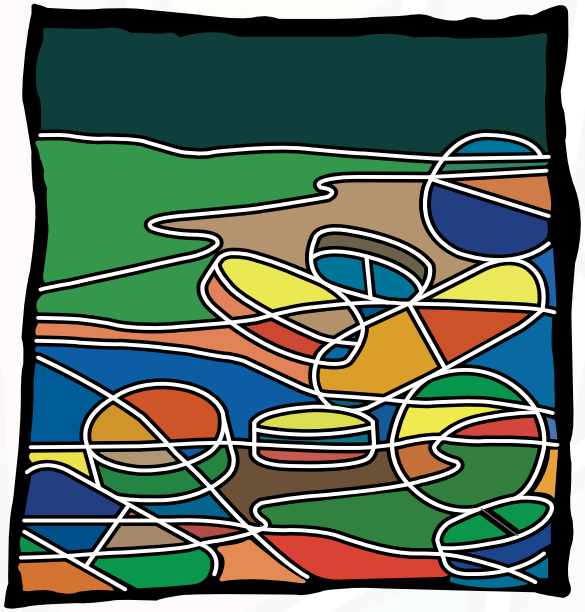
SHAMROCK®

Together we can improve the quality of Life®

## APIs



## INTERMEDIATES


## VETERINARY

**YOUR GLOBAL API PARTNER**

# Contents


SHAMROCK
TOGETHER WE CAN
IMPROVE THE
QUALITY OF LIFE

# Company's Profile

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.


SHAMROCK®
Celebrates
23
years
Of
Success

SHAMROCK®

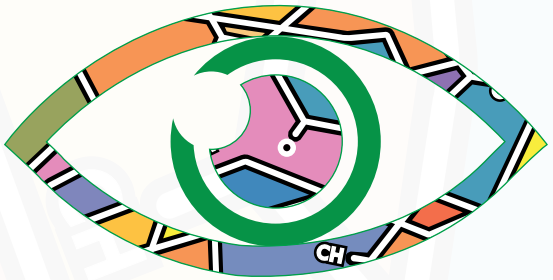
# OUTSTANDING
## EXPORT PERFORMANCE AWARD


Supported by
Government of India

pharmexcil

BC INDIA
Pharmacy of the World
Responsible Healthcare

# Mission / Vision



## Our Vision

To provide human society with premium quality products and services for promotion of better health care through effective, safe and high quality products competing in the global environment and subsequently improving the quality of life.

## Our Mission

To become a major global player in service of the Pharmaceutical & Health Care Industry, strategically placing ourselves as a market and a customer driven company.

# Core Business Area

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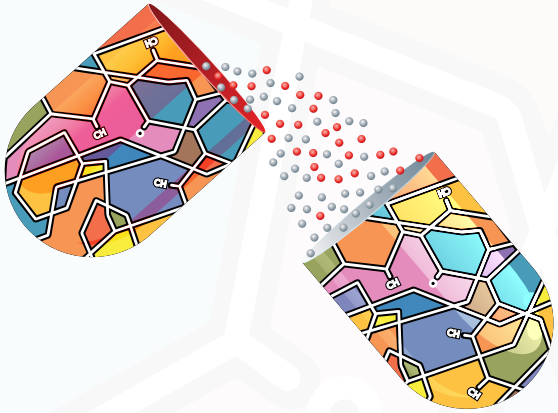
## API Intermediates

BULK™ PHARMACEUTICAL & CHEMICAL DIVISION
Building Chemistry for Life℠

- Active Pharmaceuticals Ingredients
- Intermediates
- Fine Chemicals



## Veterinary

medivet™
Dedicated to Animal Health Care℠

- Veterinary Raw materials
- Pre-mixes / Feed Supplements

## R & D

SHAMROCK™ RESEARCH & DEVELOPMENT
Where Research is Developing.™

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

## Nutraceuticals

Nutrasciences
New Leaf in Nutraingredients

- Neutraceuticals - Dietary Supplements / Ingredients

## Global Operations & Network

- Global Network on Exclusive Basis
- Exclusive Partnership Increasing Profits & Sales Representative Office

# Milestones

- Pioneers in developing business in the Latin American Market, Middle East & entral 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.
- First company from India to enter Iran market for Intermediates with technology transfer and buy back agreements.
- First 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" 2016-2017 & 2017-2018 by 'Pharmexcil', [A Pharmaceutical Export Promotion Council] Govt. of India.
- Started Fermentation manufacturing. Project to be completed by 2020.
- All original & technical documentation will be issued by the Factory and Shamrock as the holder and vendor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# CHEMISTRY IS AN ART AND NOT JUST A SCIENCE

