



ENRICHED BY **EXPERIENCE...**
EMPOWERED BY **RESEARCH.**





Certificate of Registration

This Certificate certify that the Management System of

STANDHARDT INNOVATIONS PVT LTD

Registered Add: - No-07, Shaktivijay CHS Ltd, Varachha Road, Varachha Road
Surat -395006, Gujarat, India.

has been audited by ICV and found to be
in compliance with the requirements of the standard

ISO 9001: 2015

(Quality Management Systems)

**This certificate is valid for
the following scope:**

Custom Research, Manufacturing and Sales Services of Niche Chemicals,
Pharma Intermediates and Active Pharmaceuticals Ingredients (APIs)

Certificate No.	: IN/1444699/2022
Certificate Issue Date	: 27/12/2022
1st Surveillance Due Date	: 27/11/2023
2nd Surveillance Due Date	: 27/11/2024
Date of Expiry	: 26/12/2025



CEO

ICV ASSESSMENTS PVT. LTD.

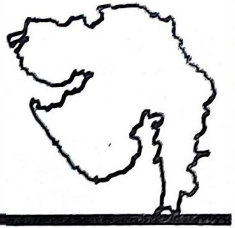
25, First Floor, Prabhu Complex, Shiva Market, Pitampura New Delhi - 110034
+91 - 11-41548315, info@icvassessments.com, www.icvassessments.com

- Validity of this Certificate is subject to completion of surveillance audit on or before of due date. In case Surveillance audit not allowed to be conducted this Certificate shall be suspended / withdrawal.
- This Certificate is intellectual Property of ICV and Certificate should be returned to ICV in case of non compliance of certification procedure. Authenticity of this certificate can be verified at www.icvassessments.com



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : SL-GMP/23084482

G.M.P. CERTIFICATE

This is to certify that M/s. *STANDHARDT INNOVATIONS PRIVATE LIMITED, SECOND FLOOR, SHOP NO.A-215, R.S.NO.277 PAIKI SHRI HARISMRUTI, CO.OP.HOU.SOC.LTD, PLOT NO.-CM-1, CITY CENTRE, GIDC, ANKLESHWAR - 393 002, DIST.- BHARUCH* is holding valid drug manufacturing loan licenses in Form No. 25A & 28A bearing No. G/25A/5793-A & G/28A/7098-A, MFGD. AT : *PLOT NO:-561, PHASE - II, OPP: VATVA RAILWAY STATION, G.I.D.C, VATVA, AHMEDABAD - 382 445* issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules thereunder. Under the said licenses the firm is permitted to manufacture & sell drugs covered under the following categories.

Dosage Form (s)	Category (ies)
Bulk Drugs (APIs)	General

The parent firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE - M of Drugs & Cosmetics Act 1940 & Rules There under.

The manufacturing plant of parent firm is subjected to inspection at suitable intervals by competent authority.

THIS CERTIFICATE IS EXCLUSIVELY ISSUED FOR EXPORT PURPOSE ONLY.

This certificate is valid from Dt: 22/08/2023 to 04/04/2025.



(Dr. H. G. KOSHIA)

Commissioner
Food & Drugs Control Administration
Gandhinagar, Gujarat State

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

FORM 25-A

Fresh License

(See Rule 70-A)

Loan Licence to manufacture for sale [or for distribution of] drugs other than those specified in [Schedules C, C(1) and X]

1. Number of licence and date of issue No G/25A/5793-A Date: 17-Jan-2023

2. Directors

of M/s. STANDHARDT INNOVATIONS PRIVATE LIMITED , SECOND FLOOR, SHOP NO. A-215, R.S. NO. 277 PAIKI SHRI HARISMURTI, CO.OP.HOU.SOC.LTD., PLOT NO.-CM-1, CITY CENTER, GIDC, ANKLESHWAR-393002, DIST.-BHARUCH is hereby granted a loan licence to manufacture the following drugs being drugs other than those specified in [Schedules C, C(1), and X] to the Drugs & Cosmetics Rules, 1945, on the premises situated at PLOT NO. 561, PHASE-II, OPP: VATVA RAILWAY STATION, G.I.D.C., VATVA, AHMEDABAD - 382 445

under the direction and supervision of the following competent technical staff:

(a) Competent technical staff (Names): Approved technical person of DILIGENT LIFE CARE

(b) Names of Drugs As Approved & Annexed

3. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licences for sale.

