DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/25/2024-8/2/2024*
	FEI NUMBER 3009864167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Guvvala Kumar Reddy, Plant Head - Operations

FIRM NAME	STREET ADDRESS
Gland Pharma Limited, Units I+II Pashamylaram Site	54 55 64 - 68 Plots 42 - 52, Sy No 166; 171 172 - 177 Sangareddy Dist
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 502307 India	Human Drug 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

Aseptic Processing Simulations (Media Fills) are deficient for the following reasons:

A) The Aseptic Processing Simulation (APS, Media Fill) procedure SOP QA-0020-009, effective 31 May 2024, titled Procedure for Aseptic Process Simulation (Media Fill) is deficient in that it does not require tracking and trending of all types and time duration of interventions that occur during aseptic process simulations and actual finish product filling.

For example, addition of stoppers during APS or finished product filling involves transfer of closed stopper bags via the mobile LAF cart (Grade A) to the stopper RABS cabinet (Grade A). The operators and mobile LAF cart traverse through the Grade B room to move the RABS, where the stopper (b) (4) and LAF cart door are opened. This placement of stopper bags through the (b) (4) is not recorded in APS or finished product batch records, and at some point in the process the stopper bags are opened in the RABS (b) (4) via (b) (4) (b) (4) intervention using (b) (4) but there is no record of a (b) (4) process between

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Jeffrey P Raimondi, Investigator	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 08-02-2024 15:55:57	8/2/2024

placement of the bags into the RABS(b) (4) and opening of the bags and addition to the (b) (4) Other interventions are not recorded for their duration during APS and finished product filling to ensure that the APS media fill adequately mimics and validates the aseptic filling process.

B) Breakdown activities and the duration in which they have occurred, are not considered as part of establishing the activities to be challenged during media fills. For example, during filling of (b) (4) Injection, USP batch #(b) (4) filling stopped due to improper stoppering and was captured under breakdown # PD/120/04-23, as an(b) (4) intervention occurring from (b) (4) for a total duration of 01:47:33. The subsequent media fill #MFV/23/011 performed from 29-30 July 2023, did not evaluate if this breakdown (or any of its activities) and the duration in which the (b) (4) (01:47:33) should be simulated.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A)Procedure PD-0077-010, Performing of Filling Interventions, does not prohibit operators from performing sanitization of RAB(b) (4) with sterile(b) (4) prior to receiving a finger dab. The following are examples of operators who performed initial setup activities and sanitized the(b) (4) (b) (4) with sterile(b) (4) prior to finger dab:

1.Setup activities for (b) (4) Injection, USP, Batch #(b) (4) was performed by operator (b) (6) and concluded at (b) (4) This same operator performed sanitization of

the (b) (4) with sterile (b) (4) starting at (b) (4), which is prior to being finger dabbed.

2.Setup activities for (b) (4) Injection, USP, Batch (b) (4) was performed by operator (b) (6) and concluded at 11:15:43. This same operator performed sanitization of the (b) (4) with (b) (4) starting at 11:15:44, which is prior to being finger dabbed.

3.Setup activities for (b) (4) Injection, USP, Batch #(b) (4) was performed by Operator (b) (6) and concluded at (b) (4) This same operator performed sanitization of the (b) (4) with sterile (b) (4) starting at (b) (4) which is prior to being finger dabbed.

4.Setup activities for (b) (4) Injection, USP, Batch #(b) (4) was performed by Operator (b) (6) and concluded at 09:03:29. This same operator performed sanitization of the (b) (4) with sterile (b) (4) starting at 09:03:34, which is prior to being finger dabbed.

There is no assurance that the finger dab data after sanitization is an accurate representation of the actual conditions of the operators gloves during setup activities.

B)Monitoring of non-viable particles of the Grade A (ISO 5) (b) (4) zones and mobile LAFs are not performed during dynamic operations to ensure the Grade A environment is maintained during the routine manual transferring process of the sterile equipment parts and tools.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/25/2024-8/2/2024*
	FEI NUMBER 3009864167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Guvvala Kumar Reddy, Plant Head - Operations

FIRM NAME	STREET ADDRESS
Gland Pharma Limited, Units I+II Pashamylaram Site	54 55 64 - 68 Plots 42 - 52, Sy No 166; 171 172 - 177 Sangareddy Dist
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 502307 India	Human Drug Manufacturer

C)Gowns of operators working within Grade A LAF areas such as the (b) (4) Zones and Sterile Storage areas (both are used to hold/transfer sterilized materials), and sterile (b) (4) areas (to perform aseptic connections) are not held to Grade A specification of no growth. Although these operators are standing completely inside these Grade A areas, the specification for the personnel monitoring for the fore arms, elbows, upper back, and hood are less than (b) (4) fu/plate.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

The firm has reported 22 of 46 deviations in 2023 where aseptic filling lines in Unit II and 3 deviations in Unit-1 experienced multiple breakdowns, affecting the aseptic filling process.

The firm has reported repeated Lab Incidents and Lab Out of Specification (OOS) results from 2022-2024. Approximately 30% of the lab incidents in 2023 were for failed HPLC content assay and related substance tests, intended for finished product release, where the test was stopped during the run sequence when it was noticed that system suitability or reference standard peak shapes were poor. Some OOS were reported where the test progressed but failed at the stage of sample injection yielding a poor result. Common instances were reported to be poor peak shape and failed system suitability or injections due to repeated HPLC column and equipment failures.

The firm has not established appropriate preventive maintenance program based on historical maintenance data to assure that production and analytical equipment and instruments can reliably operate as intended for aseptic production and analytical release testing of finished drug products.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/25/2024-8/2/2024*
	FEI NUMBER 3009864167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Guvvala Kumar Reddy, Plant Head - Operations

FIRM NAME	STREET ADDRESS
Gland Pharma Limited, Units I+II Pashamylaram Site	54 55 64 - 68 Plots 42 - 52, Sy No 166; 171 172 - 177 Sangareddy Dist
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 502307 India	Human Drug Manufacturer

*DATES OF INSPECTION

7/25/2024(Thu), 7/26/2024(Fri), 7/29/2024(Mon), 7/30/2024(Tue), 7/31/2024(Wed), 8/01/2024(Thu), 8/02/2024(Fri)

X Jeffrey P Raimondi
Investigator
Signed By: Jeffrey P. Raimondi -S
Date Signed: 08-02-2024 15:56:25

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, National Expert Jeffrey P Raimondi, Investigator X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 08-02-2024 15:55:57	8/2/2024