# Core Pharmaceutical Products

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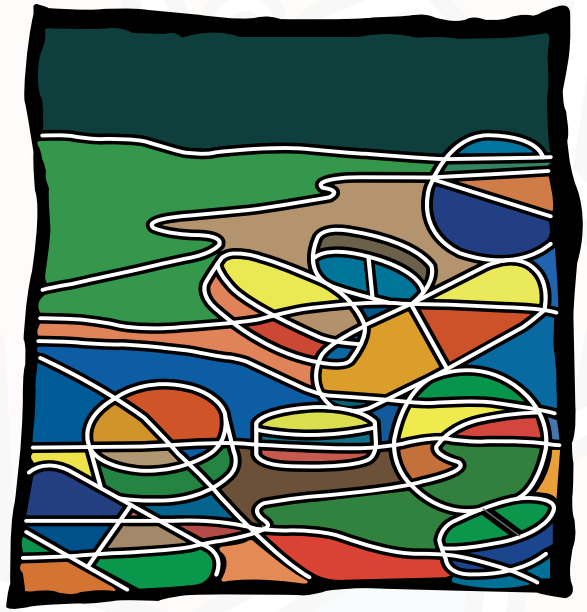
## YOUR GLOBAL API PARTNER

### APIs



### INTERMEDIATES


### VETERINARY

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

# Pharmaceutical Maze India

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## The Pharmacy For The World

Ranks 3rd largest exporter in terms of volume.

Ranks 4th in Asia Pacific Market Share.

## Catalyzing Growth

India's Pharma export stood at USD **15.32 BN** (2015) from USD 3.89 BN In past 11 years. Growth at a CAGR of 21% over the Last decade.

## A Promising Growth

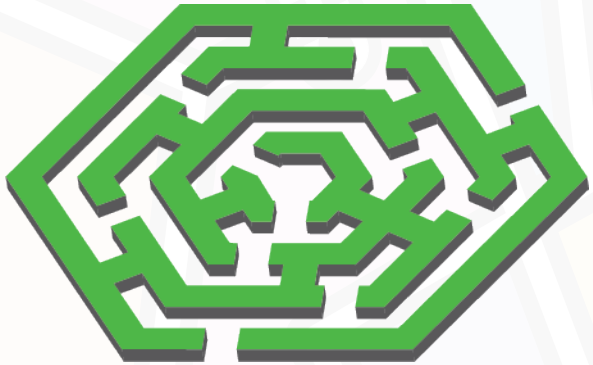
India's pharmaceutical sales are expected to reach USD **27 BN** by 2016.

## The Excellence Beyond Compare

Globally more than 90% of formulations Approvals for Anti-tubercular & Anti-malarial (WHO Pre-qualified) have been granted to India.

## The Files Of Health

A total of **3602** Drug Master Filings (DMF's) at USFDA were filed until December 2014 which is the highest outside of the USA.



# Pharmaceutical Maze India

SHAMROCK

## World Renowned Quality

**1400** WHO GMP approved manufacturing units.

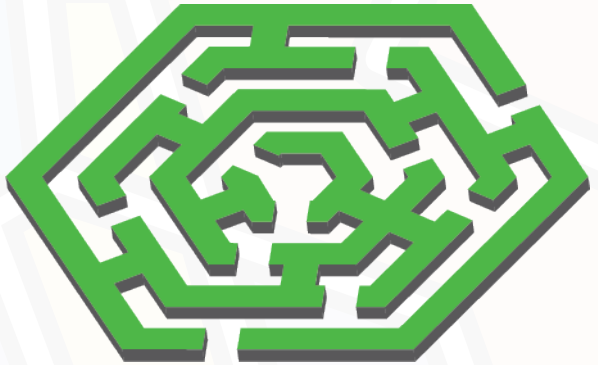
55% Formulation exports accounts to highly regulated market endorsing Indian industry adherence to highest standard of quality.

## Manufacturing Excellence

India has been accredited with approximately **1187** CEP's more than **950** TGA approvals & **605** sites approved by USFDA.

## A Pharma Hub

More than **1200** Manufacturing units. Over **3000** Pharma companies in India & growing at an exceptional rate. India produces more than **400** essential Bulk Drugs. **30%** of the Bulk Drugs imported into USA are from India.



