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

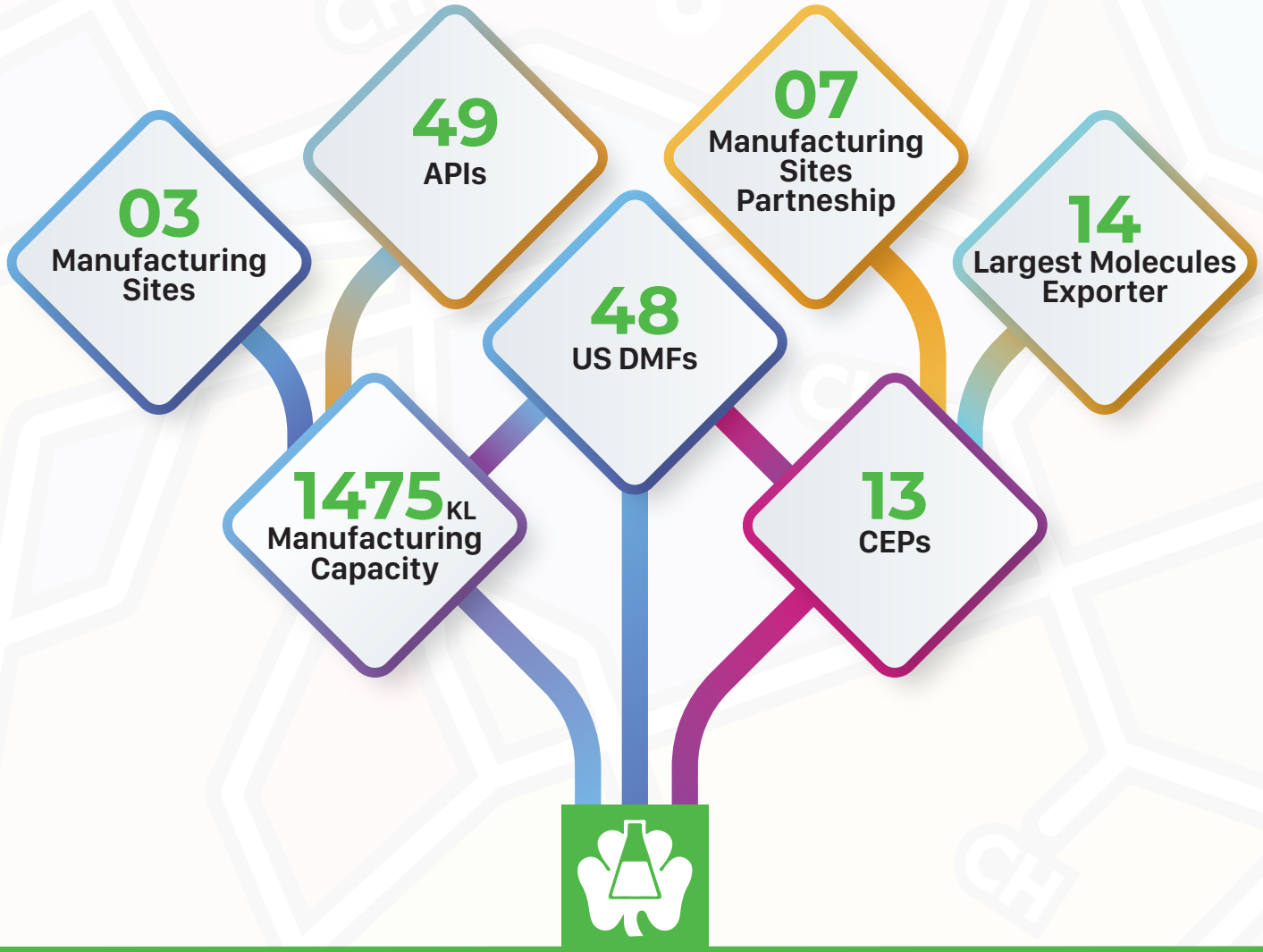
- Nutraceuticals - Dietary Supplements / Ingredients

Shamrock Pharmagroup

We are **Shamrock Pharma Group** dedicated for providing customer a high-quality **APIs & Intermediates** from our manufacturing & contract manufacturing facilities.

We believe in customization according to customers and market requirements and to meet the quality standards and documentation to provide a long term supply chain for APIs.

Currently Shamrock has a portfolio of **49 APIs**, have **3 manufacturing sites** 100 percent owned by Shamrock and **7 manufacturing sites** in partnership and exclusive basis. Total volumes are more than **1475 KL** & we are the largest exporter of **14 Molecules** from India. We have **48 USDMFS** & **16 CEPs**. We also have **R&D Center** of more than **4000 sq mtrs** in Bavla Ahmedabad & other in-house R&D labs where are developing various molecules every year.



