SHAMROCK®

Together we can improve the quality of Life®

API

INTERMEDIATES

VETERINARY

"Your API Partner In India"

Core Business Areas

API's & Intermediates

BULK™ PHARMACEUTICAL & CHEMICAL DIVISION

Building Perfect Chemistry for Life™

- Active Pharmaceuticals Ingredients
- Intermediates
- Fine Chemicals

Veterinary

medivet™

Dedicated to Animal Health Care™

- Veterinary Raw Materials
- Pre-mixes / Feed Supplements

Research & Development

SHAMROCK™ RESEARCH & DEVELOPMENT

Where Research is Developing...™

- Custom Synthesis
- Technology Transfer (Non Infringing Route of Synthesis) / Technical Collaboration

Nutraceuticals

Nutrasciences

New Leaf in Nutraingredients

- Nutraceuticals - Dietary Supplements / Ingredients

Introduction

At **Shamrock Pharmachemi Pvt. Ltd.**, we believe in understanding the customer and the market before developing and manufacturing products.

We believe in customization according to customer's as well as market requirement.

By meeting customer & market needs, we have increased our revenue and created a platform to increase profit margins on a long term and sustainable basis.

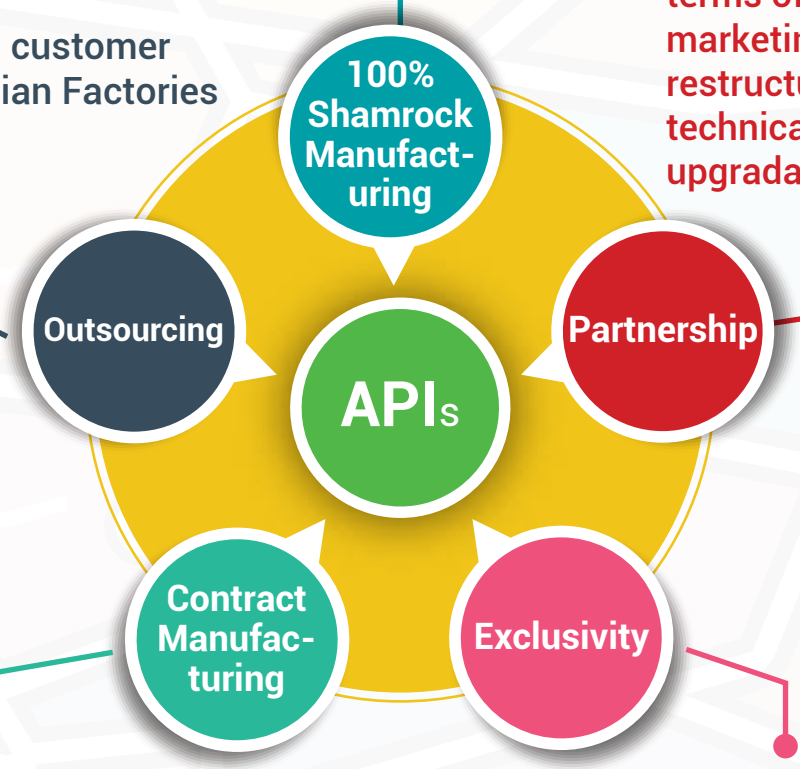
- **Shamrock Pharmachemi Pvt. Ltd.**, is involved in manufacturing and exports of APIs, Intermediates and Veterinary products.
- An established and recognizable company of high repute in the industry with unique expertise in international marketing of API's & Intermediates.
- Shamrock is focused on API's & Intermediates from basic stage manufacturing with almost no dependency on imports, self sustainable model aiming for leadership position in exclusive and speciality API's.
- Shamrock is a larger exporter of 14 Molecules from India and this number is growing every year.
- Shamrock is exclusively tied up with 7 manufacturing facilities & 2 R&D centers manufacturing high quality speciality APIs & Intermediates and several other facilities on contract manufacturing basis apart from outsourcing.

