

WELCOME TO



SANIKA CHEMICALS PVT. LTD.

Established in year 1998





SANIKA CHEMICALS PVT. LTD.

Established in year 1998,

OVERVIEW...



- > SANIKA CHEMICALS PVT. LTD. was established in the year 1998 and is engaged in the manufacturing of 'API intermediates' located at 'MAHAD MAHARASHTRA'
- ➤ Located near commercial capital of India Mumbai and on the national highway.
- Easy access by Road, Rail, Air and Sea to all parts of the world.
- ➤ Distance from factory to Jawaharlal Nehru Port Trust is about 128 km and from factory to air port is about 200 kms.
- Easy availability of qualified technical team.
- ➤ Abundant availability of Manpower and other facility as it is located in MIDC zone.
- ➤ It is fast growing & establishing a strong presence in the domestic as well as global market.
- > SANIKA CHEMICALS PVT. LTD is accredited by ISO 9001:2008 audited by TUV for the compliance of the Quality Management System & awarded with 'UDYOG PATRA AWARD' in the year 2005 by 'Central Government of India'

KEY CONSIDERATIONS...



Strong Operational Efficiency

- ➤ Manufacturing plant for intermediates with full fledged Quality control and Quality assurance department
- ➤ All the operational facilities to ensure seamless production of API 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

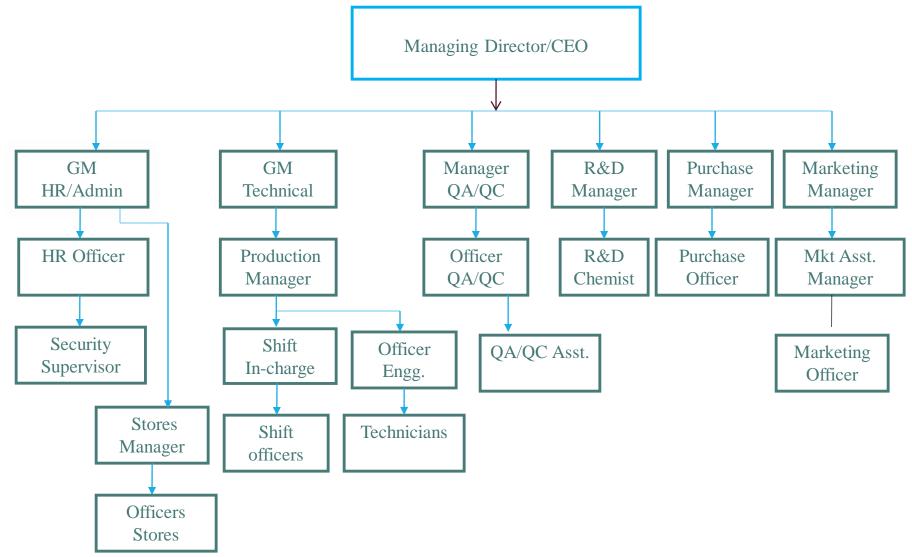
➤ Well entrenched relationships with several institutions and pharmaceutical companies in India and abroad.

Proven Research Capabilities

- ➤ Company has a well Qualified and Experienced R&D & Technical team, an independent Research & Development wing approved by Department of Scientific and Industrial Research (DSIR). The Ministry of Science and Technology, Government of India,
- Focused on delivering cost-effective quality products, which in turn provide customers a competitive advantage in their market place.

ORGANOGRAM...





ACCREDITATIONS...



- > ISO 9001:2008 approved.
- **➤** Holding Star Export House Certificate.
- ➤ R&D Centre Recognized by Department of Science & Industrial Research, Government of India.

> "Sanika Chemicals" Mahad plant is audited and approved by European Customers for API Intermediates.

ISO 9001:2008



DSIR APPROVAL



Management system as per

ISO 9001:2008

In accompanies with TOV (NDIA procedures, it is harney certified that

SANIKA CHEMICALS PVT. LTD.

