

# Creating a world of Niche Injectables



**GLAND PHARMA LIMITED**  
(A FOSUN PHARMA Company)



# about GLAND

Gland Pharma is an exclusive manufacturer of Parenterals from India developing niche products for Indian and Global Pharmaceutical Markets. Gland Pharma pioneered Heparin Technology in India and has a position of leadership in the Glycosaminoglycans (GAGs) range of Molecules

## State-of-the-Art Facilities

### World Class Manufacturing

#### Flagship Injectable Plant

Dundigal, Hyderabad 

##### Capacities

- ▶ Vials: 240 million units/year
- ▶ Lyo Vials: 48 million units/year
- ▶ Ampoules: 60 million units/year
- ▶ PFS: 60 million units/year
- ▶ Bags: 5 million units/year
- ▶ Ophthalmics: 45 million units/year

##### Capabilities

###### 12 Manufacturing Lines

- ▶ 6 Vial Lines with 8 Lyophilizers (1 - 100 ml)
- ▶ 1 Ampoule Line (1 - 10 ml)
- ▶ 2 PFS Lines (0.5 - 5 ml)
- ▶ 2 Bag Lines (Fill volume 50 - 500 ml)
- ▶ 1 Ophthalmic Line

#### Penems Plant

Pashamylaram, Hyderabad

##### Capacities

###### 2 Manufacturing Lines

- ▶ Lyo Vials - 8 million units/year
- ▶ Dry Powder - 4 million units/year

##### Capabilities

- ▶ 1 Vial Line - Powder Filling (2 - 100 ml)
- ▶ 1 Vial Line with 2 Lyophilizers (2 - 100 ml)

#### Pashamylaram Plant

Pashamylaram, Hyderabad

##### Capacities

- ▶ Vials: 132 million units/year
- ▶ Lyo Vials: 18 million units/year
- ▶ Ampoules: 120 million units/year

##### Capabilities

###### 8 Manufacturing Lines

- ▶ 1 Vial Lines (2 - 100 ml)
- ▶ 1 Vial Lines with 3 Lyophilizers (2 - 100 ml)
- ▶ 2 Ampoule Lines

#### Oncology Plant

Visakhapatnam

##### Capacities

- ▶ Vials 11 million units/year
- ▶ Lyo Vials 5 million units/year

##### Capabilities

- ▶ 3 Lines with 4 Lyophilizers (2 - 100 ml)
- ▶ Filling at 5°C temperature
- ▶ Manufacture of products sensitive to SS liners



# Highlights

- A global Injectable player
- Leading Injectable manufacturer with in-house API development & manufacturing facilities
- Pioneers in Heparin technology in India
- First Indian Company to set up a State-of-the-Art facility for Pre-filled Syringes (PFS)
- First US FDA approved Liquid Injectable Plant in India
- US FDA approved since 2003; also approved by MHRA (UK), TGA (Australia), BGV (Hamburg, Germany) and ANVISA (Brazil)
- Marketing partnerships in over 90 countries and 5 continents
- Dedicated Oncology Facility Approved by US FDA, Health Canada, TGA (Australia), AGES (Austria), BGV (Hamburg, Germany) and ANVISA (Brazil)

## Vertically integrated **One-Stop Shop**

### Active Pharmaceutical Ingredients - APIs

#### Development

- ▶ Synthetic Chemistry
- ▶ Analytical Chemistry

#### Manufacture

- ▶ API scale up
- ▶ Multiple Suites with various Batch Sizes
- ▶ API facilities approved by EDQM & US FDA

### Finished Product

#### Development

- ▶ Formulation development
- ▶ Analytical development
- ▶ Method development
- ▶ Packaging development

#### Manufacture

- ▶ Finished product manufacturing
- ▶ Quality Control & Quality Assurance
- ▶ Packaging
- ▶ Warehousing
- ▶ Shipping & Logistics



## Quality Control & Quality Assurance

- Well established quality systems
- Highly experienced personnel
- Well-equipped in-house Quality Lab



## Research & Development

### Synthetic R&D

- Process development for niche APIs
- Patent non-infringing process
- Pilot and scale up studies

### Formulation R&D

- Formulation development
- Pre-formulation studies
- Lyo-cycle development and scale up

### Analytical R&D

- Analytical method development and validation
- Impurity determination and characterization
- Primary reference standard preparation and standardization



## Services

### Contract Manufacturing

- ▶ PFS
- ▶ Vials (Lyo & Liquids)
- ▶ Ampoules
- ▶ IV Bags
- ▶ Ophthalmics

### Contract Research & Development

- ▶ Synthetic Chemistry
- ▶ Formulation Development
- ▶ Analytical Methods and Validations
- ▶ Stability Studies

### Out-licensing of Products

- ▶ Regulated Markets
- ▶ Semi Regulated Markets

### Regulatory

- Experienced in generic CTD/eCTD regulatory filings

### Other Services

- Clinical Batch Manufacturing



# Global Generic Injectable Player Providing Total Solutions

## Manufacturing Facilities approved by

- FDA - USA
- HC - Canada
- UK - MHRA
- WHO - Geneva
- TGA - Australia
- BGV - Hamburg (Germany)
- SAHPRA - South Africa
- SUKL - Czech Republic
- ANVISA - Brazil
- INVIMA - Colombia
- MOH - Russia
- NAFDAC - Nigeria
- NDA - Uganda
- PPB - Kenya
- FMHACA - Ethiopia

In over  
**60**  
countries  
& **5**  
continents



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