

# RAMPEX LABS PVT LTD

PRESENTATION BY

Prasanth.C  
Executive Director

Dated: 00/00/2019

# Way Forward.....

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# A Brief About Rampex....

Rampex was founded in 2004 and in the initial years we have out-sourced manufacturing of our products to other facilities. From January 2008 we commenced production in our own facility located in the out-skirts of Hyderabad which we refer to as Unit-1. In Oct 2014 we purchased our second manufacturing facility located in Pharma City-Vizag which is called as Unit-2. Since inception we have catered to large Indian as well as European Generic Players and a few Innovators also. We have nearly 110+Clients worldwide with our Unit-1 having been inspected and approved by the USFDA in March 2016 and Our Unit-2 has received Written Confirmation Certificate for our API Olanzapine (Form-II) which also has CEP granted.

# Highlights-Unit I



- Five Production Blocks
- USFDA Approval
- Equipped for handling High-Pressure Reactions
- Local Exhaust Ventilation System
- Powder Processing Rooms with  $5\mu$  Air Filtering
- Total Built Up Area is 5670 Sq.Mt and Total Area is 20639Sq.Mts
- Total Capacities 120KL comprising of 40+Reactors

# EIR Report From USFDA



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Quality Surveillance Assessment  
Inspection Assessment Branch  
10903 New Hampshire Avenue  
Building #51, Room 4316  
Silver Spring, MD 20993

TELEPHONE: 301-796-3254  
FAX: (301) 847-8742

March 21, 2016

Mr. Prasanth Chemuduri,  
Executive Director  
Rampex Labs Pvt., Ltd.  
Plot No. 151, S.V. Co-Operative Industrial Estate  
Village Road  
IDA Bollaram, Medak District, India

Reference FEI 3008479404  
Reference inspection date (s): 10/05/2015-10/09/2015  
Establishment Locale: India


Dear Mr. Prasanth Chemuduri,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at the above address or number.

Sincerely,

  
Concepcion Cruz  
Branch Chief  
Inspection Assessment Branch

Enclosure: EIR

# Highlights-Unit 2



- Three Production Blocks
- Received WHO GMP and Written Confirmation approval from CDSCO
- Equipped for handling High-Pressure Reactions
- Powder Processing area with ISO Class-8 AHU facility
- Total Built Up Area is 10820.92 Sq.Mt and Total Area is 12439.66Sq.Mts
- Total Capacity is ~ 105KL comprising of 40+Reactors

# Written confirmation From CDSCO



GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
Central Drugs Standard Control Organization

CERTIFICATE NO. :

WC-0447

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site:

M/s Rampex Labs Pvt. Ltd.,  
Plot No. 34-C, Jawaharlal Nehru Pharma City,  
Parawada Visakhapatnam Dist.  
A.P., India

2. Manufacturer's licence number: 21/VP/AP/2011/B/CC

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1	Olanzapine IP/BP/USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) One (01) ONLY

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection of the plant: 26<sup>th</sup> & 27<sup>th</sup> April, 2018

The Written Confirmation remains valid until: Three Years from the date of issue.

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: Central Drugs Standard Control Organisation  
FDA Bhawan, Kotla Road,  
New Delhi- 110 002, India

Name and function of responsible person: Dr. S. Eswara Reddy,  
Drugs Controller General (India)

E-mail:

Telephone no.:

Fax no.:

dcic@nic.in,  
+91-11-23236965  
+91-11-23236973

  
Signature

Stamp of the authority and date



05 JUL 2019

# Major Chemistry Capabilities

Reaction Capabilities	Reagents Handled
Curtius Rearrangement	Diazomethane
Heck Coupling	Diphenyl Phosphyl azide
Michael Addition	Palladium Chloride
Swern Oxidation	Palladium on Carbon
Knoevenagel Condensation	Raney Nickel
Gewald Reaction	Thioacetic acid
Friedel Crafts Alkylation	Sodium Cyanide
Friedel Crafts Acylation	Nitric acid
Mannich Reaction	Phosphorus Oxy Chloride
Perkin Reaction	Hydrogen Peroxide
Pinner Reaction	Potassium dichromate
Dieckmann Reaction	50% Cyannamide Solution
Wolff kishner reaction	Sodium Borohydride
Wohl Ziegler reaction	Aluminium tri sec Butoxide
Schotten-Baumann Reaction	Hydrochloric acid Gas
Hydrogenation Reaction	Aluminium Chloride
Grignard Reaction	Di-Benzoyl-D-Tartaric acid Monohydrate
Nitration Reaction	Vitride Solution
Halogenation Reaction	N-Bromo succinamide
Oxidation and Reduction Reactions	Stannous Chloride



# R & D – FACILITIES

- ✓ Two Synthetic Labs with Twelve Fume hoods
- ✓ Fully equipped ADL available to support R&D
- ✓ ADL has Seven HPLCs and Two GCs
- ✓ Capable of handling Milligram Scale to Kilogram Scale Reactions
- ✓ Channelized Process for developing Products to file DMFs with Regulatory Markets

# QA- RESPONSIBILITIES

- ✓ To release Drug Intermediates for dispatch
- ✓ To conduct Internal Audits and to face External Audits
- ✓ To prepare documents for Annual Product Quality Review
- ✓ To handle Quality Complaints and to handle Return Goods/Product Recalls
- ✓ To conduct Inter Departmental Trainings
- ✓ To handle Vendor Qualification Procedure

# Major List Of Instruments at QC

Instruments	Unit-1	Unit -2
HPLCs	6	4
GCs	2	3
UV/Vis	1	1
IR	1	1
pH Meters	3	1
Potentiometry	1	1
Polarimeter	0	1
Melting Point Apparatus	1	1
Moisture Analyzer	1	1
Vaccum Oven	1	1
Hot Air Oven	2	2
Water System-Millipore	1	1
Analytical Balances	2	2
Server	1	1
UV Cabinet	1	1
Stability Chambers	1	2
Karl Fischer Titration	1	1



## LIST OF RAMPEX's PRODUCTS & KEY CLIENTS

# ACTIVE PHARMA INGREDIENTS

S.No.	API NAME	CAS No.	Pharmacopoeia
1	OLANZAPINE (OLANZAPINE FORM-2)	132539-06-1	IP, USP, EP & BP
2	OLANZAPINE (OLANZAPINE FORM-1)	132539-06-1	IP, USP, EP & BP
3	NEBIVOLOL HYDROCHLORIDE	152520-56-4	IP
4	RACECADOTRIL	81110-73-8	IP, EP, BP & IHS
5	CHLORZOXAZONE	95-25-0	USP

# INTERMEDIATES-I

S. No.	CHEMICAL NAME	CAS NUMBER	API NAME
1	1-(2,3-DICHLOROPHENYL) PIPERAZINE	41202-77-1	ARIPIPIRAZOLE
2	1-(2,3-DICHLOROPHENYL) PIPERAZINE HYDROCHLORIDE	119532-26-2	
3	7-HYDROXY 3,4-DIHYDRO CARBOSTYRIL	22246-18-0	
4	7-(4-BROMOBUTOXY)-3,4-DIHYDROCARBOSTYRIL	129722-34-5	
5	(2R,3S)-3-(N-BOC-AMINO)-1-OXIRANE-4-PHENYLBUTANE	98760-08-8	ATAZANAVIR
6	3-iodo-6-nitroindazole	70315-70-7	AXITINIB
7	(E)-3-[2-(PYRIDIN-2-YL)ETHENYL]-1-(TETRAHYDRO-2H-PYRAN-2-YL)-1H-INDAZOL-6-AMINE	886230-76-8	
8	2,2'-DITHIO-2,2-BIS (N-METHYLBENZAMIDE)	2527-58-4	
9	ETHYL 4-(1-METHYL-5-NITRO-1H-BENZIMIDAZOL-2-YL) BUTANOATE	3543-72-4	BENDAMUSTINE
10	ETHYL 4-(5-AMINO-1-METHYL-1H-BENZIMIDAZOL-2-YL) BUTANOATE	3543-73-5	
11	4-{5-[BIS-(2-HYDROXY-ETHYL)-AMINO]-1-METHYL-1H-BENZOIMIDAZOL-2-YL}-BUTYRIC ACID ETHYL ESTER	3543-74-6	
12	METHYL 4-[(5,6,7,8-TETRAHYDRO-3,5,5,8,8-PENTAMETHYL-2-NAPHTHALENYL) CARBONYL] BENZOATE	153559-45-6	BEXAROTENE