OFFICE: 212, The Great Eastern Chambers. Plot No. 28, Sector 11, CBD Belapur, Navi Mumbai - 400 614,

WORKS: Plot No. E-28 MIDC Area, Mahad. Dist - Raigad, Maharashtra,

India

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Manufacture & Sale of Organic Intermediates.

Certificate Registration No. 986 01 00086 Audi Rissor for 96674/2014

Valid Links 21, 12,2017

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DOVERNMENT OF WOM MINISTRY OF SCIENCE AND TECHNOLOGY Department of Scine Life and industrial Receives. Training process, New Metrors Road. New Dolls - 110009

#1/80 1/195 60 (IN 198 195

F. No. TURIV-RDM141/2016

Dated; 29th March, 2017

Mis. Sanika Chemicals Pvt. Ltd. A/212, The Great Eastern Chambers Plot No - 28, Sector -11 CBD, Belapur Nev: Mumbai - 400 614

Subject: RECOGNITION OF YOUR IN HOUSE RAD UNIT(s)

Dear Sire.

This has releience to your application for imagnition of your in-House R&D unit(s) by the Department of Scientific and Industrial Research.

- This is to inform you that it has been decided to accord recognition to the In-House R&D unit(s) of your firm at Plot No. A-145/3 Khairann, MIDC, TTC Industrial Area, Navi Mumbal from 21.03.2017 to 31.03.2019. Terms and conditions pertaining to this recognition. are given overlaaf.
- Kindly acknowledge the receipt of this letter.

Yours faithfully

(Spart pande (Dr. S. K. Deshpande) Scinntist-G

STAR EXPORT HOUSE



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FACILITIES...



Factory is located at Mahad, 200 km from Mumbai. Total area measures 10600 sq. Mtr. Various sections are :

- **➤ Administrative Block & Quality Control**
- > Warehouse Block
- > Production Block consisting of
 - ► Glass Lined Reactors
 - > SS Reactors
 - Centrifuge
 - > Filters
 - Blender
 - > Fluid Bed Dryers
 - Sifters

➤Utilities & Support functions

- Boiler
- > Thermopack
- > Chilled Brine
- Cooling Tower
- ➤ Air Compressor
- Diesel Generator

REACTION CAPABILITIES...



- > Friedel Craft
- **>** Bromination
- > Chlorination
- > Oxidation
- ➤ Diazotisation
- > Cyanation
- > Demethylation
- > Nitration
- > Cyclization
- Grignard Reaction
- > Distillation under vacuum up to1 torr

LIST OF EQUIPMENTS...



Sr. No.	Description	Capacity	Quantity	MOC
1	SS Reactor	0.6 KL	1 No.	SS316
2	SS Reactor	1 KL	1 No.	SS316
3	SS Reactor	1.4 KL	1 No.	SS316
4	SS Reactor	2 KL	3 No.	SS316
5	SS Reactor	6.3 KL	1 No.	SS316
6	Glass Lined Reactor	1 KL	2 No.	Glass lined
7	Glass Lined Reactor	2 KL	3 No.	Glass lined
8	Glass Lined Reactor	3 KL	2 No.	Glass lined
9	Glass Lined Reactor	4 KL	1 No.	Glass lined
10	Glass Lined Reactor	6.3 KL	1 No.	Glass lined
11	Centrifuge	36"	4 No.	SS316
12	Fluid bed Dryer	120 kg	1 No.	SS316
13	SS Kettle Reboiler with column	6.4 KL	1 No.	SS304

TOTAL VOLUMETRIC CAPACITY: 46 KL





14	Sparkler Filter	14" X 10 Plates	1No.	SS316
15	Multimill	100 kg/hr	1No.	SS316
16	Vibro Sifter	24"	1 No.	SS316
17	Blender	1000 lit.	1 No.	SS316

LIST OF UTILITY EQUIPMENT

Sr. No.	Description	Capacity
1	Steam Boiler	3000 kg/hr
2	Process Cooling Tower	250 TR
3	Utility Cooling Tower	100 TR
4	Chilled Brine plant	30 TR @ -20 ⁰ C
5	Air Compressor	50 CFM
6	Scrubber	
7	Vacuum Ejectors (3 Nos.)	
8	Diesel Generator	250 KVA



LIST OF QUALITY CONTROL INSTRUMENTS

Sr. No.	Instrument	Qty
1	Gas Chromatography Netel, Shimadzu, Agilent	03 Nos.
2	HPLC-Shimadzu	02 Nos.
3	Melting point apparatus	01 Nos.
4	Karl Fischer apparatus	01Nos.
5	Analytical Balance	02 Nos.
6	pH Meter	01Nos.

