



Centaur Pharmaceuticals Pvt. Ltd.

API Division - Ambernath Facility

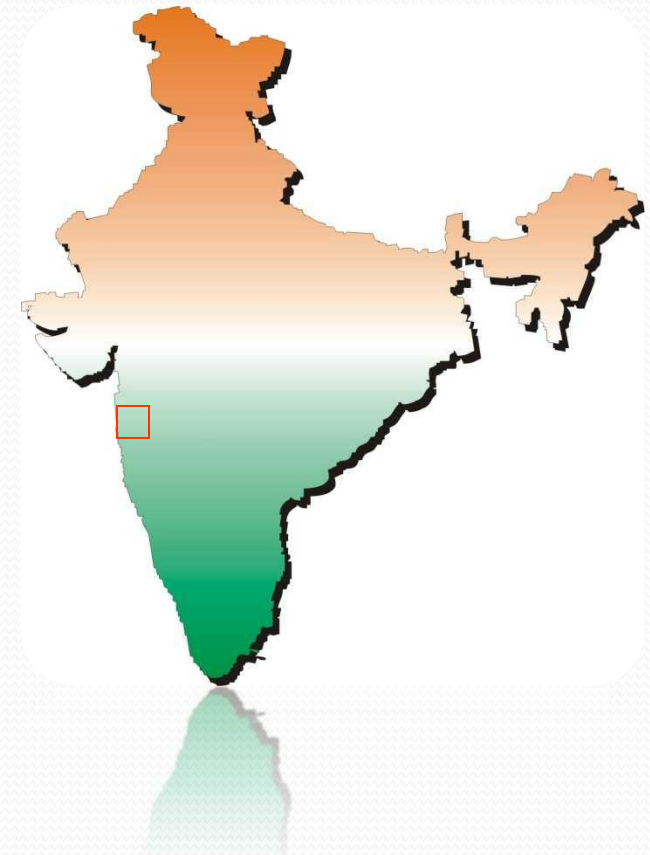
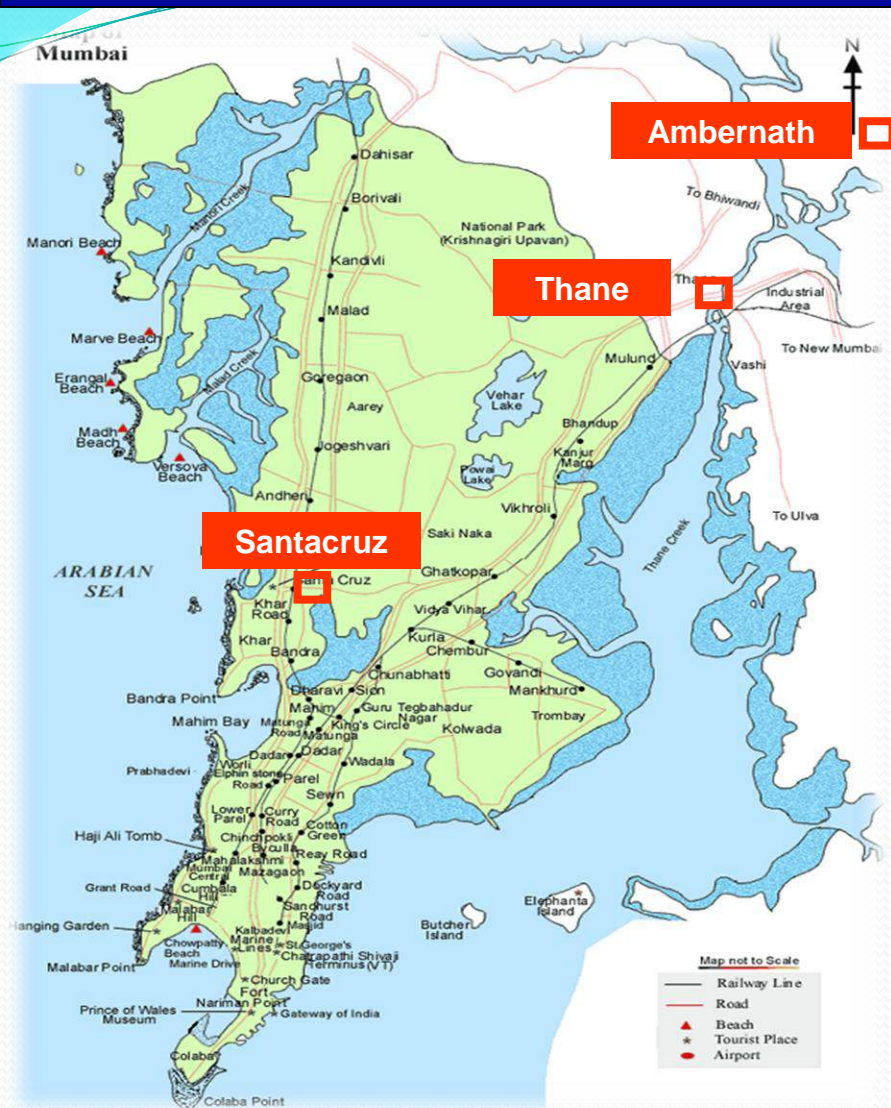


