



SHAMROCK®
SHAMROCK PHARMAGROUP



UNIMARK
REMEDIES LIMITED

USFDA / EUGMP APPROVED API FACILITY - VAPI




COMPANY OVERVIEW:

- **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 cater 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**.

BUSINESS STRATEGY:

- The company is focusing on developing a niche product portfolio apart from its existing blockbusters and create a highly value-added proposition.
- The company is fully backward integrated manufacturing the products from basis root internally and externally to ensure **no dependency on imports** and fully flexible and economical to compete in the global market.
- Our regulatory approval and standards will make sure that our competitiveness will not affect our quality standards of our **API's**.
- The company is developing **FDF** and have already brought four approved **ANDS** for its **API's** with a view to entre the generic market with a strategic tie up without competing with its customers.
- The company is also partnering an offering **finished formulation dossier** of its **API's** in order for the customers to register the dossiers and conch the generic formulations in their markets.

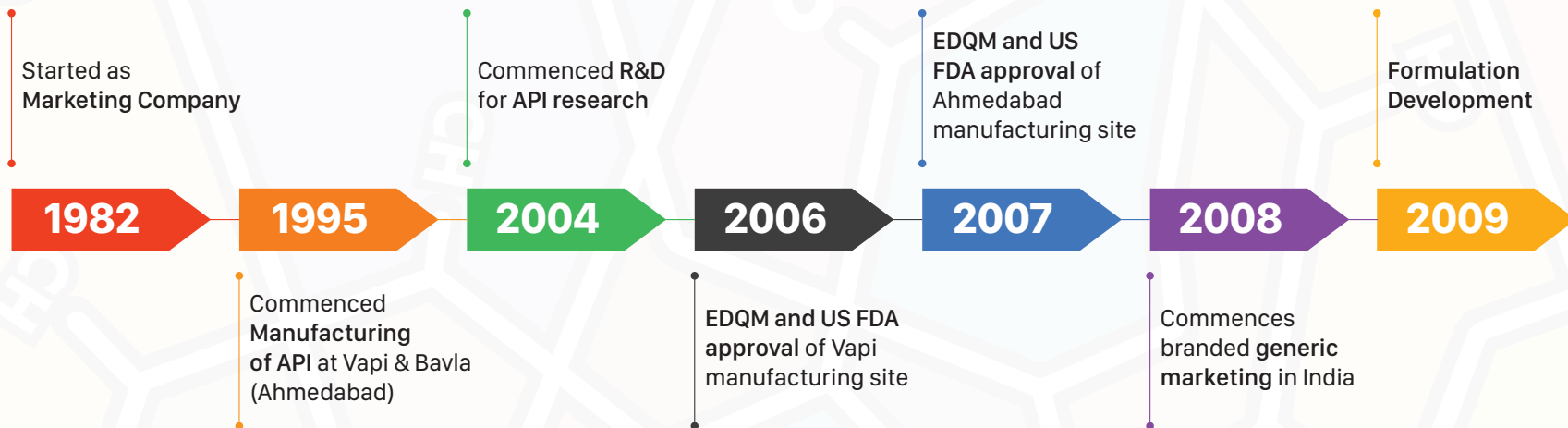
Approvals: APIs

API Portfolio		49
USDMF		38
CEP		14
Approvals For APIs		USFDA, EUGMP, MHRA, TGA, KFDA, Cofepris Mexico, Anvisa (Brazil), Taiwan, WHO GMP, Russia

FDF / Generics

US ANDA Approved / Filed		16 Products (4 approved - 12 under approval)
EU Marketing Authorization Approved		13 Products
Canada Approved		4 Products
ROW Approved		18 Approvals

MILESTONES & KEY ACHIEVEMENTS:



MILESTONES & KEY ACHIEVEMENTS:

Initiated Green field project for its fully integrated Sterile facility at Ahemdabad

2010

2011

Filing for Drug Products in advanced regulatory markets - First MA submission of Motelukast

2013

Successfully cleared US FDA renewal audit at Vapi facility

2014

Successfully cleared EU GMP renewal audit at Vapi facility
First ANDA approval of Montelukast Sodium (IR & Chewable Tablets) in US

2015

Renewal of US FDA audit at Vapi API facility

2023

Change in the ownership and Management

2026

Research based \$ 200 million Generic company

KEY EQUIPMENT & INFRASTRUCTURE

Utility Capacity	
ITEM	PARTICULARS
Boiler	2x2 THP, 1x3 TPH
DG Set	100% power backup with 1 DG set
Hot Oil System	1x5, 1x2 Lac K Cal / Hr
Chilled Brine	-100C - 125 TR
Chilled Brine	-400C - 56 TR
Chilled Water	50C - 220 TR
Cooling Water	1500 TR
Compressed Air	125 CFM
Compressed Nitrogen	50 M3 / Hr
Purified Water System	2 KL / Hr
Sanctioned Power	1400 KVA

