DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	2/23/2023-3/3/2023*
	FEI NUMBER 3015162096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gary L Jones, Pharmacy Supervisor	
FIRM NAME Prisma Health Outsourcing Facility	STREET ADDRESS 1071 Holland Rd Ste 2
CITY, STATE, ZIP CODE, COUNTRY Simpsonville, SC 29681-5709	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm was found d to have a plastic sleeve used to hold a laminated form affixed the side of your ISO 5 LAFUs within your firm's ISO 7 Filling Suite to show the operational status and manufacturing activities occurring within the unit. Neither the plastic sleeve nor the laminated sheet was part of your firm's cleaning and disinfectant schedule. It has not been deemed cleaned/disinfected the pharmacist/interim quality personnel.

B. Your firm's compounding technicians were observed writing on paper batch records within your firm's ISO 7 Filling Suite during aseptic processing of the sterile drug, Ketamine 30mg/6mL, Lot (b) (4), processed on 2/24/2023. Paper within the cleanroom has the potential of shedding and increasing the particulate count in addition to being a source of cross contamination within the ISO 7 Filling suite. The paper batch records were observed being placed atop the nonprotected laptop keyboard sitting on the stainless steel table.

C. Your firm hangs a bottle of (b) (4) on the bar along the top of the ISO 5 LAFU during aseptic processing. Your firm failed to adequately assess the affect it potential have on the unidirectional air flow pattern within the processing environment. During a review of your firm's static and dynamic smoke studies for product Family Group (b)(4) and Family (b)(4) the (b) (4) bottle was observed hanging on the top left-hand side of the bar. However, your firm failed to assess the airflow pattern resulting from the bottle in the placement location.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 03-03-2023 13:13:40	3/3/2023

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OBSERVATION 2

Aseptic processing areas are deficient in that floors and walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

A. Your firm use (b) (4) trash cans, which has a hard to clean and disinfect surface within your ISO 7 Gowning and ISO 7 Filling suite containing your firm's (b) (4) ISO 5 LAFU. The surface has the potential of retaining foreign particulates and microbiological organisms that may pose a risk to aseptically processed drug products.

B. Your firm uses a laptop computer on a stainless steel table within your firm's ISO 7 Filling Suite used for data entry during aseptic processing. The none protected laptop keyboard has hard to clean areas that prevent adequate cleaning and disinfecting resulting in potential sites for microbiological growth and possible site for cross contamination. Your firm's technician was observed during the production of the sterile drug, Ketamine HCL Injection Solution 30 mg/6 mL (5mg/mL) Syringe, Qty. (b) (4) syringes, Lot #(b) (4) , fail to disinfect (b) (5), (b) (7) sterile gloves prior to returning to the ISO 5 LAFU following data entry. Additionally, you firm's Pharmacy Supervisor reported the laptop keyboard is not included in its EM sampling plan.

OBSERVATION 3

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

Specifically, Your firm's documented procedure for responding to your firm's (b) (4) Monitoring System is inadequate. For example, your firm's procedure, Addressing Alarms Issued by (b) (4) Monitoring System, SOP.QC.006 fail to include a list of possible responses when an Alert/ Action Limit has been reached and a criteria/specification for the selection of each firm created responses. On 6/1/2022 at 10:30 pm, during a review of your firm's differential pressure alerts, one of the responses found was "Self-Correction". Your firm's procedure failed to establish a definition to the meaning/

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 03-03-2023 13:13:42	DATE ISSUED 3/3/2023

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specification for the selection of this response.

OBSERVATION 4

Reporting Issue

1. Your facility failed to submit a complete report to FDA for the June 2021, December 2021, June 2022, and December 2022 product reporting periods, identifying all the drug products that you compounded during the previous 6-month period, such as Ketamine HCl injection solution 10mg/2mL, Ketamine injection solution 100mg/20mL, Ketamine injection solution 30mg/6mL, and Phenylephrine HCl in NS 50mg/250mL. [Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]].

***DATES OF INSPECTION**

2/23/2023(Thu), 2/24/2023(Fri), 2/27/2023(Mon), 2/28/2023(Tue), 3/01/2023(Wed), 3/02/2023(Thu), 3/03/2023(Fri)

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