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Location Map

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■ Mumbai – Santacruz	30 kms
■ Santacruz – Ambernath	60 kms
■ Airport – Santacruz	5 kms



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Company : API Division launched in 1988

Promoters :



Mr. S. D. Sawant

Over 50 years experience in
the Pharma Industries
Specialization in marketing
and finance



Dr. S. D. Sawant

Over 40 years experience in
Pharma Industries
Specialization in R & D and
Production



- ❑ Ambernath facility is designed for production, processing and control of APIs.
- ❑ It is situated in the Chikhholi MIDC - Ambernath in Thane district of Maharashtra, INDIA.
- ❑ Total plot area - 60000 sq. ft.
- ❑ Total Employees - 155
- ❑ This facility is ICH Q7 compliant
- ❑ Approved by USFDA, AFSSAPS (EU GMP), KFDA , ANVISA (Brazil), COFEPRIS (Mexico), WHO (Local) & ISO for Quality as well as HSE.



Factory	: Ambernath
Management	: 21
Staff	: 83
Helpers	: 51
Total	: 155

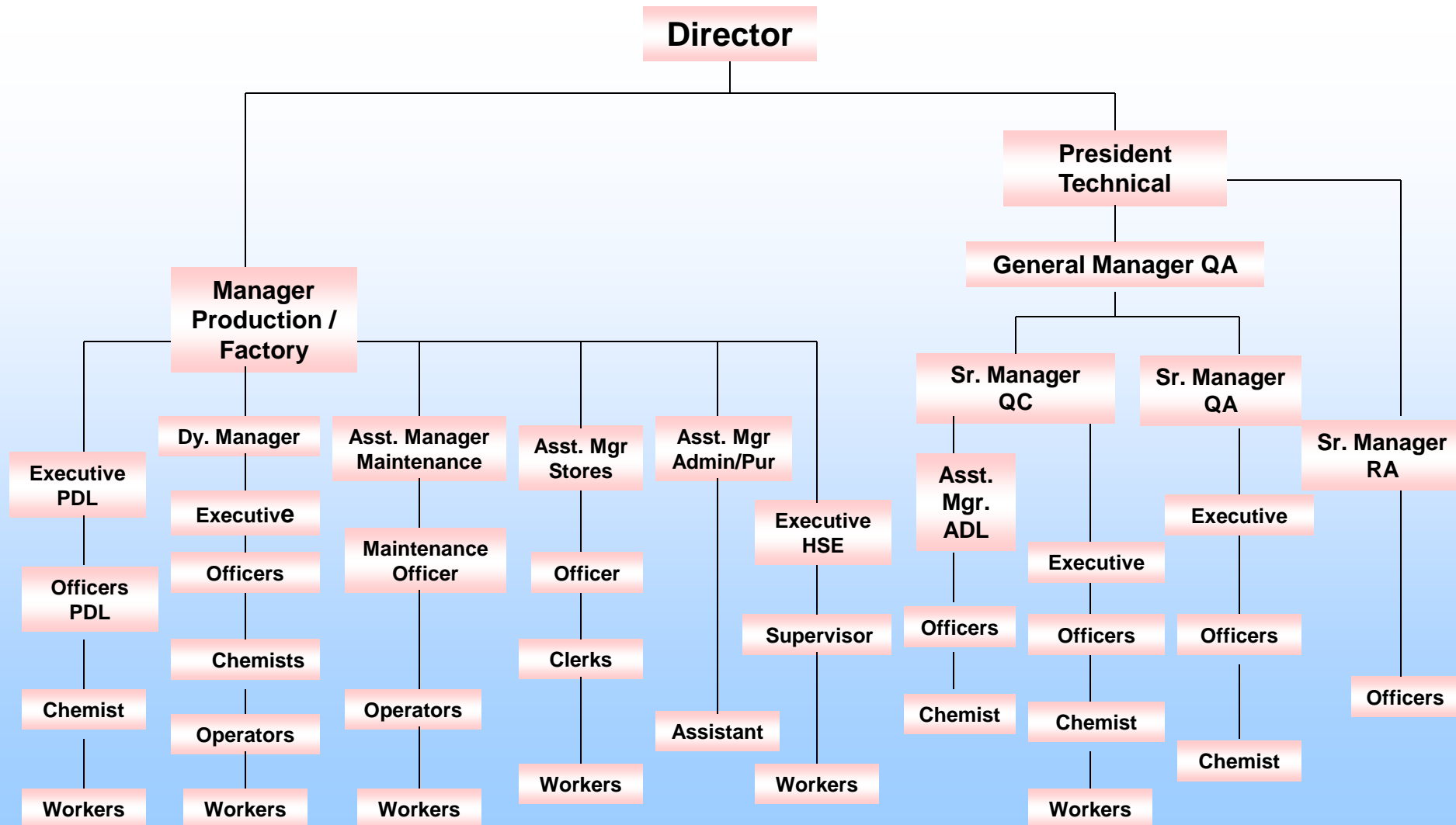
This excludes watch & ward and gardeners

