DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	5/10/2022-5/20/2022* FEI NUMBER 3004034796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Charles Michael Harrison, Pharmacist In-charge

FIRM NAME	STREET ADDRESS
Delta Pharma, Inc.	114 W Mulberry St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ripley, MS 38663-1709	Outsourcing Facility

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

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm's location for gowning prior to entering the corridor that leads to the anteroom and classified areas is inadequate to minimize contamination of the Room 3 (anteroom) and Room 2 (ISO 8). Currently, face masks, head-beard cover, gloves, shoe covers, and gown are donned in the hallway (a non-classified, non-controlled area) prior to entering the corridor (a non-classified, controlled area). The same shoe covers are worn in the Room 3 and Room 2. Personnel may choose to wear dedicated-scrubs in lieu of a gown; however, the dedicated-scrubs are worn in Room 2, Room 3, the corridor, the gowning hallway, and other areas in the facility. We observed personnel in dedicated-scrubs leaving the corridor to retrieve additional materials during operations.

This is a repeat observation from FDA inspections ending on 10/02/2013, 05/24/2016, and 02/23/2017.

OBSERVATION 2

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

According to GMP-SOP-0026, your stated contact disinfectant time for (b) (4) is 10 minutes, which is in alignment with the cleaning efficacy study performed under protocol P2671. However, this dwell time contradicts the established sporicidal contact time of 30 minutes, set forth by the manufacturer.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator Regan T Harp, Investigator	X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 05-20-2022 00:44:10	5/20/2022

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OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, during the media fill run on 05/18/2022, the bag of sterile rubber stoppers was oriented in such a position inside the ISO-5 laminar hood where the opened end of the bag was not exposed to first-pass air.

OBSERVATION 4

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, your (b) (4) . On 05/16/2022, your media fill run yielded the following three consecutive failures for the automated (b) (4) : (b) (4) . There is no information given in the procedure that would elaborate on the conditions for which a filter failure can be repeat tested, such as a decision-making tool. For example, the current procedure states that after a second failed attempt, an incident report is opened, and a third attempt may be performed. But there is no explanation why this third attempt should be performed. Ultimately the current procedure does not explain the justification on how a final passing result invalidates the the first two successive negative test results, or whether a third attempt failure will ultimately deem the (b) (4) as compromised.

In addition, GMP-SOP-0030, Revision 03, does not require the documentation of a gross leak failure. The automated (b) (4) does not print a report for gross leak failures, and there is no log (or equivalent) of such occurrences.

This is a repeat observation from the inspections ending 10/02/2013, 05/24/2016, and 02/23/2017.

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OBSERVATION 5

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

Specifically, your environmental monitoring procedure (SOP-GMP-0042, Revision 04) for the ISO-5 area includes the use of viable air apparatus that samples 6000L of air in (b) (4) increments. Plates are changed after (b) (4) sample is collected. You were unable to provide a qualification study, or equivalent, showing that the TSA plates used can sustain viability after the prolonged sample collection.

This is a repeat observation from 05/24/2014 and 02/23/2017.

*DATES OF INSPECTION

5/10/2022(Tue), 5/11/2022(Wed), 5/12/2022(Thu), 5/13/2022(Fri), 5/16/2022(Mon), 5/18/2022(Wed), 5/19/2022(Thu), 5/20/2022(Fri)

X Regan T Harp
Investigator
Signed By: 2003426285
Date Signed: 05-20-2022 00:44:41

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator Regan T Harp, Investigator	X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 05-20-2022 00:44:10	5/20/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."