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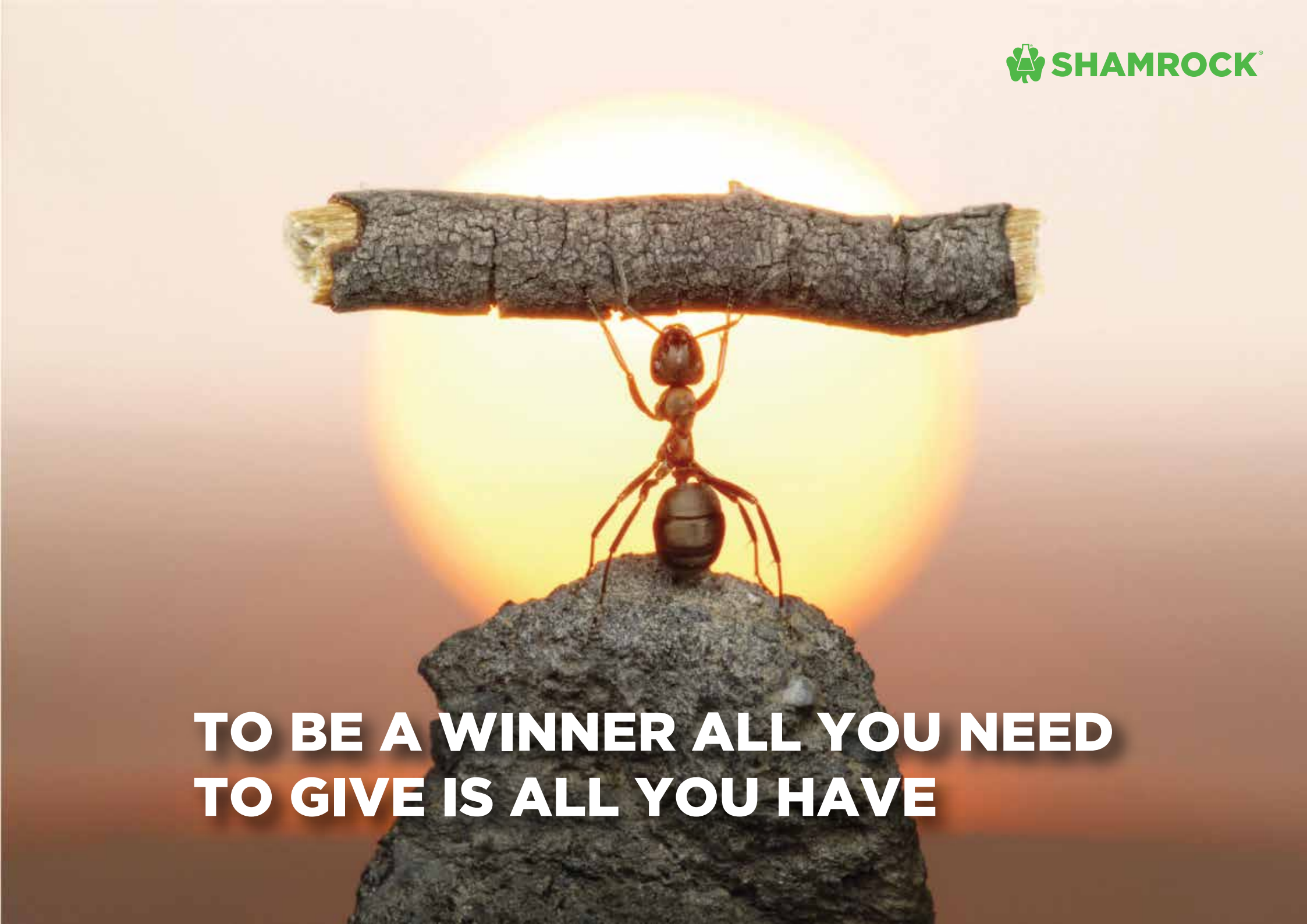
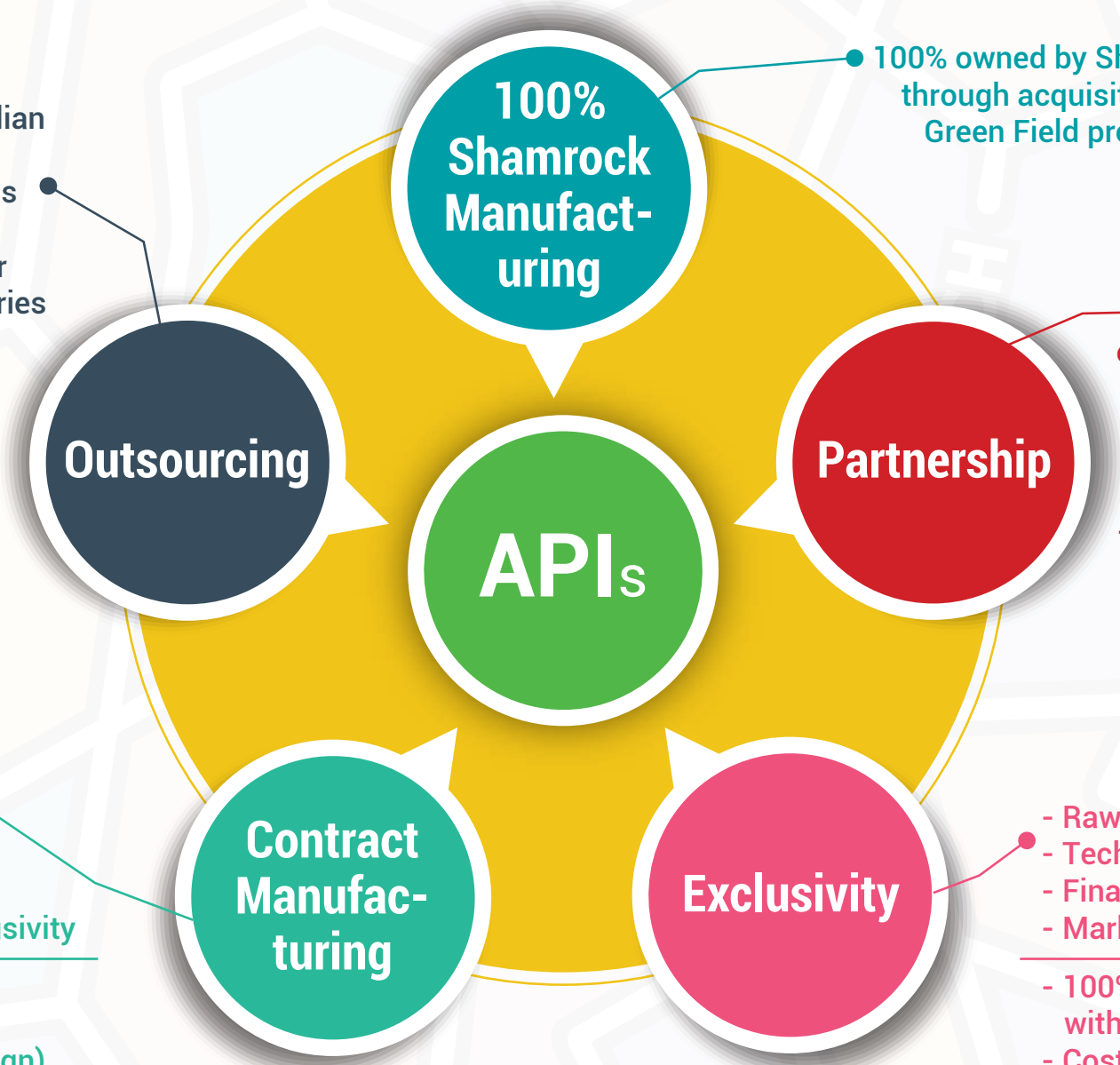