Production	: 52
QC	: 35
QA	: 12
Engineering	: 15
Stores	: 06
Admin	: 06
PDL	: 17
RA	: 03
ADL	: 08
IT	: 01
Total	: 155



Organization Chart - Factory

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- Bromazepam
- Clonazepam
- Clobazam
- Nitrazepam
- Nortriptyline Hydrochloride
- Oxazepam
- Zaleplon
- Zolpidem Tartrate
- Zopiclone



Alprazolam IP/BP/USP/EP/JP	Loxapine HCl	Propiverine HCl JP
Aripiprazole	Loxapine Succinate	Rivastigmine hydrogentartrate
Benzydamine HCl BP	Melitracen HCl	Sodium Oxybate
Brimonidine Tartrate	Methylphenidate HCl USP/BP/EP	Stiripentol
Bromazepam BP/EP	Metolazone USP/EP/BP	Temazepam BP/EP/USP
Chlordiazepoxide IP/BP/USP/EP	Metopimazine	Tetrabenazine
Chloropyramine HCl	Midazolam BP/EP/USP	Tetrazepam BP/EP
Clobazam BP/EP/IP	Midazolam HCl	Tiemonium methyl sulfate
Clonazepam BP/USP/EP/IP	Midazolam Maleate	Timolol Maleate IP/BP/USP/EP
Clorazepate dipotassium USP/EP	Milnacipran HCl	Triazolam USP
Clotiazepam JP	Nicorandil	Zaleplon USP
Diazepam IP/BP/EP/USP	Nimorazole	Zolpidem Tartrate IP/BP/EP/USP
Es-Zopiclone	Nitrazepam IP/BP/EP	Zopiclone BP/EP
Etizolam JP	Nortriptyline HCl IP/BP/USP/EP	Zuclopentixol HCl BP
Flupentixol dihydrochloride EP/BP	Olopatadine HCl USP	
Fluphenazine HCl IP/EP/USP/BP	Oxazepam IP/BP/USP/EP	
Flurazepam hydrochloride USP/JP	Phenazepam	
Flurazepam Monohydrochloride EP/BP	Pitofenone HCl	
Lorazepam BP/USP/EP	Prazepam EP	

- North America
- South America
- Europe
- Africa
- Asia
- Japan



- India's largest Manufacturer & Exporter of Psychotropic APIs
- APIs, Intermediates, Process Development, Contract Manufacturing
- Commitment, technical prowess, competence, systems oriented approach
- Clients include National / International Pharmaceutical Majors
- Ensure compliance to statutory & regulatory requirements.
- To train the employees, to enhance skill & knowledge.



- Five separate product lines & two pilot plants
- Proper spacing between Reactors / Equipments
- Lighting and Ventilation
- Easy Accessibility



Water system:

1. Source of Raw Water:

Potable Water from state government.

2. Storage of Raw Water:

Underground storage tank.

3. Treatment of Raw Water:

Ion exchange treatment to get Demineralized water (DM).

4. Reverse Osmosis Treatment of DM Water:

RO treatment to get Purified water with UV treatment.

24 hrs. circulation loop with user sampling points.



