



Swati Spentose Pvt Ltd Flagship Site at Vapi, Gujarat

**SWATI SPENTOSE PVT. LTD.**

September 2011



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## Site-Overview

FDA Compliant Facilities

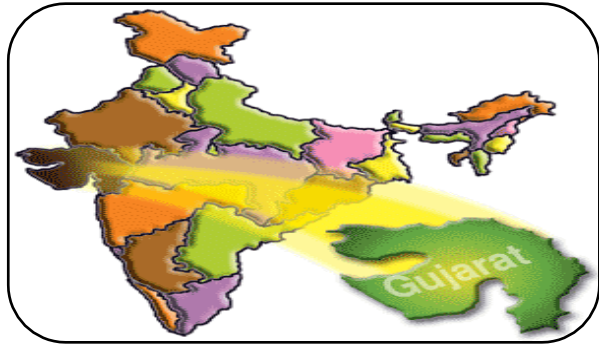
Infrastructure

Production Capacities

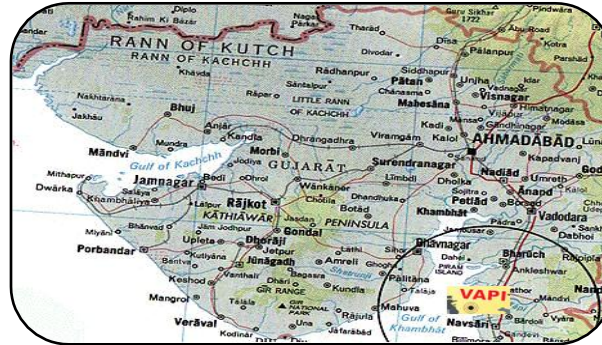
Production Blocks

Human Resources

# Site Overview



Map of India



Vapi



Asia's largest effluent treatment plant at Vapi with 80million L processing/day

Designed by M/s. Dev Techno – a leading consultant with more than 30 years of experience, designing 10+ API & 30+ formulation facilities complying with global FDA norms, such as – J.B. Chemicals, Macleods, Zandu, etc

Compliant as per the guidelines of international regulatory agencies such as USFDA, UKMHRA, EDQM, TGA- Australia, MCC-South Africa

Upgradable to Supervisory Control And Data Acquisition (SCADA) base

The facility and product mix has a potential of generating revenues around USD150 million per annum at 100% capacity in the next 5 years

Ultra-filtration Block with an Annual Manufacturing Capacity of 18 MT Polysaccharides (API)

Multipurpose block for upto 300 MT capacity for low value API's . Pilot plant facilities for high value APIs in the range of USD 10-100K per kg

Site- Overview

**FDA Compliant Facilities**

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# FDA Compliant Facilities



**Site at Vapi**



**Reactors**



**Nitrogen Plant**



**GSPC Gas Line**

Facilities consist of world class Glass Line reactors, Stainless Steel reactors, High Purifying water system, etc

World class utilities with high efficiency and environment friendly operations

Non-polluting captive effluent treatment facility : Fully compliant with environmental, health & safety guidelines as per global industrial standards

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## Air System

- Manufactured by Carryair, India
- Covers the entire production building under class 10K and Lab under 100K
- Automatic temperature and humidity control
- Prefiltration by 10 and 5 micron filter and terminal HEPA filter of 0.3micron
- Individual AHU for different areas to avoid cross contamination
- Designed as per latest USFDA guidelines



## Water System

- Manufactured by Veolia-Doshion, France
- Designed for generation of 2.0M<sup>3</sup>/hour pure water
- Distribution loops SS316L with electropolishing and deadlag valves
- Raw water is pre-treated by using Multi Grade Filter (MGF) and Water Softener (SFR), consists of four steps: UF, RO, EDAAE and UV
- Controlled through PLC and HMI
- Designed to process water for all the latest pharmacopoeial grade material



## Nitrogen Plant

- Manufactured by Airox, India
- 10M<sup>3</sup>/hour capacity
- 99.9% purity gas generation with SSIP
- Supplies Nitrogen to the entire plant including manufacturing, processing and packaging



## Solvent Distribution

- Pumps manufactured by Alpha Laval, Switzerland
- Four 12 K.L S.S. 304 underground storage tanks
- Unloading and distributing from the solvent tank through automatic flowmeter
- Solvents are not exposed directly to the reactors minimizing loss and optimum control

