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	9/23/2024-10/22/2024* FEI NUMBER 1000076625

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John W. Howell Sr. , Execcutive Vice President of Operations

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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

A. Your firm distributed seven (7) batches of your drug products using Certificates of Analysis (COAs) containing passing bacterial endotoxin testing (BET) results when in fact the COAs pulled from your contracted testing laboratory's database indicate that the true results of the BET were Out of Specification (OOS):

Date Made	Product Name	Batch Number	Failing Results	Specification w/ Failing Results	False Passing Results	Specification w/ Passing Results
4/20/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	03132023@(b) (4	530.40 EU/mL	(b) (4)	27.23 EU/mL	(b) (4)
7/14/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	07142023@(b)	706.59 EU/mL		<100.00 EU/mL	
10/5/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ	10052023@(b)	398.37 EU/mL		177.09 EU/mL	

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EMPLOYEE(S) SIGNATURE
Christina K Theodorou, Investigator
Juanita P Versace, Investigator
Rahi D Patel, Investigator
Julia N Alvarez, FDA Center Employee

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	SOLUTION					
10/6/2023	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	10062023@(b)	559.99 EU/mL	(b) (4)	126.01 EU/mL	(b) (4)
1/25/2024	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	01172024@(b) (4	264.09 EU/mL		<100.00 EU/mL	
5/1/2024	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	04302024@(b) (4	603.96 EU/mL		<200.00 EU/mL	
7/11/2024	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	07092024@(b) (4	282.22 EU/mL		282.22 EU/mL	

B. Your firm distributed approximately thirty-one (31) of your compounded drug products that received out of specification result for BET from your contracted testing laboratory from March 2023 to August 2024. For example, on 1/22/2024 your firm received notice of an Out of Specification (OOS) (i.e. failure to meet specification) result for bacterial endotoxins for Pentosan and Glucosamine injection solution, lot # 01152024@(b) (4) of 1,483.73 EU/mL, exceeding your specification of (b) (4) EU/mL. Although your contracted laboratory concluded the OOS results were valid after their internal OOS laboratory investigation, confirming the original OOS on 1/25/24 with results of 1,815.32 EU/mL and 1,435.59 EU/mL, your firm dispensed the nonconforming lot of Pentosan and Glucosamine injection solution, lot # 01152024@(b) (4)

The following table provides a list of some of the distributed batches that received an OOS result from your contract testing laboratory.

Date made	Product Name	Batch Number	Endotoxin Result	Specification
1/10/2024	PENTOSAN POLYSULFATE AND	01082024@(b) (4)	9825.05	(b) (4)

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Kennett Square, PA 19348	Producer of Sterile and Non-Sterile Drug Products

	GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION		EU/mL	EU/mL
2/16/2024	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	02022024@[b](4)	23,765.27 EU/mL	(b) (4) EU/mL
3/15/2024	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	03152024@[b]	19,947.64 EU/mL	(b) (4) EU/mL
4/4/2024	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	04032024@[b](4)	31,674 EU/mL	(b) (4) EU/mL
5/8/2024	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	05072024@2[b]	1358.82 EU / mL	(b) (4) EU / mL

C. Your firm failed to conduct bacterial endotoxin testing (BET) for approximately six (6) batches of your glucosamine containing products and subsequently distributed the batches:

- Lot # 07252024@[b](4) HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION
- Lot # 07302024@[b](4) PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION
- Lot# 08132024@[b](4) HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION
- Lot# 08212024@[b](4) PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML

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100 MG/ML INJ SOLUTION

- Lot# 08292024(b) (4), HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION
- Lot# 09102024@(b) (4), ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION

OBSERVATION 2

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

Specifically,

A. Review of your firm's air visualization "smoke" study videos shows insufficiencies for example:

1. Your media fills and smoke studies are not representative of your production operations. For example, during the execution of your media fill studies titled, *Media Fill Testing (Smoke Study) High Risk Inj Solution* 08162024@(b) (and 08162024@(b) (4 and Smoke Studies *Smoke Study 08.16.24 PS-169 FDA (Hazardous Sterile Filling Room) and Smoke Study 08.16.24 PS-172 FDA (Non-Haz Sterile Filling Room)*, you utilized the services of a second operator to assist your filling technician. The secondary operator in both videos were observed entering into the ISO 5 environment while your filling technician maintained their hands inside the same ISO 5 environment. Per SOP, SOP ID: CP.CTECH.0040.000 *ASEPTIC TECHNIQUE*, section 6.4.14, *only one (1) trained pharmacist or pharmacy technician may be in the ISO Class 5 environment at a time*.

2. In the smoke study video titled, *Smoke Study 08.16.24 PS-169 FDA (Hazardous Sterile*

Filling Room), at video timestamps 02:33 and 04:11, your operator was observed to be moving the tubing from their right hand into their left hand, thereby allowing the tubing and connections to touch the product contact ends of the stoppers within the open stopper packet compromising the sterility of the stoppers. Your operator uses sterile (b) (4) to ensure that the product contact end of the stoppers remain sterile.

3. There are multiple instances in your smoke studies where First Pass Air (FPA) is being blocked or collects and creates a vortex around the vials being filled by your operator. For example,

   i. *Smoke Study 08.16.24 PS-169 FDA (Hazardous Sterile Filling Room)*, the sleeved forearm of your operator is seen blocking FPA above the open stopper package throughout the video, for example at video timestamps 00:39, 02:29, 06:14 and 13:05. At timestamp 03:39 the smoke wand is moved further to the back of the unit and smoke can be seen swirling at the back edge of the vials which continues until timestamp 04:17.

   ii. *Smoke Study 08.16.24 PS-172 FDA (Non-Haz Sterile Filling Room)*, smoke is seen creating a vortex in the space in front of the operator's torso and rotating back toward the vials at time stamp 00:18, 03:43-04:06 and 06:17-06:26. The positioning of the operator and the video camera does not allow for visualization of the airflow over the vials as the technician fills them. At timestamp 0:17, the technician is observed to be selecting a stopper with the sterilized (b) (4) and leaves their arm and hand in a resting position over the open packet of stoppers blocking FPA.

B. You do not conduct personnel sampling, such as but not limited to, glove fingertip testing of the

second technician that was observed to be present during the execution of your dual media fill and air visualization "smoke" study videos. This secondary technician added vial trays to the ISO 5 zone, removed filled vials from the ISO 5 zone and removed any trash generated.

C. On 09/27/2024 the (b) (4) (b) (4) Asset ID# (b) (4) which is located in PS-170, was loaded beyond the scope of your validation studies. For example, (b) (4) (b) (4) was observed to have items on the bottom portion (b) (4) stacked high enough to potentially touch the bottom of the third shelf above it. Further, items placed on the first shelf where stacked high enough to potentially touch the top of the unit. Your IQOQPQ for the (b) (4) does not maintain any loading pattern that includes loading items on the bottom portion of the (b) (4) nor stacking items to the top of the unit. Items on the second shelf were of a mixed sizes and shapes. For example, (b) (4) flasks were loaded on the shelf with other items that were stacked in the back right corner, high enough to potentially touch the bottom of the first shelf. Your IQOQPQ does not maintain any loading pattern that include this schematic.

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 investigate the multiple Out of Specification (OOS) failures for bacterial endotoxin testing (BET).