Air Classification :

- Ventilation and Air Filtration in process area – comfort zone.
- Controlled area with 0.3 micron filtration in
 1. Final product handling area,
 2. Final product dispensing room,
 3. Pilot plant.

Warehouse Facility

Raw Material & Finished Goods
Stores - Area : 12000 Sq.ft
Staging - Area : 1650 Sq.ft

Production Facility

Area : 25000 Sq. ft

Laboratory Area

Area : 2100 Sq.ft.

Utility Area

Area : 5500 Sq.ft

Pilot plant

Area : 1975 Sq.ft

ADL

Area : 1600 Sq.ft.

Major Production Equipment

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SR NO.	CAPACITY	M.O.C.	DESCRIPTION	EQUIPMENT NO.
01	3000 LIT	S. S. 316	REACTORS – 12 NOS	RV-101, 102, 201, 202, 204, 205, 206, 207, 302, 303, 401 & 402
02	2000 LIT	S. S. 316	REACTORS – 02 NOS	RV 208 & RV 301
03	1000 LIT. & 3000 LIT	M.S. + GLASS	GLASS LINED REACTOR – 03 NOS	RV-203, RV-404 & RV - 403
04	36" Dia	S. S. 316	CENTRIFUGES - 4 NOS	CF-101 & 102 , 301 ,201
05	500 LIT. & 250 LIT	S. S. 316	ROTOCONE VAC. – 10 NOS	RD-001, 002,101,102,103, 201, 202,401,402 & 403.
06	500 LIT	S. S. 316	NUTSCHE FILTERS – 12 NOS	NF, 001 , 002 & 101, 102,103,104,105, 201, 202, 203, 301,302.
07	250 Kg / Hr	S. S. 316	PULVERISERS – 5 NOS	PL-001 , 002, 003, 101, 102
08	100 Kg/Hr	S. S. 316	VIBRO SIFTERS – 5 NOS	SF-001, 002, 101, 102, 103
09	10 Kg/Hr	S. S. 316	MICRONIZER	MIC-002
10	500 LIT	S. S. 316	BLENDER	BL-001
11	11 PLATES	S. S. 316	FILTER PRESSES – 7 NOS	FP-101,102 ,001,003,103,201, 202



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Major Production Equipment (Pilot plant)

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SR NO.	CAPACITY	M.O.C.	DESCRIPTION	EQUIPMENT NO.
12	150 LIT & 250 LIT & 500 LIT	S.S. 316	REACTORS – 4 NOS	RV 502 & 501,505 & 506
13	160 LIT. & 500LIT	M.S. + GLASS	GLASS LINED REACTOR 2 NOS	RV 503 ,504
14	50 LIT.	S.S. 316	ROTOCONE VAC. DRYER 2 NOS	RD 501, RD 502 and RD 503
15	250 LIT. & 100 LIT	S. S. 316	NUTSCHE FILTERS 3 NOS	NF 003, NF – 501 & NF 502
16	7 PLATES	S.S. 316	FILTER PRESSES	FP-501



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Sr. No	DESCRIPTION	CAPACITY	EQUIPMENT No.
1.	BOILERS 2 Nos.	600 Kg/HR each	BO-001/B0-002
2.	AIR COMPRESSOR	298 CFM, 75 HP.MOTOR non-lubricant	AC-004
3	Nitrogen Generator (Plant)	3 m ³ /hr	NP-001
4.	BRINE CHILLING PLANT 6 Nos..	3.75 TR at -20 ⁰ C (2 NOS) 15 TR at -15 ⁰ C (2 NO) 75 TR at 7 °C (2 Nos.) 16 TR at 7 °C (1 No.)	CP-001 ,CP-002 & CP-003, CP-004, CP-006, CP-007 and CP-008
5	COOLING TOWER FOR PROCESS 2 Nos.	160TR (2 Nos.)	CT-004 & 005
6	D.M.PLANT WITH RO	1000 Lts/Hr.	DMP – 001 & PWP – 001
7	COOLING TOWER FOR CHILLING PLANT 5 Nos.	20 TR (1 No.) 60 TR (2 Nos.) 30 TR (2 Nos.)	CT-101 CT-006, CT-007, CT-008 & CT-009
8	HOT WATER GENERATOR	3.0 LAC K.CAL/ Hr	HWG-001
9	DIESEL POWER GENERATOR 2 Nos.	380 KVA / 40 KVA	DG-002 / DG-003