# TO BE A WINNER ALL YOU NEED TO GIVE IS ALL YOU HAVE

# Shamrock Manufacturing Business Model

SHAMROCK




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

100% owned by Shamrock through acquisition or Green Field project

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

SHAMROCK®

# TRANSFORMING ABILITIES TO REALITIES

# Manufacturing Facilities

Factory Profile available for each Manufacturing Location


All factories approved: **cGMP, WHOGMP, USFDA, EUGMP, COS, DMF, TIP, KFDA, ANVISA, COFEPRIS, UK MHRA, TGA**. All original & technical documentation will be issued by the Factory and Shamrock as the holder and vendor.

100% Exports & Auditable facilities approved by International Generic Companies & MNC's

# Manufacturing Facilities

SHAMROCK

Total Columes (Reactors Volumes) 1250 Cu. Mtr

More Than 200 Technical Staff in all the Factories with R&D, Production & QA Capabilities

Plant Capabilities to execute various processes & reactions multi stage processes & hazardous reactions handled are from 40°C to 200°C and Pressure - Handles upto 15 ATM

# Pilot Plant

SHAMROCK

New Molecules are commercially scaled up in pilot with validation

Pilot scale up of more than 15-20 products every year

Pilot Equipment volumes ranging from 50 liters to 1500 liters

In kilo lab scale from 5 liters to 50 liters

Pilot trails conducted for volumes from 10kgs to 1000kgs


SHAMROCK
THE RACE FOR QUALITY HAS
NO FINISH LINE

# Research & Development

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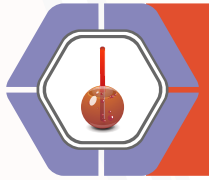
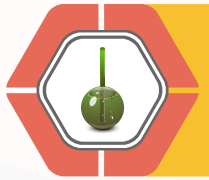
Technology Transfer is part of our Business Development of new products.



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

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



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

Unique service offer of free technology tansfer purely as a business partnership and buyback arrangement

# Quality Assurance & Quality Control

Every gram of product shipped by us is checked by the factory and inspected and counter checked by our QC to meet exacting specifications and standards of the customer.

Providing hands on Technical support with free impurity standards. Reference standards, working standards, MOA, analytical validation compliance as per USFDA and EDQM and complete analytical validation process.

