



# GLAND PHARMA LIMITED

August 12, 2025

BSE Limited  
Corporate Relationship Department  
Phiroze Jeejeebhoy Towers  
25<sup>th</sup> floor, Dalal Street  
Mumbai - 400 001  
Scrip Code: 543245

National Stock Exchange of India Limited  
Listing Department  
Exchange Plaza, 5th floor  
Plot no. C-1, Block G, Bandra Kurla Complex  
Bandra (East), Mumbai - 400 051  
Symbol: GLAND (ISIN: INE068V01023)

Dear Sir/Madam,

**Sub: Press Release - Gland Pharma receives approval from the United States Food and Drug Administration (USFDA) for Norepinephrine Bitartrate in 5% Dextrose Injection**

Pursuant to Regulation 30 read with Part A of Schedule III of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015; please find attached announcement regarding the receipt of USFDA approval for **Norepinephrine Bitartrate in 5% Dextrose Injection 4mg/250mL (16 mcg/mL)** and **8mg/250mL (32 mcg/mL)** single Dose Bags.

This is for your information and records.

Yours truly,

**For Gland Pharma Limited**

**Sampath Kumar Pallerlamudi**  
**Company Secretary & Compliance Officer**

**Encl:** As above



## **Gland Pharma Receives Approval for Norepinephrine Bitartrate in 5% Dextrose Injection Bags**

**Hyderabad, Aug 12, 2025:** Gland Pharma Limited (Gland or Company), a generic injectable & ophthalmic-focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application filed through its partner for **Norepinephrine Bitartrate in 5% Dextrose Injection, 4 mg/250 mL (16 mcg/mL) and 8 mg/250 mL (32 mcg/mL) Single-Dose Bags.**

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), NOREPINEPHRINE BITARTRATE IN 5% DEXTROSE of Baxter Healthcare Corp.

This Product is indicated to raise blood pressure in adult patients with severe, acute hypotension.

We are the exclusive First-to-File and is eligible for 180 days of generic drug exclusivity.

According to IQVIA, the product had US sales of approximately USD 55 million for the twelve months ending June 2025.

### **About Gland Pharma Limited (BSE: 543245, NSE: GLAND)**

Gland Pharma was established in 1978 in Hyderabad and has grown over the years from a contract manufacturer of small-volume liquid parenteral products to become one of the largest injectable-focused companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India, and other markets. It operates primarily under a business-to-business (B2B) model and has an excellent track record in developing, manufacturing, and marketing sterile injectables. It has a wide range of injectables, including vials, ampoules, pre-filled syringes, lyophilized vials, dry powders, infusions, oncology, and ophthalmic solutions. It also enjoys the distinction of having pioneered Heparin technology in India. For more information, log on to: [www.glandpharma.com](http://www.glandpharma.com)

For investor queries, please mail us at [investors@glandpharma.com](mailto:investors@glandpharma.com)

*This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs. Actual results may vary materially from those expressed or implied by the statements herein due to economic, business, competitive, technological, and/or regulatory factors changes. Gland Pharma Limited, its directors, and any of the affiliates or employees are under no obligation to, and expressly assume, any obligation to update any particular forward-looking statement contained in this release.*