DESCRIPTION		PROVIDED TO AREA	CLASSIFICATION
AIR HANDLING UNITS 25 NOS.	9 Nos. AHU with 0.3 micron Air supply	Pharma area	Controlled Area equivalent to ISO 8 grade
	2 Nos. AHU with 0.3 micron Air supply	Pilot Plant Area	Controlled Area equivalent to ISO 8 grade
	1 No. AHU with 0.3 micron Air supply	Final Product Dispensing Area	Controlled Area equivalent to ISO 8 grade
	1 No. AHU with 0.3 micron Air supply	Microbiology Laboratory	Controlled Area equivalent to ISO 7 grade
	12 Nos. AHU with 5 & 3 micron Air supply	Intermediate process Area	Comfort zone

- **SHE Policy**
- **Statutory Compliance**
- **ETP Consisting of**
 - **Primary Chemical Treatment for Neutralization of effluent**
 - **Secondary Treatment: Biomass treatment under aerobic conditions to reduce COD.**
 - **Tertiary Treatment (Charcoal & Sand filter) to further reduce COD & also reduces suspended solids.**
 - **Effluent transfer to CETP .**

ETP – Effluent Treatment Plant

CETP – Common Effluent Treatment Plant



Comprehensive:

- Standard Operating Procedures (SOPS)
- Quality control specifications & test methods
- Batch manufacturing records & QC records
- Batch release
- Internal Audits
- Change control, Deviation control & Document control
- Investigation of Complaint , OOS & Implementation of CAPA
- Process, cleaning & analytical method validation
- Qualification & validations of equipments
- Ensure cGMP & job oriented training conducted



Quality control facility having latest analytical tools:

- Instrumentation – Equipped with HPLC, GC, FTIR, Polarimeter, Humidity Chambers, UV spectro, Laser Particle Size Analyzer.
- Wet Analysis
- Microbiological Laboratory – Equipped with LAF, Autoclave, TOC analyzer, Incubators...



Major Lab Equipments

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SR NO	NAME OF INSTRUMENTS	MAKE	MODEL
1.	GAS CHROMATOGRAPH	AGILENT	6850
2.	GAS CHROMATOGRAPH	AGILENT	6890
3.	GC x 2 No.	AGILENT	7890
4.	HPLC-AUTO SAMPLER	AGILENT	1100
5.	HPLC-AUTO SAMPLER x 7 Nos.	AGILENT	1200
6.	POLARIMETER	JASCO	P-1020
7.	FTIR	JASCO	FT/IR-4100
8.	U. V SPECTROPHOTOMETER	JASCO	V-630
9.	HPLC	JASCO	950
10.	HPLC	JASCO	1500
11	PARTICLE SIZE ANALYZER	MALVERN	MASTERSIZER-S and Mastersizer 3000
12.	UPRIGHT MICROSCOPE	OLYMPUS	CX-41
13.	LAMINAR AIR FLOW	AIRPAC	1500C-36-24-24
14	AUTOCLAVE 2 Nos.	MODI / Equitron	295 / #7451FA
15	BOD INCUBATORS – 2 NOS	NEWTRONIC EQUIPMENT CO.	NEC-106RSS
16	PHOTOSTABILITY CHAMBER	NEWTRONIC EQUIPMENT CO	PSC/213
17	HUMIDITY CONTROL OVENS-5	NEWTRONIC EQUIPMENT CO	NEC 212 R 10S
18	AUTO TITRATORS 2 Nos.	LABINDIA/ METLER	TR03051207/DL 50
19	TKA WATER SYSTEM	TKA	2135 & 2145
20	TOC ANALYZER	GE SIIEVERS	900



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- Competency in filing DMF / COS / CTD
- Proven Capabilities– 15 CoS approved & 16 US DMFs filed.
- To comply with European, US and other international regulatory bodies to ensure regulated market share.



PRODUCT	EDMF	COS	PRODUCT	EDMF	COS
Alprazolam	A	A	Nitrazepam	A	A
Benzydamine HCl	A	NA	Nortriptyline HCl	A	A
Brimonidine Tartrate	A	NA	Olopatadine HCl	A	NA
Bromazepam	A	A	Oxazepam	A	A
Chlordiazepoxide	A	A	Pitofenone HCl	A	NA
Chloropyramine HCl	A	NA	Sodium Oxybate	A	NA
Clobazam	A	A	Temazepam	A	A
Clonazepam	A	A	Tetrazepam	A	A
Diazepam	A	A	Tiemonium Methyl Sulfate	A	NA
Flupentixol Di HCl	A	NP	Timolol Maleate	A	A
Lorazepam	A	A	Zaleplon	A	NA
Melitracen HCl	A	NA	Zolpidem Tartrate	A	A
Methylphenidate HCl	A	NP	Zopiclone	A	A

