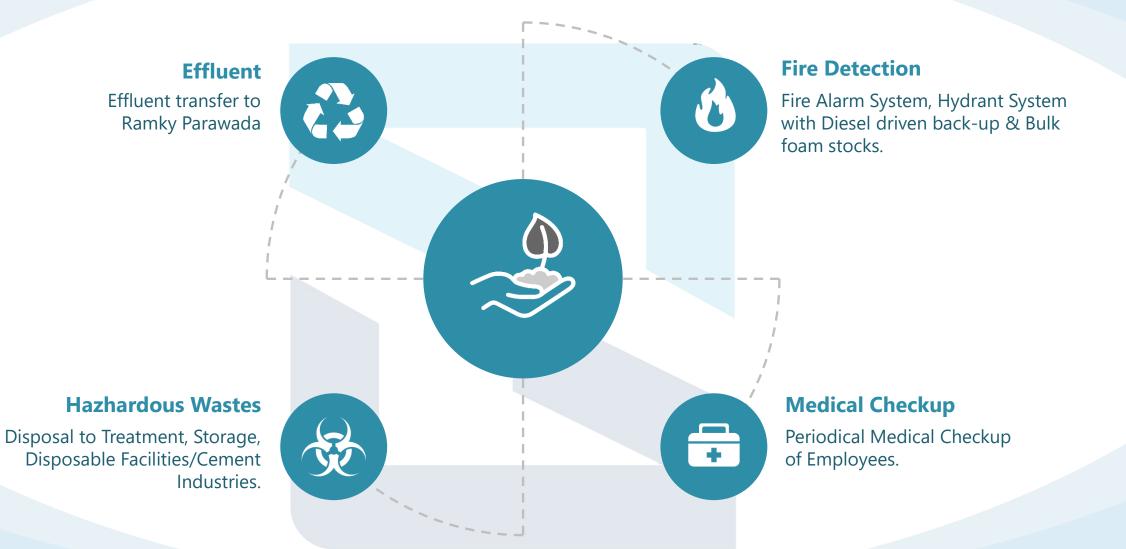
PROCESS WATER PLANT



QUALITY MANAGEMENT SYSTEM

- Documentation and Records Control
- Release of Intermediates
- Handling of Change Control / Deviations / Incidents
- Out of Specifications
- Process / Cleaning Validations
- Analytical Method Validations
- Customer Complaints / Returned Goods
- Trainings
- Pest and Rodent Control
- Calibration Program
- Preventive Maintenance Program
- Stability Monitoring
- Vendor Qualification
- Corrective Action and Preventive Action

ENVIRONMENT, HEALTH & SAFETY



LIST OF MAJOR CUSTOMERS

- Amoli Organics Pvt Ltd
- Aurigene Pharmaceuticals Services Limited (Dr. Reddys Group)
- ✤ Bajaj Healthcare Ltd
- BDR Pharmaceuticals
- Glenmark Life Sciences Limited
- ✤ Hikal Ltd
- MSN Laboratories Ltd
- Macleods Pharmaceuticals Ltd
- Optimus Drugs Private Limited
- Vasudha Pharma Chem Limited
- Codupha
- Eskayef Pharmaceuticals Ltd