# Infrastructure



**Glass Line Reactors**

- Manufactured by GMM-Pfaunder, Switzerland
- For chemical process with working capacity ranging from 1,000 to 3,000L with surface less than 0.5RA for smoothness
- Equipped with variable frequency drive to set the RPM according to the product requirement
- Equipped with safety valves and pressure gauges. Connected to the scrubber



**Stainless Steel Reactors**

- Manufactured by Pharmalab, India
- Capacity of 1000, 2000 and 3000L MOC 316L
- Surface of the reactor is less than 0.5RA to give smooth surface for better and faster CIP cleaning
- Equipped with safety valves and pressure gauges. Connected to the scrubber



**Fluid Bed Dryer**

- Manufactured by Alliance, India
- 120Kg and 60Kg capacity
- Steam heated with PLC and HMI controlled MOC 316
- Equipped with separate AHU for air suction consisting of HEPA filters
- CIP cleaning with spray nozzle



**Vacuum Tray Dryer**

- Manufactured by Grovers, India
- 48 tray capacity
- PLC and HMI controlled, MOC 316
- All inside corners curved making cleaning easier



**Centrifuge**

- Manufactured by Dparikh, India
- SS 316L and Harlan coated, 4 point suspension with full lead and body opening
- Mother Liquor to segregated tank
- Manual handling is avoided, with zero speed interlock and dynamic breaking
- Fumes directly connected to the scrubber



# Infrastructure



**Ultra-Filtration**

- Manufactured by Sartorius, Germany
- High integrity, efficiency, 1KD Membrane cassette and system of SS 316L with 0.8RA electro-polish
- High quality filtration system to ensure removal of all undesired salt to required limit



**Blender**

- Manufactured by Kevin Technologies Pvt. Ltd., Ahmedabad
- Capacity of 2000L gross volume with SS316L
- PLC and HMI controlled
- Blender charging through Powder charging system



**Multi Mill**

- Manufactured by Kevin Technologies Pvt. Ltd., Ahmedabad
- Capacity of 250Kg/hr
- SS 316L with variable frequency drive to set the RPM
- Synchronized with Blender and Sifter through Powder Charging System



**Sifter**

- Manufactured by Kevin Technologies Pvt. Ltd., Ahmedabad
- 30" diameter with SS316L
- Autocharging and dumping facility
- Synchronized with Blender and Sifter through Powder Charging System



**Powder processing**

- Manufactured by Vac-U-Max Asia Pvt. Ltd., Ahmedabad
- Pneumatic Powder Transfer System from Blender to Multimill and Sifter
- With Auto Sequence Controller

# Quality Control-Quality Assurance



## Capillary Zone Electrophoresis

- Manufactured by Beckman Coulter
- It is the 1<sup>st</sup> Fourth Generation instrument
- Used for charged molecules
- High voltage application
- Capillary temperature control
- System suitability is performed with PDA detection



## HPLC

- Manufactured by Merck Hitachi
- Two types: Isocratic and Gradient HPLC
- Constant pressure mode
- High pressure elution technique



## Gas Chromatography

- Manufactured by Eshita
- Temperature range: 5degC above ambient to 400degC in step of 0.1degC
- Flame ionization detector
- Used for the purity of raw materials and drugs as per pharmacopoeia method



## UV Visible Spectrophotometer

- Manufactured by Jasco
- Suitable for routine, QC and research applications
- Has a wavelength range of 190nm to 900nm provided by a deuterium lamp and a tungsten iodine lamp
- Capable of scanning from 10nm/minute to 4,000nm/min



## FTIR

- Manufactured by Shimadzu
- Incorporation of high energy ceramic light source, temperature controlled, high sensitivity DLATGS detector
- Achieves highest S/N ratio
- Prints out the spectra for standards and samples

# Infrastructure



## Boiler

- Manufactured by Thermax
- 850Kg/hour capacity
- Auto control of high temperature and high pressure cut off
- Natural gas base system boiler complying environmental friendly condition
- 88% thermal efficiency



## Chiller

- Manufactured by Voltas
- 35 T.R capacity
- Having cooling capacity: -5°C
- R 22 gas based and a Microprocessor control panel
- Methyl Ethyl Glycol (MEG) is used as the medium of cooling with 5KL distribution tank



