



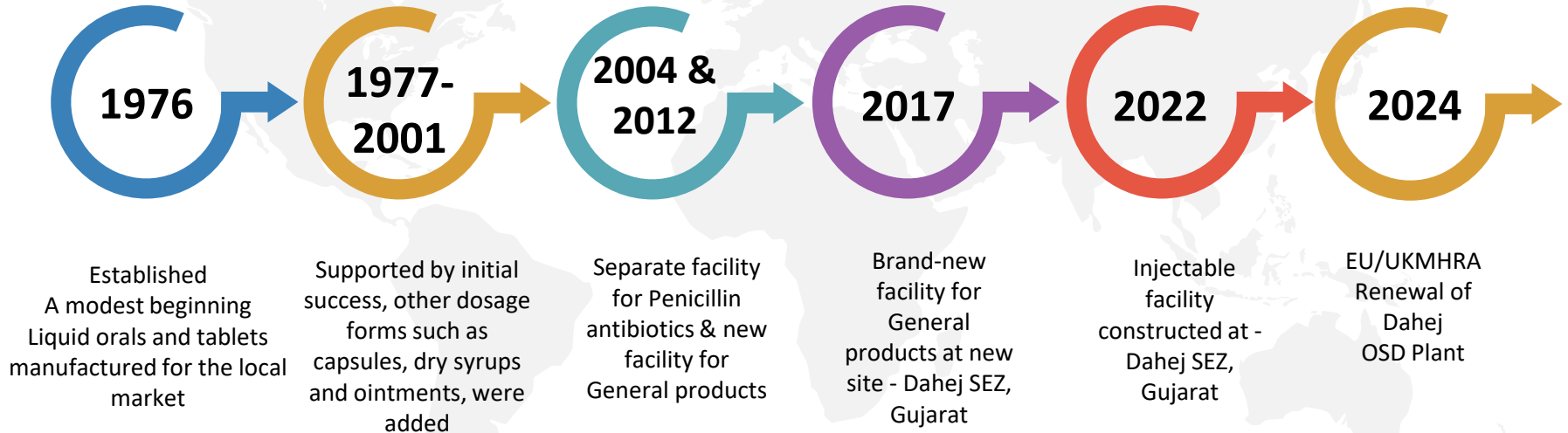
Milân Laboratories (India) Pvt. Ltd.

Corporate Profile



Scan here for our
Brochure & Products list

Introduction To Milan



**All replete with modern state of the art and most
current cGMP compliant systems**

Manufacturing Infrastructure – Panvel

Dosage Forms

SRA Approvals

General
Plant 1



Liquid Orals,
Creams and
Ointments
(General Block)

EU GMP,
TGA,
SAHPRA

General
Plant 2



Tablets,
Capsules, Dry
Syrups
(General Block)

UK MHRA, USFDA,
EU GMP,
WHO-PQ, SAHPRA
TGA

Penicillin
Plant



Tablets,
Capsules, Dry
Syrups
(Penicillin Block)

UK MHRA,
EU GMP,
SAHPRA

1st UK MHRA Approval Granted in 2008

**Successfully retained thereafter, with addition of
many other SRA Approvals**

**Over 14 years of experience in Stringent Regulated
Markets**

**R&D facility recognition by DSIR- Government of
India (DSIR - Department of Scientific and
Industrial Research)**

SITE 1

Navi Mumbai
Maharashtra

Product Segments & Global Presence

Product Segments

Oral FDFs from General and Penicillin section, as well as topical creams and ointments from the General section, across multiple therapeutic areas such as:

•Antibiotics

•Anti-hypertensives

•Anti-diabetics

•Anti-depressants

•Anti-asthmatics

Analgesics & Antipyretics

•Laxatives

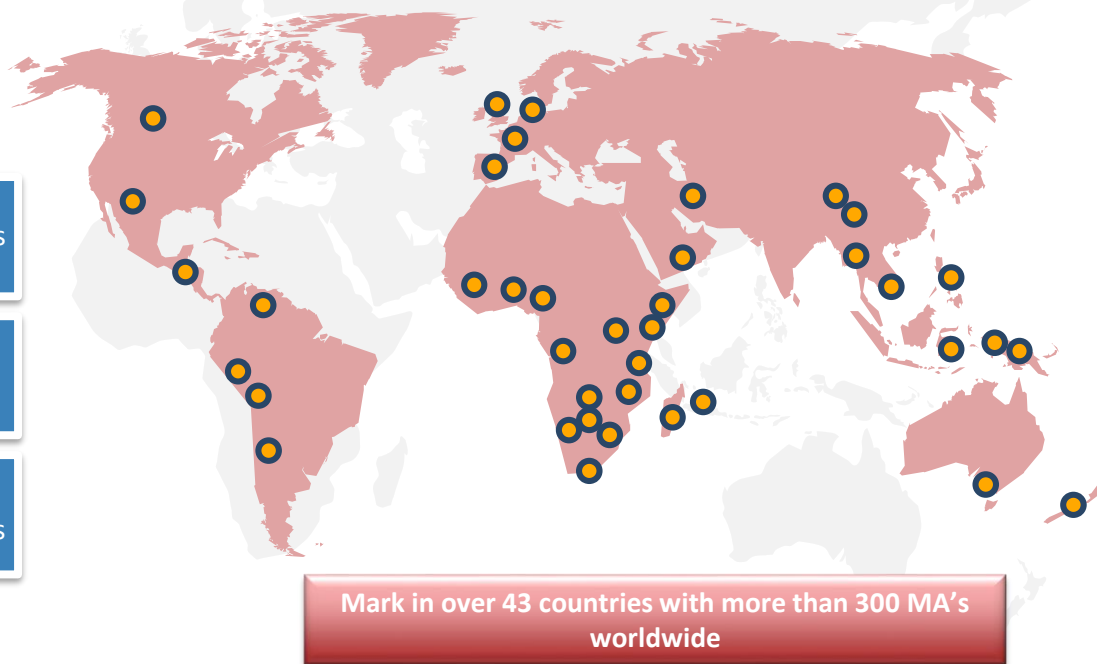
•NSAID's

•Nasal decongestants

•Cough Syrups

•Antacids, etc.

Geographic Presence



Manufacturing Infrastructure - Dahej



Manufacturing Infrastructure - Dahej



Dosage Forms

SRA Approvals

General
Plant



Tablets
(General
Block)

UK MHRA,
USFDA,
SAHPRA

SITE 2

Dahej SEZ
Gujarat

General
Plant



Low RH &
Effervescent
Tablets

UK MHRA,
USFDA,
SAHPRA

Injectable
Plant



Injectables

WHO GMP

Diversified And Built A Cutting Edge

Sterile Injectable

&

Low RH & Effervescent Tablet Facility

At The Dahej Site

Manufacturing capacities – OSD, Liquids & Semisolids

Site 1 | General Plant 1

Process	Equipment (nos.)	Total Equipment Capacity	Monthly Output
Liquid Section			
Manufacturing	1	2,000 Litres	950,000 Bottles
Filling	1	3,800 Bottles/hour	
Cream / Ointment Section			
Manufacturing	1	500 Kgs	900,000 Tubes
Filling	1	3,600 Tubes/hour	

Site 1 | General Plant 2

Process	Equipment (nos.)	Total Equipment Capacity	Monthly Output
Tablet Section			
Granulation	2	1,250 Litres	90,000,000 Tablets
Blending	3	2,550 Litres (2 x 1250 + 1 x 150)	
Compression	3	405,000 Tablets/hour	
Capsule Section			
Filling	1	90,000 Capsules/hour	3,450,000 Capsules
Dry Syrup Section			
Filling	1	2,000 Bottles/hour	240,000 Bottles

Manufacturing capacities

Site 1 | Penicillin Plant

Process	Equipment (nos.)	Total Equipment Capacity	Monthly Output
Tablet Section			
Mixing	1	1,000 Litres	65,000,000 Tablets
Capsule Section			
Mixing	1	1,500 Litres	75,000,000 Capsules
Filling	1	150,000 Capsules/hour	
Dry Syrup Section			
Mixing	1	1,000 Litres	1,225,000 Bottles
Filling	1	2,500 Bottles/hour	

Site 2 | Dahej - General Plant

Process	Equipment (nos.)	Total Equipment Capacity	Monthly Output
Tablet Section			
Granulation	4	4,000 Litres	1,500,000,000 Tablets
Blending	4	8,250 Litres (3 x 1250 + 1 x 4500)	
Compression	4	3,000,000 Tablets/hour	

Manufacturing capacities – OSD, Liquids & Semisolids

Site 2 | Low RH & Effervescent Tablet

Process	Equipment (nos.)	Total Equipment Capacity	Monthly Output
Tablet Section			
Granulation	1	600 Litres	4,600,000 Tablets
Blending	1	600 Litres	
Compression	1	192,000 Tablets/day	

The SVP Facility



The SVP Facility

Intro

- Located at Dahej SEZ, Gujarat
- Features state of the art aseptic processing technology, equipment and systems with minimum human intervention for manufacturing small volume parenterals
- Designed considering compliance to stringent global regulatory standards
- All process equipment's designed to comply latest cGMP standards and 21 CFR Part 11 requirements, control systems of all equipment's have UPS backup
- Integration and synchronisation considered for process equipment's

Product Categories

- Sterilized Liquid Injectables in Vials
- Sterilized Lyophilized Injectables in Vials
- Terminally Sterilized Liquid Injectables in Ampoules and Vials