A – Available

NA – Not Applicable

NP- Not Planned



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Sr. No.	PRODUCT	US DMF No.	Date
1	ALPRAZOLAM	20827	August 2007
2	ZOPICLONE	21059	November 2007
3	DIAZEPAM	21860	July 2008
4	OXAZEPAM	22060	September 2008
5	LORAZEPAM	22460	January 2009
6	CLONAZEPAM	22580	February 2009
7	TIMOLOL MALEATE	23630	March 2010
8	BRIMONIDINE TARTRATE	23880	June 2010
9	CHLORDIAZEPOXIDE	25335	September 2011
10	TEMAZEPAM	25364	October 2011
11	NORTRIPTYLINE HCI	25380	October 2011
12	Es-ZOPICLONE	26164	June 2012
13	TETRABENAZINE	26308	August 2012
14	MILNACIPRAN HCI	026577	December 2012
15	TRANLYCYPROMINE SULFATE	026808	February 2013
16	ZALEPLON	27568	September 2013



- ☞ ISO 9001:2008 Certification since April 2001.
- ☞ Accreditation Certificate -PMDA Japan- June 2008.
- ☞ ISO 14001:2004 Certification- September 2010
- ☞ OHSAS 18001:2007 Certification- September 2010
- ☞ WHO-GMP re-certification – June 2013.
- ☞ EU GMP – ANSM (Afssaps French) audited – Zopiclone, Bromazepam, Timolol Maleate & Tiemonium methyl sulfate – March 2011.
- ☞ US FDA approved – August 2011.
- ☞ KFDA approved – September 2012
- ☞ ANVISA approved – October 2012
- ☞ COFEPRISS approved – November 2013
- ☞ ZOPICLONE COS approved - November 2002.
- ☞ ALPRAZOLAM COS approved - March 2003.
- ☞ ZOLPIDEM TARTRATE COS approved - January 2004.
- ☞ BROMAZEPAM COS approved – March 2006.
- ☞ CLOBAZAM COS- approved – November 2006.
- ☞ CLONAZEPAM COS – approved- October 2007.
- ☞ NORTRIPTYLINE HCI COS – approved- January 2009.
- ☞ DIAZEPAM COS – approved- December 2009.
- ☞ OXAZEPAM COS – approved- November 2010.
- ☞ LORAZEPAM COS – approved – March 2011
- ☞ TIMOLOL MALEATE COS –approved- July 2011
- ☞ CHLORDIAZEPOXIDE COS – approved- December 2011
- ☞ NITRAZEPAM COS- approved- December 2011
- ☞ TEMAZEPAM COS –approved- November 2012
- ☞ TETRAZEPAM COS – approved January 2013



Quality Standards and certification

Authority	Date	Result
ISO 9001:2008	Inspected Date 14 th - 15 th April 2014	Acceptable
ISO 14001:2004	Inspected Date 14 th - 15 th April 2014	Acceptable
BS OHSAS 18001:2007	Inspected Date 14 th - 15 th April 2014	Acceptable

Regulatory Compliance and History

Authority	API	Date	Result
WHO GMP Local (Renewal Audit)	Refer certificate	Inspected on 18 th May 2013	Acceptable
ANSM (Afssaps) EU GMP (Renewal Audit)	Bromazepam, Zopiclone Timolol Maleate, Tiemonium methyl sulfate	Inspected on 21 st -24 th March 2011	Acceptable
ANSM (Afssaps) EU GMP (Initial Audit)	Zopiclone	Inspected on 13 th -15 th December 2007	Acceptable
US FDA	Zopiclone, Clonazepam, Lorazepam, Timolol Maleate.	Inspected on 8 th – 11 th August 2011	Acceptable
US FDA (Initial Audit)	Alprazolam	Inspected on 5 th – 8 th May 2008	Acceptable
KFDA Korea	Timolol Maleate	3 rd & 4 th September 2012	Acceptable
ANVISA Brazil	Alprazolam & Bromazepam	27 th – 31 st October 2012	Acceptable
COFEPRISS Mexico	Alprazolam, Diazepam, Clonazepam Nortriptyline HCl, Methylphenidate HCl & Fluphenazine HCl	28 th October – 1 st November 2013	Acceptable



Thank You

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