# INTERMEDIATES-II

13	N-BENZHYDRYL PIPERAZINE	841-77-0	CINNARIZINE
14	5-(2-CHLOROETHYL)-4-METHYL THIAZOLE HYDROCHLORIDE	6001-74-7	CLOMETHIAZOLE
15	ETHYL 3-[(3-AMINO-4-METHYLAMINO-BENZOYL)-PYRIDIN-2-YL-AMINO]-PROPIONATE	212322-56-0	DABIGATRAN
16	4-CYANOPHENYLGLYCINE	42288-26-6	
17	ETHYL 3-(2-(((4-CYANOPHENYL) AMINO) METHYL)-1-METHYL-N-(PYRIDINE-2-YL)-1H-BENZO [D] IMIDAZOLE-5-CARBOXAMIDO) PROPANOATE	211915-84-3	
18	ETHYL 4, 5-BIS (2-METHOXYETHOXY)-2-AMINOBENZOATE HCL	183322-17-0	ERLOTINIB
19	6,7-BIS-(2-METHOXYETHOXY)-4(3H)-QUINAZOLINONE	179688-29-0	
20	4-[(4,6-DICHLOROPYRIMIDIN-2-YL) AMINO] BENZONITRILE	329187-59-9	ETRAVIRINE
21	N-(2-METHYL-5-NITROPHENYL)-4-PYRIDIN-3-YL PYRIMIDIN-2-AMINE	152460-09-8	IMATINIB
22	N-(2-METHYL-5-AMINOPHENYL)-4-(3-PYRIDYL)-2-PYRIMIDINE	152460-10-1	
23	4-(4-METHYL PIPERAZINO METHYL) BENZOIC ACID DIHYDROCHLORIDE	106261-49-8	
24	4-(4-METHYL-1-PIPERAZINYL) METHYL BENZOYL CHLORIDE DIHYDROCHLORIDE	106261-64-7	
25	4-[(4-METHYLPIPERAZIN-1-YL) METHYL]-N-[4-METHYL-3-[(4-PYRIDIN-3-YL PYRIMIDIN-2-YL) AMINO]-PHENYL]-BENZAMIDE	152459-95-5	
26	3-(DIMETHYLAMINO)-1-(PYRIDIN-3-YL) PROP-2-EN-1-ONE	55314-16-4	IMATINIB, NILOTINIB

# INTERMEDIATES-III

27	7,8-DIMETHOXY-1,3-DIHYDRO-2H-3-BENZAZEPIN-2-ONE	73942-87-7	
28	3-(3-CHLOROPROPYL)-7,8-DIMETHOXY-1,3-DIHYDRO-2H-3-BENZAZEPIN-2-ONE	85175-59-3	IVABRADINE
29	7,8-DIMETHOXY-3-(3-IODOPROPYL)-1,3-DIHYDRO-2H-3-BENZAZEPIN-2-ONE	148870-57-9	
30	1-ACETYL-4-(4-HYDROXYPHENYL) PIPERAZINE	67914-60-7	KETOCONAZOLE
31	N-(4-METHYL AMINOBENZOYL)-(L)-GLUTAMIC ACID DIETHYL ESTER	2378-95-2	METHOTREXATE
32	6-FLUORO-3,4-DIHYDRO-2-OXIRANYL-2H-1-BENZOPYRAN	99199-90-3	
33	6-FLUORO-3,4-DIHYDRO-2H-1-BENZOPYRAN-2-CARBOXYLIC ACID	99199-60-7	NEBIVOLOL HYDROCHLORIDE
34	METHYL 6-FLUORO-3,4-DIHYDRO-2H-1-BENZOPYRAN-2-CARBOXYLATE	874649-82-8	
35	BENZOIC ACID, 3-[(AMINOIMINOMETHYL) AMINO]-4-METHYL-, METHYL ESTER, NITRATE	1025716-99-7	
36	4-METHYL-3-[[4-(3-PYRIDINYL)-2-PYRIMIDINYL]AMINO] BENZOIC ACID	641569-94-0	NILOTINIB
37	3-(4-METHYL-1H-IMIDAZOL-1-YL)-5-(TRIFLUOROMETHYL)ANILINE	641571-11-1	
38	3-[(AMINOIMINOMETHYL) AMINO]-4-METHYL BENZOIC ACID METHYL ESTER MONONITRATE	641569-96-2	



