DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	12/2/2024-12/20/2024* FEI NUMBER 3013736415

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

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

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

Specifically,

A. Your firm failed to adequately assess and implement an effective corrective and preventative action plan to remediate numerous findings of foreign material described as, cardboard, hair, fiber, or other, inside the (b) (4) tray packs containing un-filled sterile syringes. These syringe tray packs are received from (b) (4) syringe suppliers in configurations of (b) (4), (b) (4), and (b) (4) units. Since November 2023, your firm documented over 1200 supplier concern reports of foreign material found in these syringe tray packs and continued to use them as container closures in your manufacturing activities. Your firm continues to provide (b) (4) supplier complaints to syringe suppliers regarding the foreign materials found in sterile syringe trays. Foreign material was reported in the following batches:

   i. 27 units rejected from Phenylephrine HCl 100 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (1,000 mcg/10 mL), Lot (b) (4), Expiration: 05/20/2025;
   ii. 105 units rejected from Phenylephrine HCl 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (800 mcg/10 mL) (KC), Lot: (b) (4), Expiration: 05/25/2025; and,
   iii. 60 units rejected from Rocuronium Bromide 10 mg/mL 5 mL fill 6 mL Syringe (50 mg/5 mL), Lot (b) (4), Expiration 02/17/2025.

   The foreign material stemming from the syringe trays was a known issue found during your supplier qualification noted in the 2019 Questionnaire.

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B. Your firm failed to perform adequate risk assessments for drug products that were released in cases where Environmental Monitoring or Personnel Monitoring samples were not collected during production. For example:

Deviation Number	Drug Product	Lot number	EM missing
DEV-2024-0490	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill Syringe (30 mg/30 mL)	(b) (4) Compound date: 10/10/2024, Expiration: 01/23/2025	Aseptic Compounder fingertip samples
DEV-2023-0572	Diltiazem HCl 125 mg in 0.9% Sodium Chloride 125 mL Bag	(b) (4) Compound date: 10/30/2024, Expiration: 02/27/2025	Aseptic Compounder fingertip samples
DEV-2024-0185	Vancomycin HCl 1.5 g added to 0.9% Sodium Chloride 500 mL Bag (1500 mg/500 mL)	(b) (4) Compound date: 03/20/2024, Expiration: 07/18/2024	Continuous non-viable particulate
DEV-2024-0266	Diltiazem HCl 125 mg in 0.9% Sodium Chloride 125 mL Bag	(b) (4) Compound date: 05/06/2024, Expiration: 09/03/2024	Aseptic Assistant Fingertip samples
DEV-2024-0413	Rocuronium Bromide 10 mg/mL 5 mL fill 6 mL Syringe (50 mg/5 mL)	(b) (4) Compound date: 08/06/2024, Expiration: 11/04/2024	Surface Samples from End of Run

C. Your firm has not adequately justified the release of finished drug products that had opened

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deviations due to exceeding the critical, major, and minor defect rate limits during the 100% visual inspection. Your firm has approximately 60 deviations since October 2023 that were opened due to exceeding the levels of critical, major, and minor defect classification defect levels. For example:

i. Deviation 2024-0320 was opened due to exceeding the critical defect limit identified in three (3) syringes of non-integral or non-functional container, e.g. broken syringe (Defect Rate Limit (DRL) for critical defects is (b) (4) . According to ILP-001-W, part of the definition of a critical defect is regarding defects that may cause serious adverse reaction or death to the patient if the product is use. Your firm's root cause and impact assessment were not adequate to release Phenylephrine HCl 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (800 mcg/10 mL), Lot (b) (4) , since the acceptance qualified limit (AQL) passed, and it was determined that there was no impact identified.

ii. Deviation 2024-0329 was opened due to exceeding a critical defect limit rate for 6 non-integral or non-functional container, e.g. broken syringe, identified and calculated to be a DRL of 1.6%. (DRL specification is (b) (4)) for Fentanyl Citrate 10 mcg/mL in 0.9% Sodium Chloride 50 mL fill Syringe (500 mcg/50 mL), Lot (b) (4) . After your investigation determined the root cause to be material damaged that was sent from the syringe manufacturer, your firm release the batch lot and stated that there was no impact on additional units since the yield percentage was within the acceptable range at (b) (4) and there were no additional units found during AQL.

iii. Deviation 2024-0064 was opened due to exceeding a major DRL at (b) (4) for 8 units rejected for particulate/material in solution which exceeds the specified limit of (b) (4) for Fentanyl Citrate 50mcg/ml in 100ml Bag (5,000 mcg/100ml), Lot (b) (4) Expiration 04/26/2024. This batch was released based on identifying the particulate as plasticizer in the inner filling port sealing film of your sterile bag. This was determined to be an intrinsic material to your process.

