**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Drive, Room 2032<br>Rockville, MD 20857 | 2/19/2025-2/25/2025* |
| | FEI NUMBER<br>3010142300 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Raghu Ramachandra Rao Kambaladinne, Vice President, Quality Assurance

| FIRM NAME | STREET ADDRESS |
|---|---|
| Gland Pharma Limited | Plot No: 49 & 50, J N Pharmacity |
| CITY, STATE, ZIP CODE, COUNTRY<br>Parawada, Visakhapatnam, Andhra Pradesh, 531019 India | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Substance Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

Cleaning of the aseptic areas including the Grade A and Grade B areas of the Sterile Area (b) (4) was observed on February 21, 2025. The cleaning process observed was the (b) (4) cleaning which includes a spray and wipe on the surfaces with (b) (4) (b) (4) Several deficiencies of the cleaning process were observed including but not limited to the following:

- Several times during the cleaning of the return risers, view walls, and (b) (4) in the LAF402, LAF407, and Grade B areas, the operators were dousing the walls with (b) (4) and disinfectant. The (b) (4) and disinfect were observed to be pooling on the floor. The operators were observed walking on the wet floors and moving throughout the Grade A and B areas of the Sterile Area – (b) (4)
- Disinfection of the area was deficient in that the disinfect was doused on the walls without the proper use of wipes or mops to ensure the disinfectant touches all required surfaces for the expected contact time. This was observed multiple times including when the operator sprayed disinfectant on the view window and it was observed to only contact part of the window. The

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P Parikh, Investigator<br>x Ashar P Parikh<br>Investigator<br>Signed By: Ashar P. Parikh -S<br>Date Signed: 02-25-2025<br>12:28:24 | 2/25/2025 |

disinfectant was not spread or applied to all areas of this view window with a mop or wipe.

- There was no disinfectant applied to the Grade A side of the (b) (4) that separates Grade A from Grade B.
- Excess (b) (4) could not properly be removed from the mop as the mop did not fit properly into the mop wringer. (b) (4) was observed dripping from the mop onto the floor several times during the cleaning process.
- Personnel moving repeatedly from Grade B to Grade A and back with no sanitization.

In addition, the cleaning and disinfection process observed on February 21, 2025 consisted of (b) (4) operators and started at (b) (4) and concluded at (b) (4) which is (b) (4) The previous (b) (4) cleaning and disinfection process for these same areas in (b) (4) ranged in time from (b) (4) to (b) (4) long.

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**OBSERVATION 2**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. The review of the most recent airflow visualization / smoke study revealed the study is inadequate as the smoke generated is very thick and concentrated in only one area. The airflow patters are difficult to visualize and to determine if there is any turbulence caused by the interventions being performed.

B. Your firm does not document the number of sterile room (b) (4) employee shoes that are cleaned on a (b) (4) basis and the cleaning record does not specifically mention the use of the disinfectant (b) (4)

[redacted] Furthermore, these shoes can be sterilized up to [redacted] times, per the manufacturer, however your firm does not track the number of sterilization cycles each shoe has been exposed to. In addition, your firm does not track the number of sterilization cycles your sterile room [redacted] goggles are exposed to.

## OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

[redacted] API (sterile) batch [redacted] manufactured in April 2023, failed to meet the customer specification for particle size distribution (PSD) and was rejected. The root cause was determined to be a lack of [redacted] monitoring during [redacted] As part of your investigation into the failure, additional data was generated from the subsequent [redacted] batches [redacted] through [redacted]

The most recent batch of [redacted] batch [redacted] manufactured in May 2024 also failed the product specification for PSD. The investigation into this failure resulted in another possible root cause of the product solution becoming too concentrated due to [redacted] There is currently no control measure for the [redacted] in the batch record. Three of the four proposed CAPAs from this investigation have not yet been implemented to date as your firm has not manufactured any additional batches of [redacted] since May 2024.

Without adequate process controls for the manufacturing of this sterile drug substance, there is no

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assurance that your drug substance manufacturing process remains in a validated state.

***DATES OF INSPECTION**

2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri), 2/24/2025(Mon), 2/25/2025(Tue)

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Ashar P Parikh, Investigator

x Ashar P Parikh
Investigator
Signed By: Ashar P. Parikh -S
Date Signed: 02-25-2025
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