Fully loaded QC with all latest instrumentation including GC, HPLC, NMR, FTIR, GCMS particle size analyzer, UV and Elemental analysis by AAS.

# Regulatory Affairs

SHAMROCK

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.
- Methos of Analysis - Besides/in additional to 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 Finished formulations and APIs.
- Bio-equivalence and Bio-Availability Studies are available.

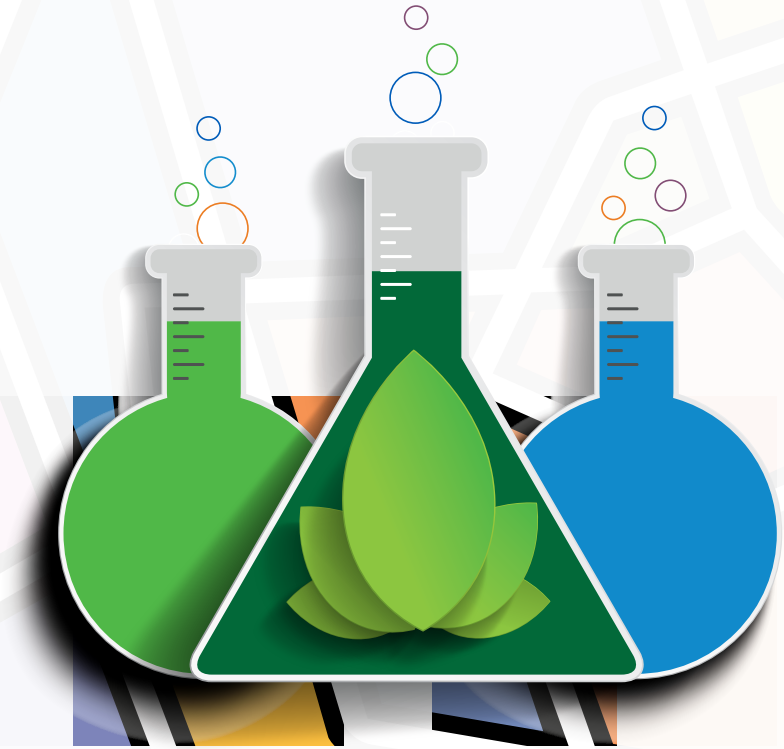
**Due to the above technical support guaranteed by the Company, the customers opt to purchase several products from the company as the availability of such documents fulfill customers technical and regularity requirements and hence we are able to develop a long term business relationship with several customers.**

# Technical Regulatory 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:

- Complete Documentation available for each and every product including advanced Intermediates, APIs (Human & Veterinary) and even FDFs
- Drug Master File (USDMF, EQDM, KDMF, JP PDA (Japan), ANVISA, COFEPRIS (Mexico)
- Technical information package for each product includes Routes of Synthesis, Impurity Profiling, Characterization of Impurities/Isomers, Residual Solvents, MOA, Stability Studies/Validation
- Impurity Reference Standard, Toxicity Data, Stability Studies, Registration Dossier for FDFs
- BE/BA Studies (Actual Subjects at Cost)



# Technology Transfer

SHAMROCK

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

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

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

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


SHAMROCK
WORKING TOGETHER
WORKS

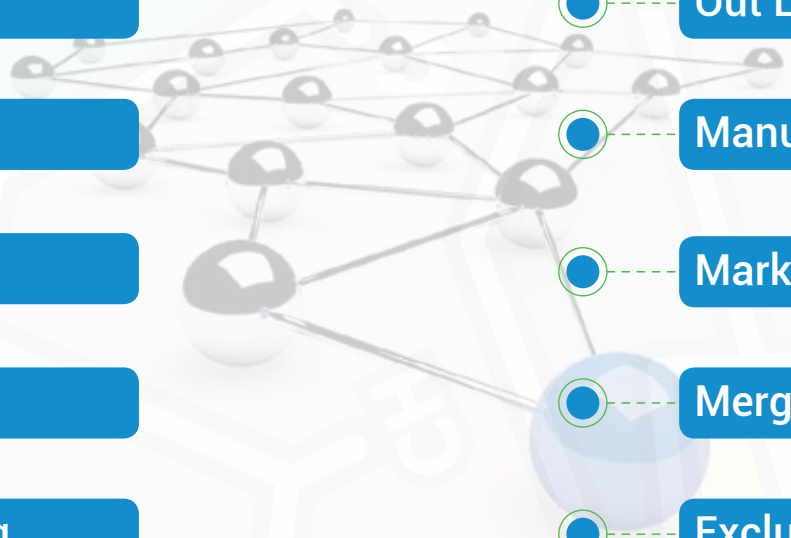
# Complete Package Beyond APIs

SHAMROCK

We are looking to build a Worldwide Global Network of Exclusive Marketing Partners in each country to achieve our company Mission, Vision & Objective and give a personalized local service to the customers thereby improving business opportunity of Profits & Sales.

