DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	6/1/2023-6/28/2023* FEI NUMBER 3010840309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sarah J. McCoy, Director, Plant Operations

FIRM NAME	STREET ADDRESS
SterRx, LLC	141 Idaho Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plattsburgh, NY 12903-3987	Outsourcing Facility 503B

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 was a failure to handle and store components and closures at all times in a manner to prevent contamination.

Specifically:

You do not maintain the sterility of the cap and interstitial space making up the container closure of Blow-Fill-Seal (BFS) IV bags containing sterile drug products. Furthermore, the container closure is not designed such that the user can sanitize these surface(s) before spiking for administration to a patient. More specifically:

The cap and interstitial space making up the container closure of BFS IV bags containing drug products produced on (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602), are not maintained sterile and may become contaminated during the production process. The surfaces of component (cap) contact equipment including the (b) (4) (b) (4) (b) (4) (b) (4) and (b) (4) (b) (4) with (b) (4) are not sterilized (b) (4) blow-fill-seal and capping operations. Furthermore, the (b) (4) that (b) (4) (b) (4) are, by design, in direct contact with the(b) (4) of every cap during transfer to the capping/sealing station on the BFS (b) (4) equipment train. These (b) (4) are (b) (4) sanitized only with (b) (4) which has not been demonstrated effective on spore forming microorganisms. Non-routine (b) (4) sanitization of the (b) (4) with (b) (4) is performed only when (b) (4) . Additionally, the following factors contribute to contamination risks for drug products produced on (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602):

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	Edmund F Mrak, Investigator Pushpa S Jayasekara, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 06-28-2023 16:06:00	6/28/2023

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a. The design of the cap (b) (4) with (b) (4) and a (b) (4) (b) (4) may challenge methods used to reduce or eliminate microbial contamination. (b) (4) are in direct contact with the (b) (4) of caps during transfer to the capping/sealing station on the BFS (b) (4) equipment train.

b. Your environmental monitoring (EM) program has recovered spore forming microorganisms within the ISO 5 classified (b) (4) BFS (b) (4) (Equipment # E0581) and Capper (Equipment # E0602) (b) (4) including locations adjacent to cap contact equipment. For example: Your Nonconformance Detail Report PR# 40921 reports that pre-batch EM performed on 07/13/2022 for 150mEq Sodium Bicarbonate in 5% Dextrose Lot # (b) (4) recovered 1 CFU/1000L identified as *Domibacillus sp*. from airborne viable sampling in the location of the BFS/ (b) (4) and post-batch EM recovered 1 CFU/1000L identified as *Paenibacillus provencensis* in the location adjacent to the Cap (b) (4). You rejected 150mEq Sodium Bicarbonate in 5% Dextrose Lot # (b) (4) and your investigation reported that: "Materials contributed as (b) (4) was used to sanitize some areas within the BFS (b) (4) and is not effective against the microorganisms identified." You continue to use sterile (b) (4) wipes to sanitize surfaces including the (b) (4) inside the ISO 5 classified (b) (4)

c. The (b) (4)" observed hanging within the (b) (4) adjacent to the cap (b) (4) bowl is not designed for effective sanitization and appeared to be corroded and had broken (b) (4) parts with (b) (4) pieces missing from the tool. Although the (b) (4)" is reportedly used post run for removal of caps from equipment, the inadequately sanitized (b) (4) may accumulate contaminants including microorganisms that may be shed in the (b) (4) environment during filling operations.

d. You accepted and have not corrected non-unidirectional circulating airflow conditions observed during your dynamic airflow visualization study in the ISO 5 (b) (4), which is the area prior to the caps entering the cap (b) (4) bowl. The condition was reported in

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RPT-0099, Report for (b) (4) BFS (b) (4) E0581, approved (b) (4) .

The (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602) is used to produce drug products intended to be sterile including but not limited to 16 mg Norepinephrine in 0.9% Sodium Chloride, 250 mL (b) (4)), Lot # (b) (4) Manufacturing date: (b) (4) , expiry date: 02/15/2024, release date: 03/17/2023.

OBSERVATION 2
Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically:

On 06/02/2023 during aseptic blow-fill-seal operations on the (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602) (b) (4) for production of 150 MEQ Sodium Bicarbonate D5W Injection 1,000ML (12.6 MG/ML) Lot #(b) (4) we observed an operator gowned in non-sterile garb enter the BFS (b) (4) at (b) (4) (b) (4) to clean out resin of malformed bottles from the BFS mold. Although the operator donned sterile arm sleeves and sterile gloves before breaching the ISO 5 space, their head and torso gowned in non-sterile hood, face mask, safety glasses, and coverall entered the ISO 5 space during the intervention. Additionally, the operator's skin was exposed around their safety glasses and border of the hood and mask during the intervention.