A. Your firm provided OOS Investigational Reports for eighteen (18) of thirty-one (31) batches conducted by your firm that were generated specifically for the purposes of this FDA Inspection and were not taken at the time of occurrence. Your firm management stated that none of the actions identified in the documents were taken as corrections nor was there an investigation

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into the root cause(s) for the failing endotoxin results. For example, the investigations contain a call log indicating that patients and/or their prescriber were contacted regarding the BET results and to inquire if patients suffered any adverse effects due to the contaminated product. None of the patients or their prescribers were contacted. Further, the OOS investigation documents mention "lab interference" when the OOS investigations from your contracted laboratory confirmed the OOS results received indicating that no laboratory error contributed to the OOS result. Your firm did not request a copy of the OOS investigations from your contracted testing laboratory and therefore were not part of your own review into the OOS results. The following list of eighteen (18) batches were OOS for endotoxin.

Product Name	LOT #
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	01082024@(b)
ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	01092024@(b)
HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	01092024@(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	01152024@(b)
ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	02022024@(b)
HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	02202024@(b)
HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	03012024@(b)
ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ	03012024@(b)

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SOLUTION	
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	03152024@(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	04032024@(b)(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	04202024(b) (4)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	05072024@(b)(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	06212024@(b)(b)
ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	07092024@(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	07092024@(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	07152024@(b)(b)
ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	07222024@(b)
PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	12062023@(b)

B. Your firm did not conduct an investigation into the OOS result for batch 08202024@(b) (4) The COA indicated the OOS result was received by your firm on 09/09/2024. A total of thirty-two (32) days passed since the receipt of this OOS. You did not conduct an OOS investigation until

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10/11/2024, when the COA was reviewed during the current FDA inspection.

OBSERVATION 4

The quality control unit lacks the responsibility and authority to approve all components and drug products.

Specifically, your quality unit did not conduct any final review or approval of the COAs received from your contracted testing laboratory. There were a total number of thirty-one (31) batches that received an OOS result of which seven (7) COAs were altered to show passing results for BET. Review of your batch records does not show any indication of a receipt and review of the COAs received from your contracted testing laboratory. Further, the *Logged Formula Worksheet, Final Observation and Status*, allows for the entry of the sterility and endotoxin results received from your contracted testing laboratory, a pharmacist verification of the results and an overall batch disposition, however it is not utilized. There is no indication of who has final approval of your executed batch records and their testing results.

OBSERVATION 5

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, you do not verify the conformance of a product to the manufacturer COA for any of the active pharmaceutical ingredients received into your facility or to ensure that components utilized by your firm are pharmaceutical grade. For example, the COAs issued by one of your suppliers for N-Acetyl-D -Glucosamine USP, lots (b) (4) and (b) (4) states "FOR NUTRACEUTICAL USE ONLY". You

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distributed the following drug products containing glucosamine that were out of specification for endotoxin by this supplier:

Date made	Name	Lot Number	API Lot number
7/14/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	07142023@(b)(	(b) (4)
8/16/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	08142023@(b) (4)	
10/5/2023	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	10052023@(b)(	
10/6/2023	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	10062023@(b)(	
12/6/2023	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	12062023@(b)(	
1/10/2024	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	01082024@(b) (4)	
1/12/2024	ACETYL-D-GLUCOSAMINE * (100ML) 200 MG/ML INJ SOLUTION	01092024@(b) (4)	
1/16/2024	PENTOSAN POLYSULFATE AND GLUCOSAMINE (50ML) 250 MG/ML 100 MG/ML INJ SOLUTION	01152024@(b) (4)	
1/17/2024	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	01092024@(b)(	

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1/25/2024	HA/ CHONDROITIN/ ACETYL-D-GLUCOSAMINE (100ML) 5MG/50MG/150MG/ML INJ SOLUTION	01172024@[(b) (4)]	(b) (4)

*DATES OF INSPECTION

9/23/2024(Mon), 9/24/2024(Tue), 9/25/2024(Wed), 9/26/2024(Thu), 9/27/2024(Fri), 10/01/2024(Tue), 10/03/2024(Thu), 10/07/2024(Mon), 10/09/2024(Wed), 10/10/2024(Thu), 10/15/2024(Tue), 10/17/2024(Thu), 10/22/2024(Tue)

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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."