DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	8/17/2021-9/8/2021* FEI NUMBER 1000076625

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Wayne Sartorio Sr., Pharmacy Director

FIRM NAME	STREET ADDRESS
Boothwyn Pharmacy LLC	221 Gale Ln
CITY, STATE, ZIP CODE, COUNTRY Kennett Square, PA 19348	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products

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

Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

On August 19, 2021, during sterile production of "TRICHLORMETHAZIDE- DEXAMETHASONE ACETATE 10 MG/0.5 MG/ML INJ" (lot 08192021@11) and "GLYCOPYRROLATE 0.2 MG/ML INJ" (lot 08192021@12), in the biological safety cabinet (BSC), your pharmacy technician (b) (6) manipulated sterile connections between the respective (b) (4) housing units and the (b) (4) sterile vials such that the filter housing blocked the exposed vial openings from first pass air. Moreover, the pharmacy technician's left hand blocked first pass air to the vials immediately to the left of those being filled for approximately half of the (b) (4) vials of each lot.

OBSERVATION 2

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sena G Dissmeyer, Investigator
Tanya R Syffrard, Investigator

X Sena G Dissmeyer Investiga or Signed By: Sena G. Dissmeyer -S Date Signed: 09-08-2021 1 :2 :32

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9/8/2021

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A. On August 19, 2021, your pharmacy technician (b) (6)) did not clean the interior ceiling "grate" of the BSC before and after producing "TRICHLORMETHAZIDE- DEXAMETHASONE ACETATE 10 MG/0.5 MG/ML INJ" (lot 08192021@11) and "GLYCOPYRROLATE 0.2 MG/ML INJ" (lot 08192021@12), purported to be sterile. She stated she does not clean the ceiling "grate" during routine (b) (4), or (b) (4) cleaning, nor between products. Hazardous products are routinely produced in the BSC, such as "PROGESTERONE 150 MG/ML INJ" (lot 08172021@4) produced on August 17, 2021.

B. On August 20, 2021, your pharmacy technician (b) (6) did not clean the interior back wall "grate" of the laminar airflow workstation (LAFW) before and after producing "AMMONIUM CHLORIDE 2% INJ" (lot 08202021@5), purported to be sterile. He stated he does not clean the back wall "grate" of the LAFW during routine (b) (4) cleaning, nor between products.

C. Your pharmacy technician (b) (6) stated he does not clean product-contact utensils, such as spatulas and (b) (4) and (b) (4), with a deactivating agent after producing hazardous non-sterile drug products. These utensils are sprayed with (b) (4) to the sink for cleaning with household liquid detergent and water. Hazardous active pharmaceutical ingredients used in non-sterile production include, for example, but not limited to, testosterone, estriol, estradiol, tretinoin, and progesterone.

D. You have no assurance that your cleaning process removes detergent residue from your reusable glassware and utensils. Your pharmacy technician (b) (6) stated he uses a household liquid detergent, (b) (4) to clean reusable glass beakers and utensils that are routinely used in the production of your hazardous and non-hazardous sterile and non-sterile drug products.

OBSERVATION 3
Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas.

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Your pharmacy technician (b) (6) did not disinfect four of the outer surfaces of the (b) (4) and none of the outer surfaces of the (b) (4) beaker of the filling solution before bringing them into the ISO 5 classified laminar airflow workstation (LAFW) on August 20 and 25, 2021. Furthermore, the technician did not sanitize his gloves while transferring the (b) (4) from the ISO 7 to ISO 5 classified areas. (b) (6) then produced "AMMONIUM CHLORIDE 2% INJ" (lot 08202021@5) and "AMINOCAPROIC ACID 250 MG/ML INJ" (lot 08252021@5), respectively, purported to be sterile drug products.

Your pharmacy technician (b) (6) did not disinfect two of the (b) (4) outer surfaces of the (b) (4) and none of the outer surfaces of the (b) (4) beaker of the filling solution before bringing them into the ISO 5 classified BSC on August 18, 19, and 20, 2021. Furthermore, the technician did not sanitize her gloves while transferring the (b) (4) from the ISO 7 to ISO 5 classified areas. (b) (6) then produced "FOLIC ACID 10 MG/ML INJ" (lot 08182021@6), "TRICHLORMETHAZIDE- DEXAMETHASONE ACETATE 10 MG/0.5 MG/ML INJ" (lot 08192021@11), and "ACETYLCYSTEINE 200 MG/ML INJ" (lot 08202021@6), respectively, purported to be sterile drug products.

OBSERVATION 4

The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

Specifically,

A. Your pharmacy technician (b) (6) did not allow the required (b) (4) contact time (also known as "dwell time"), per your procedures and the cleaning agent manufacturer's use directions, for your disinfectant/sporicidal cleaning agent (b) (4) when used on the floor of the sterile suite containing the laminar airflow workstation (LAFW), during (b) (4) cleaning on August 20, 2021. Most areas of the floor had a drying time of less than (b) (4). Additionally, (b) (6) did not use the

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disinfectant/sporicidal cleaning agent on the ceiling and walls of the ISO 7 classified buffer room. You failed to establish an adequate contact time for your sporicidal agent used to disinfect your aseptic processing areas. (b) (6) stated that the disinfectant/sporicidal cleaning agent may be allowed to dry prior to (b) (4), though the surface may not be touched afterwards for that length of time.

B. Your pharmacy technician (b) (6) did not clean the (b) (4) located between the ISO 8 classified preparation room and the ISO 7 classified buffer room with a sporicidal agent or any cleaning agent during direct observation of the (b) (4) cleaning of the sterile suite containing the LAFW on August 20, 2021.

