



SHAMROCK®

Together we can improve the quality of Life®



**API
UNIT II**

KAKKALUR



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YOUR API PARTNER IN INDIA

Location

API Unit II - Kakkalur, South Tamilnadu, Chennai.



API Unit II is located at Kakkalur, Tamilnadu in South India, 1hr 15min from Chennai Anna International Airport



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- **Vision**
To be one among the **Top 5 API Companies** in our customers mind.
- **Mission**
To Excel in **Development and Manufacturing** of API both Qualitatively and Quantitatively.
- **Overview**
Freehold land of 1.851 acres Established as an Export Oriented Unit (EOU), WHO, cGMP Compliant.

NOV 2013

Commercial Operations

FEB 2015

US FDA Approval

JAN 2016

2nd Successive
USFDA Audit

DEC 2017

3rd Successive USFDA
Audit & Approval

JUN 2018

15 USDMF, 2 EDMF &
1 TGA & New Zealand DMF

Research & Development

- Equipped with 23 fume hoods and 2 walk-in hoods.
- Capable of developing eco-friendly, non-infringing robust processes for API's.
- Experienced in all therapeutic areas like Prostaglandins, Steroids, Nucleosides etc.
- Handling of all diversified reactions especially Stereo specific, Stereo selective and Chiral resolutions.
- Dedicated team for impurity preparations, technology transfer, cost reduction, intellectual property evaluations and to address DMF deficiencies.
- Skilled scientists to develop novel polymorph of API's.

Analytical Development Capabilities

- Robust Method development, validation and transfer
- Stability study of bulk drugs and intermediates
- Kinetics & mechanism of degradation of bulk drugs & intermediates
- Structure elucidation & characterisation of API's & intermediates
- Impurities isolation by Prep. LC
- Multi-nuclear NMR-1(400 MHz)
- HPLC – 21 Preparative HPLC - 1
- LCMS – 1 GCMS - 1
- GC – 2 UV - 1
- DSC - 1 IC - 1



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Quality Control Infrastructure

- HPLC - 6
- UV - 1
- Stability Chambers - 5
- Photo Stability Chamber - 1
- Malvern - 1
- GC - 4
- FTIR - 1



Quality Assurance

Successfully completed

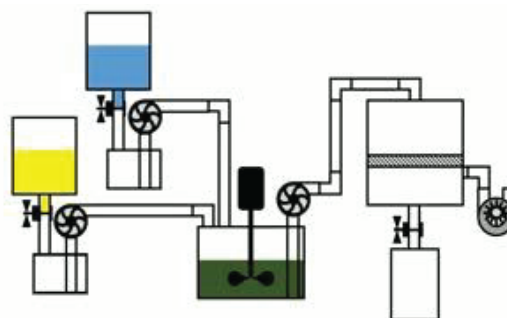
- US-FDA Audits - 3 (2015, 2016 & 2017)
- QP Audits - 2
- More than 20 Customer Audits
- More than 5 Third Party Audits
- WHO-GMP from CDSCO

Microbiology Lab Standards

- LAF Room - 1
- Bio Safety Cabinet - 1
- Autoclave - 2
- Incubators - 4
- Microscope - 1
- Colony Counter - 1

Production

- All Glass Unit-1
- All Glass Unit-2
- All Glass Unit-3
- Pilot Plant
- Manufacturing Block - Hydrogenator
- Micronizer & Spray Drying Unit



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Kilo Lab – Existing

All Glass Unit 1

- Glass Reactors - 3 (100/50/20 L)
- Nutsche Filter - 1 (35 L)
- Centrifuge - 1 (12 inches)
- Dryer - 1 (6 trays Vacuum Tray Dryer)

All Glass Unit 2

- Glass Reactors - 7 (200/200/100/100/50/50/20 L)
- Nutsche Filter - 1 (500 L)
- Centrifuge - 1 (24 inches)
- Dryer - 1 (3 trays Vacuum Tray Dryer)

All Glass Unit 3

- Glass Reactors - 3 (100/50/20 L)
- Nutsche Filter - 1 (50 L)
- Centrifuge - 1 (24 inches)
- Dryer - 1 (3 trays Vacuum Tray Dryer)



Total Volume = 1000 L

Kilo Lab - Proposed

Kilo Lab-4 - Pilot Plant-2

- Glass Reactors - 3 (600L / 2X1KL)
- SS Reactors - 4 (600L / 3X1KL)
- Glass Column - 1
- Centrifuge - 2 (36 Inches)
- Dryer - 2 (VTD & RCVD Dryer - 2 (VTD & RCVD)
- Miller, Sifter & Blender

