

# Creating a world of **Niche Injectables**



**GLAND PHARMA**



# 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: 250 mil units/year
- › Ampoules: 150 mil units/year
- › PFS: 40 mil units/year
- › Lyo Vials: 30 mil units/year
- › Bags: 30 mil units/year
- › Ophthalmics: 50 mil units/year

#### Capabilities

##### 12 Manufacturing Lines

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

#### Penems Plant

Pashamylaram, Hyderabad

#### Capacities

- 2 Manufacturing Lines
- › Lyo Vials - 8 mil/year
- › Lyo Vials - 5 mil/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: 200 mil/year
- › PFS: 100 mil/year
- › Lyo Vials: 50 mil/year
- › Ampoules: 100 mil/year

#### Capabilities

##### 8 Injectable Manufacturing Lines

- › 2 Vial Lines (2 - 100 ml)
- › 2 Vial Lines with 6 Lyophilizers (2 - 100 ml)
- › 2 PFS Lines (0.5 - 10 ml)
- › 2 Ampoule Lines

#### Oncology Plant

Visakhapatnam

#### Capacities

- › 1.4 mil units/year

#### Capabilities

- › 2 Lines with 3 Lyophilizers (2 - 100 ml)
- › Filling at 5°C temperature
- › cRABS in Grade-B area
- › 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, approved by TGA, BGV, EU SUKLA, UK MHRA
- ▣ Marketing partnerships in over 90 countries and 5 continents
- ▣ Dedicated Oncology facility US FDA approved in 2014

## 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

- Quality systems well established
- **Highly experienced Quality Control 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 Vials
- ▶ 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

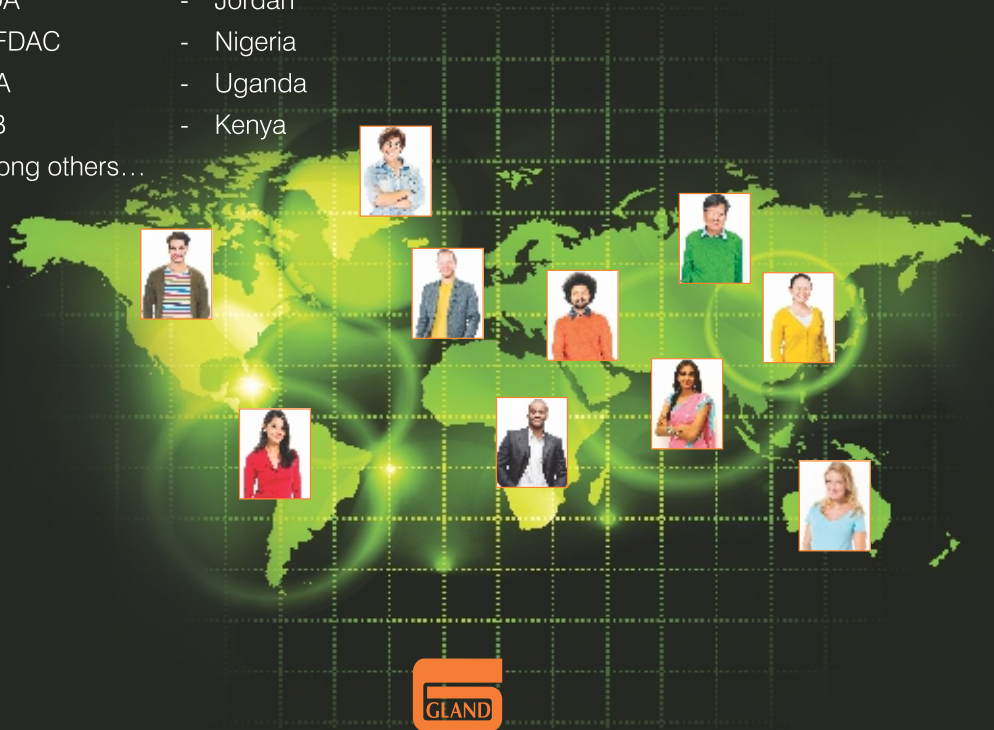
# “Global Generic Injectable Player providing total solutions”

Manufacturing “Facilities” approved by

- FDA - USA
- MHRA - UK
- WHO - Geneva
- TGA - Australia
- BGV - Hamburg (Germany)
- SUKL - Czech Republic (EU)
- ANVISA - Brazil
- INVIMA - Colombia
- JFDA - Jordan
- NAFDAC - Nigeria
- NDA - Uganda
- PPB - Kenya

Among others...

In over  
**90**  
countries  
& **5** continents



**GLAND PHARMA LIMITED**

Regd. Office: 6-3-865/1/2 Greenland Apts., Ameerpet, Hyderabad - 500 016, India  
Tel: +91-40-6662 1010 | Fax: +91-40-2340 2229 | e-mail: gland@glandpharma.com  
www.glandpharma.com