Welcome to

Sai-Tech Pharmaceuticals Pvt. Ltd.

(WHO GMP certified company)

1.0 Overview…..

SAI-TECH PHARMACEUTICALS PVT.LTD. was founded in 2014 with a vision to become leading research based health management company by establishing Research, Manufacturing & Marketing capabilities.

- Located in the commercial capital of India Mumbai .
- Easy access by road, rail, air and sea to all parts of the world.
- Distance from factory to Jawaharlal Nehru Port Trust is about 30 km and from factory to airport is about 28 kms.
- Easy availability of qualified technical team.
- Abundant availability of Water and power as it is located in MIDC zone.
- It is fast growing & establishing a strong presence in the domestic as well as global market.

2.0 Key Consideration …..

Strong Operational Efficiency

- An integrated manufacturing plant for intermediates & APIs.
- This Plant has all the operational facilities to ensure seamless production of APIs and advanced intermediates.

Strong Management Team

- Promoters of the Company are professional technocrats having extensive industry experience of more than 25+ years
- Managed by professionals with average industry experience of about 20 years

Excellent Client Relationships

- Well entrenched relationships with several institutions and pharmaceutical companies in India as well as abroad.

Proven Research Capabilities

- Qualified and experienced R&D & technical team, an independent research & development wing and a full fledged Quality Assurance (QA) department.
- Focused on delivering cost-effective quality products; which in turn provide customers a competitive advantage in their market place

3.0 Promoters and Directors…..

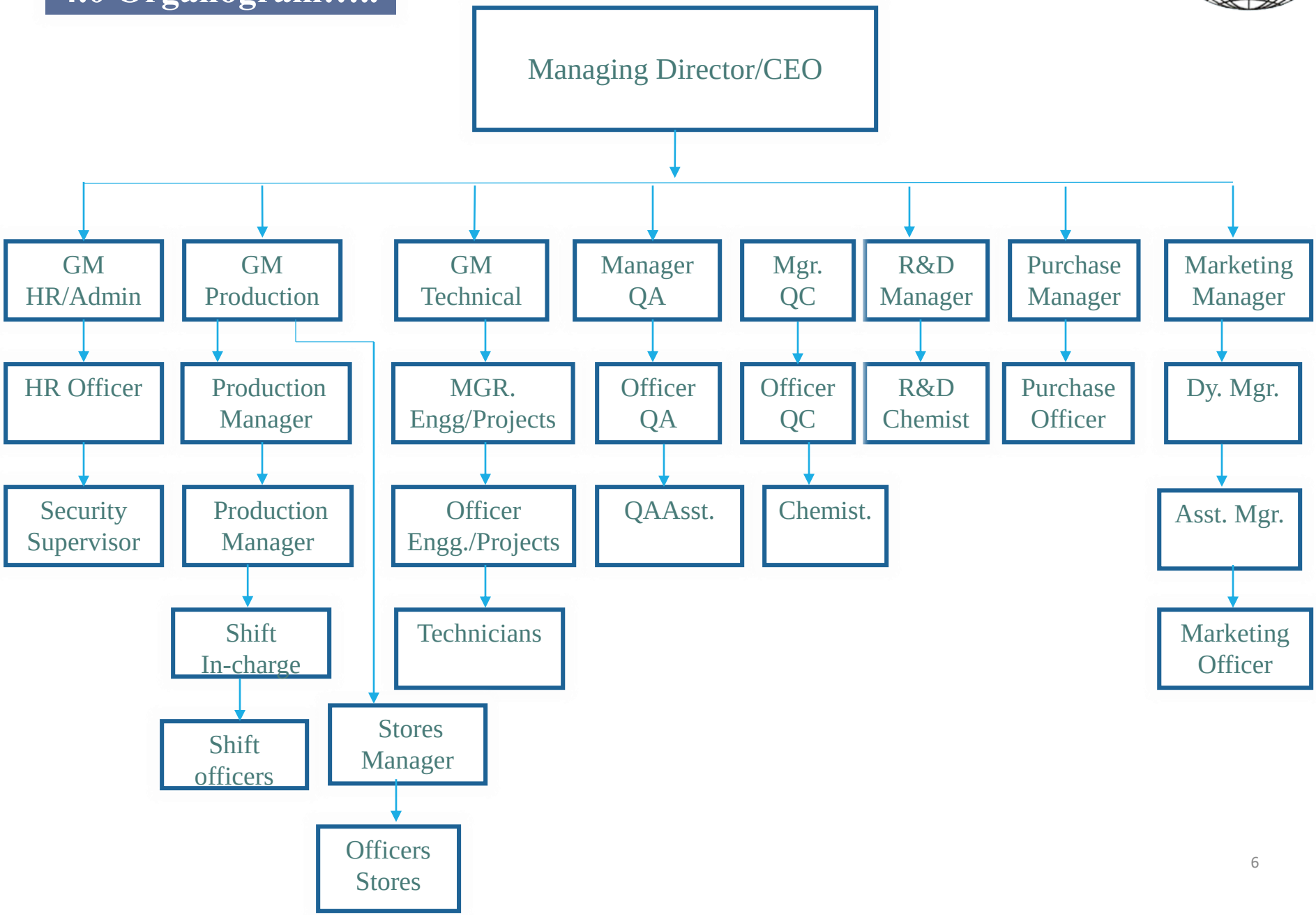
Mr. Rajan G. Thakur (Managing Director)