REPEAT OBSERVATION

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OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,
Your firm failed to adequately validate the manufacturing process for your sterile injectable products across multiple product lines, e.g., Vancomycin, Potassium Chloride, Norepinephrine, Potassium Phosphate, Phenylephrine, Diltiazem, and Oxytocin. From October 2023 until December 2024, your firm initiated approximately 24 manufacturing investigations classified as "Confirmed for potency OOS" representing 34 lots of sterile drug products.

Your firm fails to address the root causes of "variable potency results" when using commercially available starting materials in order to ensure finished drug product produced are made consistently and remain within a state of control. Your firm failed to demonstrate the manufacturing process is capable of producing products that consistently meet established specifications and deliver a quality product.

Deviation #	Initiated	Product	Lot Number	Disposition
DEV-2023-0573	10/31/2023	Vancomycin	(b) (4) and (b) (4)	Rejected
DEV-2023-0682	12/7/2023	Vancomycin	(b) (4) and (b) (4)	Rejected
DEV-2024-0095	1/31/2024	Potassium Chloride	(b) (4)	Rejected
DEV-2024-0116	2/12/2024	Norepinephrine	(b) (4) and (b) (4)	Rejected
DEV-2024-0129	6/27/2024	Norepinephrine	(b) (4) and (b) (4)	Rejected

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DEV-2024-0134	2/20/2024	Vancomycin HCl	4 lot #s	Rejected
DEV-2024-0137	2/21/2024	Norepinephrine	(b) (4) and (b) (4)	Rejected
DEV-2024-0172	3/14/2024	Potassium Phosphate	(b) (4)	Rejected
DEV-2024-0173	3/14/2024	Vancomycin	(b) (4)	Rejected
DEV-2024-0199	3/29/2024	Potassium Chloride	(b) (4)	Rejected
DEV-2024-0263	5/7/2024	Vancomycin	(b) (4)	Rejected
DEV-2024-0280	5/9/2024	Phenylephrine	(b) (4)	Rejected
DEV-2024-0300	5/21/2024	Diltiazem	(b) (4)	Rejected
DEV-2024-0335	6/26/2024	Potassium Chloride	(b) (4)	Rejected
DEV-2024-0350	7/10/2024	Oxytocin	(b) (4)	Rejected
DEV-2024-0355	7/12/2024	Potassium Chloride	(b) (4)	Rejected
DEV-2024-0361	7/17/2024	Norepinephrine	(b) (4)	Rejected
DEV-2024-0373	7/22/2024	Oxytocin	(b) (4) (b) (4)	Rejected
DEV-2024-0468	9/23/2024	Succinylcholine	(b) (4) (b) (4)	Rejected

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DEV-2024-0532	11/8/2024	Vancomycin	(b) (4) and (b) (4)	Open
DEV-2024-0548	11/15/2024	Vancomycin	(b) (4)	Open

In addition, CAPA-2024-0008 was initiated on March 18, 2024, for the sterile injectable product line Vancomycin, to address the variability of the potency within the compounding process which has not been closed. Your procedure, QMS-011, version 13, *Corrective and Preventative Action Process*, is silent with respect to assigning a meaningful timeframe to review, evaluate, and implement an effective CAPA.

OBSERVATION 3

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

Specifically,

A. Your facility has not established a procedure for (b) (4) cleaning of the metal diffusers covering the HEPA filters within the (b) (4) Laminar Air Flow Hoods (LAFH) used to produce drug products that are purported to be sterile. Your firm produces approximately (b) (4) lots of drug products daily across (b) (4) ISO-5 LAFHs located in your clean room suite. For example, on 12/04/2024, your operator manufactured the following two different drug products in ISO-5 LAFH (b) (4) ((b) (4)) with only a sanitization to the top, bar, walls, and deck of the LAFH, missing the front of the metal diffuser before producing the second drug product manufactured in the same (b) (4) LAFH. Your firm failed to adequately clean the LAFH to prevent potential cross-contamination.

   i. Fentanyl Citrate 2mcg/ml and Bupivacaine HCl in 0.9% Sodium Chloride 250ml bag, Lot (b) (4), Expiration 01/10/2025.

   ii. Rocuronium Bromide 10mg/ml 5ml fill 6ml syringe (50mg/5ml), Lot (b) (4), Expiration 03/04/2025.