4. The licence shall be in force From : 17-Jan-2023 To 16-Jan-2028

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and cosmetics Act, 1940.

Signature : (This Document is Digitally Signed.)

Designation : Dr. H. G. KOSHIA

Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 17-Jan-2023

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the [competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to undertake during the currency of the licence to manufacture for sale additional of drugs he should apply to the Licensing Authority for the necessary endorsement to the licence provided in Rule 69-A. This licence will be deemed to extend to the drugs so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.



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STANDHARDT INNOVATIONS PRIVATE LIMITED

Print Date : 18/03/2023 03:36 PM

FORM 28-A

Fresh License

(See Rule 76-A)

Loan Licence to manufacture for sale (or for distribution of) drugs specified in Schedules C, C (1) [excluding those specified in schedule X]

1. Number of licence and date of issue No G/28A/7098-A Date: 17-Jan-2023

2. Directors

of M/s. STANDHARDT INNOVATIONS PRIVATE LIMITED , SECOND FLOOR, SHOP NO. A-215, R.S. NO. 277 PAIKI SHRI HARISMURTI, CO.OP.HOU.SOC.LTD., PLOT NO.-CM-1, CITY CENTER, GIDC, ANKLESHWAR-393002, DIST.-BHARUCH is hereby granted a Loan licence to manufacture on the premises situated at PLOT NO.561, PHASE - II, OPP : VATVA RAILWAY STATION, G.I.D.C, VATVA, AHMEDABAD - 382 445

the following drugs being drugs specified in schedules C & C (1) (Excluding those specified in schedule X) to the Drugs and Cosmetics Rules 1945.

Names of Drugs :

As Per List Approved & Annexed

3. Names of approved competent technical staff :

Approved technical person of DILIGENT LIFE CARE

3.A The licence shall be in force from 17-Jan-2023 To 16-Jan-2028

4. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

(This Document is Digitally Signed.)

Signature :

Dr. H. G. KOSHIA

Designation :

**Commissioner
Food & Drugs Control Administration
Gujarat State.**

Date:- 17-Jan-2023

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified Schedule C and/or C (1) not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(A). This licence will be deemed to extend to the items so endorsed.
3. Any change in the (competent technical staff) shall be forthwith reported to the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.



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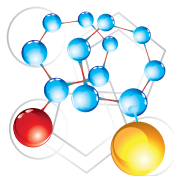
STANDHARDT INNOVATIONS PRIVATE LIMITED

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Standhardt Innovations has been serving the Pharma industry for over 10 years. Below are the activities of Standhardt Innovations:



Bulk Drugs Manufacturing Unit at Panoli and Ahmedabad GUJARAT.



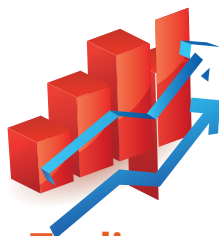
Research & Development Lab at Ahmedabad Chemical Synthesis, Analytical Development, Pilot Plant



