

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

DISTRICT ADDRESS AND PHONE NUMBER One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax: (781)587-7556	DATE(S) OF INSPECTION 10/8/2019-11/19/2019*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME SCA Pharmaceuticals	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

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,

The firm failed to adequately investigate the following:

- A. There have been seven confirmed failures for in-house sterility testing of finished sterile drug products since October 2018 using a (b) (4) method for detection of fluorescence in individual microorganisms ((b) (4)). All associated batches (1218003930, 1219007440, 1219008117, 1219008696, 1219009160, 1219009289, & 1219012541) were rejected; however, the investigations did not take into account the identity of the contaminating microorganism(s) to determine its source. For example:
 - Out-of-Specification Laboratory Investigation Report OOS 18-087-W was initiated on 10/15/2018 for the sterility test failure of Buffered Lidocaine 1% in Sodium Bicarbonate 8.4% (b) (4) Syringe lot number 1218003930. The potential root cause(s) was determined to be human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance 12/10/2018.
 - Out-of-Specification Laboratory Investigation Report OOS 19-049-W was initiated on 03/22/2019 for the sterility test failure of Buffered Lidocaine 1% in Sodium Bicarbonate 8.4% (b) (4) Syringe lot number 1219007440. A definitive root

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cause had not been determined but the Deviation Investigation (DV-19-312-W) indicated the possible root cause was human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 06/17/2019.

- Out-of-Specification Laboratory Investigation Report OOS 19-055-W was initiated on 04/18/2019 for the sterility test failure of Hydromorphone HCl 0.2mg/mL in 0.9% Sodium Chloride (b) (4)(b) (4) (b) (4) lot number 1219008117. The potential root cause identified in Deviation Investigation (DV-19-385-W) was human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 09/05/2019.
- Out-of-Specification Laboratory Investigation Report OOS 19-066-W was initiated on 05/11/2019 for the sterility test failure of Vancomycin HCl 1.25g added to 0.9% Sodium Chloride (b) (4) lot number 1219008696. The potential root cause identified in Deviation Investigation (DV-19-472-W) was human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 08/05/2019.
- Out-of-Specification Laboratory Investigation Report OOS 19-071-W was initiated on 05/28/2019 for the sterility test failure of Glycopyrrolate 0.2mg/mL (b) (4) Syringe (b) (4) lot number 1219009160. The potential root cause identified in Deviation Investigation (DV-19-553-W) was human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 08/30/2019.
- Out-of-Specification Laboratory Investigation Report OOS 19-074-W was initiated on 05/31/2019 for the sterility test failure of Phenylephrine HCl 40mcg/mL in 0.9% Sodium Chloride (b) (4) Syringe (b) (4) lot number 1219009289. The potential root cause identified in Deviation Investigation (DV-19-554-W) was

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human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 08/30/2019.

- Out-of-Specification Laboratory Investigation Report OOS 19-123-W was initiated on 09/25/2019 for the sterility test failure of Phenylephrine HCl 100mcg/mL in 0.9% Sodium Chloride (b) (4) Syringe (b) (4) lot number 1219012541. A definitive root cause had not been determined but the Deviation Investigation (DV-19-810-W) indicated the possible root cause was human error; however, the investigation did not identify the contaminating microorganism(s). The investigation was approved by Quality Assurance on 10/18/2019.

Furthermore, it was noted that from January 2019 to October 2019 the firm had approximately 105 occasions in which Personnel Exit Monitoring had exceeded the action limit specification for zero objectionable organisms mostly concerning samples taken from operator hoods (32 occurrences) and chests (50 occurrences); however, the firm had not identified a potential cause for this trend until the Environmental and Personnel Monitoring (b) (4) Trend Report which was approved by Quality on 10/29/2019 during the inspection. Examples of the objectionable organisms recovered were *Bacillus cereus*, *Staphylococcus aureus*, *Moraxella osloensis*, and *Roseomonas mucosa*.