Kilo Lab-5

- Glass Reactors - 10 (3X200/4X100L/50/20/10L)
- Centrifuge - 3 (24 Inches)
- Dryer - 3 (Vacuum Tray Dryer)
- Microniser, Miller, Sifter & Blender

Kilo Lab-6 - (Sterile Facility)

- Glass Reactors - 7 (200/2X100/2X50/20/10L)
- Glass Column - 1
- Centrifuge - 2 (12 inches)
- Dryer - 2 (Vacuum Tray Dryer)
- Miller, Sifter & Blender
- Water System for Injection (WFI)

Total Volume = 7.5 KL



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Pilot Plant Facility- Existing

Pilot Plant

- Stainless Steel Reactors - 4 (1, 1, 2, 3 KL)
- Glass Lined Reactor - 1 (2 KL)
- Centrifuge - 2 (36 Inches)

Powder Processing Area

- Glass Lined Reactor - 1 (2 KL)
- Centrifuge - 1 (36 Inches)
- Dryers - 2
(24 trays Vacuum Tray Dryer & 24 Trays Hot Air Dryer)
- Miller, Sifter & Blender

Batch Size - 15 to 150 kg - Total Volume – 11 KL

Manufacturing Facility - Existing

Manufacturing Block – I

- Stainless Steel Reactors - 3 (0.5, 1.5, 3.5 KL)
- Glass Lined Reactor - 1 (3 KL)
- Centrifuge - 2 (36 & 48 inches)
- Dryer - 2
(12 & 48 trays Vacuum Tray dryer)
- Miller & Sifter

Powder Processing Area

- Glass Reactors - 1 (3 KL)
- Centrifuge - 1 (48 Inches)
- Dryers - 2
(48 Trays Vacuum Tray Dryer & 1 KL Rotocone Vacuum Dryer)
- Miller (150 kg/hr Cadmill) & Sifter

Batch Size - 50 to 200 kg - Total Volume – 11.5 KL

Manufacturing Facility - Proposed

Manufacturing Block - II (STREAM I)

- Stainless Steel Reactors - 3 (3, 4, 6 KL)
- Glass Lined Reactor - 2 (3, 4 KL)
- Centrifuge - 2 (48 Inches)
- ANFD - 1 (1 KL)
- Dryers - 2 (Vacuum Tray Dryer & Rotary Pedal Vacuum Dryer)

Clean Room - Powder Processing

- Glass Lined Reactor - 1 (4 KL)
- Centrifuge - 1 (48 Inches)
- Dryers - 2 (Rotary Pedal Vacuum dryer & Rotocone Vacuum dryer)
- Microniser, Miller, Sifter & Blender (1 Each)

Batch Size - 50 to 300 kg - Total Volume – 51 KL



Manufacturing Block - II (STREAM II)

- Stainless Steel Reactors - 2 (4, 6 KL)
- Glass Lined Reactor - 3 (3, 4, 5 KL)
- Centrifuge - 2 (48 Inches)
- ANFD - 1 (1 KL)
- Dryers - 2 (Vacuum Tray Dryer & Rotary Pedal Vacuum Dryer)

Clean Room - Powder Processing

- Glass Lined Reactor - 1 (5 KL)
- Centrifuge - 1 (48 inches)
- Dryers - 2 (Vacuum Tray Dryer & Rotocone Vacuum Dryer)
- Miller / Sifter (1 Each)

YOUR API PARTNER IN INDIA**Hydrogenator And Spray Dryer Facility**

- Hydrogenator SS Reactor - 3 (25L, 100L, 1000L)
- Micronizer - 1 (2 kg to 120 kg / Hr)
- Spray dryer - 1 (7.5 kg / Hr Solvent Evaporation Rate)

**Warehousing Facility - Proposed**

- Warehouse Area : 22,500 Sq.ft
- Separate Raw Material Storage Area for
 - Solids - Liquids
 - Packing Materials - Hazardous Chemicals
- Separate Finished API Storage Area for
 - Controlled room temperature (20-25°C)
 - Cold room temperature(2-8°C)

**Utilities Infrastructure - Existing**

- Purified Water System - 1000 L/Hr
- 2 Boiler 600 kg/hr - Bio Fuel
- 1 Boiler 500 kg/hr - Bio Fuel
- 2 Chillers - 20 TR (-20°C) & 20 TR (-35°C)
- 4 UPS - 40 KVA, 40 KVA, 40 KVA, 130 KVA
- 3 DG - 70 KVA, 250 KVA & 500 KVA
- 1 HT - 495 KVA