Exports to over 30 countries



Human Resource
100+



Topline
USD 10 Million +

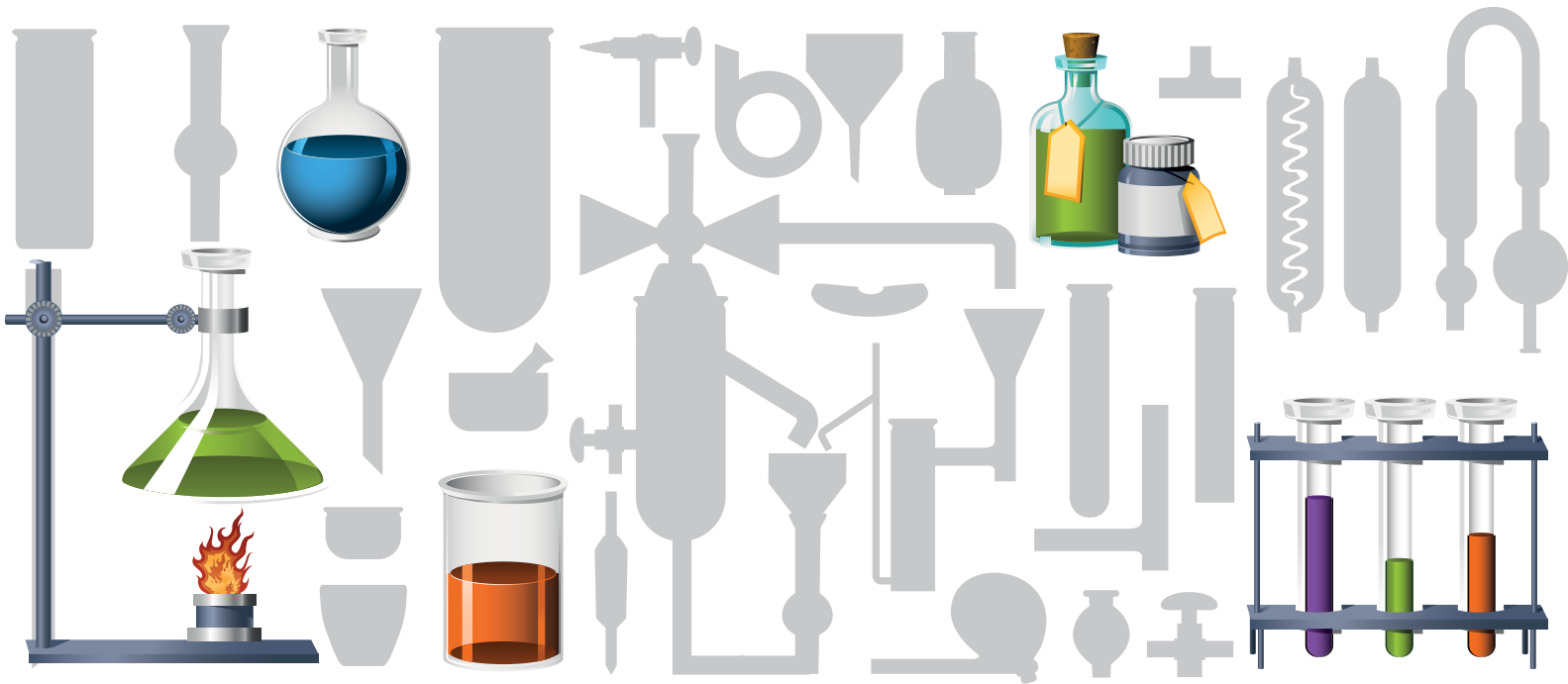


Private Limited Company

Enriched by Experience... Empowered by Research.

Standhardt Innovations is one of the leading manufacturers of Active Pharmaceutical Ingredients (API's). Established in 2012, the company has grown several folds over the last twenty years and achieved several credits besides of course, building a strong base of trust amongst its customers. It is now recognized as one of the largest producers of macrolides in the country.

SIPL's story has always been that of magnificent metamorphosis. The R&D Division is another feather in our cap. We believe that research lies at the heart of progress. This is especially true of the pharmaceutical industry. The state-of-the art facility has 3 labs: The Analytical Development Lab, The Chemical Synthesis lab and The Pilot Plant.



Analytical Development Lab

Reliable and reproducible analytical methods are essential to both the pharmaceutical development and the evaluation of drug product to meet the defined Industry Standards of potency, purity and stability. Analytical chemists work to develop, qualify and validate or refine analytical methods to meet these demands.

We have a state-of-the art analytical lab required for method development activities that lead to characterization and profiling of products. We have a young and passionate team which can be leveraged to suit the requirements.