SHAMROCK®

11 MANU-FACTURING SITES

104 APIs MFG. & EXCLUSIVE

16 CEPs

24 YEARS IN BUSINESS

1475 KL TOTAL MFG. CAPACITIES

14 MOLECULES LARGEST EXPORTER

06 R&D LABS IN HOUSE & CRO

APIs • CARBAPENEMS • INTERMEDIATES • R&D

Manufacturing • Exclusive • Contract

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

"YOUR API PARTNER IN INDIA"

Manufacturing Sites (Owned & Exclusive)

API UNIT I

Unimark Remedies Ltd.
Vapi
Installed Capacity: **220 Kl**
Status: **Shamrock Owned**

API UNIT II

Penem Pharmachemi
Bavla
Installed Capacity: **186 Kl**
Status: **Shamrock Owned**

API UNIT III

CRAMS
Bavla

Status: **Shamrock Owned**

API UNIT IV

NB Health Care Pvt. Ltd.
Bavla

Status: **Partnership**

API UNIT V

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

API UNIT VI

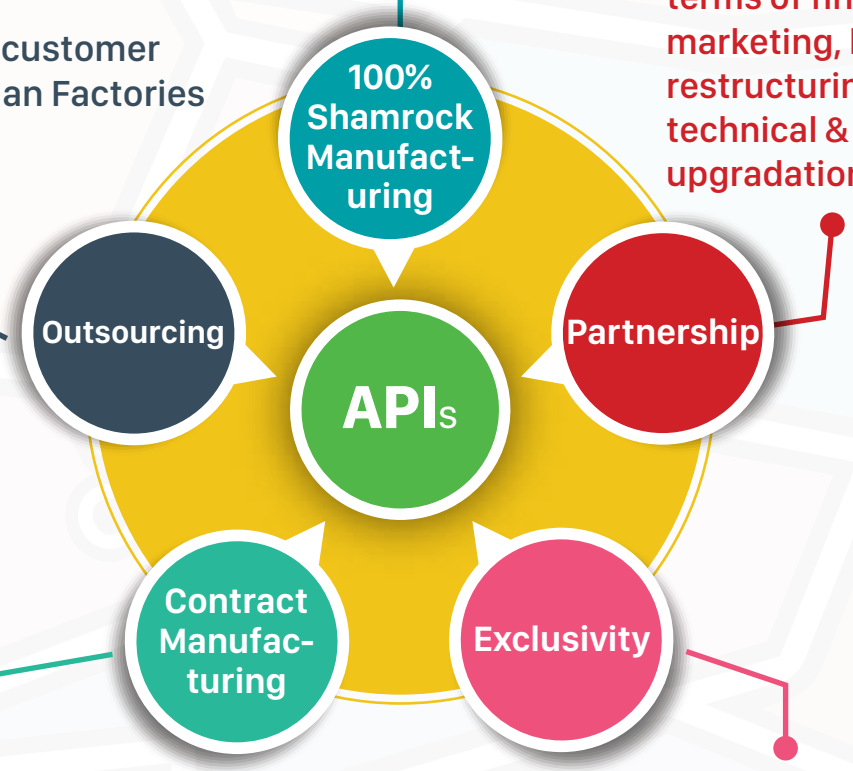
Suleshvari Pharma
Ankaleshwar
Installed Capacity: **140 Kl**
Status: **Partnership**

API UNIT VI

Shankar Soya Concepts
Indore

Status: **Partnership**

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

UNIMARK REMEDIES LIMITED

(A SHAMROCK PHARMA GROUP)

USFDA / EUGMP APPROVED API FACILITY - VAPI

- **Unimark Remedies Ltd.,** is a manufacturing company which aims to provide affordable generic **API's** for the local and global markets.
- The company has a manufacturing record of more than **18 years** and have been approved, inspected and audited by **US FDA, EU** and other regulatory bodies for more than 6 times.
- The company has been recently acquired by **SHAMROCK PHARMA GROUP** and is now 100% owned by them. The new management brings in more accountability, commitment and better upgraded facilities and **GMP standards** to meet the high quality and regulatory requirements of global markets.
- It has the state-of-the-art facilities, latest technological capabilities and have optimized the chemical processes for all its API's.
- The state-of-the-art facility is designed to carter to all regulatory markets including **US. EU, CANADA** and **RoW**.
- The company API facilities are approved by **USFDA, EDQM, TGA, UKMHRA** and **WHO**, it's a fully compliant **CGM facility**.