Manufacturing Business Model

100% owned by Shamrock through acquisition or Green Field project

- Advantage of Local Indian Pricing
- Bundle of multiple API's in small lot
- Product from customer approved Indian Factories

Partnership with existing promoters for adding value in terms of finance, marketing, business restructuring and technical & regulatory upgradation



- Supply Intermediates
- Technology
- Finance
- Marketing
- Customer / Country Exclusivity

- 100% Sales by Shamrock
- Cost Competitive Control
- Plant Exclusivity (Campaign)

- Raw Material
- Technology
- Finance
- Marketing

- 100% Exclusive partnership with Shamrock
- Cost competitive Control
- Plant Exclusivity

All factories approved:

cGMP, WHO GMP, USFDA, EUGMP, COS, DMF, TIP, KFDA, ANVISA, COFEPRIS, UK KHRA, TGA

MANUFACTURING SITES (OWNED & EXCLUSIVE)

API UNIT III

URL
Vapi
Installed Capacity: **220 Kl**
Status: **Shamrock**

API UNIT IV

URL
Bavla
Installed Capacity: **186 Kl**
Status: **Shamrock**

API UNIT V

Susaah Laboratories
Telangana
Installed Capacity: **50 Kl**
Status: **Partnership**

API UNIT VI

Punjab Chemicals
Chandigarh
Installed Capacity: **65 Kl**
Status: **Exclusive**

API UNIT IX

Shreegen Pharma
Bidar
Installed Capacity: **100 Kl**
Status: **Exclusive**

INTERMEDIATE I

Suleshvari Pharma
Ankaleshwar
Installed Capacity: **140 Kl**
Status: **Partnership**

NUTRA UNIT I

Shankar Soya Concepts
Indore

Status: **Partnership**

APIs • INTERMEDIATES • VETERINARY • R&D

Manufacturing • Exclusive • Contract

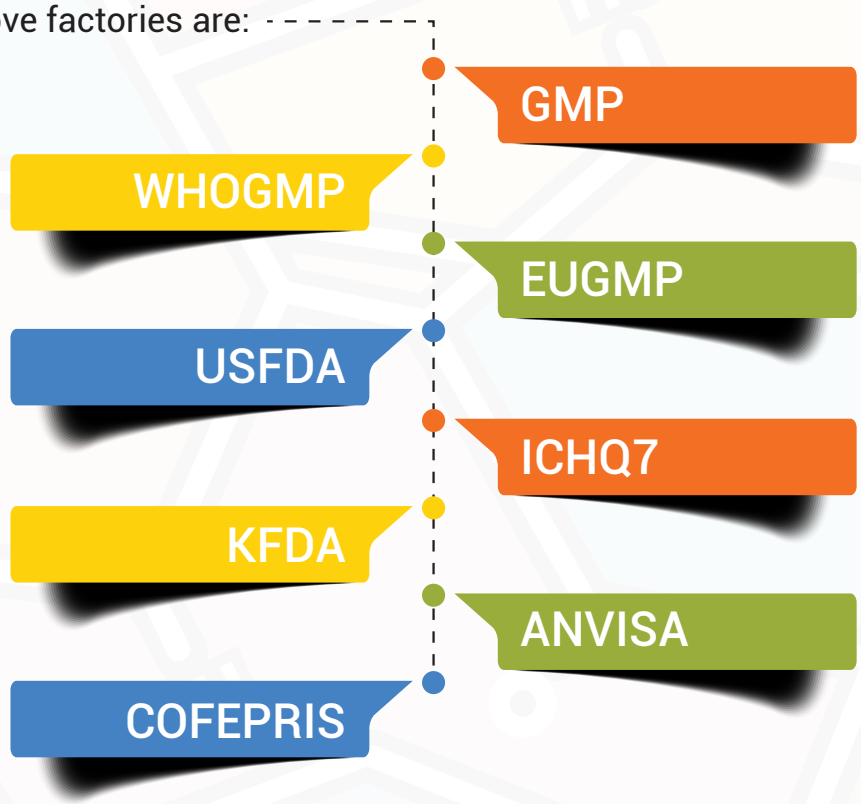
• cGMP • EUGMP • USFDA • ICHQ7 Compliant Facilities • EUDMF
• USDMF • CEP • Technical & Regulatory Support