- He is Graduate in Chemical Engineering
- He is heading Manufacturing, Marketing & Purchase Department & having about 30 years of vast experience.
- He has been responsible for steering "STPL" into manufacturing of ACTIVE PHARMACEUTICAL INGREDIENTS.

Mrs. Savita R. Thakur (Executive Director & Head Finance)

- She is Science graduate.
- She is heading Human Resources, commercial ,accounts & finance departments.
- Experienced in commercial division.

4.0 Organogram…..



5.0 Overall Premises…..

Total area of the Sai-Tech Pharmaceuticals Pvt. Ltd. is about **60,000 sq.ft.**

Premises comprises of various section and department.

Sr. No.	Section
1.0	**Warehouse**
2.0	**Production Area**
3.0	**Utility Department**
4.0	**Quality Control**
5.0	**Microbiology**
6.0	**Quality Assurance**

5.1. Warehouse …….

- **Warehouse measures 252 sq.mt. located on ground floor and mezzanine floor which consisting of:**

  - Receiving bay
  - De-dusting bay
  - Quarantine
  - Sampling booth
  - Approved raw material stores/Rejected raw materials
  - Dispensing booth
  - Dispensed material storage

- **Warehouse department is responsible for receipt issue and reconciliation of raw materials and packing materials.**

- **Proper records of each of the raw materials are maintain in stock register.**

5.2 Production Area …..

GENERAL INFORMATION:-

- Total area of the unit is **1195 sq. mtr.** with 2 floors.
- Production facility is made for manufacturing 2 different products simultaneously on campaign basis.
- Total volumetric capacity of all the reactors is **25 KL**.
- Plant and Machineries is specifically designed, selectively sized and located for appropriate operations.
- Equipment are constructed for easy cleaning and to prevent contamination.
- Segregated areas are provided for intermediate and final product processing.
- Adequate ventilation, air conditioning and air filtrations is provided to prevent environmental hazards.
- Potable water is source form MIDC and treated as per EP guidelines using RO followed by UV treatment.

Production area…..

Reaction capabilities:-

- Formylation
- Oxidation
- Condensation
- Diazotization
- Cycliazation
- Reduction
- Hydrolysis
- Sulphonation
- Acylation
- Amination
- Acylation
- Halogenation
- Amidation

Production List of Equipment …..