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B. Your firm's VAL-24-034-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-24-034-FR:

i. The firm's disinfectant study protocol notes that it was conducted on coupons of materials (flooring, stainless steel, glass, polypropylene, polyvinylchloride, aluminum, acrylic, Reyno bond) only; however, the final study report of the disinfectant notes that the study encompassed stainless steel coupon, polypropylene coupon, one LAFH, an analytical balance. Totes utilized during production were not included in the study.

ii. No evaluation of other organisms, i.e. Bacillus subtilis

iii. The application of the sanitizer was not applied in the same manner as that used during the normal cleaning process.

iv. Not including the ATCC numbers of the specimens in the protocol

v. Not accounting for the longest times when the sanitizer would be exposed to ISO 7 conditions in an open bin and using saturated wipes.

According to the manufacturers' instructions for (b) (4), a minimum contact time of (b) (4) is required to effectively reduce the presence of bacteria, mold and other spore forming organisms. You have no scientific rationale to support that your (b) (4) contact time is sufficient in the destruction and removal of microbial contamination in your ISO 5, 7, & 8 cleanrooms.

OBSERVATION 4

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

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Specifically,

A. Your firm fails to recertify your ISO-5 Laminar Air Flow Hoods when the metal diffusers, in front of the HEPA filters, are removed, cleaned front and back and then placed back inside the LAFH before resuming normal production of drug products purported to be sterile. According to your LAFH equipment manual, the metal diffuser should only be taken off by the certifier and your firm performs the removal and attachment of the metal diffuser coverings without performing a risk assessment or scientific rationale for its removal and replacement by your sanitization operators. On 10/22/2024, your firm removed and cleaned the diffuser on LAFH #(b) (4) and did not recertify the LAFH after this operation. Your firm then compounded Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/30 mL) Lot (b) (4) in LAFH #(b) (4) on 10/22/2024.

B. White totes used in your ISO7 cleanrooms are not smooth and easily cleanable and have handle areas and ridges which are difficult to clean. Your cleaning study, ES-23-026 and validation, VAL-23-074, did not account for these surfaces or the difficult to clean areas. These areas of concern can harbor microorganisms that could contaminate drug product purported to be sterile.

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm failed to adequately calculate the theoretical and actual batch yield steps at each phase of the production process for all sterile drug process. Your firm's calculated actual batch yield steps are not inclusive of all products produced during the manufacturing run. For example, during the production of Phenylephrine HCl 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (800 mcg/10 mL) (KC), Lot: (b) (4), Expiration: 05/25/2025, (b) (4) units were filled of which 105 units were rejected before visual inspection. Your validated theoretical yield is (b) (4) in your batch

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record. Your firm proceeded to the next production step when the actual yield failed to meet the validated range of (b) (4) .

OBSERVATION 6

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

Specifically, your operators were observed utilizing sterile goggles that are not designed to prevent microbial contamination. The sterile goggles have holes on the top and bottom allowing for potential particulates from operator's skin to have egress. The sterile goggles are a part of the sterile gowning used for operators in your cleanroom and when preparing sterile drug product in your (b) (4) ISO-5 Laminar Air Flow Hood. For example, on 07/16/2024, an excursion, EXC-2024-0173, report was initiated due to a recovery of 1 CFU/plate (specification (b) (4)) identified as *Staphylococcus epidermis* and, separately, *Staphylococcus warneri* in the ISO-5 environment left, right, and center viable surface samples taken during the production of Phenylephrine HCl 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill Syringe (800 mcg/10 mL) (KC) Lot (b) (4) Expiration 01/12/2025.

OBSERVATION 7

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

Specifically,

Section 10.2.1.2 of SOP # LAB-007-W, *Environmental and Personal Monitoring of Classified Areas,* Revision: 37, states "A minimum of one (1) active viable air sample must be collected (b) (4) during compounding activities." Your firm's procedure is deficient in that you do not collect active viable air environmental monitoring samples that are representative of the beginning, middle, and end manufacturing process. For example, during the (b) (4) manufacturing process for sterile drug product Oxytocin 30 units added to 0.9% Sodium Chloride 500 mL Bag, Lot (b) (4) , Expiration 02/09/2025, only one (1) active viable air sample is collected during production activities. The same

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practice is utilized for the (b) (4) manufacturing production for Succinylcholine Chloride 20 mg/mL 10 mL fill Syringe (200 mg/10 mL) Lot: (b) (4) , Expiration: 05-Dec-2024. There is no assurance the one active viable air sample is representative of the entire manufacturing process for the production of sterile drug products.

***DATES OF INSPECTION**

12/02/2024(Mon), 12/03/2024(Tue), 12/04/2024(Wed), 12/05/2024(Thu), 12/06/2024(Fri), 12/09/2024(Mon), 12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri), 12/16/2024(Mon), 12/17/2024(Tue), 12/19/2024(Thu), 12/20/2024(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."