QUALITY POLICY...



We are in the business of developing, manufacturing and marketing of Pharmaceutical Intermediates for domestic and international markets.

We are committed to achieve customer satisfaction and shall continue to strive to meet changing expectations both stated and implied through Continual quality improvement.

Adheres to cGMP requirements.

Meeting the national the international regulatory requirements.

Market leadership.

Speedy response to the customers.

The quality policy shall be integrated and implemented by involving every individual in the organization

sd/-RAJAN THAKUR Managing Director

QUALITY ASSURANCE...



- The prime responsibility of Quality Assurance department is to ensure implementation of quality systems and good manufacturing practices as per ICH Q7 guidelines.
- ➤ 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.

QUALITY ASSURANCE...



- 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.

> Documentation Includes-

- > Site Master File
- ➤ Batch Manufacturing Records
- > SOPs covering each functions
- ➤ Batch Release
- ➤ Product Quality Reviews
- ➤ Complaint reviews
- ➤ Change Control
- Deviation Control
- ➤ CAPA (Corrective And Preventive Action) Reprocess/ Rework
- ➤ Validation/Revalidation
- > Training
- ➤ Self Audit

CUSTOMER AUDITS...



Sr. No.	NAME OF THE CUSTOMER	STATUS
1	AARTI DRUGS	APPROVED
2	AARTI INDUSTRIES	APPROVED
3	AUROBINDO	APPROVED
4	CIPLA LIMITED	APPROVED
5	FORMIL	APPROVED
6	GLOCHEM	APPROVED
7	HETERO DRUGS LTD.	APPROVED
8	HIKAL	APPROVED
9	LUPIN	APPROVED
10	MEDILUX	APPROVED
11	MYLAN LABORATORIES	APPROVED
12	RAKS PHARMA	APPROVED
13	TEVA	APPROVED

RESEARCH AND CDEVELPOMENT...



• Introduction:

We have got a full fledge R&D centre with all modern equipments & technology.

In-house expertise ensures a quick turnaround time in product development and commercial production.

• 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.

R&D SNAPSHOTS...











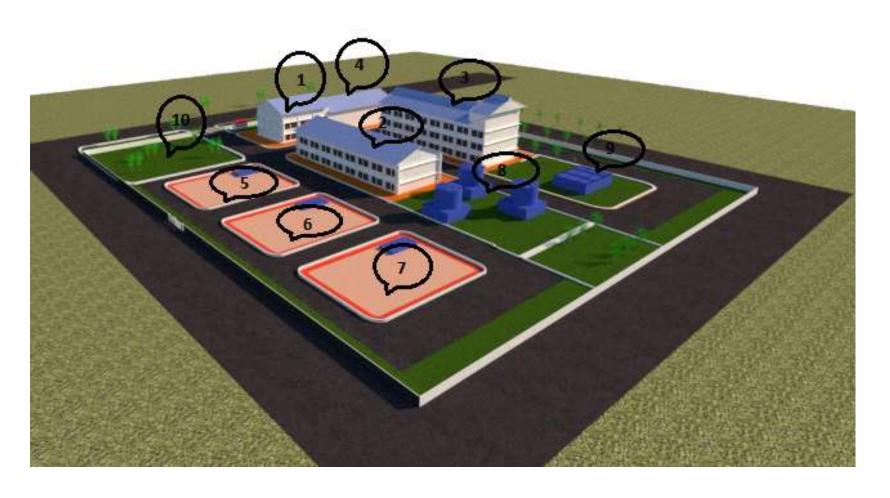
SAFETY HEALTH AND ENVIRONMENT...