"Your API Partner In India"

Manufacturing Facilities

Exclusive | Contract | Outsourcing

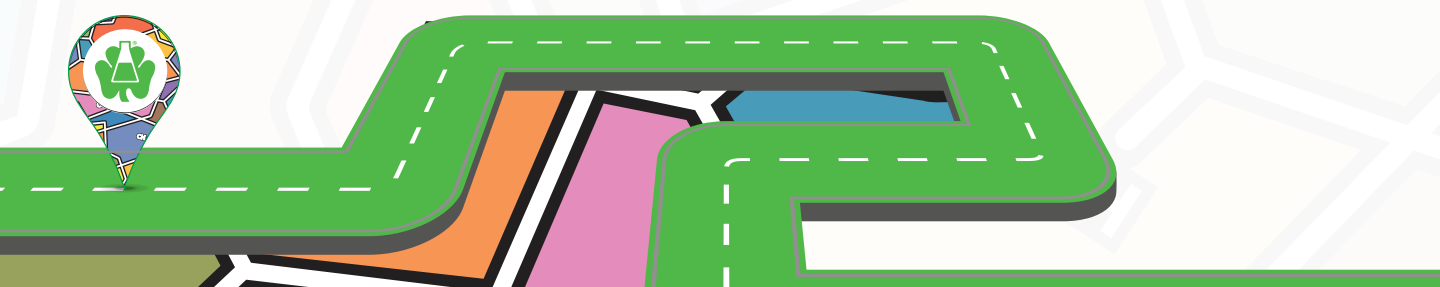
All the above factories are:



- **100% exports** audited by several companies [Generic & MNCs]
- Large volumes more than **1450 KL** [from our **5 Owned** Manufacturing sites]
- More than **200** technical **skilled staff** in R&D, Production, QA-QC, in each factory
- **Factory profile** PPT file **available** for each manufacturing site
- Facilities capable of multi purpose reaction capabilities, multi stage processes, batch processes from **1KL to 10 KL** in MS, SS and GLR
- Temperature: **Minus 40°C to 200°C** and **hydrogenation**/pressure up to 15 ATM

Milestones

- Pioneers in developing business in the Latin American Market, Middle East & Central European Market.
- In 1990 pioneered international export marketing and sales from India on a long term contract manufacturing basis with overseas generic FDA approved producers.
- Developed the Iraq market and obtained tender business worth 80 Million Dollars. To be 1st company from India to transfer technology from India to API stage with buy back agreement.
- 1st company from India to enter Iran market for Intermediates with technology transfer and buy back agreements.
- Similarly 1st company from India to transfer finished products with technology against buy back of APIs with regulatory documentation.
- Largest exporter of Pharmaceutical grade PC-Lecithin from India.
- Largest exporter of Anti-hyperphosphopamic API from India.
- Largest exporter of Lovastatin (Fermentation) from India volume approx 400 tons.
- Developed in-house technical capability and created largest exclusive production of water solution based polymer, monoamine used for API production.
- Largest exporter of various APIs and Intermediates form India.
- In 2017-18 reached revenue of more than 45 million exports and become government recognized two star export house status. On going achievement for 2020.
- "Outstanding Export Performance Award" by 'Pharmexcil', [A Pharmaceutical Export Promotion Council] Govt. of India.
- All original & technical documentation will be issued by the Factory and Shamrock as the holder and vendor



API Development Cycle

- Customer Request/Market Potential
- Research & Development/Technology Transfer
- Kilo Lab Scale Up
- Pilot Plant Scale Up - Validation Batches
- Commercialization Plant Scale Up
- Regulatory Filings - EDMF, USDMF, KDMF, cGMP
- QA & QC Validation of Process MOA
- Vendor Approval with All Customers [Audit, Commercial Audit]
- Commercial User Trial With Customers
- Long Term And Profitable Growth Plan For API's
- Happy Customer