Furthermore, your procedure Number: SOP-P-0463, Interventions for BFS (b) (4) permits (b) (4) defined "Critical Aseptic Interventions within (b) (4) BFS, &(b) (4) Transition Ar*ea (* (b) (4) ". Production operators performing in-process interventions within the ISO 5 classified (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602) (b) (4) while donned in non-sterile garb may contribute microbial and other contaminants to the ISO 5 environment

and component (cap) contact equipment and increase the risk of drug product contamination.

OBSERVATION 3

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

Specifically:

1. Your environmental monitoring (EM) program for the (b) (4) (Equipment # E0581) and Capper (Equipment # E0602), does not include direct monitoring (sampling) of the (b) (4) cap (b) (4). The (b) (4) locate caps in position on the cap (b) (4) (b) (4) and by design they are in direct contact with the (b) (4) of every cap during transfer to the capping/sealing station on the BFS (b) (4) equipment train. Furthermore, these (b) (4) are (b) (4) sanitized only with sterile (b) (4) wipes which has not been demonstrated effective on spore forming microorganisms. Non-routine (b) (4) sanitization of the (b) (4) with (b) (4) is performed only when (b) (4).

   The (b) (4) BFS (b) (4) (Equipment # E0581) and Capper (Equipment # E0602) is used to produce drug products intended to be sterile including but not limited to 16 mg Norepinephrine in 0.9% Sodium Chloride, 250 mL ((b) (4)), Lot # (b) (4), Manufacturing date: (b) (4), expiry date: 02/15/2024, release date: 03/17/2023.

2. Your environmental monitoring (EM) program for the (b) (4) Bag Filling/Sealing Machine with (b) (4) (Equipment # E0655) does not include monitoring of all critical aseptic operations. For example:

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a. You do not conduct environmental monitoring in the critical ISO 5 classified filling zone of the (b) (4) (b) (4) Bag Filling/Sealing Machine during the aseptic transfer of needles from the (b) (4) (b) (4) to the filling position.

b. You do not conduct airborne viable monitoring continuously throughout filling operations on the (b) (4) Bag Filling/Sealing Machine.

The (b) (4) Bag Filling/Sealing Machine with (b) (4) (Equipment # E0655) is used to produce drug products intended to be sterile including but not limited to 0.2mg Fentanyl/0.125% Bupivacaine in 0.9% Sodium Chloride, 100mL ((b) (4)), Lot # (b) (4) Manufactured on 06/01/2023.

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.

Specifically:

The design and your operation of (b) (4) Bag Filling/Sealing Machine with (b) (4)) equipment number E0655 do not facilitate aseptic setup and aseptic filling of drug products including but not limited to 0.2mg Fentanyl/0.125% Bupivacaine in 0.9% Sodium Chloride, 100mL ((b) (4)), Lot # (b) (4) Manufactured on 06/01/2023 as follows:

a. You lack adequate evaluation and controls to determine if unidirectional airflow is continuously maintained from the ISO 5 (b) (4) environment to the filling tower. A gap around the (b) (4)

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in the critical filling positions (b) (4) would allow air to enter near the filling needle from the machine space if unidirectional airflow is not maintained.

b. Continuous operation and performance of the filling positions (b) (4) located in the critical filling zone is not adequately monitored to ensure that there is no backflow and potential contamination of the filling zone.

c. Post filling system product flow path (b) (4)), production operators handle the sterilized filling needles with sanitized (b) (4) gloved hands during transfer of the filling needles from the (b) (4) (b) (4) (b) (4) to the filling position for aseptic filling of drug products including 0.2mg Fentanyl/0.125% Bupivacaine in 0.9% Sodium Chloride, 100mL ((b) (4) .

d. Your dynamic airflow visualization study performed in the (b) (4) Bag Filling/Sealing Machine and reported in RPT-0157, Final Report for (b) (4) Filling and Sealing Machine E0655 shows that post filling system (b) (4) production operators obstruct first pass HEPA filtered air over the filling needles with their (b) (4) gloved hands during transfer of both filling needles from the (b) (4) (b) (4) to the filling position for aseptic filling of drug products including 0.2mg Fentanyl/0.125% Bupivacaine in 0.9% Sodium Chloride, (b) (4) ((b) (4)

OBSERVATION 5

Routine calibration and checking of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically:

From 05/24/2023 to 06/06/2023 you manufactured drug products including 0.2mg Fentanyl/0.125%