- > WE ARE MEMBERS OF COMMON EFFLUENT TREATMENT PLANT (CETP) FINAL EFFLUENT AFTER TREATMENT IS DISCHARGED TO CETP.
- > WE ARE MEMBERS OF SOLID WASTE DISPOSAL MANAGEMENT & THE SOLID WASTE GENERATED WITHIN THE FACTORY IS BEING SENT FOR LAND FILLING
- ➤ EFFLUENT TREATMENT PLANT HAVING PRIMARY TREATMENT FACILITY AND DISCHARGE CONNECTED TO COMMON EFFLUENT TREATMENT PLANT FOR FURTHER TREATMENT.
- > PLANT AND MACHINERY ARE DESIGNED AS PER SAFETY NORMS HAVING APPROPRIATE EMERGENCY ESCAPES.
- > SELF SUPPORTED BOILER CHIMNEY TO TAKE CARE OF BOILER EMISSIONS.
- > SCRUBBERS ARE INSTALLED TO TAKE CARE OF GASEOUS EMISSIONS.
- > PERSONAL PROTECTIVE EQUIPMENTS
- MEDICAL AID

EXPANSION PLANS (SANIKA CHEMICALS)





- 1. Administration Block and Quality Unit
- 3. Production Block
- **5. Space for Expansion**
- 7. Space for expansion
- 9. Effluent Treatment Plant

- 2. Ware House
- 4. Utility Block
- 6. Space for Expansion
- 8. Tank Farm
- 10. Garden

FUTURE EXPANSION PLANS IN VACANT SPACE...



- Total area of the premises is about 10,600 sq mt.
- Out of which existing plant occupied land is about 45%
- > 55% vacant land for future expansion.
- Planning to utilized the vacant space for expansion.
- This will strengthen and give us support for our forward integration.
- We are planning for dedicated facility as per customer requirements.
- We can also include numbers of new unit operations to our chart.

BUSINESS SET UP ...



We are constantly working to broaden the pipeline of products and to make an impact in the international markets.

We aim to spread our brand across physical boundaries, to be present where ever our customers require products.

Our Global Reach

1. Europe

3. SEA

2. Middle East

4. Asian country (Korea, Japan)

PRODUCT LIST (REGULAR PRODUCT)...



PRODUCT NAME	CAS#	INTERMEDIATE OF
2-Methyl Acetophenone	577-16-2	Agrochemicals, Perfumery
3-Metoxy Acetophenone	586-37-8	Rivastigmine
3-Hydroxy Acetophenone	121-71-1	Phenylephrine, Rivastigmine
4-Hydroxy Acetophenone	99-93-4	Atenolol
4-Methoxy Acetophenone	100-06-1	Cosmetics, Perfumery
4-Methyl Acetophenone	122-00-9	Celecoxib, Zolpidem, Triprolidine, Perfumery
3-Methoxy Propiophenone	37951-49-8	Pharmaceuticals
3-Hydroxy Propiophenone	13103-80-5	Pharmaceuticals
4-Hydroxy Propiophenone	70-70-2	Isoxsuprine, Ritodrine
4-Methyl Propiophenone	5337-93-9	Tolperisone, Perfumery
4-Hydroxy 3-Methoxy Acetophenone	498-02-2	Flavours & Fragnances, Iloperidone
2-Phenylbutyric Acid	90-27-7	Tamoxifen, Butamirate
2-Phenylbutyryl Chloride	36854-57-6	Tamoxifen, Butamirate

PRODUCT LIST (REGULAR PRODUCT) Contd...



