

# BROOKS LABORATORIES LTD

*Dedicated Carbapenem Facility Presentation*

# Brief Company Background

- ❖ Brooks Laboratories was incorporated in 2002.
- ❖ Company has an experience of more than 14 years in the field of Pharmaceutical Manufacturing.
- ❖ Brooks has established itself in the field of injectables and specializes in formulations of Co-Amoxiclav Oral solids.
- ❖ Last 12 years Brooks has earned a good reputation in terms of quality manufacturing process.
- ❖ Brooks does contract manufacturing for Reputed companies like – Zydus Cadila, Alkem, Intas, Aristo, Wockhardt etc.
- ❖ Brooks is ISO 9001:2008 Certified Company.

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# Manufacturing Facility

- ❖ Brooks has 2 manufacturing units
  - Unit I – Baddi, Himachal Pradesh
  - Unit II – Baroda, Gujarat.
- ❖ Unit I Baddi, Himachal Pradesh
  - Injections (Liquid & Dry Powder)*
  - Tablets*
  - Dry Syrup*
  - Eye / Ear Drops*
- ❖ Unit II Baroda, Gujarat
  - Dedicated Carbapenem Injection Plant*

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# Brooks Laboratories Ltd.

*Dedicated Carbapenem Facility*



# Brooks Laboratories – Unit II Baroda

## Highlights of Baroda Plant – Dedicated Plant for **CARBAPENEMS**

- ❖ Unit II Located at Baroda, which is very close to City and located on NH8 Mumbai - Baroda Highway.
- ❖ The new plant is very well connected to major cities of India by roadways, airways and railways.
- ❖ 45 Minutes is the Flying time from Mumbai to Baroda.
- ❖ The Plant has abundant supply for Water, Fresh Air and Electricity.
- ❖ Some big and reputed pharma companies like Sun Pharmaceuticals and Alembic have manufacturing units in Baroda.
- ❖ Baroda being a Cosmopolitan city has good Educational Institutes hence has got good talent and degree holders for Pharmaceutical Industry. Talented Manpower Selection is easier and good.

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# Brooks Laboratories Ltd. – Unit II Baroda

## Highlights of Baroda Plant – Dedicated Plant for **CARBAPENEMS**

- ❖ The new plant in Baroda is built on a land spread measuring 100,000 sq. meters.
- ❖ The built up Area is 11000 Sq. Meters, built on Ground plus one floor.
- ❖ Independent AHUs with latest technology and HEPA filters (EU14) at supply and return in the entire manufacturing areas.
- ❖ The AHU employs Bag-in / Bag-out system
- ❖ The plant has machines which are 21 CFR compliant.
- ❖ The Plant houses separate areas for Production, Quality Control, Microbiology, Service Area, Utility Area, Water System, Administration Blocks, Laundry Area, Canteen for Factory Staff, Training Centre for Staff and a Separate Formulation Development and Pilot Area.

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# Brooks Laboratories Ltd. – Unit II Baroda

## Highlights of Baroda Plant – Dedicated Plant for **CARBAPENEMS**

- ❖ The Plant operations are controlled by BMS (SCADA).
- ❖ System has been Designed addressing Data Integrity subject at the highest level in the entire plant operations.
- ❖ The plant has been designed for a logical and easy flow of Man and Material.
- ❖ The new plant at Baroda has all the features of personnel and environment safety.

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# Brooks Laboratories – Unit II Baroda

*Dedicated Plant for CARBAPENEMS*

The facility has been designed and is constructed and built with a view to comply to International cGMP & ICH Guidelines.

- ❖ US FDA
- ❖ TGA-Australia
- ❖ UK MHRA
- ❖ MCC- South Africa,
- ❖ WHO GENEVA and
- ❖ Other Regulatory bodies of Latin America like ANVISA-Brazil, INVIMA-Columbia etc.

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# Brooks Laboratories – Unit II Baroda

*Dedicated Plant for CARBAPENEMS*

Capacity – Dry Powder Injections – 50 Million vials per year



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# Brooks Laboratories – Unit II Baroda

*Dedicated Plant for CARBAPENEMS*

## TESTING LABORATORY

- ❖ Independent well equipped Testing Laboratory.
- ❖ Adequate well experienced staff having hands-on expertise on Analytical Method Development.
- ❖ All major equipment installed viz. HPLC, GC, Osmometer, Liquid Particle counter, Polarimeter, K F Instrument, UV Spectrophotometer etc.
- ❖ Separate Air Handling Units for QC and Microbiological Testing Area.

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# Brooks Laboratories – Unit II Baroda

*Dedicated Plant for CARBAPENEMS*

## SITE TRANSFERS / CONTRACT MANUFACTURING

- ❖ Brooks' Baroda plant is fully geared in terms of machines and man-power to execute a Site Transfer and long terms supplies of quality products under Supply Agreement.
- ❖ The Manufacturing plant can take up contract manufacturing for, Injections.
- ❖ Highly qualified team for Technology Transfer can execute the Site Transfer project with utmost professionalism and achieve desired timelines.

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# Formulation Development

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- ❖ Adequate well experienced staff having hands-on expertise in product development.
- ❖ Formulation development is a part of R & D center, which is housed in the new manufacturing facility.
- ❖ Separate Analytical Method Validation Cell and Technology Transfer Cell in place.
- ❖ Capability to develop Generic equivalence of brands of US & EU markets.

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# Regulatory Affairs

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- ❖ Regulatory department has an expertise to develop Dossiers / ANDAs in CTD / eCTD and ACTD formats for Regulated and Semi Regulated markets.

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# Raw Material Sourcing

- ❖ Identified and Selected API suppliers with established DMF source.
- ❖ Company has already signed Long Term Supply Agreements with various suppliers across the globe for Supply of DMF / COS grade API.
- ❖ The company is considering only those Vendors which are able to offer Product DMF.

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# Recent Pictures of the Plant

*Dedicated Injection Plant for Carbapenems*







Reception and Administration Block

Conference cum  
Training Hall





Mirror Glaze EPOXY Flooring in Production Area



Injection Washing Tunnel



Injection Washing Tunnel

# Automatic Dry Powder Injection Filling Machine



Rubber Bung Washing  
Autoclave





Stability Chambers



ETP Plant



# Dedicated Plant - *CARBAPENEMS*





*Thanks for your attention.*

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