



SHAMROCK®

Together we can improve the quality of Life®



WANKSONS
CHEMICAL INDUSTRIES PVT. LTD.



**API
UNIT I**

ANKLESHWAR



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CHEMICAL INDUSTRIES PVT. LTD.

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Location

API Unit 1 - GIDC, Ankleshwar -393002. Bharuch (Gujarat)



API Unit 1 is located at Ankleshwar just 120 Km from Vadodara airport which is the largest chemical zone of India

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- An ISO-9001-2008 Certified Company
- GMP Certified & cGMP Compliant Company
- ICH Q7A Compliant Company
- FDCA Gujarat Approved As Per Schedule M
- Manufacturers Of Drug Substances & Their Intermediates
- Privately Owned Company

API Unit 1 has a GMP, FDA approved facility for the manufacture of APIs, which consists of MS Glass Lined Reactors, SS Reactors, Crystallisers, Centrifuges and Dryers. The API processing area is designed under regulations of Clean Room Concept, with Air Handling Systems and other regulations.

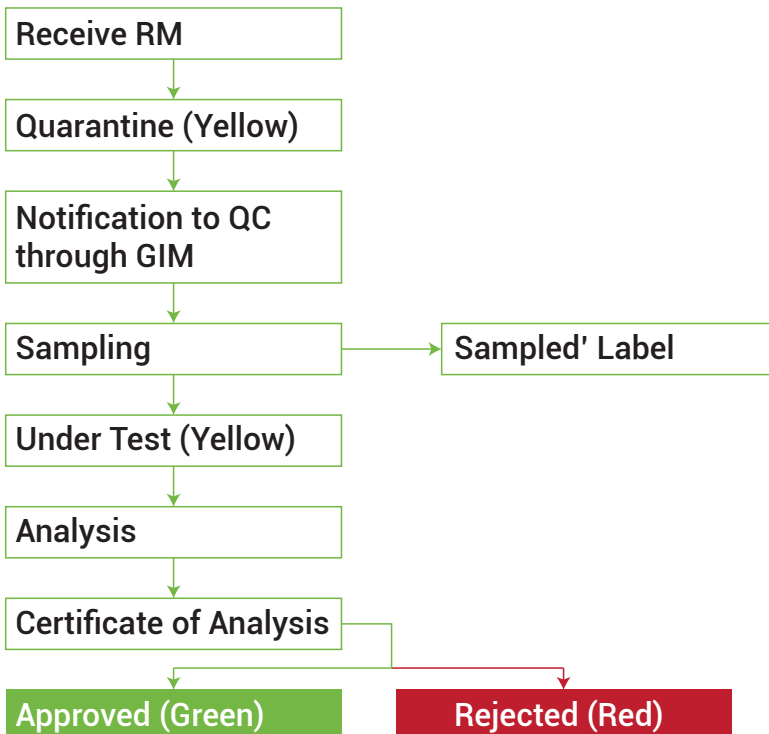
The manufacturing is supported by an In-process Control Laboratory to check and ensure the smooth running of unit operations. There is a full-fledged maintenance team for Civil, Mechanical, Electrical and Instruments. The team ensures systems validation at regular intervals.

Process Equipments of various sizes and volumes:

- Stainless Steel Reactors
- Glass Lined Reactors
- Centrifuges
- Rubber Lined Centrifuges
- Nutsche Filter, Pressure Filter, Sparkler Filter
- Vacuum Tray Dryer, Fluid Bed Dryer, Tray Dryer etc..

Equipment	Capacity (kilo)	Total Capacity
• SSR	1 to 6	24
• GLR	1.6 to 5	22.1

Raw Material Control:



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Production Department:

- Qualified & Trained Personnel
- Adequate Space
- Process Equipments As Per The Type Of Reaction And Usage
- Batch Manufacturing Records
- Equipment Status Boards
- Equipment Cleaning As Per SOP
- Equipment Log Book
- In-process Control Testing In-house
- House Keeping & Temperature Humidity Maintaining Log Book

Materials Department:

- Procured From Approved Vendors
- Identification Of Components
- Fifo System
- Only Approved Materials Used For Manufacturing
- Quality Status
- Storage Of Finished Products
- Distribution Of Qa Released Products
- Separate Area For Sampling & Dispensing Of Raw Material

Powder Processing:

- In Clean Environment
- One Product manufactured at a time
- Hygienic Conditions maintained
- No scope for cross contamination

Quality Policy:

- API Unit 1 manufactures and markets drug substances and their intermediates, which will satisfy continuing needs of our customers.
- This will be achieved by application of sound Quality Management System and adopting current Good Manufacturing Practices and complying all regulatory requirements.
- While doing so we shall keep in mind safety of our employees, all work processes as well as our natural environment.
- The company shall manufacture products of high quality.
- We consider our human resources as one of the biggest asset. Our qualified and trained staff is provided constant training to upgrade their knowledge and stay conversant with state of art technology.
- We value motivation amongst our personnel as an important factor to make them more competent and quality conscious.
- The company shall make available all the requisite measures and resources to achieve the above goals.



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Quality Management System:

- Quality Management system of the company ensures that the drugs manufactured by the company conforms to the standards, required by the current Good Manufacturing Practices. The company's Quality Assurance Department strives to maintain the Product quality through critical evaluations, inspection and verification of the manufacturing process during the entire stages of manufacture. The Quality Assurance department is entrusted with the duties of overseeing all the operations right from the entry of the Raw Material/ packing materials, Manufacture of the intermediate products to final dispatch of the product to the market. During the entire manufacturing process all the section actively co-operate with the QA department to ensure adequate confidence in the Quality of the end product produced as per cGMP. The company's Quality Control Department strives to maintain the product quality through In process analysis as well as finish product analysis of the product during the entire stages of manufacture.

Quality Control Department:

- Qualified and Trained Personnel
- Basic Equipments available with all measuring instrument in calibration Status
- Operations performed by following SOPs
- Specifications and Analytical Procedures as per customer requirements and Pharmacopoeia
- Reference Standards, working standards as per product requirements

Quality Control Equipment's:

- Analytical Balance
- Karl Fischer Titrator
- Melting Point Apparatus
- pH meter
- Muffle Furnace
- UV Chamber
- TLC Chamber
- HPLC
- GC With Head Space
- Ultra Sonic Bath etc...



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List Of QC Equipment:

Instrument Name	ID. No.	Make	Model
TLC CHAMBER	TLC-QC-001	JAY LAB	-
KARL FISCHER TITRATOR	KFT-QC-001	ANALAB	AQA-CAL
HOT PLATE	HP-QC-001	ELTEK	M 3 D
HOT AIR OVEN	HAO-QC-001	JAY LAB	-
U.V. CABINATE	UVC-QC-001	JAY LAB	-
MUFFEL FURNACE	MUF-QC-001	JAY LAB	-
DIGITAL PH METER	PHM-QC-002	TOSHWIN	DP-505
MELTING POINT APPARTUS	MPA-QC-001	VEEGO	VMP-D
ANALYTICAL BALANCE	BAL-QC-001	METTLER TOLEDO	MS105DU
GAS CHROMATOGRAPH	GC-QC-001	THERMO SCIENTIFIC	CERES 800 PLUS
HPLC	HPLC-QC-001	SHIMADZU	LC-2010 CHT
DESICATOR	DES-QC-001	BOROSI	-
ULTRASONIC BATH	USB-QC-001	GLASSCHEM	-
HUMIDITY CHAMBER	STB-QC-001	MACK PHARMA	MK-20 H
STABILISER	STBI-QC-001	ABC POWER SYSTEM	SERVO SARTHI
UPS	UPS-QC-001	UTL	SWI 15 EOU
VACCUM OVEN	VCO-QC-001	PARNASHA ENG.	-
U.V SPECTRASCEAN	UVS-QC-001	THERMO SCIENTIFIC	UV-2700
HEAD SPACE (GC)	HPGC-QC-001	THERMO SCIENTIFIC	HS-50
INFRARED	IR-QC-001	-	HS-50



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Utility:

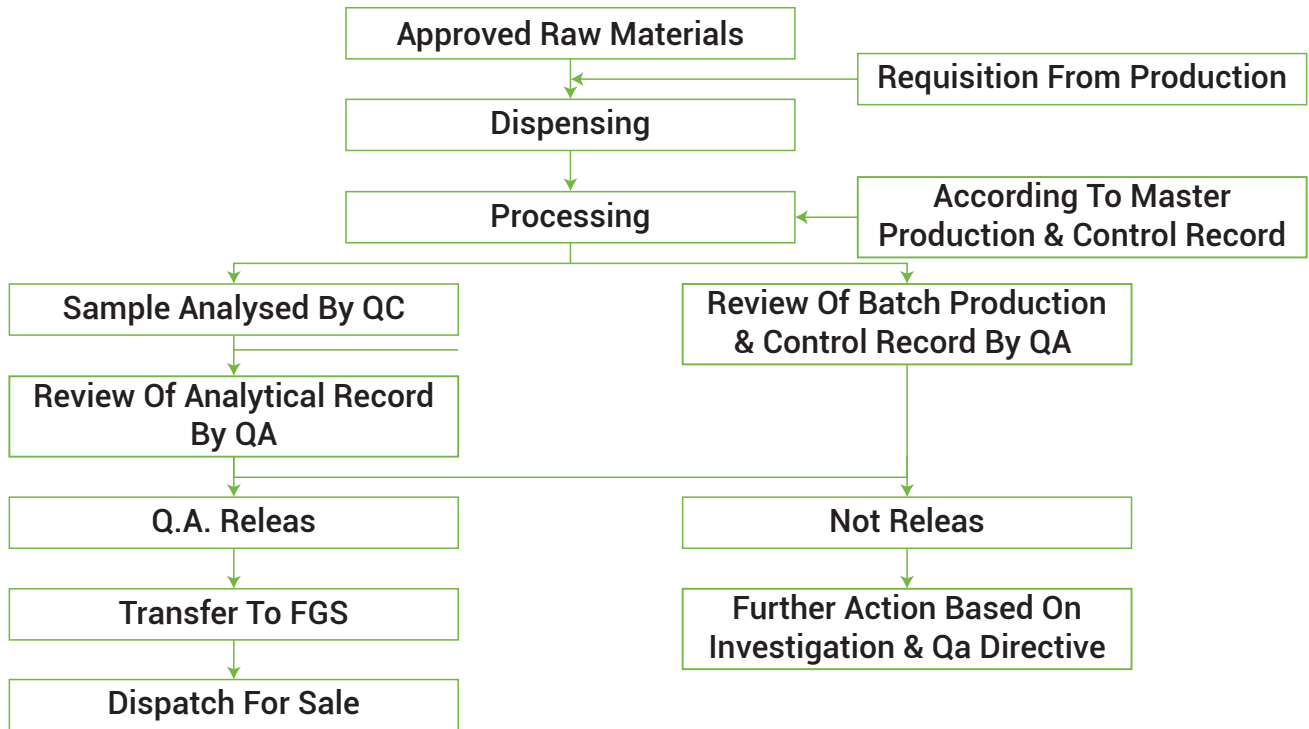
Equipment Name	Capacity
Cooling Tower x 2	200 TR / 250 TR
Chilling Plant Temp (-15) x 2	40 TR
Boiler (GAS fire)	800 KG
High Vacuum System 4 – stage Graphite	1 Tor
Vacuum system (Watering) x 3	700 mg
Scrubber x 2	Acidic / Alkaline
DM Water plant	5 KL /Regeneration
MS Tank x 3	15000
HDPE Tank x 5	5000
HDPE Tank x 3	2000
HDPE Tank x 3	1000
HDPE Tank	10000
RCC Tank	40000


Man Power Utilization For Each Department:

Section	Asst Managers/ Executives/Officers	Chemists/Clerks	Operators	Skilled Workers	Unskilled Workers
Admn.& Personnel	01	01	--	01	01
Production	04	02	03	12	--
QA	04	02	03	12	--
QC	02	03	--	01	--
Utility & Eng	02	--	01	02	--
R&D	01	01	--	01	--
Stores	01	01	--	--	02
House Keeping	--	--	--	--	04

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Flow of Processing Activities



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