## Improve Business Opportunities, Growth & give Joint Venture & Collaboration proposal to pharma companies for:

- New Product Launch
- Registration of FDFs
- Technology Transfer
- Joint Venture
- Contract Manufacturing
- Exclusive Sourcing for Generic Companies
- Out Licensing/In Licensing
- Manufacturing New APIs
- Marketing Authorization
- Merger & Acquisition
- Exclusive Marketing



**Detailed Exclusive Partnership proposal is available on request.**

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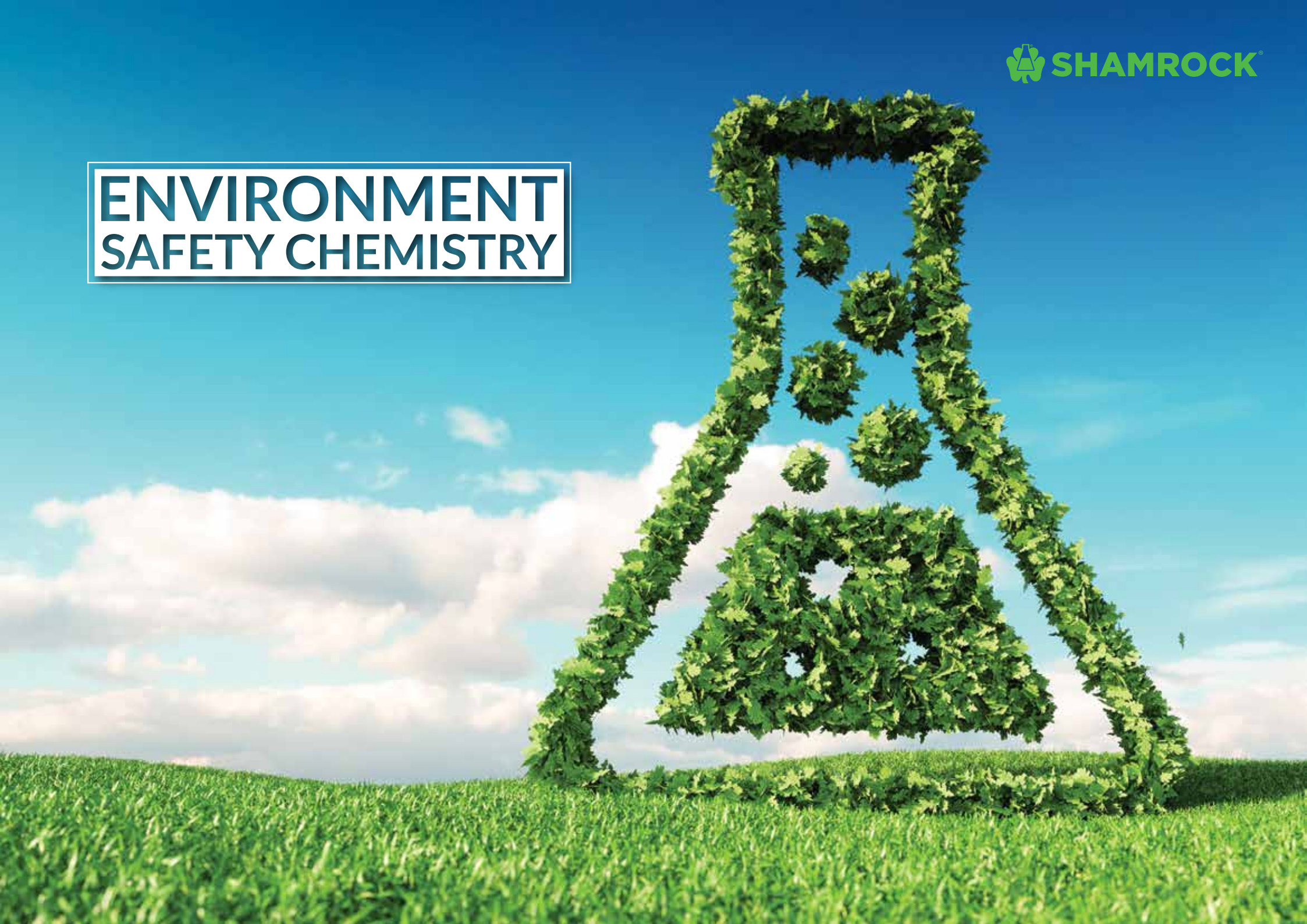
# ENVIRONMENT
# SAFETY CHEMISTRY



# Nvirochemstock Environmental Solutions

SHAMROCK

We are looking to build a worldwide global network of Exclusive Marketing Partners in each country to achieve our company mission & vision & objective and give a personalized local service to the customers thereby: improving business opportunity. Profits & Sales.