PRODUCT NAME	CAS#	INTERMEDIATE OF
4-Methoxy Phenacyl Bromide	2632-13-5	Raloxifene HCl
2-Chloroethyl piperidine HCl	2008-75-5	Raloxifene, Flavoxate
2-Chloroethyl Morpholine HCl	3647-69-6	Pharmaceuticals
6-Methoxy-2-(4-Methoxy Phenyl) benzo [b] thiophene	63675-74-1	Raloxifene HCl
4-(2- piperidino Ethoxy) Benzoic Acid-HCl	89407-98-7	Raloxifene HCl
6-Hydroxy-2-(-4-Hydroxyphenyl) benzo [b] thiophene	63676-22-2	Raloxifene HCl
M-Chloro Propiophenone	34841-35-5	Bupropion HCl
4-Methyl Phenacyl Bromide	619-41-0	Zolpidem
Zolpidic Nitrile	768398-03-4	Zolpidem
Zolpidic Acid	189005-44-5	Zolpidem
Ketosulphone	221615-75-4	Etoricoxib
Methyl-6-Methyl Nicotinate	5470-70-2	Etoricoxib

PRODUCT LIST AS PER CUSTOMER REQUIREMENT...



PRODUCT NAME	CAS#	INTERMEDIATE OF
4-Methyl Thio Acetophenone	1778-09-2	Etoricoxib
Phenetole	103-73-1	Perfumery
2,4 DiChloro Acetophenone	2234-16-4	Ketoconazole & other anti fungal bulk
4-Ethoxyacetophenone	1676-63-7	Pharmaceuticals
4-Methyl Sulfonyl Acetophenone	10297-73-1	Etoricoxib
Benzophenone	119-61-9	Cosmetic, Perfumery & Pharma
P-Hydroxy Benzophenone	1137-42-4	UV - Absorber & Pharmaceuticals
4-Methoxy Benzophenone	611-94-9	Perfumery
2-Bromo 4-Methyl Propiophenone	1451-82-7	Pharmaceuticals
2-Bromo-3-Chloro Propiophenone	34911-51-8	Bupropion HCl
Anisole	100-66-3	Perfumery, Organic Synthesis
4-Methyl Thio Benzyl Cyanide	18991-39-4	Etoricoxib
Propiophenone	93-55-0	Bupropion HCl, Phenyl propyl amine, Flavours and Fragrances

PRODUCT LIST AS PER CUSTOMER REQUIREMENT Contd...



PRODUCT NAME	CAS#	INTERMEDIATE OF
4-Methoxy Propiophenone	121-97-1	Dimestrol
Alpha-Bromo-P-Benzyloxy Propiophenone	35081-45-9	Isoxsuprine, Ritodrine
Ninhydrin	485-47-2	Lab Reagent
4-Hydroxycoumarin	1076-38-6	Warfarin, Zonisamide
4-Chloro-4'-Hydroxybenzophenone	42019-78-3	Fenofibrate
m-Acetamido Phenol	621 - 42 - 1	Cinitapride
3-Methoxy Phenacyl Bromide	5000-65-7	Pharmaceuticals
Alpha-Bromo-O-Chloro Phenyl Acetic Acid	141109-25-3	Clopidogrel
3,4-Dimethoxy Cinnamic Acid	2316-26-9	Donepezil
4-Methoxy Cinnamic Acid	830-09-1	Pharmaceuticals
Cis Bromo Benzoate	61397-56-6	Ketoconazole
Cis Tosylate	134071-44-6	Ketoconazole
Alpha-methylamino-3-Hydroxy acetopheone Sulphate	679394-62-8	Phenylphrine HCl
4-Methylsulphonylphenylacetic acid	90536-66-6	Etoricoxib

CUSTOMERS DOMESTIC MARKET...



- ➤ Aarti Drugs Limited
- > Aarti Industries Limited
- > Aurobindo Pharma Ltd.
- **➤** Cipla Limited
- Divis Laboratories
- > Dr. Reddy's Laboratory
- > Glenmark Pharmaceuticals
- **➤** Glochem Limited
- > Hetero Drugs Limited
- **Kumar Organics**
- **Lupin limited.**
- ➤ Mylan Laboratories Limited





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MAJOR CUSTOMERS EXPORT MARKET...



- > Aceto Pharma
- > DKSH
- > Formil Quimica
- **➤** La fenice Trading







SANIKA CHEMICALS PVT. LTD. GALLERY...











SANIKA CHEMICALS PVT. LTD. GALLERY...













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THANK YOU?