- B. On 08/14/2019 the firm had initiated an Out-of-Specification Investigation Report OOS-19-111-W for a potency failure for the T90 (90 days) stability sample of Heparin Sodium 10units/mL in 0.9% Sodium Chloride (b) (4) lot number 1219008741, result 82%, specification (b) (4)%. The OOS result was confirmed and the firm had initiated a Deviation Investigation (DV-19-711-W) on 08/15/2019 to investigate this failure. The firm had identified the root cause as inconclusive and took the following corrective actions: (b) (4)

[Redacted] . The firm had not conducted a health hazard

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- evaluation of the sub-potent product nor had they notified the customers who had received (b) (4) lots of this product with the 90 day BUD, some of which are currently within expiry.
- C. On 08/16/2019, the firm initiated a Deviation Investigation Report DV-19-716-W to investigate leaking within the (b) (4) (b) (4) assembly (SCA part# (b) (4)) at the (b) (4) side during (b) (4) testing. The firm isolated this leaking (b) (4) to one lot of (b) (4) (lot number (b) (4)). This (b) (4) lot was used to manufacture (b) (4) batches of products in which (b) (4) batches had been distributed. The investigation indicated that the leaking would occur between (b) (4) (b) (4). The firm concluded that based on investigational testing, sterility testing, successful (b) (4) testing and risk assessment that the leaking of the (b) (4) (b) (4) had no impact to patient safety; however, the firm had not provided samples from the lot of defective (b) (4) (b) (4) to their vendor for evaluation and confirmation that the (b) (4) would function as designed. The manufacturer of the (b) (4) (b) (4) (b) (4) had provided a written assessment of the functionality of the (b) (4) on October 21, 2019 (during the inspection) without an evaluation of this lot of defective (b) (4).
- D. The Quality Unit failed to adequately investigate consumer complaints by not evaluating retentions samples and returned product when applicable for confirmation of the reported complaint. For example:
- Customer Complaint Form CUS-18-189-W, dated 11/13/2018, indicated that a customer called stating the nurse from the floor was reporting more hemorrhages on the L&D floor than normal. They had five patients in one day hemorrhage. The customer was requesting potency data on Oxytocin 20units added to 0.9% Sodium Chloride 1000ml Bag lot number 1218004043. The investigation concluded that there was no impact to product identified as the potency of lot number 1218004043 was confirmed to be within specification via batch record review. The firm did not conduct an evaluation of retain samples. The investigation was approved by Quality on 12/27/2018.

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- Customer Complaint Form CUS-19-028-W, dated 2/26/2019, indicated that a customer had administered (b) (4) different bags of Oxytocin 20units added to 0.9% Sodium Chloride 500mL Bag lot number 1219006051 to (b) (4) different pregnant patients and in which their cervixes did not dilate after receiving this product. The investigation concluded that there was no impact to product identified as the potency of lot number 1219006051 was confirmed to be within specification via batch record review. The firm did not conduct an evaluation of retain samples. On 05/22/2019 the firm received (b) (4) units from lot number 1219006051 from their customer. The units were not evaluated but instead were destroyed. The investigation was approved by Quality on 04/03/2019.
- Customer Complaint Form CUS-19-051-W, dated 04/25/2019, indicated that a customer stated that Oxytocin 20units added to 0.9% Sodium Chloride 1000mL Bag lot number 1219007516 was not working on patients. The investigation concluded that there was no impact to product identified as the potency of lot number 1219007516 was confirmed to be within specification via batch record review. The firm did not conduct an evaluation of retain samples. The investigation was approved by Quality on 05/20/2019.

Furthermore, the firm has had sixteen Out-of-Specification Investigations involving sub-potent Oxytocin 20 and 30 unit products compounded from October 2018 to March 2019. Each of these investigations confirmed the potency out-of-specification result and the batches were rejected; however, the above mentioned complaint investigations did not contain an evaluation of these Out-of-Specification Investigations within the investigation summary. As a result of these investigations the firm initiated Change Control TCC#19-073-W (3/18/2019) to update the compounding process to (b) (4) (Oxytocin 20 units (F008446-A-W-02-05) & Oxytocin 30 units (F08544-A-W-02-04)).

OBSERVATION 2

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Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

- A. The firm failed to adequately qualify their method for Sterility Testing via (b) (4) in that during the method transfer, (b) (4) Performance Qualification for SCA Pharmaceuticals Windsor, CT (approved 11/28/2017, CT0051 & 01/08/2018, CT0052) the firm did not verify each product type via (b) (4) but instead only conducted testing using (b) (4) conducted by (b) (4) analysts. The firm has used this method routinely to test and release sterile drug product since (b) (4).
- B. The firm's method for sterility testing (b) (4) Procedure for Sterility Testing via (b) (4) (SOP LAB-020-W), allows for (b) (4) with the (b) (4) ingredient for sterility testing.

***DATES OF INSPECTION**

10/08/2019(Tue), 10/09/2019(Wed), 10/10/2019(Thu), 10/11/2019(Fri), 10/15/2019(Tue), 10/16/2019(Wed), 10/17/2019(Thu), 10/18/2019(Fri), 11/04/2019(Mon), 11/05/2019(Tue), 11/06/2019(Wed), 11/07/2019(Thu), 11/19/2019(Tue)

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