R&D/Kilo Lab/Pilot Plant

New Molecules are validated and commercially scaled up in pilot

Pilot scale up of over 15-20 products every year

Pilot trials conducted for volumes from 10kgs to 1000kgs

Pilot Equipment volume ranges from 50 liters to 1500 liters

In kilo lab scale from 5 liters to 50 liters

Technology Transfer

Technology Transfer is part of our business development of new products

We offer free of cost technology transfer for Finished Dosage Forms (FDFs) with Registration Dossier, Bio Equivalence & Bio Availability (BE&BA) Studies & Stability Studies against buyback agreement of APIs

Full Hand-on Technical Support with documentation provided including visit of our Technical team to the manufacturing site for transfer and scale up of technology transfer

Similarly for technical transfer available for APIs with Drug Master File, Impurities, Reference Standards, MOA against buyback agreement of Advanced Intermediates

Unique service offer of free Technology Transfer purely as a business partnership and buyback arrangement

Technical & Regulatory Documentation Affairs Support

To offer our customers a complete range of services, we have a seperate Regulatory Affairs Division who provide all technical documentation and support with regards to APIs, Intermediates, and fine chemicals. This mainly includes the following:

- Drug master file is available - Open part of the DMF as per the EEC format against a Secrecy Agreement directly from the customer. All the documents can be provided to the customer on request. Drug Master File (USDMF, EQDM, KDMF, JDMF (Japan), ANVISA, COFEPRIS (Mexico)
- Methods of Analysis - Besides/in addition to the official phamacopoeia.
- Material Safety Data Sheet (MSDS)/BSE - TSE Certificate.
- Reference Working Standards and Purity Standards.
- Impurity Profile complying to ICH guidelines (Organic inorganic residual solvents).
- Toxicity Data.
- Stability Studies.
- Registration Dossiers for FDF - Finished formulations and APIs.
- Bio-Equivalence and Bio-Availability Studies are available.
- Complete Documentation available for each product including advanced intermediates, APIs (Human & Veterinary) and FDFs.
- Technical information package for each product includes Routes of synthesis, impurity profiling, characterization of impurities/isomers, residual solvents, MOA, stability studies/validation.

Due to the above technical support guaranteed by Shamrock, our customers opt to purchase several products from Shamrock and hence we are able to develop a long term business relationship with customers.

Quality Assurance & Quality Control

Every gram of product checked by factory QC and counter checked by our QC to meet the exacting specifications standards of the customers.

Fully loaded QC complying GLP standards with all the latest instrumentations including GC, HPLC, NMR, FTIR, GCMS particle size analyzer, UV and Elemental analysis by AAS.

Full validation report available along with Method of Analysis and all technical support.

Impurity profiling with reference standards, working standards.

Snapshot

SHAMROCK®

Together we can improve the quality of Life®

FACILITIES	cGMP, WHO GMP, EU GMP, USFDA, ICHQ7, Audited & Approved by several companies
REGULATORY SUPPORT & DMF	USDMF, EUDMF, CEP, WC, Impurities Certificate/ Working standard, Analytical validation, Method validation and Stability data
RESEARCH & DEVELOPMENT	• Custom synthesis, Product technology, R&D to Kilolab-Pilot-Commercial Scaling • Multi Reaction Capabilities
API SUPPORT	FDF Registration Dossier, FDF Technology Transfer, BE/BA Studies (EU/PICS Apporved), Stability Studies, Marketing Authorization, Impurity Profiling
API INTERMEDIATES	Technical DMF, ROS (non-infringing), Impurity Profile, Residual Solvents, Stability Data, MOA Validatin, ICHQ7 standard auditable, GMP
TECHNOLOGY TRANSFER FROM INTERMEDIATE TO API , API TO FDF (WITH DOSSIER)	At no cost against agreements

- Manufacturing Facilities
- Quality Control
- Clean Room
- Pilot Plant
- Production Plant
- Research & Development

SHAMROCK®

Together we can improve the quality of Life®

Corporate Office:
83-E, Hansraj Pragji Building, Off Dr.E.Moses Road, Worli, Mumbai, 400 018. INDIA
Phone : +(91-22) 4077 8877
Website : www.shamrockpharmagroup.com
Email : sales@shamrockindia.com

Scan QR Code