SERVICES OFFERED

- Product Analysis as per Pharmacopias
- Impurity Profiling & Identification
- Particle size Analysis
- Analytical Method Development & Validation
- Residual Solvent Analysis
- Stability Studies
- Related substance Analysis
- Polymorphism Detection

FACILITIES

- Stability Chambers
- Muffle Furnace
- Cooling Cabinets
- Deep Freeze Cabinets
- Milli-Q Ultra Pure Water System

EQUIPMENT

- Gas Chromatograph
- HPLC with PDA Detector
- HPLC UV-VIS Variable Wavelength Detector.
- Particle Size Analyzer
- Polarimeter
- Spectrophotometer
- FTIR
- Differential Scanning Colorimeter
- Thermogravimetric Analyzer
- Potentiometric Autotitrator

Chemical Synthesis Lab

The Chemical Synthesis Lab conducts lab scale reactions to develop processes and products. By physical and chemical manipulations involving one or more reactions, our chemists devise reliable, reproducible reaction processes that are scalable.



SERVICES OFFERED

- Process Development & Method Improvements
- Isolation, Manufacturing & Characterization of Impurities
- Application of Statistical Designs from Process Development

UTILITIES

- Fume Extraction
- High Vacuum
- Nitrogen
- Heating / Cooling

EQUIPMENT

- All Glass Flasks upto 5 lt.
- Rotavapors
- Hot & Cold Water Baths
- Vacuum Ovens
- High Pressure Autoclaves from 1lt. to 3lt.
- Specialized Cylindrical Glass Flasks to mimic reactor conditions





Pilot Plant

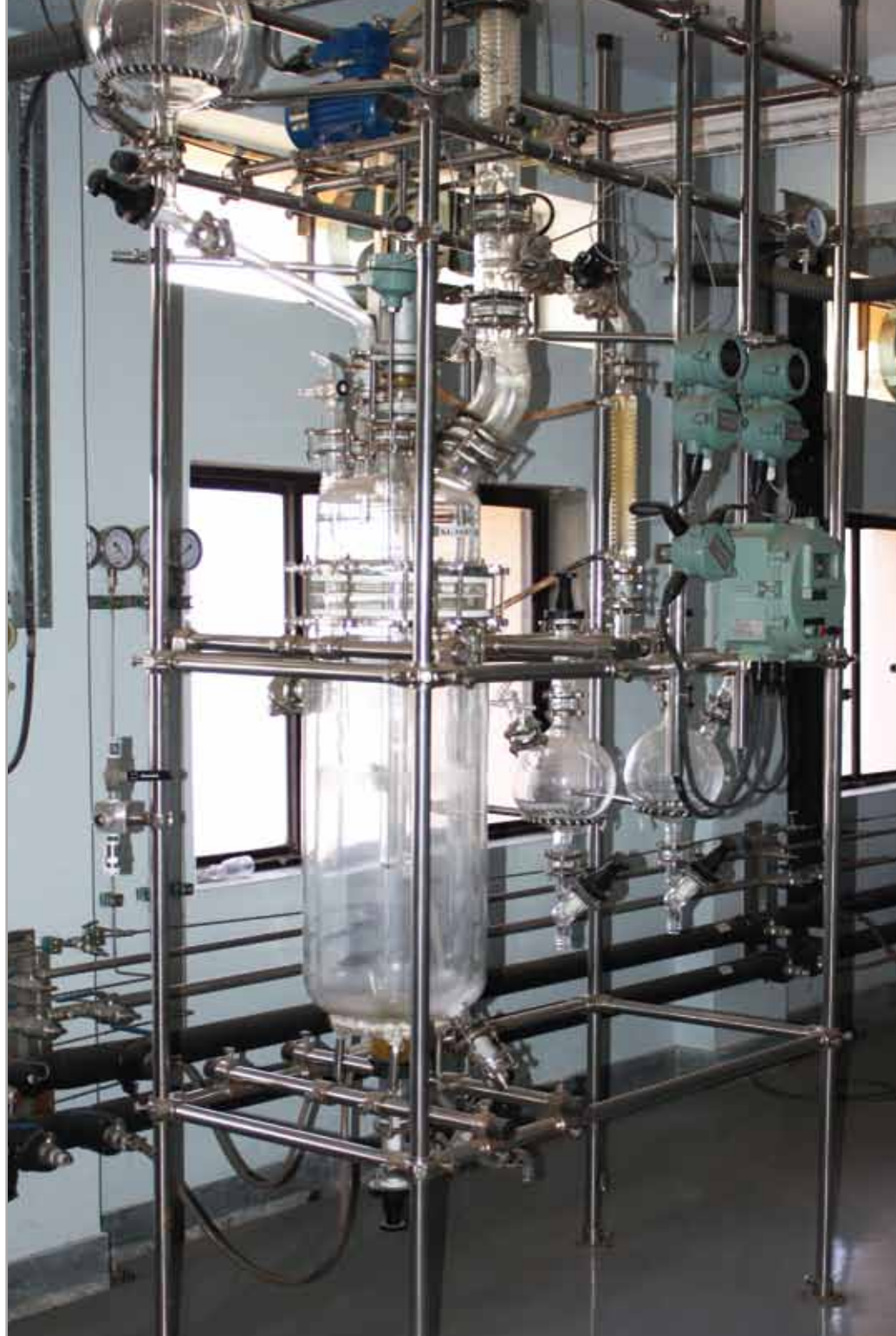
The Pilot Plant is well equipped with facilities to scale up processes developed in the Chemical Synthesis Lab and to facilitate the manufacturing of active pharmaceutical ingredients for clinical trials and validations.

