

#### **Business Activities**



Bulk Drugs Manufacturing



R&D



**Formulations** 



**Export&Imports** 



Central Warehouse & CFA



Distribution

#### **Group Profile**



82+ years of experience

**Business Handled** 

Approx. US \$ 1 Billion p.a

#### **16 Entities**



1,700+

**4<sup>TH</sup> Generation** Family Business

#### **Business Locations**

5 Bulk Drug Manufacturing Units Vapi, Boisar, Thane, Surat, Jhagadia

2 Research & Development Unit Navi Mumbai & Vapi

1 Formulation Manufacturing Unit Vapi

Exporting to nearly 50% of global markets (Currently 85+ markets)

Including USA, UK, South Africa

3 Warehouses CFA, Central Hub Bhiwandi

4 Distribution Depots
Within Mumbai Limits
1 Hospital Distribution Depot
Kalbadevi













# S Kant Healthcare Ltd.

Factory

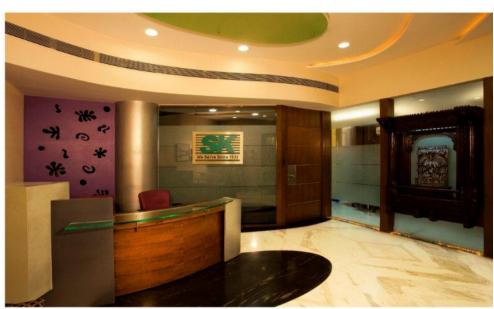
Plot- 1802-1805, G.I.D.C Vapi, Gujarat — 396 195

Tel: 0260 2422516 Fax: 0260 2430527 Email: skhl@sk1932.com

Head Office:

3-A Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai 400 018 Tel: 022 6622 7575 Fax: 022 6622 7500 email: info@sk1932.com

## **Head Office, Mumbai**









### **Pictorial View Of The Plant**







### **Pictorial View Of The Plant**









# Site **Components Area Occupancy** Formulation Manufacturing 4100 Sq.meters 600 Sq.meters **Bulk Drugs Manufacturing** QC/QA Lab 800 Sq.meters RM/PM/FG Warehouse 3200 Sq.meters 800 Sq.meters **Utilities & Effluent Treatment Plant** Flammable Solvent Shed 200 Sq.meters

# **Dosage Forms Manufactured**

Formulation Manufacturing	Bulk Drugs Manufacturing
<ul> <li>Solid Dosage Forms- Non- Beta Lactum</li> <li>Tablets (Uncoated, Film / Sugar / Enteric Coated, Bilayered, Sustained / Modified / Extended Release)</li> <li>Capsules (Powder / Pellet)</li> <li>Dry Powder (Bottles / Sachets)</li> </ul>	Anti-Malarials (Artemisinin Based)  •Dihydroartemisinin  •Artemether  •Artesunate  •Alpha Beta Arteether
<ul><li>Topical Formulations</li><li>Ointment, Creams, Gels</li></ul>	Anti-Malarial •Lumefantrine
Oral Liquids • Syrup, Suspensions	Metallic Stearates  •Magnesium Stearate  •Zinc Stearate  •Calcium Stearate

# **Installed Capacity: Formulation**

Section	Installed Capacity
Tablets	5.0 Million/Day
Capsules	2.0 Million/Day
Liquid Oral	22 Kilolitres/Day
	~ 0.20 Million Bottles/Day
Ointments & Creams	600 Kg/Day
	~ 0.05 Million Tubes/Day
Dry Powder	0.05 Million Bottles/Day

## **Personnel**

Sr. No	Department	Number of Employees
1	Production	75
2	Quality Control	37
3	Quality Assurance	22
4	Storage & Distribution	13
5	Technical & Engineering Services	25
6	Administration & F&D	19
Total N	lumber of Employees	191

### **Quality Policy**

- •The Company shall continue to maintain high standards of Quality of its products meeting **cGMP**, **GLP** & **GWP** norms.
- •Products shall continued to be manufactured and marketed meeting all quality parameters related to Identity, purity, safety, quality and efficacy through well defined Quality Assurance and **Validation** system.
- •Company shall continue to comply with current **National and International regulations** as applicable and continuously move towards meeting stringent global standards.
- •Major thrust shall be given on Quality Upgradation and Product Integrity on continuous basis to achieve higher level of **customer satisfaction**.
- •Continuous training shall be given to the employees in the organization to enhance their skill in performing their assigned tasks.