# INTERMEDIATES-IV

39	2-(2- AMINOPHENYLAMINO)-5-METHYLTHIOPHENE-3-CABONITRILE	873895-41-1	OLANZAPINE
40	4-AMINO-2-METHYL-10H-THIENO [2, 3-B] [1, 5] BENZODIAZEPINE HYDROCHLORIDE	138564-60-0	
41	2-AMINO-5-METHYLTHIOPHENE-3-CARBONITRILE	138564-58-6	
42	5-METHYL-2-[(2-NITROPHENYL) AMINO]THIOPHENE-3-CARBONITRILE	138564-59-7	
43	3-(2-CHLOROETHYL)-9-HYDROXY-2-METHYL-6,7,8,9-TETRAHYDRO-4H-PYRIDO[1,2-A]PYRIMIDIN-4-ONE	130049-82-0	PALIPERIDONE
44	6-FLUORO-3-(4-PIPERIDINYL)-1, 2-BENZISOXAZOLE HYDROCHLORIDE	84163-13-3	POSACONAZOLE
45	1-(4-HYDROXYPHENYL)-4-(4-AMINOPHENYL) PIPERAZINE	74853-08-0	
46	[4-[4-(4-HYDROXYPHENYL)-1-PIPERAZINYL] PHENYL] CARBAMIC ACID PHENYL ESTER	184177-81-9	
47	1-(4-HYDROXYPHENYL) PIPERAZINE	56621-48-8	POSACONAZOLE, ELUBIOL
48	(E)-3-(4-AMINO-3,5-DIMETHYLPHENYL) ACRYLONITRILE HYDROCHLORIDE	661489-23-2	RILPIVIRINE

# INTERMEDIATES-V

49	3-QUINUCLIDINONE HYDROCHLORIDE	1193-65-3	
50	3-(R)-(+/-) QUINUCLIDINOL	1619-34-7	
51	R-(-)-3-QUINUCLIDINOL	25333-42-0	
52	(±)-1-PHENYL-1,2,3,4-TETRAHYDRO ISOQUINOLINE	22990-19-8	SOLIFENACIN
53	(S)-1-PHENYL-1,2,3,4-TETRAHYDRO ISOQUINOLINE	118864-75-8	
54	(R)-5-(2-AMINOPROPYL)-2-METHOXYBENZENESULFONAMIDE	112101-81-2	TAMSULOSIN
55	N-BOC PIPERAZINE	57260-71-6	TENELIGLIPTIN
56	1-(2-METHOXYPHENYL) PIPERAZINE HYDROCHLORIDE	5464-78-8	URAPIDIL
57	ETHYL 5-AMINO-1-BENZOFURAN-2-CARBOXYLATE HYDROCHLORIDE	183288-42-8	
58	ETHYL 5-AMINO-1-BENZOFURAN-2-CARBOXYLATE	174775-48-5	VILAZODONE
59	3-(4-CHLOROBUTYL)-5-CYANOINDOLE	143612-79-7	
60	BIS-2-(CHLOROETHYL) AMINE HYDROCHLORIDE	821-48-7	

Thank you