SERVICES OFFERED

- Scale-Up of processes developed in the Chemical Synthesis Lab
- Manufacturing of Active Pharmaceutical Ingredients for Clinical Trials and Validations

FACILITIES

- Spot Extractors
- Epoxy anti-static flooring
- Data Loggers
- Scrubbers
- Huber Cryostat for Temperatures from -20°C to $+200^{\circ}\text{C}$
- Chilling and Vacuum Systems
- Nitrogen Purging for Inert Atmosphere
- RO Water Purification System



● EQUIPMENT

Sr. No.	Description	Other details	Quantity (Nos.)
1	MS-Glass lined Reactor vessel-6300 Ltrs.- with M.S. Jacket Make : Standhardt Glass (hydrabad)	Vertical gearbox with 15 h.p f.p. motor. Condenser: 20 M ³ Seal: Single Mechanical Stirrer: Anchor One Tantalum Tip on FBV for temperature sensing as well as earthing	1
2	MS-Glass lined Reactor vessel-5000 Ltrs.- with M.S. Jacket Make : Glasscoat	Vertical gearbox with 15 h.p f.p. motor. Condenser: 16 M ³ Seal: Single Mechanical Stirrer: Anchor One Tantalum Tip on FBV for temperature sensing as well as earthing	3
4	MS- Glass lined Reactor vessel of 3000 Ltrs.- with M.S. Jacket Make : Glasscoat.	Vertical gearbox with 7.5 H. P. FP Motor. Condenser: 12 M ³ Seal: Single Mechanical Stirrer: Anchor One Tantalum Tip on FBV for temperature sensing as well as earthing	1
5	Glass line Reactor vessel of 2000 Ltrs with M.S. Jacket Make : Glasscoat	Vertical gearbox with 5 H. P. FP Motor. Condenser: Graphite Seal: Single Mechanical Stirrer: Anchor One Tantalum Tip on FBV for temperature sensing as well as earthing	2
6	Glass line Reactor vessel of 1000 Ltrs with M.S. Jacket Make : GMM.	Vertical gearbox with 5 H. P. FP Motor: Seal: Single Mechanical Stirrer: Anchor	1
7	Glass line Reactor vessel of 1600 Ltrs with M.S. Jacket Make : GMM.	Vertical gearbox with 5 H. P. FP Motor: Seal: Single Mechanical Stirrer: Propeller Dip Pipe Available	1
8	SS 316 Reactor – capacity 6000 Ltrs. SS linpade coil Make : Bharat industries	Vertical gearbox with 7.5 H. P. Motor; Single Mechanical Seal; Stirrer: Anchor Condenser: 20 M ³ Single Pass	1
9	SS 316 Reactor – capacity 3000 Ltrs. SS linpade coil Make : Bharat industries	Vertical gearbox with 3 H. P. Motor; Seal: Single Mechanical Stirrer: Anchor Condenser: 15 M ³ Single Pass	1
9	SS 316 Reactor – capacity 4000 Ltrs. SS linpade coil Make : Bharat industries	Horizontal Gear Box with 5 HP FP Motor Seal: Single Mechanical Stirrer: Anchor Condenser: 11 M ³ Four Pass	1

Reg. Office : B/7 Shaktivijay Soc, Hirabaug Varachha Road, Surat - 395006, Gujarat.