Sr. No	Equipments	Capacity	Quantity	MOC
1	SS Reactor	2.5 KL	02	SS316
2	SS Reactor	2.0 KL	02	SS316
3	Glass Lined Reactor	3.0 KL	01	MSGL
4	Glass Lined Reactor	2.0 KL	06	MSGL
5	Glass Lined Reactor	1.0 KL	06	MSGL
6	Centrifuge	36”	3 Nos.	SS316
7	Centrifuge Full Body Opening	36”	2 Nos.	SS316
8	Fluid Bed Dryer	120 Kg	1 Nos.	SS316
9	Rotary Cone Vacuum Dryer	500 litre	3 Nos.	SS316L
10	Sparkler Filter	14”X10 Plates	2 Nos.	SS316
11	Multimill	100 kg/ hr	2 Nos.	SS316
12	Vibro Sifter	30”	1 Nos.	SS318
13	Vibro Sifter	24”	1 Nos.	SS316
14	Octagonal Blender	1000 Litre	2 Nos.	SS316

Total Volumetric Capacity = 25 KL

5.3 Utility Area - Purified Water System

Potable water received from MIDC water supply which is further treated for generation of purified water.

The process consists of following.

- Pressure Sand Filter
- Softener
- Micron filtration
- Reverse Osmosis
- UV
- Hot water sanitizable distribution system.
- Testing of purified water as per EP guidelines

Air Handling System

Air handling systems are provided in the following areas.

a. In powder processing area class 100000 (Grade D)
b. In stores, reactor hall 1 & 2 Filtered air through 5 micron
c. Microbiology laboratory Class 100000, class 10,000 & LAF class 100
d. Finished product storage class 100000

Desired Air Changes and pressure differentials are maintained as per cGMP guidelines

Purified Water System

Air Handling System

Utility Area – Equipments List ……

Sr. No	Equipments	Capacity	Nos.
01	Process Cooling Tower	250 TR	01
02	Utility Cooling Tower	250 TR	01
03	Process Chilling Plant	60 TR @ 7 C	01
04	Utility Chilled Water Plant	60 TR @ 7 C	01
05	Chilled Brine Plant	14.1 TR @ -20 C	01
06	Air Compressor	50 CFM	01
07	Scrubber	2500 CFM	01
08	Water Ring Vacuum Pump	90 m3 /HR	02
09	Water jet/Steam Jet Ejectors	--	02
10	Air Handling Units	--	--
11	Purified Water System	--	--
12	ETP	--	--

5.4 Quality Unit - Quality Control…..

Quality control is involved in following activities

- Preparation of test method related to raw material, in-process and intermediates, packing material and finished Active Pharmaceutical Ingredients (API).
- Calibration of measuring and analytical instruments.
- Sampling of raw material, Intermediates, finished product and packing material.
- Analysis of raw material, in-process, intermediate, packing material, finished active Pharmaceutical Ingredients (API) and other related and miscellaneous material.
- Stability evaluation
- Analytical method validation.

Quality Unit - Quality Control……*cont*

Sr. No.	Instrument	Make	No. of Units
1	HPLC	Shimadzu	1
2	HPLC	Agilent	1
3	GCHS	Shimadzu	1
4	GCHS	Agilent	1
5	Autotitrator	Spectralab	1
6	FTIR	Shimadzu	1
7	UV Spectrophotometer	Shimadzu	1
8	Stability Chamber	Thermolab	3

Quality Unit - Microbiology Department …..

Involves in the Microbiological evaluation of environment, water and finished products.

Sr. No	Equipments	Nos.
01	Horizontal Autoclave	01
02	Vertical Autoclave	01
03	Colony Counter	01
04	Oven	01
05	B.O.D Incubator	02
06	Bacteriological Incubator	01

Sr. No	Equipments	Nos.
01	Analytical Balance	01
02	Laminar air flow	01
03	Cyclo mixer	01
04	Microscope	01
05	pH meter	01

Quality Unit - QC & Microbiology …..

Quality Unit - Quality Assurance Department …..

- The prime responsibility of QA department is to ensure implementation of good manufacturing practices and good laboratory practice as per ICH Q7 guidelines and as per the Schedule ‘M’ by Indian FDA.

- Quality Assurance department is overall responsible for implementing various QA systems viz.
  - Implementation of SOPs,
  - Document change control,
  - Out of Specification investigation,
  - Deviation control,
  - Market complaints,
  - Training, Batch release etc.

- Respective department will draft the SOP and send to QA, QA will check the feasibility of the SOP with the current standard and issue the SOP for the implementation.

- All the SOPs, deviations, Change control, and OOS investigation report, validation protocols, etc. are to be approved by Head of QA.

