DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	7/20/2021-7/27/2021* FEI NUMBER 3012039582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael H. Roberge, Owner

FIRM NAME	STREET ADDRESS
Compounded Solutions in Pharmacy, LLC	810 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Monroe, CT 06468-2809	Producer of Non-Sterile and Sterile Drug

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

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, on 7/22/2021, a cleanroom operator was observed not disinfecting individually packaged supplies and drug vials immediately prior to them being introduced into the ISO 5 area for any of the observed prescriptions prepared such as Timolol/Brimonidine Ophth PF 0.5%-0.2% Solution (Lot # 07222021@40; BUD 7/25/2021), Testosterone (AQ) Ophth PF 0.03% Suspension (Lot # 07222021@28; BUD 7/25/2021), and Triple P 15/0.5/10 Injectable (Lot # 07222021@50; BUD 10/20/2021).

OBSERVATION 2

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 7/22/2021, a cleanroom operator was observed allowing the sleeves of the gown being donned to touch the floor of the ISO 7 buffer room during the gowning process. That operator then proceeded with that same gown to aseptically fill Testosterone (AQ) Ophth PF 0.03% Suspension (Lot # 07222021@28; BUD 7/25/2021), a process that requires him to extend his gloved hands and gowned arms into the ISO 5 hood.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mindy M Chou, Investigator Johnna L Bleem, Investigator	X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 07-27-2021 17:12:48	7/27/2021

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Specifically, Section 8.4.1 of the SOP # 3.020, entitled, "Cleaning and Maintenance of the Clean Room Facility" allows (b) (4) cleaning to be performed with either the sterile (b) (4) for the non-hazardous BSC. The firm does not use sporicidal cleaning agents in the ISO 8 Anteroom.

OBSERVATION 4

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed.

Specifically, the cleanroom differential pressure for the Non-Hazardous Sterile Compounding Room and the Anteroom were observed with a differential pressure reading of "(b) (4)" from 11/2/2020 thru 12/16/2020 and from 2/16/2021 thru 2/17/2021, respectively. Per SOP # 3.010, entitled, "Sterile Compounding Area Requirements", the minimum differential positive pressure gauge reading for physical separations between non-hazardous controlled areas is "(b) (4)" of the water column. No investigation was initiated by the firm to assess the impact on the sterile drug products produced during the differential pressure excursion. The following are examples of sterile drug products produced during the differential pressure excursion timeframes: Triple P 30/3/40 Injectable (Lot # 12012020@46; BUD 2/25/2021); (b) (4) (Lot # (b) (4) ; BUD 11/23/2020); and Doxycycline Ophth 0.025% Solution (Lot # 11172020@42; BUD 11/20/2020).

OBSERVATION 5

Cleaning practices used by the firm for cleaning of ISO 5 areas do not support appropriate environmental cleanliness for sterile drug production.

Specifically,

(A) On 7/22/2021, sterile wipes used to clean the ISO 5 area were observed exposed to conditions worse than ISO Class 5 air quality. The opened packet of sterile wipes were observed left on top of a container and exposed to ISO 7 environment. These wipes were used to clean the ISO 5 area between batches and after production.

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(B) On 7/23/2021, the technician (b) (6) who performed (b) (4) cleaning of the Compounding (b) (4) (b) (4) in the Biohazard Room was observed with his head and arm inside the (b) (4) while performing cleaning of the equipment's back walls, thereby, exposing non-sterile garbs inside the ISO Class 5 (b) (4). The technician (b) (6) was also observed with exposed skin around the face and with his face and exposed skin inside of the ISO 5 area. Upon discussion with the cleaning technician (b) (6), it was revealed that he does not use additional tools to assist him with the cleaning of the hard to reach areas, as observed in the Biohazard Room, in any of the ISO 5 hoods, to minimize the chance of an employee's head, shoulder, etc. entering the ISO 5 Hood.

OBSERVATION 6

The firm held product in conditions that does not ensure the integrity of the finished drug product and could therefore be injurious to health.

Specifically, we observed the firm deviated from manufacturer instructions in the (b) (4) (NDC: (b) (4) package insert without adequate scientific rationale to ensure the integrity of the finished drug product in order to prevent any degradation, impurities, or different strength than the label claim. The firm stores the reconstituted drug product in (b) (4) at a temperature above the recommended temperature in the manufacturer's label (b) (4)). In addition, the firm uses the reconstituted (b) (4) as a stock solution and (b) (4) the solution after a (b) (4) cycle; however, the manufacturer's labeling states the product should not be (b) (4) once (b) (4). (b) (4) per vial (Lot # (b) (4)) was reconstituted on February 17, 2021 for the production of (b) (4) (Lot # (b) (4)) and the reconstituted stock vial was assigned a beyond-use date of May 18, 2021. The reconstituted stock vial (Lot # (b) (4)) was used in the production of Ceftazidime Ophthalmic 50 mg/mL Solution (Lot # 02172021@22; BUD 3/3/2021) on February 17, 2021. The (b) (4) (Lot # (b) (4)) was again used in the production of Lot # (b) (4) (BUD 3/24/2021) on March 10, 2021, and for Lot # (b) (4) (BUD 4/26/2021) on April 12, 2021.

OBSERVATION 7

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Personnel engaged in non-sterile compounding did not ensure the prevention of contamination of compounded products with foreign matter.

Specifically, operators performed non-sterile drug compounding on a countertop in uncontrolled space, without the appropriate clothing for the compounding performed (e.g., facemask, hair bonnet).

***DATES OF INSPECTION**
7/20/2021(Tue), 7/21/2021(Wed), 7/22/2021(Thu), 7/23/2021(Fri), 7/26/2021(Mon), 7/27/2021(Tue)

X Johnna L Bleem
Investigator
Signed By: Johnna L. Bleem -S
Date Signed: 07-27-2021 17:13:42

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EMPLOYEE(S) SIGNATURE
Mindy M Chou, Investigator
Johnna L Bleem, Investigator

X Mindy M Chou
Investigator
Signed By: 2000648922
Date Signed: 07-27-2021
17:12:48

DATE ISSUED
7/27/2021

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."