## Vapor Absorption Machine

- Manufactured by Voltas
- 100 TR capacity, with Natural gas fired facility
- Fully automatic controlled with microprocessor and environment friendly
- Medium of cooling: Water
- Vacuum Absorption Machine is dedicated for AHU supply



## Vacuum Pump

- Manufactured by Joiyam Engineering, Ahmedabad
- Capacity of 150M<sup>3</sup>/hour
- Two stage vacuum pump to create vacuum upto 700mm Hg
- Autocontrolling facility with Vacuum switch



## Air Compressor

- Manufactured by Anist Iwata, Switzerland
- 100 CFM/hour capacity
- Non-metallic gaskets
- Oil free compressor with refrigerated dryer and 0.02 micron filter



**Electric Panel Room**

- Department wise/Floor wise electric panels are provided for isolating power without distribution to other areas

Main panel synchronized with D.G. for auto start when main power fails

- Automation control/Reliable power
- With UnderVoltage facility



**Transformer**

- Manufactured by Voltmap Transformer, India
- 1000KVA OLTC type
- Step down transformer 11000 volts to 440 volts
- All safety features like Buchholz relay
- Oil free transformer



**Generator**

- Manufactured by Sterling Watson, India
- Alternator- Steam Fold and Engine- Penta Volvo
- 500 KVA D.G. set
- All safety and auto start facility control panel in line with Central Pollution Control Board (CPCB)



**Uninterrupted Power Supply**

- Manufactured by Prompt, India
- Three sets of UPS
- Online Uninterrupted Power Supply to all critical areas like Micro, Stability and Q.C. laboratory
- Emergency lightings



## Fire System

- Manufactured by Shena Enterprises
- Complete hydrant system
- Consist of main and jockey pump to keep the line pressurized for any time use with autocontrolling facility
- Main water of 2.8lacs Liter capacity
- Highdent foam monitor point
- Sand Buckets available on every floor



## Effluent Treatment Plant

- Installed by Kadam Enterprises
- 60,000L/day effluent treatment capacity
- Biological treatment along with pre, primary, secondary and tertiary treatment facility
- Diffuse type aeration
- Also consist of Zero discharge treatment plant, designed by Permionics
- CPCB compliance facility



## Zero Discharge

- Manufactured by Permionics and Membranes Pvt. Ltd.
- Capacity of 4M<sup>3</sup>/hour
- Tube settler and Reverse Osmosis methods used
- Effluent water can be recycled completely
- Hydronautic membranes



## Scrubber

- Manufactured by Rangoli Fiberglass
- 18000M<sup>3</sup>/hour suction capacity
- Two stage air-scrubbing system with circulation pump and tank
- Absorbs all fumes and is disposed off to ETP