- QA department is responsible for issue of controlled copies of blank BMR to production for day-to-day manufacturing activities.

- Review of all completed batch documents and release of the finished products based on batch review is the responsibility of QA.

- Quality Assurance department is responsible for conducting in-house audits and training.

- Company also respect and follow the laws and guidance of the supplying country before starting the business.

6.0 Research & Development ……

- ***Introduction:***

  We have got a full fledge R&D centre with all modern equipments & technology .
  In-house expertise in product development ensures a quick turnaround time in API development, commercial production and to cater DMF data.

- ***Purpose:***

  - For manufacturing product from gram to kilogram scale .
  - For laboratory to Commercial scale Up
  - Contract Research Projects.

- ***Features:***

  - Dedicated R&D team of trained scientists.
  - Proven capabilities in developing products as per the global requirements.
  - Independent AR&D development.
  - Proven capabilities of developing Analytical Method & Validation.
  - Our lab has all equipments for process evaluation up to 5 Kg level.

7.0 Safety Health and Environment ……

- Full fledged effluent treatment plant having primary, secondary and tertiary treatment facility.
- We are members of common effluent treatment plant (CETP) final effluent, after treatment, is discharged to CEPT.
- We are members of solid waste disposal management & the solid waste generated within the factory is being sent for land filling
- Plant and machinery are designed as per safety norms having appropriate emergency escapes.
- Self supported boiler chimney to take care of boiler emission
- Personal protective equipments
- Medical aid
- Proper air ventilation and air filtrations in all the manufacturing areas.

8.0 Business Strategy of the company …..

- **Sai-Tech Pharmaceuticals Pvt. Ltd.** strives to be a globally recognized player in the niche therapeutic categories.

- Company wishes to be a partner of choice for the worldwide pharma organizations for their need of API products thereby creating synergies between their expertise and our superior manufacturing strengths.

- Our Current Strategy aims at expanding our reach in global market

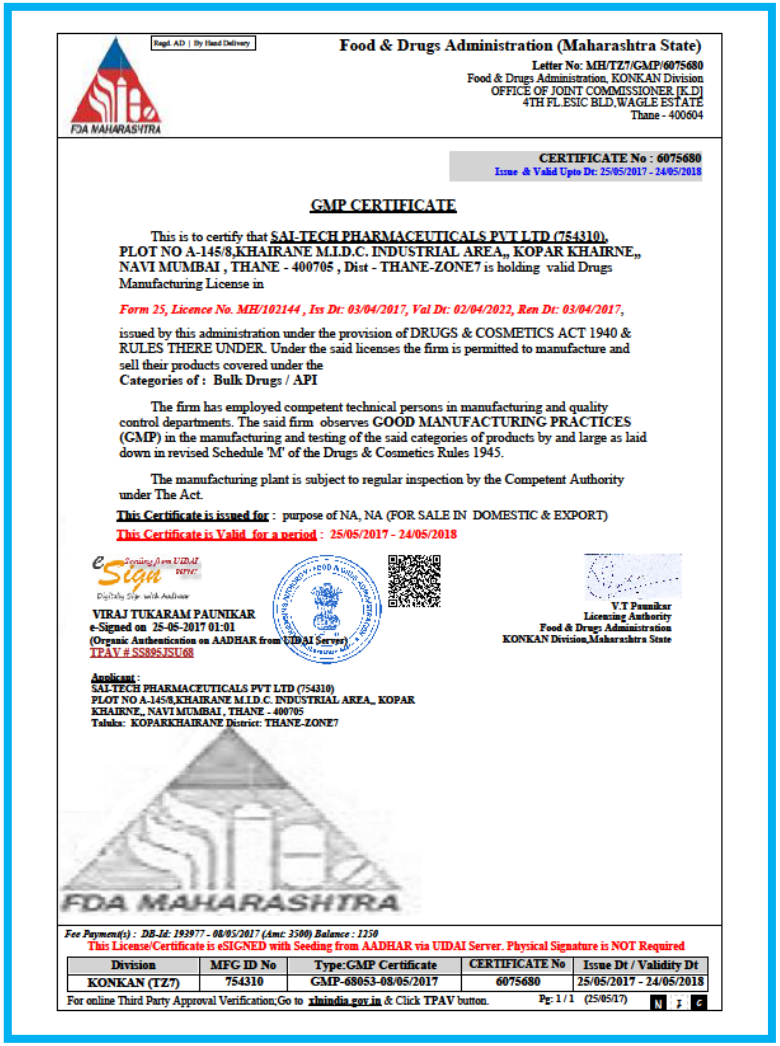
- **Sai-Tech Pharmaceuticals Pvt. Ltd.** seeks marketing strategic partnership in API in regulated/Semi regulated markets and wishes to appoint key distributors/networking agents for it's exclusive product mix in various countries.