PENEM
PHARMACHEMI PVT. LTD.
(A SHAMROCKPHARMA GROUP)

CARBAPENEM

INTEGRATED FACILITY FROM CHEMICAL TO Sterile (Vials)

- Board spectrum β-lactam antibiotics
- Leading developer of Carbapenem at USFDA compliant facility
- Producing Intermediates and Side Chains in-house (No dependency on imports)
- Dedicated facility for Carbapenems / Orals Sterile /APIs / FDF
- Largest Integrative Plant from Chemical to Vials (Sterile)
- Dedicated R&D for Carbapenems
- USFDA / EUGMP / PMDA / KFDA / MHRA / TGA Approved
- 16 DMFS (Technical & Sterile) for Carbapenems

SHAMROCK CRAMS

Contact Research & Manufacturing Services

• Research • Develop • Manufacture • Repeat

- R&D Building : **52,000 sq. ft.**
- Pilot Plant Capacity : **70 KL with Clean Room**
- Major Reaction Capabilities : **Hydrogenation, Reduction, Cryogenic Reactions, Chiral Synthesis**
- Manufacturing Blocks : **5 Blocks of 240 KL total**
- Major Equipment's R&D : **Fume Hoods, Hydrogenators & Fermenters**
- Plants : **SSR, GLR's, Distillation Columns & Hydrogenators**
- Technical Strength : **80**

SHAMROCK CRAMS • Research • Develop • Manufacture • Repeat

- Technical evaluation & Identifying ROS.
- Patent / IP evaluation (Non infringing ROS).
- Setting targeted yields for efficiency.
- Setting quality standards.
- Economic & commercial viability.
- Repeated batches & validation of process R&D stage.
- Process validation at pilot stage / trials.
- Commercialization of pilot trials .
- Setting batch size.
- Scale up to commercial batches at plant level.
- Analytical method validation.
- Impurity profiling, characterization, Identification.
- Stability studies, Realtime & accelerated.
- Regulatory documentation & validation.

Partnership

API UNIT PARTNER NB HEALTHCARE

- API Unit : **7**
  (N B Healthcare) - Small Partnership - Bavla, Ahmedabad.
- Total KL : **140 KL**
- No. of Clean Rooms : **3**
  WHO GMP, EUGMP, USFDA, Standard / DMF'S under filling: **14 USDMF & 12 CEPS**
- APIs : **20 APIs**

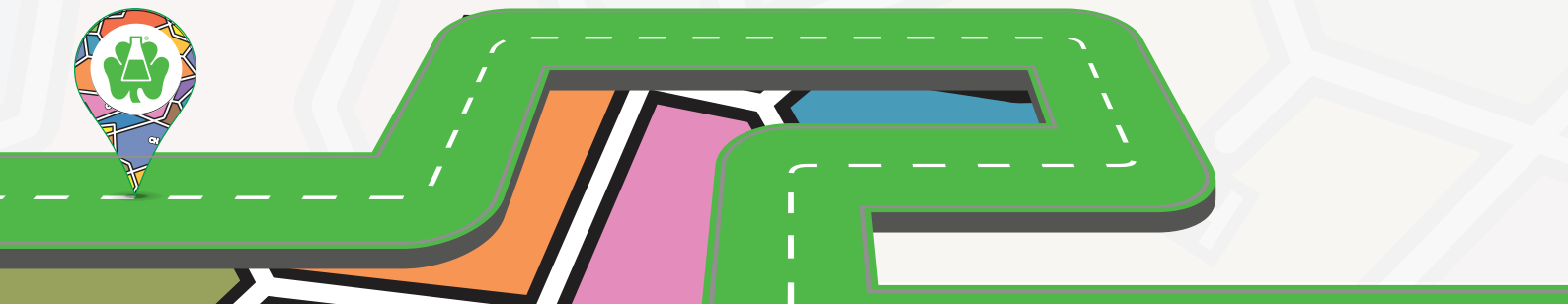

API UNIT PARTNER CHEMOX

- Total KL : **190 KL**
- No. of Clean Rooms : **3**
  Approved : WHO GMP
  Under Approval : EU Group, USFDA, Standard
- DMF's Under Filing : **7**
- API Portfolio : **15**



Milestone

- 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 2020-21 reached revenue of more than 52 million exports and become government recognized two star export house status. On going achievement for 2020.
- Acquired “Unimark Remedies Ltd.” Vapi Facility & “Carbapenem” Bavla Facility.
- “Outstanding Export Performance Award” by ‘Pharmexcil’, [A Pharmaceutical Export Promotion Council] Govt. of India.



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.

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.

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

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

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