NVIRO CHEMSTOCK
ENVIRONMENT SAFETY CHEMISTRY

## THINK GREEN

"**DON'T PAY**" (to dispose your surplus stocks)

"**WE WILL BUY THEM**" (from your doorstep)

## WASTE REDUCTION ALWAYS RECYCLED FOR PROFITS

"**SELL**" Surplus/Unwanted Stocks

"**BUY**" Peace Of Mind And Profits

SHAMROCK®

# GLOBAL OPERATIONS PROGRAMME

## EXCLUSIVE PARTNERSHIP PROPOSAL

# Global Operation Partnership & Alliances

SHAMROCK

- Join our **Global Family** as our Partner.
- **Local Distrubution** and **Warehousing** of the APIs.
- **Order Fulfilment** & manage FDF customers more efficiently with seamless integration in time - everytime.
- **Add value** to FDF companies products by offering additional proposition which includes **Technology Transfer, FDF Dossiers, Regulatory** & **Registration Technical Support** & **Document Support**.
- Exclusive **Market Research Data Base** for Local FDF manufacturing companies.
- Expert Marketing & Sales Support with **Global Networking**.
- Increase **Profitability Unit** and expand work force.

# Marketing Network & Global Reach

SHAMROCK

ALGERIA **Algiers**
ARGENTINA **Buenos Aires**
BAHRAIN **Manama**
TUNISIA **Tunis**
TURKEY **Ankara**
UAE **Dubai**
BANGLADESH **Dhaka**
BRAZIL **Pouso Alegre**
CAMBODIA **Phnom Penh**
VIETNAM **Hanoi**
YEMEN **Sanaa**
COLOMBIA **Bogota**
EGYPT **Cairo**
INDIA **Mumbai**
INDIA **Hyderabad**
INDONESIA **Jakarta**
IRAN **Tehran**
ISRAEL **Jerusalem**
JORDAN **Amman**
KUWAIT **Kuwait City**
LEBANON **Beirut**
MALAYSIA **Kuala Lumpur**
MOROCCO **Rabat**
NEPAL **Kathmandu**
OMAN **Muscat**
PAKISTAN **Islamad**
PHILIPPINES **Manila**
QATAR **Doha**
RUSSIA **Moscow**
SAUDI ARABIA **Riyadh**
SINGAPORE **Singapore**
SUDAN **Khartoum**
SYRIA **Damascus**
TAIWAN **Taipei**
THAILAND **Bangkok**


BELIZE **Belmopan**
BOLIVIA **Sucre**
URUGUAY **Montevideo**
CHILE **Santiago**
COSTA RICA **San José**
VENEZUELA **Caracas**
ECUADOR **Quito**
EL SALVADOR **San Salvador**
GERMANY **Berlin**
GUATEMALA **Gautemala City**
GUYANA **Georgetown**
HONDURAS **Tegucigalpa**
HUNGARY **Budapest**
KENYA **Nairobi**
MEXICO **Mexico City**
NICARAGUA **Managua**
NIGERIA **Abuja**
PANAMA **Panama City**
PARAGUAY **Asunción**
PERU **Lima**
SOUTH AFRICA **Cape Town**
SPAIN **Madrid**

