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	5/2/2023-5/17/2023*
	FEI NUMBER 3010683157

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott P. Luce, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, Inc.	8821 Knoedl Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Rock, AR 72205-4600	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

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

Specifically, your firm has not developed an environmental monitoring plan based upon sound scientific methods to include appropriate sampling frequency and timing. Your firm has no documentation to demonstrate that the environmental sampling performed is representative of the entire process. For example,

a) Your firm is currently performing (b) (4) viable active air sample per (b) (4) or (b) (4) whichever comes first. If the lot filling extends beyond the (b) (4), a (b) (4) sample is taken at some point during (b) (4). Your firm has not defined the timing of when the sample is to be taken during each shift and leaves that to the discretion of the person responsible for taking the sample.

b) The continuous non-viable particle monitoring system is not turned on in the ISO 5 Laminar Flow Hoods until after the connection of the (b) (4). The system is not turned on during activities performed prior to (b) (4) connection such as (b) (4) of vials, admixing, and (b) (4) connection.

Since January 1, 2023, your firm has compounded and released approximately (b) (4) lots of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Lisa R Hilliard, Investigator Megan T Ziegler, CSO	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 05-17-2023 10:58:15	5/17/2023

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drug products.

OBSERVATION 2

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, ISO 7 Cleanroom 902 is where (b) (4) of vials, admixing, and filling of syringes, IV bags and (b) (4) cassettes is performed within the (b) (4) ISO 5 Laminar Flow Hoods located in the room. The hood #s are (b) (4).

a) The last two (2) certification reports dated (b) (4) and (b) (4) for the (b) (4) ISO 5 Laminar Flow Hoods (LFH) located in Room 902 do not include measurement of the velocity of unidirectional air near the work surface.

b) Air return vents in Room 902 are at times blocked by items such as carts containing totes, laminar flow hoods, tables, and trash receptacles. A smoke study performed on July 6-7, 2022, demonstrated several instances where the airflow was not able to reach the return vent due to an obstruction such as a table. During the inspection we observed carts with totes, tables, trash receptacles and laminar flow hoods blocking the air return vents in Room 902.

Since January 1, 2023, your firm has compounded and released approximately (b) (4) lots of drug products.

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OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, on May 3, 2023, I observed the reading of environmental monitoring plates from monitoring that occurred on April 26, 2023. The media in four (4) of the plates used for passive air monitoring in the ISO 5 Laminar Flow Hoods was cracked or split in the middle. On May 5, 2023, I reviewed the environmental monitoring plates for monitoring that occurred on April 28, 2023. The media in four (4) of the plates used for passive air monitoring in the ISO 5 Laminar Flow Hoods was cracked or split in the middle. The employees reading the plates, including the employee performing the secondary review of plates, failed to document on Form LAB-007-5-LR Environmental Monitoring Release the plates with media that was cracked or split. In addition, no deviation/investigation was opened to investigate this issue.

The following lots were compounded in Hood #s (b) (4) on April 26, 2023.

- Lot #(b) (4) of Fentanyl 2 mcg/mL and Bupivacaine HCl 0.125% in 0.9% Sodium (b) (4)
- Lot #(b) (4) of Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 100 mL Bag (1,000 (b) (4)
- Lot #(b) (4) of Methadone HCl 10 mg/mL 1 mL fill 3 mL Syringe (10 mg/1 mL)

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The following lots were compounded in Hood #s (b) (4) on April 28, 2023.

- Lot # (b) (4) of Phenylephrine HCl 40 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (400 mcg/10 mL)(KC)
- Lot # (b) (4) of Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 250 mL Bag (2,500 mcg/250 mL)
- Lot # (b) (4) of Lidocaine PF 2% 5 mL fill 6 mL Syringe

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically,

a) Your firm uses an epoxy coating on several surfaces in the ISO 7 Cleanroom 902 including the wheel covers of carts and the legs of the ISO 5 Laminar Flow Hoods. On May 4, 2023, we observed the epoxy coating peeling and chipping off of the wheel covers of several carts.

b) Your firm uses sticker labels to identify cleanroom carts. On May 4, 2023, we observed the stickers on several carts peeling off in the ISO 7 Cleanroom 902.

c) Your firm uses wire shelving units coated in a green epoxy finish in several cleanrooms,

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including ISO 7 Cleanroom 902. Your firm has no documentation to show these shelving units are appropriate for use in cleanrooms.

***DATES OF INSPECTION**

5/02/2023(Tue), 5/03/2023(Wed), 5/04/2023(Thu), 5/05/2023(Fri), 5/08/2023(Mon), 5/09/2023(Tue), 5/10/2023(Wed), 5/11/2023(Thu), 5/12/2023(Fri), 5/17/2023(Wed)

X Megan T Ziegler
CSO
Signed By: Megan T. Ziegler -S
Date Signed: 05-17-2023 10:58:54

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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."