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Bupivacaine in 0.9% Sodium Chloride, 100mL ((b) (4)), Lot #(b) (4) and150 mEq Sodium Bicarbonate in 5% Dextrose, 1000 mL (b) (4)), Lot (b) (4) intended for commercial distribution using water from a unvalidated temporary water for injection (WFI) distribution loop and WFI (b) (4)). The temporary WFI loop fed directly from the new WFI (b) (4) supplied water as a component for compounding drug products through compounding area use points; supplied the (b) (4) which is used to (b) (4) compounding vessels and applicable drug product flow paths including through the (b) (4) BFS(b) (4) (Equipment # E0581) and(b) (4) Bag Filling/Sealing Machine (Equipment # E0655); and facilities and equipment cleaning. Furthermore:

a. On 06/06/2023 the(b) (4) WFI (b) (4)) alarm history displayed 28 alarm conditions occurring from 05/18/2023 to 06/05/2023 that had not been assessed by responsible persons.
b. As of 06/08/2023, CGMP critical in-line control and monitoring devices on the (b) (4) including (b) (4) , (b) (4) , and (b) (4) and (b) (4) had not been calibrated and the inputs and outputs validated.
c. You lack any records of the frequency and duration during removal of the temporary distribution loop from the (b) (4) and connection to your new distribution (b) (4) which was undergoing engineering and controls commissioning by your contractor.
d. You lack any written controls and records for reconnection of the temporary distribution loop to the (b) (4) (b) (4) for production use.

OBSERVATION 6
Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

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Specifically:

1. (b) (4) Periodic Review ((b) (4) of equipment Blow-Fill-Seal (BFS (b) (4) machine (E0581) was not completed per memorandum (b) (4) (manufacturing and laboratory equipment periodic review requirements, effective date: 08/03/2020) and written procedures (SOP-VAL-0103, Equipment/Utility and Software Validation/Qualification, effective date: 11/2/2022). No formal risk assessment was initiated to assess any product impact due to not completing the periodic review for BFS(b) (4) since December 2020. BFS equipment is associated with following activities since February 2022.
    - Total of (b) (4) batches (150mEq Sodium bicarbonate in 5% dextrose, 1000mL and 4 mg, 8 mg, 16 mg, 32 mg Norepinephrine in 0.9% Sodium Chloride, 250 mL were released
    - Total of (b) (4) batches (150mEq Sodium bicarbonate in 5% dextrose, 1000mL and 4 mg and 16 mg Norepinephrine in 0.9% Sodium Chloride, 250 mL were rejected
    - 29 investigations were initiated due to deviation and out of specifications

2. Required preventative maintenance (PM) activities for equipment Blow-Fill-Seal (BFS(b) (4)) machine (E0581) were not performed consistently and timely manner per written procedures (SOP-PM-0165, Preventative Maintenance, effective date: 08/18/2022). Maintenance History Report (10 Nov 2020 - 02 Jun 2023) and findings in the investigation PR# 47397 were shown that the BFS system preventative maintenance was not properly conducted and documented during the time frame of following investigations.

    - Product:16 mg Norepinephrine in 0.9% Sodium Chloride Injection, 250 mL BFS IV Bag
      PR# 45951
      Date Initiated: 02/07/2023

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Title: Atypical volume of rejects due to embedded specks -in the bottle (non-moving) for BFS (b) (4)

Affected batches: Lot #(b) (4) was aborted per PR45997. Lots (b) (4) and (b) (4) were released

- Product: Product:16 mg Norepinephrine in 0.9% Sodium Chloride Injection, 250 mL BFS IV Bag

  PR # 47438

  Date Initiated: 03/23/2023

  Title: Green liquid solution found on the neck of BFS IV Bag

  Affected batches: Lots (b) (4) and (b) (4)were rejected

- Product: 8 mg Norepinephrine in 0.9% Sodium Chloride Injection, 250 mL BFS IV Bag and 4 mg Norepinephrine in 0.9% Sodium Chloride Injection, 250 mL BFS IV Bag

  PR # 47716

  Date Initiated: 03/31/2023

  Title: Atypical volume of rejects due to embedded specks -in the bottle (non-moving) for BFS (b) (4)

  Affected batches: Lots (b) (4) and (b) (4) were released.

OBSERVATION 7

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Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for compliance with established standards.

Specifically:

You do not perform and document second person verification of all results from environmental monitoring samples. Instructions in your batch related environmental monitoring record and your procedure SOP-MCB-0024, Reading and Checking Plate Counts, allow that a second check is not required if sample plate results have (b) (4) For example:

Your record of batch related environmental monitoring for 16 mg Norepinephrine in 0.9% Sodium Chloride, (b) (4) ((b) (4) , Lot #(b) (4), Manufacturing date: 02/20/2023, expiry date: 02/15/2024, release date: 03/17/2023 produced on (b) (4) BFS(b) (4) (Equipment # E0581) and Capper (Equipment # E0602) does not contain second person verification for (b) (4) counts from environmental samples.

***DATES OF INSPECTION**
6/01/2023(Thu), 6/02/2023(Fri), 6/05/2023(Mon), 6/06/2023(Tue), 6/07/2023(Wed), 6/08/2023(Thu), 6/09/2023(Fri), 6/12/2023(Mon), 6/14/2023(Wed), 6/28/2023(Wed)

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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."