C. During the (b) (4) cleaning of the sterile suite containing the LAFW on August 20, 2021, your pharmacy technician (b) (6) inconsistently cleaned the walls of the ISO 7 classified ante room, switching back and forth between (b) (4) and (b) (4) such that only one solution or the other was used on sections of the walls, rather than using the (b) (4) first with a (b) (4) dwell time followed by a (b) (4) cleaning, per your cleaning procedures. For example, only (b) (4) was used to clean the back wall and far section of the right wall of the ante room. Also, both (b) (4) (b) (4) and (b) (4) were sprayed onto the (b) (4) simultaneously to clean the glass door leading from the ante room into the buffer room. No other sporicidal agent is used on a (b) (4) basis.

D. On August 19, 2021, your pharmacy technician (b) (6)) did not clean the interior ceiling "grate" of the BSC with a sporicidal agent before or after producing "TRICHLORMETHAZIDE- DEXAMETHASONE ACETATE 10 MG/0.5 MG/ML INJ" (lot 08192021@11) and "GLYCOPYRROLATE 0.2 MG/ML INJ" (lot 08192021@12), purported to be sterile. She stated she does not clean the ceiling "grate" during routine (b) (4), or (b) (4) cleaning, nor between products.

E. On August 20, 2021, your pharmacy technician (b) (6) did not clean the interior back wall "grate" of the laminar airflow workstation (LAFW) with a sporicidal agent before or after producing "AMMONIUM CHLORIDE 2% INJ" (lot 08202021@5), purported to be sterile. He stated he does not clean the back wall

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"grate" of the LAFW during routine (b) (4) cleaning, nor between products.

OBSERVATION 5

The ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

Specifically,

A. On August 19, 2021, during observation of the production of "TRICHLORMETHAZIDE- DEXAMETHASONE ACETATE 10 MG/0.5 MG/ML INJ" (lot 08192021@11), we observed the ceiling around the vent protruding from the top-center of the ISO 5 biological safety cabinet (BSC) had uneven surfaces with apparent caulking remnants. Additionally, there is a piece of white material that looked like caulk, approximately one centimeter in width and depth, hanging down from the ceiling immediately in front of the BSC access side. Your sterile pharmacy manager explained the ceiling tile had to be replaced and caulked with the replacement of the former BSC in July 2021. Also, to the right of the BSC's front-right leg, there is rust-colored staining, approximately one inch in diameter, on the tile floor.

B. Non-sterile (b) (4) were used to hold the sterile tubing line in place against the (b) (4) beaker during sterile drug production observed within the ISO 5 classified areas, in both the BSC and the laminar airflow workstation (LAFW), such as "AMMONIUM CHLORIDE 2% INJ" (lot 08202021@5) and "ACETYLCYSTEINE 200 MG/ML INJ" (lot 08202021@6).

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OBSERVATION 6

Personnel sampling was conducted after gloves had been cleaned/disinfected. Therefore, glove fingertip sampling results are not representative of the aseptic processing environment and may not provide meaningful results.

Specifically,

On August 25, 2021, your pharmacy technician (b) (6) performed fingertip monitoring testing after producing "AMINOCAPROIC ACID 250 MG/ML INJ" (lot 08252021@5) immediately after finishing production; however, prior to the fingertip monitoring sampling, he directly sprayed his gloved hands with (b) (4) (b) (4)

On August 20, 2021, the same technician performed fingertip monitoring testing after producing "AMMONIUM CHLORIDE 2% INJ" (lot 08202021@5); however, prior to the fingertip sampling, he cleaned the ISO 5 classified laminar air flow workbench (LAFW) interior ceiling, sides, and work surface with (b) (4)

OBSERVATION 7

Your media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that you can aseptically produce drug products within your facility.

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Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. Media fills did not encompass the greatest production volume, over (b) (4), before August 6, 2021. For example, aseptic lots, produced in July 2021, over a (b) (4) quantity, include "ACETYLCYSTEINE 200 MG/ML INJ" (lots 07222021@10 and 07132021@2), "METHOCARBAMOL 100 MG/ML INJ" (lot 07092021@1), and "FOLIC ACID 10 MG/ML INJ" (lot 07082021@2).

OBSERVATION 8

ISO-5 classified areas were not certified under dynamic conditions.

Specifically,

Unidirectional airflow was not verified under dynamic operational conditions representative of your aseptic processing practices. Air visualization studies ("smoke studies") performed in your ISO 5 classified biological safety cabinet and ISO 5 classified laminar airflow workbench in July 2021, January 2020, and June 2020 do not demonstrate the movement of first air around equipment, supplies, or operator manipulations as observed during sterile production operations. The smoke studies did not demonstrate unidirectional airflow, for example, around equipment such as a (b) (4) beaker, the quantity of vials filled, or the (b) (4) (b) (4) housing disrupting airflow to directly over the opening of sterile vials, as observed during production of lots 08192021@11, 08192021@12, and 08202021@5.

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OBSERVATION 9

Your facility failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products.

Specifically,

(b) (4) water is used in production of non-sterile drug products without raw material testing or a manufacturer's certificate of analysis. For example, Rx (b) (6) and Rx (b) (6) were produced with (b) (4) water without confirming the quality of the water.

***DATES OF INSPECTION**

8/17/2021(Tue), 8/18/2021(Wed), 8/19/2021(Thu), 8/20/2021(Fri), 8/24/2021(Tue), 8/25/2021(Wed), 8/26/2021(Thu), 8/27/2021(Fri), 9/07/2021(Tue), 9/08/2021(Wed)

X Tanya R Syffrard
Investigator
Signed By: Tanya R. Syffrard -S
Date Signed: 09-08-2021 14:25:10

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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."