



# GLAND PHARMA LIMITED

August 26, 2023

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: US FDA Inspection at Pashamylaram Facility, Hyderabad**

We hereby notify that the Office of Medical Device and Radiological Health Operations (OMDRHO), United States Food and Drug Administration (US FDA) conducted Pre-Market Inspection covering US FDA's Quality System/Current Good Manufacturing Practice regulations for Medical Devices (21 CFR Part 820) at the Company's Pashamylaram Facility at Hyderabad from 23<sup>rd</sup> August, 2023 to 26<sup>th</sup> August, 2023. The Company has received 2 (TWO) observations on Form 483 with respect to ANDA filed for the product to be manufactured in a PEN device at the said Facility. There is no data integrity observation.

The Company is committed to address the observations and will submit its response to US FDA within the stipulated time.

Request to take the above information on record.

Yours truly,

**For Gland Pharma Limited**

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