

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

DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street Winchester, MA 01890 (781) 587-7500 Fax: (781) 587-7556	DATE(S) OF INSPECTION 2/17/2026-3/13/2026*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew White, Chief Operating Officer

FIRM NAME SCA Pharmaceuticals, LLC	STREET ADDRESS 755 Rainbow Rd Ste B
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CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility
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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 and followed.

Specifically,

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

A. Your firm has initiated approximately 46 Excursion (EXC), representing ^{(b) (4)} batches of product, reports for microorganisms recovered from the ISO-5 critical zone in the Laminar Flow Hoods where sterile drug products are compounded. Since December 2024 organisms recovered included Staphylococcus species (epidermidis, hominis, capitis, haemolyticus), Bacillus simplex (clausii, infantis, circulans), Corynebacterium tuberculostearicum, Microcococcus luteus, and other organisms such as Kocuria, Peribacillus, Paenibacillus, Fictibacillus, Streptomyces, Cladosporium, Sphigmonas and Penicillium citrinum. These organisms have been characterized as either spore forming, or non-spore forming organisms recovered from either gloved fingertip, sleeve monitoring, active air, and/or passive air samples.

Of the approximate 46 excursions initiated affecting multiple products batches including Phenylephrine HCL 100mcg, Oxytocin, Sucinylchlorine Chloride, Fentanyl Citrate, Labetalol, Rocuronium Bromide, Hydromorphone HCL, Diltiazem DCL and a Media Fill batch, ^{(b) (4)} have been rejected and ^{(b) (4)} has been released.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Simone E Pitts, National Expert, Drugs	<small>Simone E Pitts National Expert, Drugs Signed By: SIMONE E. PITTS -6 Date Signed: 03-13-2026 17:16:11</small> X _____	DATE ISSUED 3/13/2026

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Product Name	Sample Method	Personnel	Organism	Disposition
Fentanyl Citrate 2 mcg/mL and Bupivacaine HCl 0.1% in 0.9% Sodium Chloride 250 mL Bag, Lot: 1225059964 BUD: 24 SEP 2025 (Intrathecal)	(b) (4)	Compounder 1 <small>(b) (6), (b) (7)(C)</small> Aseptic Assistant 1 <small>(b) (6), (b) (7)(C)</small>	N/A N/A	Released

*N/A = the organism was unable to be subcultured therefore, no identification was of the organism was performed.

B. Compounders and Aseptic Assistants were observed not using slow and deliberate movements in either the ISO-5 Laminar Flow Hoods or in the ISO-7 manufacturing environments observed during compounding activities on 02/19/2026. Also, compounders and aseptic assistance were not holding their hands and arms in a position within the manufacturing workspace to minimize potential air turbulence. Furthermore, Compounders and Aseptic Assistants were observed using their feet to kick garbage receptacles, power cords on the floor of the (b) (4) ((b) (4)) pumps and non-viable probes throughout the ISO-7 manufacturing area. These movement can potentially aerosolize particles and microorganisms from the floor, which can then draw into the ISO-7 clean room and subsequently into the ISO-5 Laminar Flow Hoods.

C. Your firm utilizes the (b) (4) air sampling collection device to perform air sampling in your ISO-5

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Laminar Air Flow Hoods. You have not adequately determined that placing the unit (b) (4) while conducting the test, does not violate first air principles by pushing air deflected from the unit into the critical workspace and potential reflux of air from the compounder's torso.

D. Your operators were observed utilizing sterile goggles that utilize the (b) (4) technology. You have not provided an adequate rationale to support the use of these (b) (4) goggles in the sterile core. The sterile goggles have (b) (4) allowing for potential particulates from operator's skin to egress into the surrounding environment. The sterile goggles are part of the sterile gowning used for operators in your clean room and when preparing products intended to be sterile in your (b) (4) ISO-5 Laminar Air Flow Hoods.

E. Operators conducting cleaning were observed using materials prepared in the ISO-7 clean room such as lint free dry wipes saturated in buckets with (b) (4) and then using the saturated (b) (4) wipes to clean inside the laminar flow hood and outside of the hood.

OBSERVATION 2

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,

- Your firm failed to identify the root cause of particulate contamination in your drug products intended to be sterile and failed to implement effective corrective and preventive actions to prevent recurrence. These deviation investigations have been described as, Investigation Major Particulate Matter DRL Threshold Exceedance, 100% Visual Inspection Particulate Matter Threshold Exceedance, AQL Failure, and Major DRL Particulate Matter Threshold Exceedance. Since December 2024, your firm has initiated approximately 110 deviation investigations due to visual inspection failures for particulates. The majority of the deviation reports have been

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initiated due to contaminants observed that presents as material found on the plunger, floating particulate, or adhered to the stopper barrel. Despite this recurring pattern of particulate contamination, your firm has not:

- Conducted a thorough investigation to determine the definitive root cause(s) of the particulate failures.
- Implemented corrective and preventive actions (CAPA) that address the underlying cause(s) of particulate contamination.
- Demonstrated the effectiveness of any corrective actions taken to prevent the continued occurrence of intrinsic particulates in your drug products.
- Adequately justify the classification of “Major” for particulate contamination.

The repeated occurrence of intrinsic particulate failures without adequate investigation and effective CAPA demonstrates a failure to maintain your manufacturing process in a state of control.

OBSERVATION 3

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Your firm’s VAL-24-076-FR, Disinfectant Efficacy Study for (b) (4) against EM Isolates from the Connecticut Facility Located at 755 Rainbow Road, Windsor, CT 06095, Rev.1 established a (b) (4) dwell time when cleaning with (b) (4). Your firm uses (b) (4) to clean and disinfect all classified areas. The following deficiencies were noted in VAL-24-076-FR executed in December 2024.

- i. No evaluation of other organisms other than *Bacillus subtilis (spizizenii)* and the mixed culture of

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Bacillus altitudinis/pumilus/safensis. The firm has recovered other spore forming organisms from the ISO-5 sterile compounding core including: *Penicillium citrinum*, *Streptomyces*, *Cladosporium* and related organisms *Peribacillus* and *Paenibacillus*.

According to the manufacturers' instructions for (b) (4), a minimum contact time of (b) (4) (b) (4) is required to effectively use the product as a sporicidal agent in the reduction in the presence of bacteria, mold and other spore forming organisms.

***DATES OF INSPECTION**

2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri), 3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri)

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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."