Manufacturing Capacities - SVP

Site 2 – Injectable (Vial)		
Process	Total Equipment Capacity	Monthly Output
Vial Manufacturing	600 Litres	2,800,000 Vials 480,000 Lyophilised vials
Vial Filling & Sealing	240 Vials/min	
Lyophilizer	15 sq. m	

Site 2 – Injectable (Ampoule)		
Process	Total Equipment Capacity	Monthly Output
Ampoules Manufacturing	600 Litres	3,600,000 Ampoules
Ampoules Filling & Sealing	300 Ampoules/min	
Terminal Sterilisation		

USP's – SVP Facility



Water System

Vapour Compressor System

Manufacturer: Bram-cor

Produce Water for Injection – 2300 LPH



Ampoule Filling system

Manufacturer: Truking Technology Limited

Washing: 7 cycle for washing with final rinse with WFI

Filling Capacity: 8 head filling machine with 300 ampoules/min for 2 ml ampoule

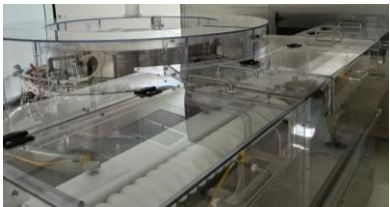
Auto inprocess sampling system



Ampoule Manufacturing and Holding System

Vessel Capacity: 6 Vessels, with capacity of minimum 10 litres to maximum 600 litres of manufacturing and holding capacity

Automatic online CIP and SIP system in all vessels



Vial Filling System

Manufacturer: IMA Life

Filling Capacity: 6 head filling machine with 300x2 ml Vial/min

100% Check weighing system of filled vials

USP's – SVP Facility



Lyophilizer System

Manufacturer: Tofflon

Capacity: 16.21 square meter 300 kg condenser Ice capacity, having automatic row by row loading and unloading system



Terminal Sterilizer

Capacity: 1,728 litres



HPHV Steam Steriliser

Manufacturer: Machine fabrik Pvt. Ltd.

Capacity: 324 litres



Incubators

Capacity: 4 BOD incubators 1,400 litres each

Walk in incubator – 2x15,000 litres and 2xCombi chamber

Incubators 500 litres each

Product Segments - SVP

Vasodialator	Seizure Prophylaxis	Anti-Ulcer	Pain Management	Nutritional Supplement	Nuromuscular Agent Reversal	Muscle Relaxant
Anti-Asthmatic	Anti-hypotensive/hypertensive	Analgesic	Anti-Psychotic	Sedative	Antiallergic	Anasthetic
Fluid therapy	Anti-Emetic	Anti-Convulsant	Antiepileptic	Diuretic	Mucolytic Agent	Iron Deficiency Anemia
	Anti-Inflammatory	Anti-Fibrinolytic	CNS Stimulant	Anti-Schizophrenia	Anti-Parkinson	
		Corticosteroid	Anti-Spasmodic	Anti-Malarial		

Capabilities

RA

- Dedicated team for product registrations and coordination with drug authorities
- Qualified individuals constantly updating their knowledge and information bank
- Efficient in query solving and completing registration formalities within timelines
- Adept at making ACTD, CTD as well as eCTD dossiers and other country specific formats

R&D

- Dedicated Research and Development Facility
- Constantly developing generic/off-patent formulations
- Formulation improvisation & process optimisation, ensuring better quality and products
- Engaged in the analytical method development and validation

In the last 3 years - Over 50 generic/off-patent formulations developed, around 40 projects in the pipeline

Recognition by DSIR- Government of India (DSIR - Department of Scientific and Industrial Research)

Capabilities

QC

- Well-equipped QC laboratory, full-fledged Microbiology section
- Analytical data management through qualified LIMS (Laboratory Information Management System)
- Lab Solutions software for connecting key analytical instruments
- Equipped with a number of sophisticated Instruments

QA

- Quality Assurance Management System events handled using a Qualified Caliber QAMS Software Includes Change Management, Deviation Management, Complaints handling, CAPA, Audit Management, etc.
- Documents controlled using DMS (Data Management) Software
- Batch record preparation and issuance through BRM (Batch Record Management) Caliber Software
- E Schedule & Nichelson training software's used
- Data Integrity ensured at all levels

Advantages of Milan

Scalability

5 Acres of free Area for future expansion

Existing relationships

API Support from reputed API manufacturers

Experience in handling Tech Transfers and CDMO activities for Multinationals:

- Zentiva
- Aspen

Seeking opportunities with multiple partners for in-licensing deals / expansion in regulated markets

New Initiatives

Injectables

- Ampoules
- Vials
- Lyophilized Products

Tablets:

- Effervescent



Thank you

For any information or clarification, please visit

www.milanlabs.com

Or drop your queries at

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