# Value Addition / Proposition (Global Operations)

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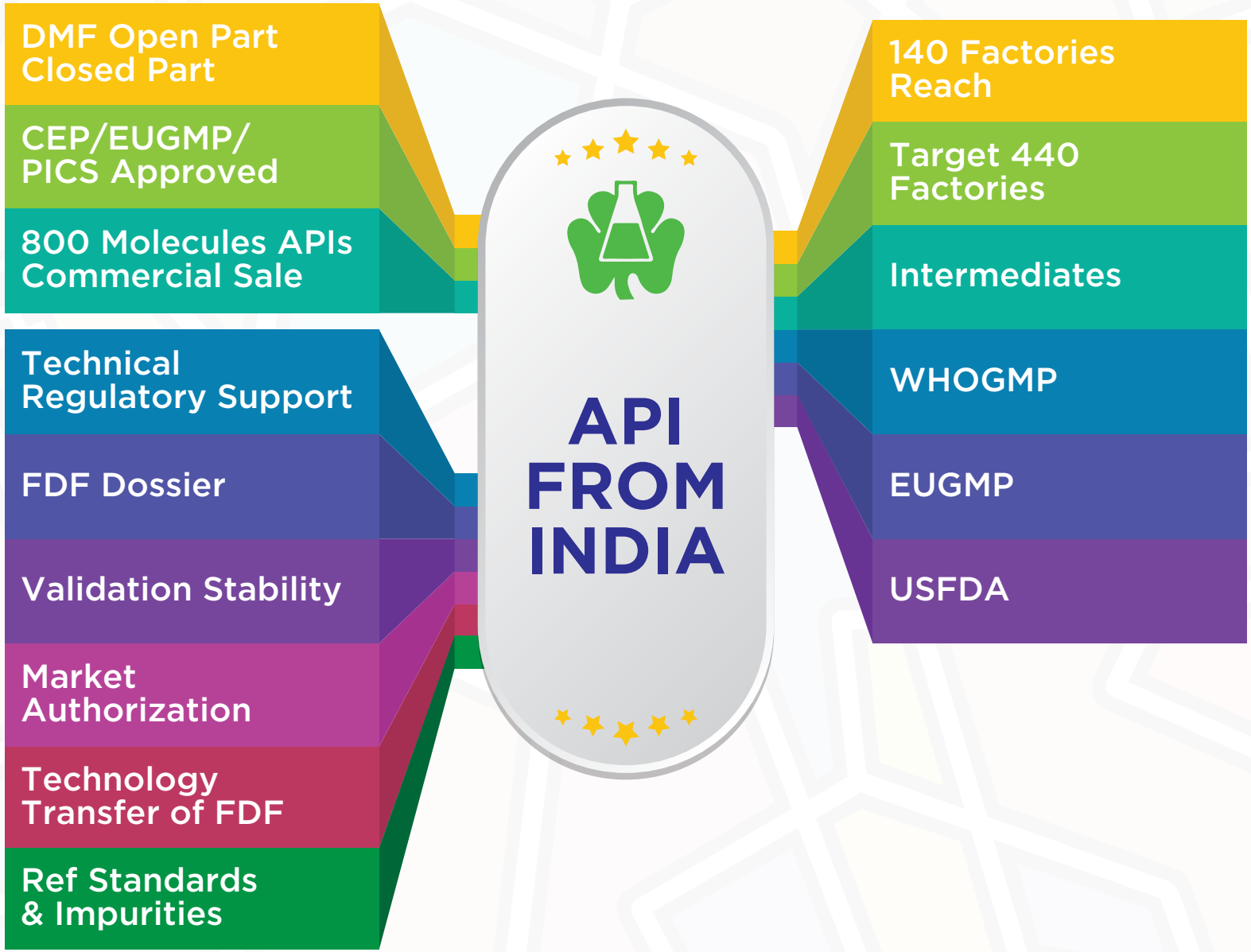

# Snapshot

SHAMROCK

## 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• 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


SHAMROCK
FROM THE DESK OF
MANAGING DIRECTOR

# Message From Managing Director

We at **Shamrock** have been a part of the historical growth of the pharmaceutical market in India and globally right from our founder Shri. Rameshchandra Khokhani. We have experienced the growth factors, potentials and challenges of the industry.

We have also been focused on international markets since 22 years and it has been a learning and enriching experience while we could have achieved much more than we have and had to jump and face many hurdles along the way.

We are completely focused and a dedicated company in APIs & Intermediates for the Pharma industry on a worldwide basis. We aspire to be the largest API marketing company worldwide.

That is a very bold aspiration for which I have a definitive vision and game plan for. We are focused on having our own manufacturing, partnership manufacturing and global exclusivity with the right factories in India.

We also aspire to have our own Global Marketing Network consisting of our Partners' Own Offices, Resident Representatives and Joint Ventures in order to work collectively and globally to serve the Pharmaceutical Industry / FDF Manufacturers.

Our **Shamrock Global Marketing Network** will benefit largely our partners in terms of business growth and partnership in an independent business unit locally. The opportunity gives to be a part global family of Shamrock and enjoy the benefits of large scale Global Operations, Volumes, Infrastructure, Investments, Joint Ventures and various services for FDF Manufacturers / customers not restricted only to the supplies of APIs.

We also would like to empower the business opportunities for our FDF customers not just by providing APIs but also the complete package of services which includes Technology Transfer, Registrations Dossiers, Clinical Studies, Marketing Authorization, In-licensing, Out-licensing, Mergers and Acquisition, Regulatory Compliances and increase business opportunities for our customers as well with the help of these services.

We welcome you to be a part of our Global Marketing Network and achieving a common vision and I am sure as a quality and dynamically aspiring entrepreneur and a professional, you will have an alliance with us which will put you right on the global map and will bring positive and most important satisfying results with high sense of achievement and belonging with our Shamrock Global Family.

All the Best as we look forward and hope to start an alliance and a partnership and hoping that you will be a part of this Pharma Global Network which will be a legacy and a strong foundation for our successors for years to come, built on strong fundamentals, ethics, moral values and culture.

Best regards,

**KAMLESH KHOKHANI**
MANAGING DIRECTOR
SHAMROCK GROUP