

Nilkanth Organics Pvt Ltd



About US

- The Nilkanth group of industries, was started as a SSI unit in 1990 under leadership of Mr.Vipul.V.Gajera in industrial estate of Ankleshwar, Gujarat, India. Starting as a small manufacturer of dyes and pigments, Nilkanth group has eventually achieved many milestones to become one of the largest manufacturers of the chemical segment in western India.
- With the right vision, consistent efforts and applications of smart strategies, Nilkanth group is now grown into a giant corporate by expanding their horizon in the field of Reactive dyes, Pigments, Pigment Intermediates, Textile Auxiliaries and fertilizers.
- The organization is built on a tradition of strong customer relationships with high ethical standards. The growth of our organization is based on innovation, quality, service, reliability, and customer satisfaction. We provide cutting-edge technology, specialty products, and innovative services to solve customer problems.
- And Now, we are further expanding in API and Pharma Intermediates with capability to manufacture a wide range of Active Pharmaceutical Ingredients (APIs) / Intermediates for pharmaceutical industry.



NOPL - Pharma Unit – Key Highlights

- One of the best Infrastructures required for Intermediate production and API production Located in centre of Ankleshwar GIDC.
- All plant and Machineries are manufactured and supplied by very reputed suppliers with latest technology
- At a time 2 API product can be produced in 2 powder processing area adjacent to intermediate plant
- Total permission from the government authorities is 300 MTPM.
- NOPL team is consist of Techno Commercial Expert with very large experience in respective field.
- A Multiproduct plant with present permission of 102 Products, covering varied therapeutic segments .
- Total around 170 KL (Plant 1) installed capacity of reactors of different MOC, Sizes and types to cater varied range of reactions/operations. Scope of adding two similar plants in existing premises for capacity enhancement .
- Flexibility and scope of customization as well as expansion to cater to any business needs.
- Zero discharge unit with all the latest technologies to handle wastewater
- Qualified equipment meeting all required cGMP norms and robust quality systems
- Purified Water system and finished product area as per cGMP norms

Location Ankleshwar, Gujarat, India



NOPL - Pharma Unit – Plot Plan



NOPL Focus Areas

- An exhaustive product portfolio, covering varied therapeutical segments with required environment clearance
- Qualified equipment meeting all required cGMP norms and robust quality systems
- Flexibility and scope of customization as well as expansion to cater to any business needs
- Purified Water system and finished product area as per cGMP norms
- The experienced and winning team of experts or advisors
- Zero discharge unit with all the latest technologies to handle wastewater

Overview of the infrastructure @ NOPL Unit 3 (Phormo Division)

Details		Unit	Remarks
Total Plot Area	20000	Sq.Mtr	
Manufacturing Plant 1 (Ground + 3)	1100	Sq.Mtr	
Reactor volume – SSR	75	KL	12 Nos from 2 to 10 KL
Reactor volume – GLR	64.6	KL	12 Nos from 2 to 10 KL
VTD,ANFD, RCVD, Centrifuge	14	Nos	
Dry Mechanical Vacuum pumps	7	Nos	
Independent Powder Processing Area	2	Nos	Each PPA is equipped with complete equipment line for FG meeting all cGMP norms
Purified Water System	1	KLPH	
Distillation column	1	Nos	
Manufacturing Plant 2	1000	Sq.Mtr	Future Expansion
Manufacturing Plant 3	1100	Sq.Mtr	
Utility Block	500		
Boiler	5	MTPH	
Chilled Brine / Chilled Water	150	TR	
Compressed Air	50	CFM	
Nitrogen Plant	75	CFM	
Effluent Treatment Plant & RO			
Waste Water Treatment	100	KLD	
RO	150	KLD	
MEE	105	KLD	
Other Infrastructure			
Ware House	700	Sq.Mtr	
Quality Control and Laboratory	244	Sq.Mtr	
Administration	80	Sq.Mtr	
Tank-farm	144	Sq.Mtr	
Misc.	144	Sq.Mtr	

Plant 1 - Intermediate



Plant 1 – Finished Product



Site Quality Assurance

- Supervision for manufacturing and all support function
- Review of Batch Records and release of intermediates and APIs.
- Review and disposition of Investigation and QMS documents.
- Annual Product Review (APQR) and Trends.
- Monitoring of Quality Index & participation in Management Review.
- Validation and Qualification.
- Stability Management.
- Document Control.
- cGMP Training and Self Inspection.
- CAPA tracking & effectiveness verification.

Site Quality Control

- Analysis of Incoming Packaging Materials.
- Analysis of In-process, Intermediates, Recovered Solvents and APIs.
- Analysis of Stability Samples.
- Analysis of Water and Environmental Monitoring samples.
- Laboratory Investigation of OOS and OOT results.
- Review of Analytical Data.

Details of the infrastructure

Details		Unit	Remarks
Effluent Treatment Plant & RO			
Waste Water Treatment	214	KLD	Primary, Secondary and tertiary treatment
RO	150	KLD	
MEE	105	KLD	Stripper + 4 Effect MEE + ATFD
Other Infrastructure			
Ware House	700	Sq.Mtr	
Quality Control and Laboratory	244	Sq.Mtr	
Administration	80	Sq.Mtr	
Tank-farm	144	Sq.Mtr	
Misc	144	Sq.Mtr	

Highlights – Operations :

Warehouse

- Raw Materials,
- Packaging Materials,
- Finished product storage
- Raw material Storage at ambient and below 25°C.
- Separate Dispensing area for Solid and Liquid.
- Separate sampling area.
- Separate area for Rejected and Return handling room.

HVAC

- Recirculation type AHUs – Below 25°C / Rh below 60%
- All processing areas, adjacent corridors, primary packing
- areas, dispensing and sampling areas are of class 100,000 air cleanliness standard.
- The core processing area air is filtered through 0.3 micron Terminal HEPA filters.
- These areas are provided different level of air pressure as per cascading to avoid any contamination.

R & D

- New Product development
- Technology Transfer
- Process monitoring and upkeeps

Engineering & Maintenance

- Equipment Qualification
- Calibrations
- Preventive maintenance
- Plant Upkeeps

EHS

- Safe Work Procedures
- Safety Trainings
- Fire Fighting System / Proper Hydrant System
- Work Permit System for all Risk
- Involving jobs
- OHC Facility
- Mutual Aid Available nearby
- Emergency Preparedness System
- ETP handling – Zero Discharge
- Adequate Pollution Control
- Measures

Current Product Portfolio – API

Chlorobutanol	IP/BP
Meloxicam	IP/BP / EP/USP
Sodium Picosulfate	BP/EP
Theobromine	BP
Loratadine	BP/EP/USP
Desloratadine	BP/EP/USP
Amlodipine Besilate	IP/BP / EP/USP
Etoricoxib	IP
Quetiapine Fumarate	IP/BP / EP/USP
Dextromethorphan HBr	IP/BP / EP/USP
Pantoprazole Sodium Sesquahydrate	IP/EP

Current Product Portfolio – API / Intermediate

Name of Intermediate	Name of the API
(+/-)trans-4-(4-Fluorophenyl)-3-hydroxymethyl-1-methylpiperidine	Paroxetine
2-chloro methyl 3,4 - dimethoxy pyridine hydrochloride	Pantoprazole
5- difluoro methoxy 2 -Mercapto benzimidazole	Pantoprazole
2- Amino 3,5 - Dibromo benzaldehyde	Amboroxol HCl

Thank You