Mfg. Unit : Plot No 33/A/1 - Panoti GIDC, Nr Maharaja Chowkdi, Panoti - 394116, Ta. Ankteshwar, Dist Bharuch, Guj.

Email : info@standhardtinnovations.com | Web : www.standhardtinnovations.com

11	Glass Assembly. 200 Ltrs.	With Condenser	1
12	SS 316 Centrifuge Make : JK Chemicals and pumps	48 " With Bag Lifting	1
13	SS 316 Centrifuge	36"	1
14	MS-RL Centrifuge Make: JK Chemicals and pumps	48" With Bag Lifting	1
15	Steam Boiler 1000 Kg/h Make : Ambica Boiler	Solid Fire (Wood/Briquette)	1
16	Steam boiler 600kg (2 Lakh Calories).	LDO	1
17	Tray Dryer	98 Tray (SS 316)	1
18	FBD- capacity 250kg.	FRP coating at contact parts	1
19	Steam jet Venturi 5 HP	High Vacuum up to 0.5 mmHg	1
20	Water jet Venturi 5 HP	Vacuum achieves 600-680 mmHg	1
21	Water jet Venturi 7.5 HP	Vacuum achieves 600-680 mmHg	1
22	Receivers	250 L, 500 L and 1000 L	Each
23	Effluent Treatment Plant	Primary, Secondary, Tertiary Capacity; 30000 Ltrs	1
24	Nutsche filter	SS 316 (Vol. 500 Lts)	1
25	Chilling Plant	Capacity 40 Tr (Up to -15°C)	02
26	HDPE Storage Tank	Storage Capacity 30 Kl	2
27	Acid Scrubber system	Primary Water and Secondary Caustic	2
28	Cooling tower	300 TR	1
29	Electric Supply	LT Connection 99 KW	1
30	DC Set	125 KVA	1
31	CETP membership at PETL	Discharge permission 70 Tankers/ Month	
32	TSDF	10.8 MT/Y	
33	Lift for material transfer	Capacity 900 kg	1

Reg. Office : B/7 Shaktivijay Soc, Hirabaug Varachha Road, Surat - 395006, Gujarat.

Mfg. Unit : Plot No 33/A/1 - Panoli GIDC, Nr Maharaja Chowkdi, Panoli - 394116, Ta. Ankteshwar, Dist. Bharuch, Guj.

Email : info@standhardtinnovations.com | Web : www.standhardtinnovations.com

Reaction Capabilities

- Oxidation / Reduction
- Hydrogenation
- Vilsmeier - Haack
- Alkylation
- Condensation
- Nitration
- Grignard Reaction
- Cyclisation
- Acylation
- Diazotization
- Substitution
- Amidation

Knowledge & Technology Support

In addition to the facilities, the lab derives benefit from the services of excellent professionals and experienced advisors. Our sound infrastructure and systems ensure smooth working of the lab. We receive Uninterrupted Power Supply and we have a DG set to ensure continued undisturbed reactions. The Effluent Treatment Plant adheres to environment friendly guidelines. In fact, we use all the treated water for gardening purposes thereby reducing the lab's carbon footprint. The area is also monitored continuously by CCTV. Fire Alarm System and Firefighting systems are in place as per norms.

We have a confidentiality policy in place which ensures complete secrecy of the processes undertaken by the lab. Our IT arrangements make it impossible for any data to be removed physically from our computers. All emails from and to the lab are also monitored. With this state of the art facility, enriched by excellent staff and systems, we are confident of enriching the industry with our research.

We have made a beginning, if you have a need we have spare capacity.

