



# GLAND PHARMA LIMITED

August 25, 2022

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 Dundigal 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 Dundigal Facility at Hyderabad from 22<sup>nd</sup> August, 2022, to 25<sup>th</sup> August, 2022. The Company has received 1 (ONE) observation on Form 483 with respect to ANDA filed for the product to be manufactured at the said Facility. There is no data integrity observation.

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

Request to take the above information on record.

Thanking you,

Yours faithfully,  
**For Gland Pharma Limited**

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



**Regd. Office:**

Survey No. 143-148, 150 & 151, Near Gandimaisamma 'X' Roads  
D.P. Pally, Dundigal, Dundigal-Gandimaisamma Mandal  
Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India  
Tel: +91-40-30510999 Fax: +91-40-30510800

**Corporate Office:**

Plot No. 11 & 84, TSIC Phase: IV  
Pashamlaram (V), Patancheru (M), Sangareddy District  
Hyderabad 502307, Telangana, India  
Tel: +91-8455-699999