9.0 Regulatory Status …..

- GMP (Approved)
- WHO GMP (Approved)
- ISO 9001 : 2015 (In-process)
- EDQM (Planned)
- USFDA (Planned)

Regulatory Status *cont.* ……

GMP CERTIFICATES



Regd. AD | By Hand Delivery

Food & Drugs Administration (Maharashtra State)

Letter No: MH/TZ7/GMP/6075680
Food & Drugs Administration, KONKAN Division
OFFICE OF JOINT COMMISSIONER [K.D]
4TH FL.ESIC BLD,WAGLE ESTATE
Thane - 400604

FDA MAHARASHTRA

CERTIFICATE No : 6075680
Issue & Valid Upto Dt: 25/05/2017 - 24/05/2018

GMP CERTIFICATE

This is to certify that SAI-TECH PHARMACEUTICALS PVT LTD (754310), PLOT NO A-145/8,KHAIRANE M.I.D.C. INDUSTRIAL AREA,, KOPAR KHAIRNE,, NAVI MUMBAI , THANE - 400705 , Dist - THANE-ZONE7 is holding valid Drugs Manufacturing License in

Form 25, Licence No. MH/102144 , Iss Dt: 03/04/2017, Val Dt: 02/04/2022, Ren Dt: 03/04/2017,

issued by this administration under the provision of DRUGS & COSMETICS ACT 1940 & RULES THERE UNDER. Under the said licenses the firm is permitted to manufacture and sell their products covered under the
Categories of : Bulk Drugs / API

The firm has employed competent technical persons in manufacturing and quality control departments. The said firm observes **GOOD MANUFACTURING PRACTICES (GMP)** in the manufacturing and testing of the said categories of products by and large as laid down in revised Schedule 'M' of the Drugs & Cosmetics Rules 1945.

The manufacturing plant is subject to regular inspection by the Competent Authority under The Act.

This Certificate is issued for : purpose of NA, NA (FOR SALE IN DOMESTIC & EXPORT)
This Certificate is Valid for a period : 25/05/2017 - 24/05/2018

eSign Signing from UIDAI portal
Digitally Sign with Aadhaar

VIRAJ TUKARAM PAUNIKAR
e-Signed on 25-05-2017 01:01
(Organic Authentication on AADHAR from UIDAI Server)
TPAV # SS895JSU68

V.T Paunikar
Licensing Authority
Food & Drugs Administration
KONKAN Division,Maharashtra State

Applicant :
SAI-TECH PHARMACEUTICALS PVT LTD (754310)
PLOT NO A-145/8,KHAIRANE M.I.D.C. INDUSTRIAL AREA,, KOPAR KHAIRNE,, NAVI MUMBAI , THANE - 400705
Taluka: KOPARKHAIRANE District: THANE-ZONE7

FDA MAHARASHTRA

Fee Payment(s) : DB-Id: 193977 - 08/05/2017 (Amt: 3500) Balance : 1250
This License/Certificate is eSIGNED with Seeding from AADHAR via UIDAI Server. Physical Signature is NOT Required

Division	MFG ID No	Type:GMP Certificate	CERTIFICATE No	Issue Dt / Validity Dt
KONKAN (TZ7)	754310	GMP-68053-08/05/2017	6075680	25/05/2017 - 24/05/2018

For online Third Party Approval Verification;Go to xlnindia.gov.in & Click TPAV button. Pg: 1 / 1 (25/05/17)

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 6/1/2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).
Certificate No.: NEW-WHO-GMP/CERT/KD/62737/2018/11/22171

