



**PENEM**

**PHARMACHEMI PVT. LTD.**

**(A SHAMROCK PHARMA GROUP)**

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**A INTEGRATED CARBAPENEMS FACILITY  
FROM CHEMICAL TO VIALS**

## COMPANY OVERVIEW:

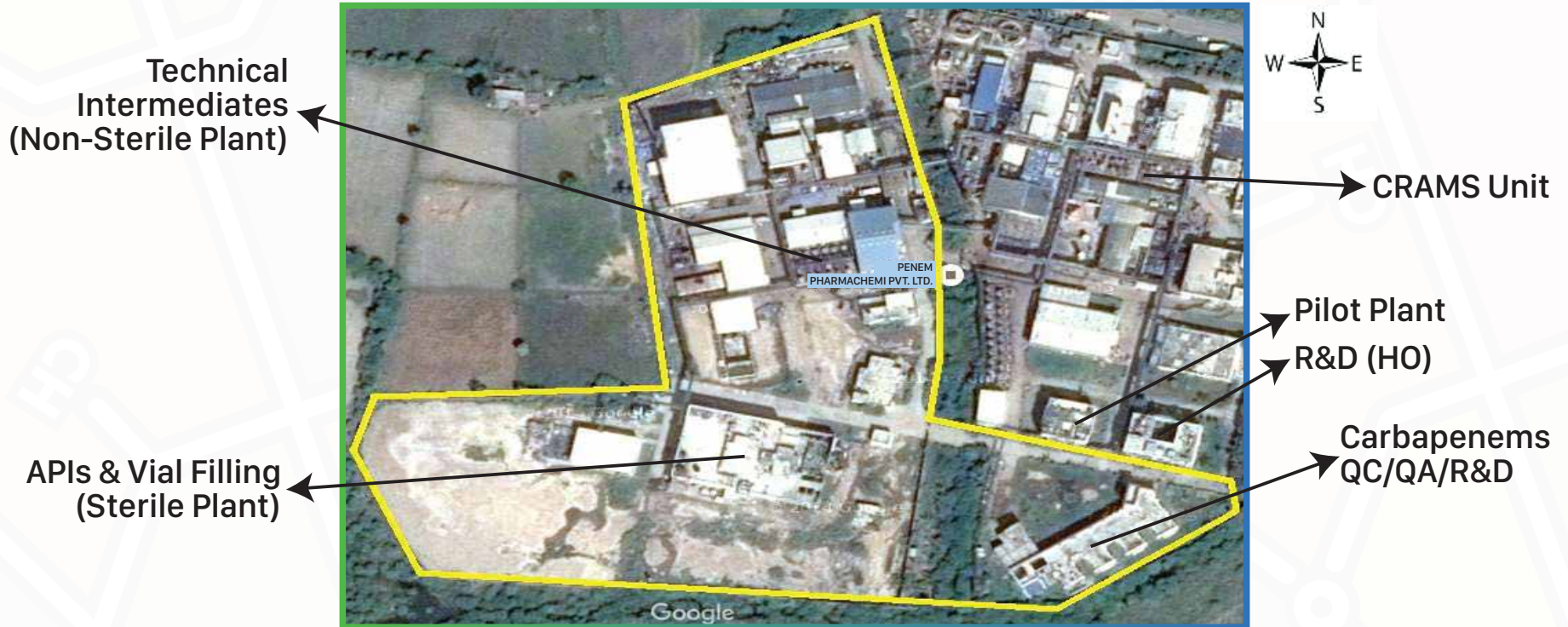
- **Penem Pharmachemi Pvt. Ltd.** is a manufacturing company which is dedicated facility for carbapenems. The company started the manufacturing operations in 2019 & built up a state of art carbapenem facility which is completely integrated from producing technical APIs, its intermediates as well as right till sterile APIs to injectable virus including lyophilization. The company has a short but strong manufacturing record and the plant was inspected and approved by **UK MHRA, TGA Australia** and was about to be audited by **US FDA & EU** before the covid period. The company was recently acquired by **Shamrock Pharma Group** and is now 100 percent 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 carbapenem.
- The state-of-the-art facility is designed to cater to all regularity markets including **US, EU, CANADA, UKMHRA, PMDA (Japan), KFDA and ROW.**
- The facility is fully compliant GMP facility.

## BUSINESS STRATEGIES & STRENGTH:

- It is the largest integrated plant facility which produces from the basic chemical stage to technical carbapenems and then also having integrated sterile and lyophilization facility till vial filling injectables.
- We have a dedicated **R&D** for carbapenems & fully equipped laboratory for process development, microbiological test and synthesis. We have already filled **16 DMFs** for carbapenems & readily available for filing as well. We have filed **ANDA** out of which two **ANDA's** are already approved for **Meropenem & Imipenem**. We are building a dedicated oral carbapenem facility for "**FAROPENEM**" which is completely starting from the basic compound.



## CARBAPENEM: SITE LAYOUT



## BAVLA PLANT: AHMEDABAD

### Plant Facilities Details

Manufacturing capabilities - Carbapenems, Technical, Intermediates, Raw Material, Sterile, APIs, Lyophilization & Injectable Vials.