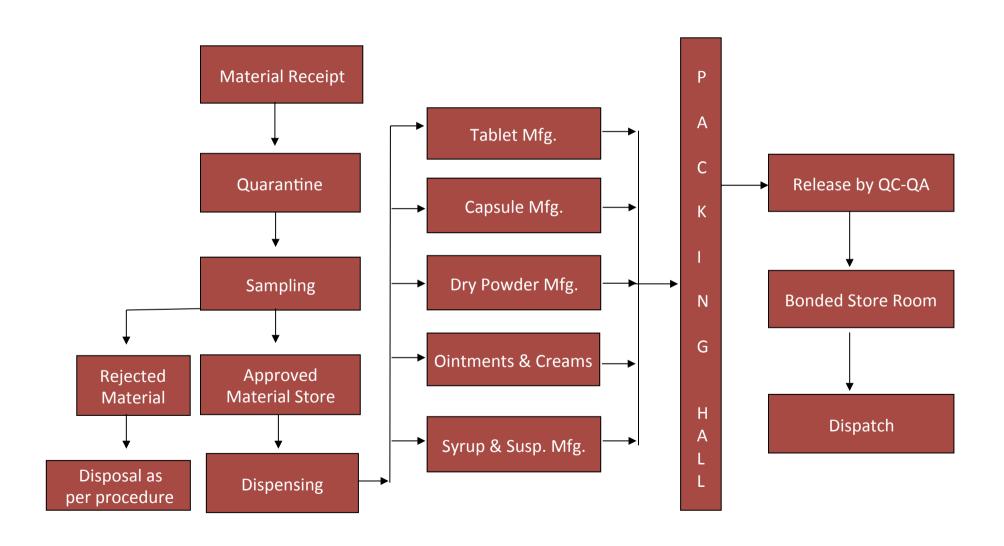
## **Environment Health Safety Policy**

- •The management of S Kant Healthcare Ltd., including people working at all levels shall ensure the highest efforts to minimize the adverse impact of its operations on the Environment, Health & Safety, ensuring compliance to the applicable legal and other requirements.
- •It shall be a prime motto of each individual in the organization with identified roles and responsibilities to implement the safe and sound practices for **control** of pollution, minimization of waste, prevention of accidents, conservation of energy and natural resources with a improved processes and better technology.
- •The organization shall conduct the **training** and **development** programs in the field of Environment (within and surrounding), Health (prevention of critical diseases and illness) and Safety (prevention of accidents) at all levels including associated contract agencies.

## **Manufacturing Areas**

Area	Existing
Granulation	2
Compression Area	5
Coating Area	3
Capsule Filling Area	2
Packing Lines	11
Cream, Ointment	1
Liquid Manufacturing	1
Suspension Mfg.	1
Powder Filling	1

### **Material Movement**



## **Material Management**

- Materials are dispensed as per the FIFO / FEFO.
- Active Pharmaceutical Ingredients (API's) are sampled 100%
- Excipients are sampled √n + 1 rule.



### **QC LABORATORY**

- QC Lab Sections:
  - 1 Instruments.
  - 2 Wet Chemistry Laboratory
  - 3 Microbiology
  - 4 Stability Study
- Adequate provision is made for storage of Control Samples i.e. Finished Products and Raw Materials.
- In the Microbiology section, segregated area for MLT with Air lock & Incubation room is provided. Testing is performed under LAF.