ETP Capacity	
ITEMS	PARTICULARS
Water Intake	350 KLPD
Water Discharge	150 KLPD
MEE Capacity	60 KLPD
ETP Capacity	200 KLPD
R.O. Capacity	200 KLPD



KEY EQUIPMENT & INFRASTRUCTURE

Equipment	Capacity	Quantity
Reactors	100 L - 1000 L	42
	1500 L - 2000 L	9
	2100 L - 3000 L	22
	3500 L - 4000 L	21
	5000 L - 6000 L	17
	TOTAL	111
Centrifuges	18", 24", 36", 48"	29
Vacuum tray dryers	6, 12, 14, 24, 28 Trays	16
Pressure & Sparkler Filters	NA	25
Clean Rooms	-	8

API PORTFOLIO:

Product	USMDF	CEP / EUDMF	Therapeutic Category
Albendazole	✓	✓	Anthelmintic
Armodafinil	✓	—	CNS stimulant
Benazepril HCl	✓	CEP	Anti-hypertensive
Buspirone HCl	✓	✓	Anxiolytic
Dronedarone HCl	✓	✓	Anti-arrhythmic
Febuxostat	✓	—	Anti-hyperuricemic
Flecainide Acetate	✓	CEP	Anti-arrhythmic
Lamotrigine	✓	✓	Anti-epileptic
Lanthanum Carbonate	✓	—	Anti-hyperphosphatemia
Lisinopril	✓	CEP	Anti-hypertensive
Meloxicam	✓	CEP	NSAID
Montelukast Sodium	✓	✓	Anti-histamine
Moxifloxacin HCl	✓	—	Antibiotic

✓ = Available

API PORTFOLIO:

Product	USMDF	CEP / EUDMF	Therapeutic Category
Nalidixic Acid	✓	✓	Antibiotic
Nimesulide	✓	✓	NSAID
Nitrofurantoin Anhydrous	—	CEP	Anti-bacterial
Nitrofurantoin Anhydrous Crystals	✓	CEP	Anti-bacterial
Nitrofurantoin Anhydrous Macrocrystals	✓	✓	Anti-bacterial
Nitrofurantoin Monohydrate	✓	CEP	Anti-bacterial
Paliperidone	✓	✓	Anti-psychotic
Pimozide	✓	—	Anti-psychotic
Ramipril	✓	✓	Anti-hypertensive
Rizatriptan Benzoate	✓	✓	Anti-migraine
Solifenacin Succinate	✓	✓	Anti-muscarinic
Tigecycline	✓	✓	Anti-microbial
Topiramate	✓	✓	Anti-epileptic

✓ = Available

US ANDA PORTFOLIO - APPROVRD:

Sr. No.	Approved & Commercialized Products	ANDA Holder	Mfg. Facility - API's
01.	Montelukast Sodium Tab 10 mg	Unimark	Unimark
02.	Montelukast Sodium Chew Tab 4.5 mg	Unimark	Unimark
03.	Lisinopril Tab 2.5, 5, 10, 15 and 20 mg	Partnership	Unimark
04.	Ramipril Cap 1.25, 2.50, 5 and 10 mg	Partnership	Unimark

Sr. No.	Filed (Pending Approval) Products	ANDA Holder	Mfg. Facility - API's
01.	Benazepril Tab	Partnership	Unimark
02.	Topiramate Tab	Partnership	Unimark
03.	Lanthanum Carbonate Chew Tab	Partnership	Unimark
04.	Lanthanum Carbonate Powder For Suspension	Partnership	Unimark
05.	Rizatriptan Tab 5, 10 mg	Unimark	Unimark
06.	Dronedarone Tab 400 mg	Unimark	Unimark
07.	Buspirone Tab 5, 10, 15, 30 mg	Unimark	Unimark
08.	Febuxostat Tab 40, 80 mg	Unimark	Unimark
09.	Nitrofurantoin Susp 25 mg/5 ml	Unimark	Unimark
10.	Solifenacin Tab 5, 10 mg	Unimark	Unimark
11.	Flecainide Tab 50, 100, 150 mg	Unimark	Unimark
12.	Moxifloxacin Tab 400 mg	Unimark	Unimark
13.	Armodafinil Tab 50, 150, 250 mg	Unimark	Unimark

USDMF - FILINGS PRODUCT PORTFOLIO:

Sr. No.	Products	DMF No.
01.	Albendazole	17754
02.	Armodafinil	24945
03.	Benazepril Hydrochloride	19479
04.	Buspirone Hydrochloride	25361
05.	Candesartan Cilexetil	23775
06.	Cilastatin Acid	28321
07.	Darifenacin Hydrobromide	26419
08.	Dronedaron Hydrochloride	25669
09.	Eszopiclone	23476
10.	Febuxostat	25761
11.	Flecainide Acetate	19272
12.	Flecainide Acetate (Process B)	23192
13.	Hydroxychloroquine Sulfate	23593
14.	Lamotrigine	22813
15.	Lanthanum Carbonate	23254
16.	Lisinopril	17626
17.	Meloxicam	18286
18.	Montelukast Sodium	20564
19.	Montelukast Sodium (NI)	21893

Sr. No.	Products	DMF No.
20.	Montelukast Sodium (Process A)	23837
21.	Montelukast Sodium (Process B)	24324
22.	Montelukast Sodium (Process C)	26439
23.	Moxifloxacin Hydrochloride	25362
24.	Nitrofurantoin ANHD	23500
25.	Nitrofurantoin ANHD (Macro)	26176
26.	Nitrofurantoin ANHD Crystals	23570
27.	Nitrofurantoin Monohydrate	23501
28.	Olmesartan Medoxomil	23617
29.	Paliperidone	23338
30.	Pimozide	22747
31.	Propofol	23723
32.	Ramipril	19522
33.	Rizatriptan Benzoate	24177
34.	Solifenacin Succinate	23965
35.	Tenofovir Disoproxil Fumarate	26319
36.	Tigecycline Tech	22247
37.	Topiramate	20932
38.	Topiramate (Process A)	23349

COS / CEPs - PRODUCT PORTFOLIO:

Sr. No.	Produts	Ref. No.	Certificate No.
01.	Montelukast Sodium (MNS)	CEP 2012-288	R0-CEP 2012-288-Rev 01
02.	Montelukast sodium B NI	CEP 2012-331	R0-CEP 2012-331-Rev 00
03.	Flecainide Acetate (CHN)	CEP 2006-005	R1-CEP 2006-05-Rev-01
04.	Buspirone Hydrochloride	CEP-2012-361	RO-CEP-2012-361-Rev.00
05.	Ramipril	CEP 2006-006	R1-CEP 2006-006-Rev-01
06.	Nitrofurantoin Anhydrous	CEP 2011-108	RO-CEP 2011-108-Rev.00
07.	Nitrofurantoin	CEP-2011-108	RO-CEP-2011-108-Rev.00
08.	Benazapril Hydrochloride	CEP 2008-273	RO-CEP 2008-273-Rev 01
09.	Nimesulide	CEP 2001-350	R1-CEP 2001-350-Rev-02
10.	Flecainide Acetate (DIPE)	CEP 2009-289	RO-CEP 2009-289-Rev-01
11.	Meloxicam	CEP 2008-301	RO-CEP-2008-301-Rev-01
12.	Lamotrigine	CEP 2009-278	RO-CEP-2009-278-Rev-00
13.	Lisinopril Dihydrate	CEP 2004-063	R1-CEP 2004-063-Rev-02
14.	Albendazole	CEP 2001-448	R1 –CEP 2004-064-Rev00

QC / QA - ANALYTICAL CAPABILITIES:

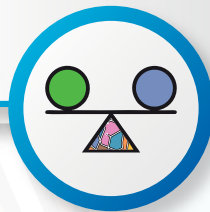
CHARACTERIZATION

- API's
- Impurities
- Photo Stability
- Degradants
- Particle Size
- Nitrosamine Studies



STABILITY

- ICH Storage
- Forced Degradation
- Sterile



METHODS

- Development
- Validation
- Stability Indicating
- Cleaning
- Particle Size
- Method Validation



INSTRUMENTATION

- NMR(300MHz)
- LCMS(Quadruple)
- ICP
- Particle Size
- Analyzer
- GC MS
- XRPD
- DSC
- TGA
- Preparative PLC
- System
- HPLC



MANUFACTURING FACILITY OVERVIEW:



Land Area : **22,774 sq. mtr.**

Manpower : **452**

Manpower : **240**

Operations

: **1995**

Current Capacity

: **226 KL**

Clean Rooms

: **11**

Expected Capacity

: **390 KL**

(2024)

Vapi Plant



Vapi Plant



Vapi Plant



Vapi Plant



Vapi Plant



Vapi Plant



Vani Plant



Vapi Plant



Vapi Plant





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A SHAMROCK PHARMAGROUP COMPANY

THANK YOU

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