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Production Blocks

Human Resources

# Production Capacities

## 14 Reactors

- 7 Glass Line Reactors : 15 KL
- 7 Stainless Steel Reactors: 15 KL



## 5 Centrifuges

- 4 x 36inch
- 1 x 24inch



- Capacity: 46 trays



## 1 Vacuum Tray Dryer



- 60 Kg/hour
- 120 Kg/hour

## 2 Fluid Bed Dryers

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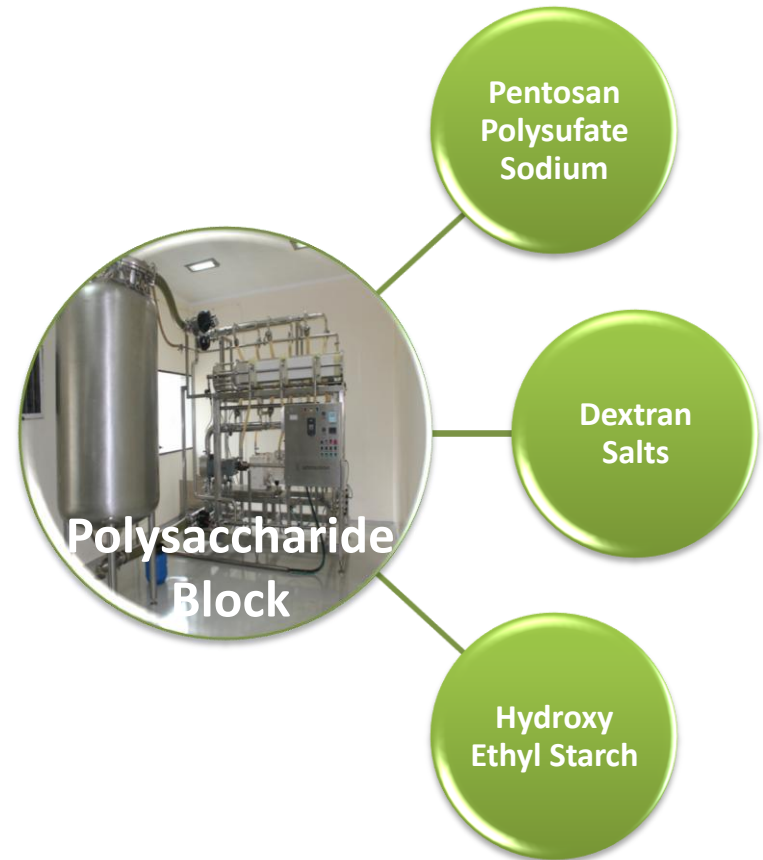
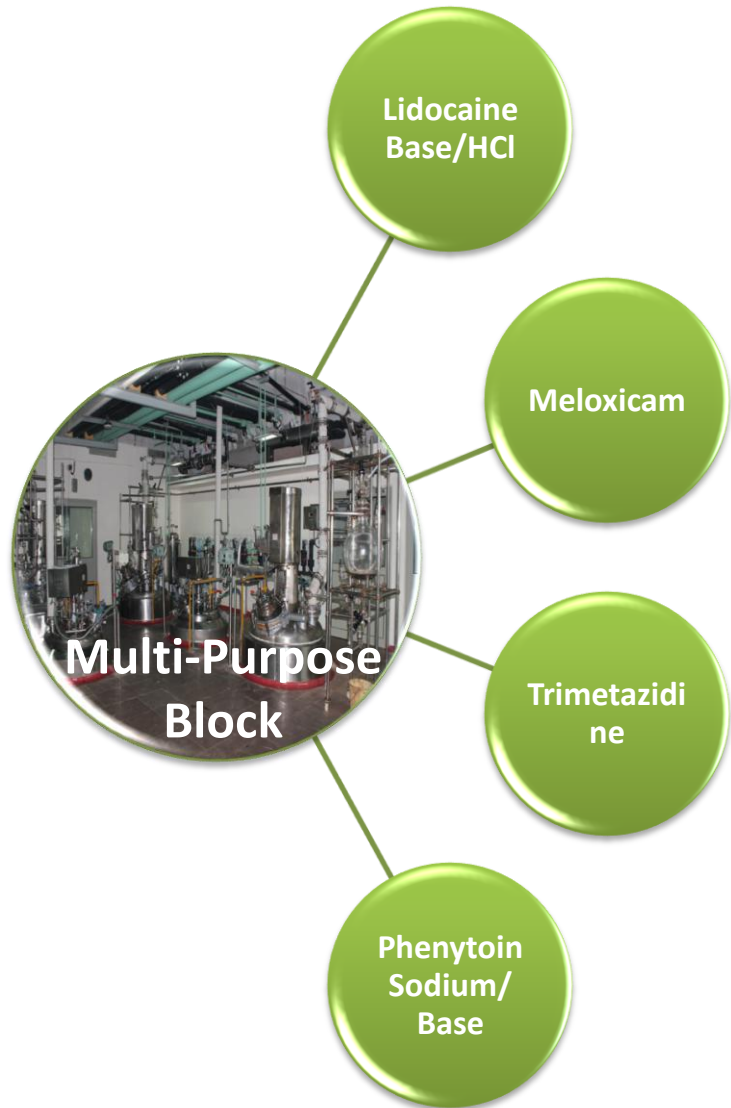
**Production Capacities**

**Production Blocks**

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# Production Blocks



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# Human Resources

**CEO**

**Head Office**

**Factory**

**Finance & A/C**  
(5)

**Marketing**  
(9)

**Admin**  
(7)

**Clinical**  
(2)

**Knowledge Center**  
(5)

**Logistics**  
(5)

**Plant Operations**  
(84)

**Finance** (3)

**Bulk Drugs** (7)

**Office** (2)

**Technical**  
(51)

**Commercial**  
(17)

**Production**  
(16)

**Accounts** (2)

**Finished Dosages** (2)

**Plant** (5)

**QC/QA**  
(16)

**R&D**  
(1)

**Operations**  
(34)

**Technical** **67**

**Commercial** **29**

**Operations** **21**

**Number of Employees 117**



# Thank you



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