### WATER SYSTEM

- Source of water is Gujarat Industrial Development Corporation (GIDC) water which is of Potable Grade
- Water purification is done by Ultra Filtration followed by Reverse Osmosis & Electro-De-Ionisation.
- Close-Loop, Distribution System is through SS316L, Electro-polished Piping using sanitary fittings.
- All user points are monitored for Chemical & Microbial testing.
- Purified water generation capacity: 4.5 M³/Hr
- Purified water quality complies with IP / BP / USP / EP



#### **HVAC SYSTEM**

- Manufacturing & primary packaging is under the controlled environment of ISO class 8.
- Corridors area maintained at higher pressure with Terminally mounted HEPA filtration conforming to ISO class 8 (Grade D).
- All core manufacturing areas are with individual AHU terminally mounted HEPA filtration.
- Clean Zone like RM Sampling / Dispensing booth and Microbial Testing LAF conforms to ISO Class 5.
- Dust Collection system is provided at designated locations like Granulation/ Compression/ Capsules.
- All HEPA filters are subjected for Integrity Testing, particle count and air-velocity measurement bi annually.



### **OTHER UTILITIES**

- Water Chilling Plant: 110 TR x 02 Nos (Hitachi Make: Screw Compressor)
- Air Compressor with Air Drier: 100 CFM x 02 Nos (Atlas Copco: Screw Compressor)
- Boiler for steam generation: 2000kg / Hr
- Effluent Treatment Plant: 150 M³ / Day

## **QUALITY MANAGEMENT SYSTEMS**

- Site Master File
- Validation Master Plan.
- Quality Manual
- SOPs
- Vendor Approval System
- RM / PM / FP
   Specifications
- Training Development
- Calibration Program
- Record & Reports

- In-process control & Monitoring
- Document Control
- Process Validation & Cleaning Validation
- Computer System Validation
- Analytical Method Validation
- Qualification Area,
   Equipment & Utilities

## **QUALITY MANAGEMENT SYSTEMS**

- Stability Studies
- Change Control
   Management
- Deviation Handling
- Incident Handling
- Out of Specification (OOS) Handling
- Corrective Action & Preventive Actions (CAPA)
- Self inspection

- Market Complaint Handling
- Product Quality Review
- Microbiological Testing & Environmental Monitoring
- Batch Record Review
- Finished Goods Release
- Personal safety, Hygiene and Pest control
- Annual Product Review

### **CONTRACT MANUFACTURING**

(Loan License / Toll Manufacturing / Contract **Manufacturing for Export & Domestic Markets)** 