#### Capacities: Per Annum

Technical : **20 Tons**

Sterile APIs : **18 Tons**

Sterile vial filling injections : **18 millions**

Land Area : **30150 sq. mtr.**

Manpower : **130 to 140**

No. of Blocks : **12 Nos.**

Operations : **2016 / 2018**

Manufacturing Capacity : **180 KL**

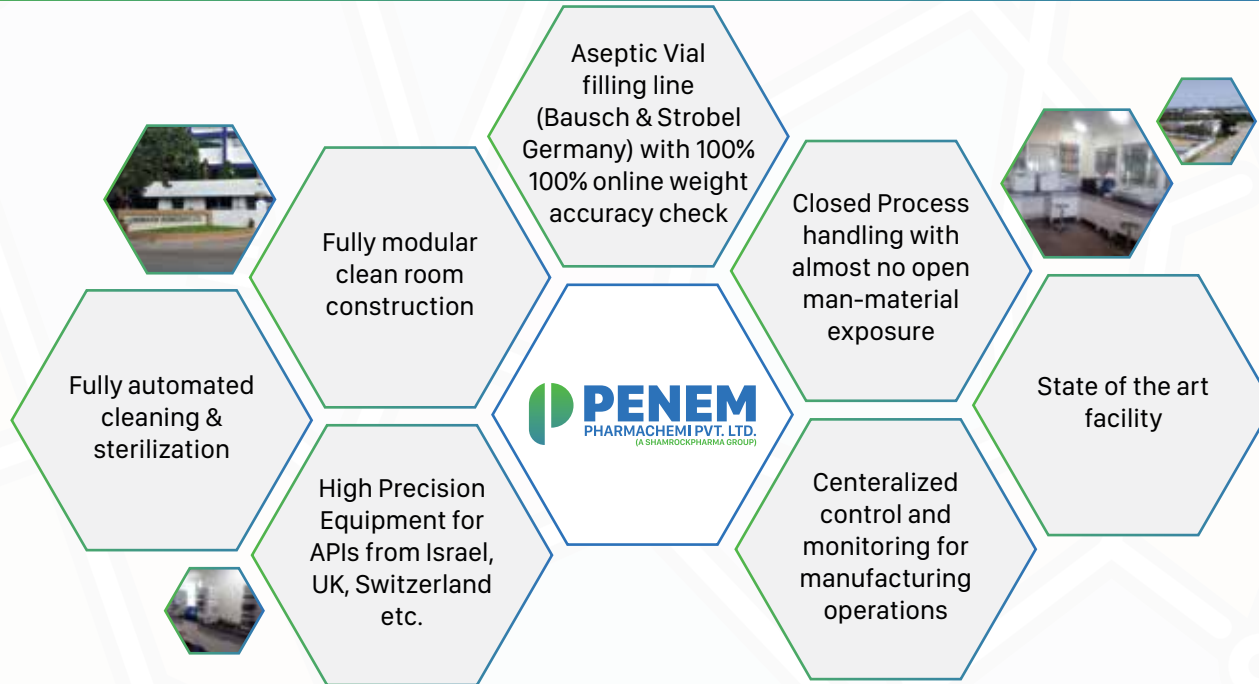
Manpower : **30 Scientists**

Employee / Workers : **120**



## BAVLA PLANT: MANUFACTURING SITE

### Plant Facilities Details



## CARBAPENEMS - PRODUCT PORTFOLIO:

ORAL CARBAPENEMS	KDMF	JDMF
Faropenem Sodium	UP	UP

STERILE APIs	US DMF	EU DMF
Meropenem	✓	✓
Doripenem	—	—
Imipenem	✓	✓
Cilastatin Sodium	✓	✓
Mixture of Sterile Imipenem, Cilastatin Sodium & Sodium Bicarbonate	✓	✓
Mixture of Sterile Meropenem and Sodium Carbonate	✓	✓

## CARBAPENEMS - PRODUCT PORTFOLIO:

TECHNICAL / NON-STERILE	US DMF	US DMF	EU DMF
Cilastatin Acid	✓	*	*
Doripenem	✓	*	*
Ertapenem	✓	UP	UP
Imipenem	✓	*	*
Meropenem	✓	UP	UP

STERILE VIALS (FINISHED DOSAGE FORMS)	DOSSIER
Meropenem 500 mg /1000 mg	✓
Imipenem + Cilastatin 250 mg + 250 mg / 500 mg + 500 mg	✓
Ertapenem 1000 mg	UP
Doripenem 250 mg / 500 mg	UP

UNDER DEVELOPMENT CARBAPENEMS
Biapenem
Lenapenem
Panipenem/betamipron
Sulopenem
Tebipenem
Tomopenem

 = Available    
  = Under Filing    
 UP = Under Preparation



## CARBAPENEM - PRODUCT PORTFOLIO:

### US DMF's Filings

Sr. No.	Product Name	DMF No.
01.	Doripenem Crude	028210
02.	Meropenem Crude	025869
03.	Imipenem Crude	028296
04.	Doripenem Sterile	028280
05.	Meropenem Sterile	028279
06.	Imipenem Sterile	028356
07.	Cilastatin Sodium Sterile	028365
08.	Sterile Mix of Imipenem, Cilastatin Sodium & Sodium Bicarbonate	028381
09.	Sterile Mix of Meropenem & Sodium Carbonate	028382

### ANDA's Approved

Sr. No.	Product Name	ANDAs
01.	Imipenem + Cilastatin 250 + 250mg & 500 + 500 mg (Powder for solution for Injection/Infusion)	Approved
02.	Meropenem 500 mg & 1000 mg (Powder for solution for Injection/Infusion)	Approved



## BAVLA PLANT:



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# THANK YOU



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