Product List

INTERMIDIATS

- 5-Bromo 2-Chloro Benzoic Acid
- 4-Hydroxy Benzyl Alcohol
- 2-Iso Propoxyethoxymethylphenol
- 2-(1-Adamantyl)-4-Bromophenol
- 4-Bromoflourobenzene
- 4-Fluoroanisole
- 2-Ethoxybenzaldehyde
- 2-(Aminomethyl)-1-ethylpyrrolidine
- 4-Aminoslyclic Acid

API's

- ALLOPURINOL
- ALBENDAZOLE
- DOXOFYLINE
- PRELOCAIN
- ADAPALENE
- CHLORTAHLIDONE
- FEBANTEL
- RIVAROXABAN
- LORNOXICAM
- MELOXICAM
- PIROXICAM
- RENOLAZIN INH
- AMROXOL HYDROCHLORIDE
- PREGABLIN
- FENBEZADOL

ANTI-DIABETIC DRUG

- VEDILAGLIPTIN
- GLIMEPIRIDE

ANTIHYPERTENSION

- BISOPROLOL FUMARATE

ANTIPROTOZOAL

- ORNIDAZOLE
- METRONIDAZOLE

HYPERPLASIA

- TAMSULOSIN HYDROCHLORIDE
- DUTASTERIDE



Product List of STANDHARDT INNOVATIONS

New Molecules

Aripiprazole	Luliconazole	Silodosin
Bromfenac Sodium	Nalidixic Acid	Sitagliptin
Bepotastine Besilate	Nateglinide	<u>Choline bitartrate/ Choline Chloride</u>
Daclatasvir Di HCl	Pitavastatin Calcium	Tapentadol
Eberconazole Nitrate	Prasugrel	Teneligliptin
<u>Rivaroxaban</u>	<u>Apixaban</u>	<u>Tricholine Citrate solution</u>

