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	10/20/2025-10/30/2025* FEI NUMBER 3010683157

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott P. Luce, Chief Execeutive Officer

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

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,

Your firm failed to establish adequate procedures to monitor personnel who directly interface with the sterile manufacturing environment, particularly during critical operations where personnel actions could impact product sterility.

Video footage (AR0125*10102*51125035913_Beginning.mp4) from the aseptic filling of Lot 1125035913 demonstrates sterile technicians entering the ISO (b)(4) LFH environment between timestamps 9:37-9:56 and performing multiple critical tasks including:
Removing filled syringes from the IS (b)(4) LFH.
Placing and removing the air sampling equipment.

Despite direct contact with the critical aseptic environment, the sterile technician performing these operations was not sampled for recovery of viable microorganisms during or after these activities.

OBSERVATION 2

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

Specifically,
Your firm has not performed airflow visualization studies inside each of the LFH that are used during aseptic production of products intended to be sterile, and has only performed these smoke studies inside three LFH, under dynamic conditions, used during aseptic production.

OBSERVATION 3
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm did not adequately investigate microbial excursions recovered from your ISO (b)(4) classified areas during aseptic production before distributing partial lots. Your firm determined that the probable root cause of the microbial contamination was improper sanitization of materials before transfer into the ISO (b)(4) classified critical areas. In each case, you concluded that only the second portion of the batch was impacted by this contamination and subsequently rejected that portion of the batch. However, your firm did not demonstrate that the contamination was limited to the materials used during the second portion of the batch production, and that there was no impact on the first portion of the batch, despite these materials undergoing the same sanitization process. These investigations include:

Excursion #	Location	Microbial Recovery	Probable Root Cause
EXC-2025-0045	(b)(4)	*Bacillus altitudinis/pumilus/safensis*	Improper sanitization of materials
EXC-2025-0080		*Solibacillus silvestris*	Improper sanitization of materials
EXC-2025-0111		*Penicillium citrinum*	Improper sanitization of materials

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Your firm approved and distributed (b)(4) syringes of Ketamine HCl 10 mg/mL in 0.9% Sodium Chloride 5 mL fill Syringe (50 mg/5 mL), lot 1125035065, BUD 07/03/2025, associated with Excursion EXC-2025-0045; (b)(4) syringes of Phenylephrine HCl 100 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (1,000 mcg/10 mL), Lot 1125035375, BUD 11/07/2025, associated with Excursion EXC-2025-0080; and (b)(4) syringes of Ketamine HCl 10 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe (50 mg/5 mL), Lot 1125035526, BUD 1/10/2026 associated with Excursion EXC-2025-0111.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug product containers conform to appropriate standards of identity, strength, quality and purity.

Specifically,
SOP-ILP-001-LR Product Inspection and Defect Classification defines critical defects as those that may cause serious adverse reactions, including those that compromise the sterility of the drug product. However, your firm's defect classification system contains the following inadequacies:

A. Your firm classifies all particulates/materials in the drug solution as major defects without distinguishing between extrinsic and intrinsic particles during the visual inspection process, some of which may increase risk of serious adverse reactions.

B. Your firm has inappropriately classified foreign material trapped between stopper ribs as a minor defect despite the potential for these particles to impact the drug solution and compromise sterility.

During visual inspection of prefilled syringes, foreign (unusual) material, including cardboard,

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was observed trapped between the stopper ribs of the syringe plunger assembly and was classified as a minor defect in the following products:
Rocuronium Bromide 10mg/mL 5mL, Lot 1125035241, BUD 08/10/2025 (b)(4) syringes distributed.
Succinylcholine Chloride 20 mg/mL 5 mL, Lot 1125035825, BUD 12/16/2025 (b)(4) syringes distributed.

Your firm's three-part syringe design utilizes a rubber tip stopper with ribs intended to form a tight seal against the barrel wall to maintain container closure integrity. The presence of cardboard particulates between the stopper ribs demonstrates that your component control and assembly processes are not adequately designed or maintained to prevent contamination of product contact surfaces.

***DATES OF INSPECTION**
10/20/2025(Mon), 10/21/2025(Tue), 10/22/2025(Wed), 10/23/2025(Thu), 10/24/2025(Fri), 10/27/2025(Mon), 10/28/2025(Tue), 10/29/2025(Wed), 10/30/2025(Thu)

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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."