On the basis of the inspection carried out on 16/10/2017, 17/10/2017 and 20/11/2017 , we certify that the site indicated on this Certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : SAI-TECH PHARMACEUTICALS PVT LTD
   Address : PLOT NO A-145/8, KHAIRANE MIDC INDUSTRIAL AREA, NAVI MUMBAI THANE 400705 MAHARASHTRA STATE, INDIA
2. Licence No. : MH102144 In Form 25

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 05 Jan 2020 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

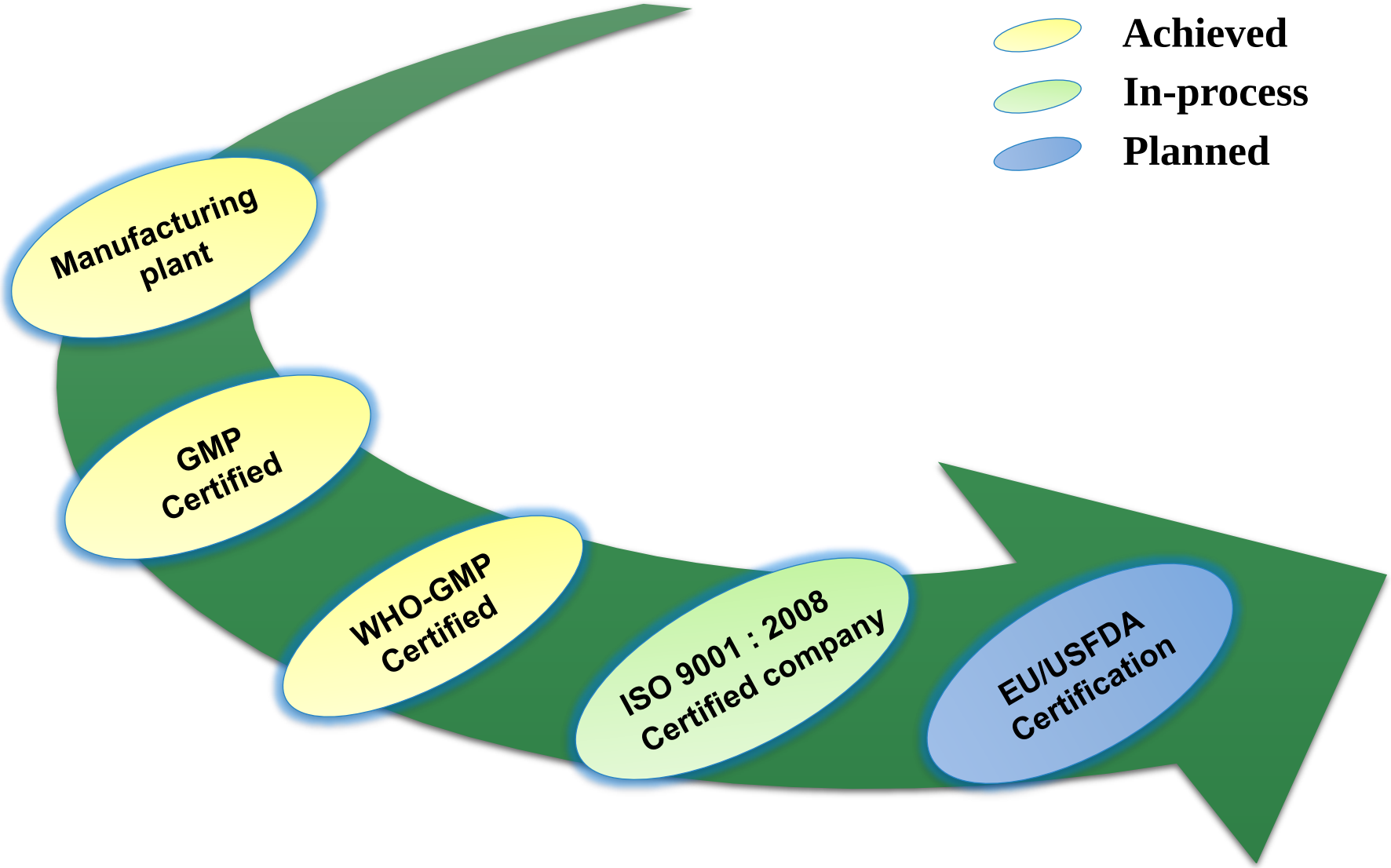
Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1IAS0236273720180106