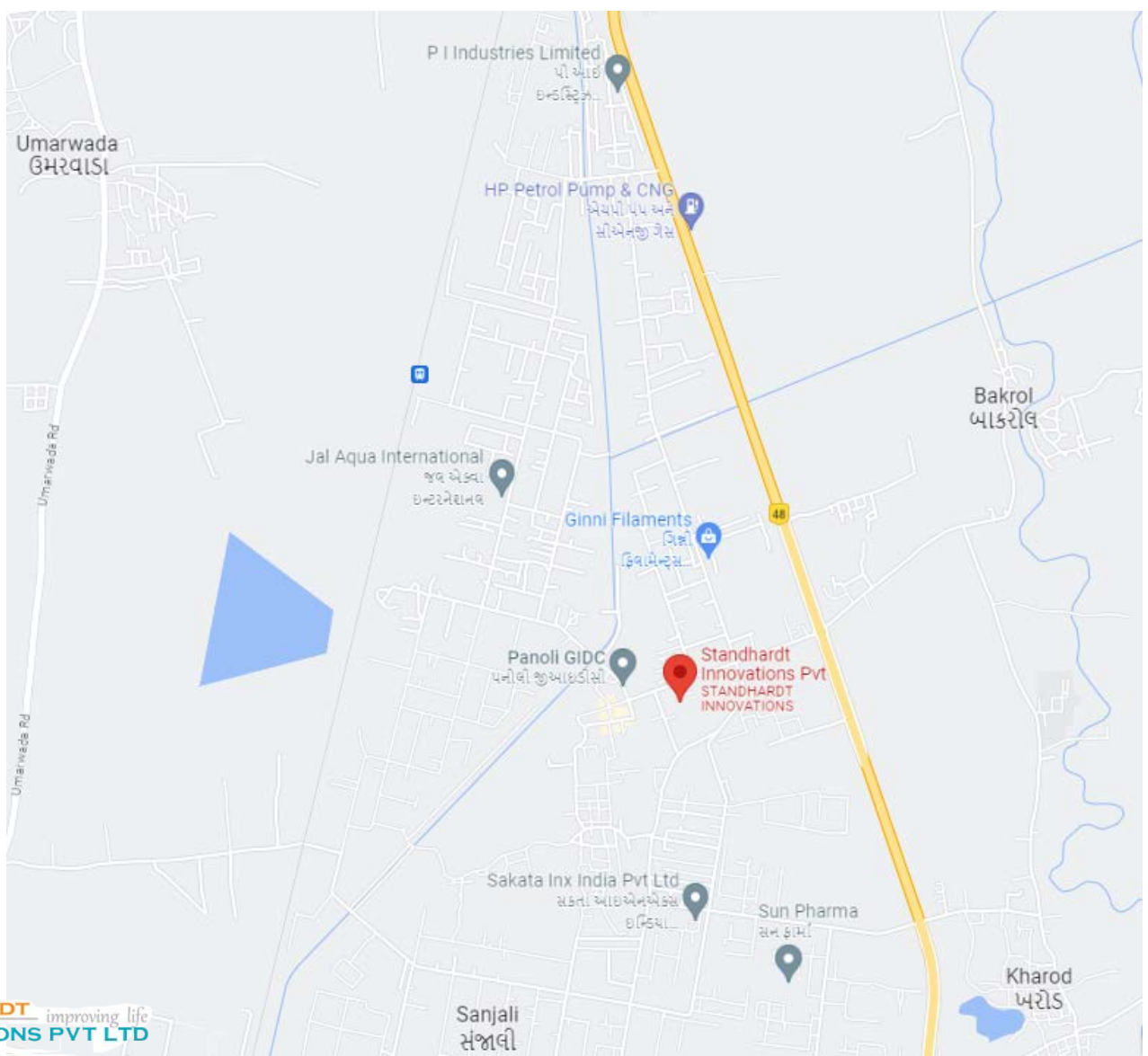
Active Pharmaceutical ingredients

Accelofenac/Diclofenac	Escitalopram Oxalate	Pantoprazole
<u>Amisulpride/ Levosulpiride</u>	Esomeprazole Sodium/Mg	<u>Pregabalin</u>
Amlodipine Besylate	Etoricoxib	Pioglitazone
<u>Adapalene</u>	Fluconazole	Quetiapine Fumarate
Atorvastatin Calcium	Flupritine Maleate	Rupatadine fumarate
Azithromycin	Gabapentin	Rabeprazole
<u>Benfotiamine</u>	<u>Hydrochlorothiazide</u>	Risedronate sodium
Buprenorphine/Naloxone	Ketorolac Tromethamine	Risperidone
<u>Bisoprolol Fumarate</u>	Lansoprazole	Rosuvastatin
Cilnidipine	Levocetizine	Sertraline
Cilostazol	Loratidine/Desloratidine	Sodium Valporate
<u>Citi choline Sodium</u>	<u>Lornoxicam/Piroxicam</u>	<u>Sevelamer HCl</u>
<u>Clopidogrel</u>	<u>Metoprolol Succinate</u>	<u>Tamsulosin/Dutasteride</u>
Dapoxetine	Methylcobalamine	Telmisartan
Deflazacort	Montelukast Sodium	Terbinafine HCl
Dexketoprofen	Nebivolol	Tolperisone HCl
Divalproex Sodium	Olanzapine	Topiramate
Domperidone	Olmesaiian medoxomil	Triclabendazole
Dorzolamide	Omeprazole	Ursodeoxycholic acid
Duloxetine/Fluoxetine HCl	Paliperidone	Voriconazole
Albendazole	Mebendazole	Fenbendazole

Pellets

Pantoprazole + Domperidone	Rabeprazole + Domperidone
Omeprazole + Domperidone	Esomeprazole + Domperidone
Pantoprazole + Levosulpiride	Rabeprazole + Levosulpiride
<u>Tamsulosin pellet</u>	<u>Dutasteride pellet</u>

LOCATION MAP



HEAD OFFICE

7/ Shakti Krupa Soc, Nr. Laxmi Hotel Hirabaug,
Varachha Road,
Surat -395006, Gujarat, INDIA

Web: www.standhardtinnovations.com
E-mail: info@standhardtinnovations.com
Phone: +91 9898713574

MANUFACTURING UNIT

Plot No - 33/A/1
Panoli GIDC - 394116
Ta - Anklेशwar, Dist - Bharuch, Gujarat, INDIA.

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