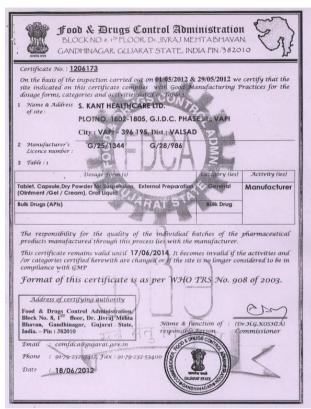


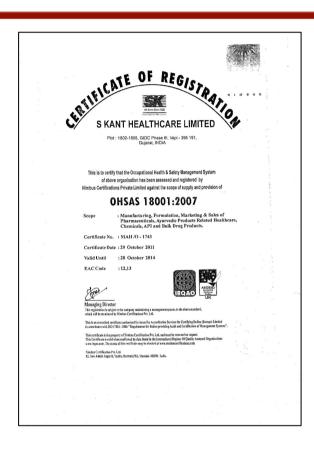




### **CERTIFICATIONS**







ISO 14001-2004

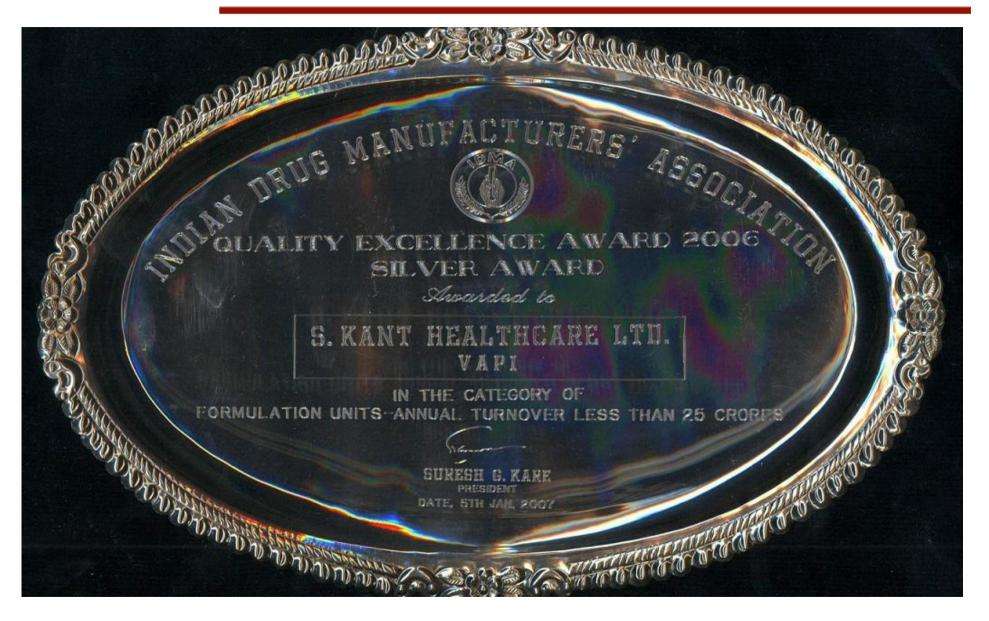
WHO-GMP SCHEDULE-M OHSAS 18001-2007 COMPLIANCE

(Environment Management System)

( Drug & Cosmetic Act,1940 Govt. of India)

( Health & Safety)

### **AWARD**



**Quality Excellence Award** 

### **ROAD FORWARD**

#### • Increasing Installed Capacities:

- Doubling our tablet manufacturing capacities from 1.5 Billion Tablets p.a. to 3.0 Billion Tablets p.a.
- Increasing liquid orals manufacturing capacity from 22,000 litres per day to 32,000 litres per day

#### Regulatory Approvals:

- WHO Prequalification for select products
- EU GMP / MHRA (U.K.) / MCC (South Africa) / USFDA
- Specific NGO's / Global Institutions

#### Infrastructure

- Installation of GC & AAS
- Automation of Packaging Lines for higher output at lower cost
- For quick 100% identification of API and Excipients NIR procurement already budgeted

### **ROAD FORWARD**

#### New Production Facility Planned:

Effervescent Solid Oral Dosage

#### ■ R & D (With API and Finished Formulations Pilot Scale):

- Approval from Department of Scientific and Industrial Research (DSIR) India and compliance with DSIR on a continual basis
- Develop high volume and / or high value products for regulated markets
- Upgrade current products for regulated markets
- Develop products Coming off patent (2016 2017)

#### Global Presence:

Grow our Global Presence in a robust but aggressive manner

#### Customer Service:

Ensure maximum growth comes from current (existing & in progress) customer base by serving them efficiently and appropriately and also by adding new products routinely.

### **KEY STRENGTHS**

- Global Presence (85+ Countries) along with a Vast Product Portfolio
- One of the very few companies globally having a single site manufacture of both API and Formulations for Artemether + Lumefantrine Formulations, thereby providing a unique & comprehensive strength on continuity of supply, quality, efficacy, pricing, etc.
- Macrolides (Erythromycin, Azithromycin, Roxithromycin, Clarithromycin, Chloramphenicol, Pyrazinamide, etc.) / Corticosteroids (Betamethasone, Clobetasol, Hydrocortisone, Dexamethasone, Triamcinolone, Etc.) / Iodine Derivatives manufactured by SK Group Companies giving backward integration for finished formulations
- High Manufacturing Capacity assures timely delivery of quality products

### **KEY STRENGTHS**

- Full fledged R & D Dept. (API & Formulations) onsite enables easy access & quick turnaround for new product development with complete pilot scale, analysis, validations & stability studies under one roof independent of the formulations plant
- SK Group having 5 API Mfg. Facilities, 1 Formulations Mfg. Facility, 2 Independent R & D Centres, 3 CFA, 1 Central Hub, 4 Distribution Depots, 1 Hospital Distribution Depot and over 82 years of presence in the pharma industry, enables the SK Group to have easy access to most pharmaceutical companies globally
- Direct 1 to 1 communication for all international dealings between the customer & a SK Family member designated to handle the account

# **THANK YOU**