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:06 Jan 2018

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

06 JAN 2018

10.0 Milestones …..



11.0 Product List - Developed APIs…..

Sr. No	Product	Pharmacopeia	CAS No.	Therapeutic Category
01	Celecoxib	EP/USP/BP	169590-42-5	NSAID (Anti-Inflammatory)
02	Raloxifene Hydrochloride	BP/USP	82640-04-8	Anti-Osteoporotic
03	Butamirate Citrtate	In-House	18109-81-4	Anti-Tussive
04	Butethamate Citrate	In-House	3639-12-1	Anti-Tussive
05	Bupropion Hydrochloride	USP	31677-93-7	Anti-Depressant
06	Etoricoxib	IP	202409-33-4	NSAID (Anti- Inflammatory)
07	Homotaurine	In- House	3687-18-1	Treatment of Alzheimer’s disease
08	Tolperisone Hydrochloride	JP	3644-61-9	Muscle relaxant

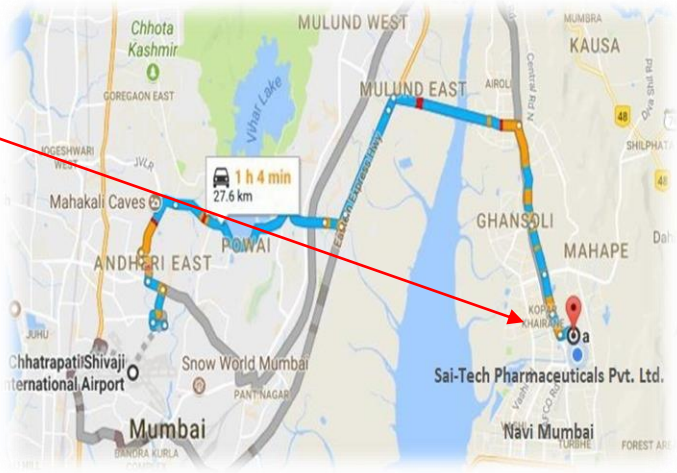
Product List - Under Development APIs cont. …..

Sr. No	Product	Pharmacopeia	CAS No.	Therapeutic Category
01	Zolpidem Tartrate	USP/EP/BP	99294-93-6	Used to treat Insomnia
02	Tamoxifen Citrate	IP/USP/BP	54965-24-1	Anti- Neoplastic
03	Brexpiperazole	EP/USP	913611-97-9	Treatment of Schizophrenia
04	Phenylephrine Hcl	USP/EP/BP	61-76-7	Decongestant, as an agent to dilate the pupil and to increase blood pressure
05	Glipizide	BP/USP	29094-61-9	Anti-Diabetic
06	Tapentadol	USP	175591-09-0	Opioid Analgesic
07	Iloperidone	EP/USP	133454-47-4	Antipsychotic

12.0 How to reach …..

- **Manufacturing Facility**

  Plot No – 145/8,
  Khairne M.I.D.C.
  Navi Mumbai - 400705.
  INDIA.
  Dist. About (28.0 km)
  from Mumbai Airport



- **Corporate Office**

  212, The Great Eastern Chambers,
  CBD Belpaur,
  Navi Mumbai – 400614.
  INDIA

13.0 Contact Details …..

MANUFACTURING FACILITY:
Sai-tech pharmaceuticals pvt. Ltd.
Plot no. A-145/8. Khairane MIDC, Navi mumbai-400705

HEAD OFFICE:
212, The Great Eastern Chambers,
Sector - 11, Plot No.28, CBD, Belapur,
Navi Mumbai, MS-400614. INDIA
Tel: +91 22-2769 6917/18/19
Cell: 08422919855/08424047394
ceo@saitechpharmaceuticals.com
mkt@saitechpharmaceuticals.com
api@saitechpharmaceuticals.com

Website: www.saitechpharmaceuticals.com

THANK YOU !