

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

DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 6/9/2021-7/26/2021*
	FEI NUMBER 3012223534

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. Svetislav Milic, Pharmacist in Charge and Owner

FIRM NAME Colonia Care Pharmacy	STREET ADDRESS 515 Inman Ave Ste A
CITY, STATE, ZIP CODE, COUNTRY Colonia, NJ 07067-1114	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

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**

Non-microbial contamination was observed in your production area.

Specifically,

- a. On 6/9/2021, we observed an unknown white to off-white powder residue and light brownish discoloration under the front return air grille located inside the ISO 5 (b) (4) Laminar Flow (b) (4) (LF<sup>(b)(4)</sup>), which was documented as having been cleaned the day before on 6/8/2021.
- b. The unclassified room where the ISO 5 LF<sup>(b)(4)</sup> is located is held under insanitary conditions. This unclassified room is utilized for the compounding of non-sterile drug products. We observed the following, but not limited to:
  - i. Dust/filth on HVAC vent and on the surface of chemo/hazardous wipe bags stored on the shelf.
  - ii. Wooden blocks to support the four legs of LF<sup>(b)(4)</sup>
  - iii. Off-white to yellowish substance stuck on the ceiling.
  - iv. Dust/filth on multiple appliances such as, but not limited to, the surface of the weighing balance, computer, camera and keyboard.
  - v. Discoloration/dark stain on the vinyl-like floor.
  - vi. Rust-like appearance (orange/reddish material) on the nails on a shelf where active pharmaceutical ingredients and raw materials are stored.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Unnee Ranjan, Investigator Jessica S Estriplet, Investigator	Unnee Ranjan Investigator Signed By: 2001555336 Date Signed 07-26-2021 09 47 35 X _____	DATE ISSUED 7/26/2021

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**OBSERVATION 2**

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

Specifically,

- a. The cleaning logs indicated that the sporicidal cleaning of the ISO 5 LF<sup>(b)(4)</sup> was performed (b)(4). You stated that the sporicidal cleaning is performed at the discretion of the pharmacist. You did not provide any scientific rationale for the frequency of sporicidal cleaning. In addition, the contact time for the use of sporicidal cleaning agent is unknown from the documents provided.
- b. On 6/25/2021, we observed that the pharmacist conducting routine cleaning of the ISO 5 LF<sup>(b)(4)</sup> did not clean the supply air grille located below the HEPA filter nor the surface of the latex glove sleeves. These surfaces are located (b)(4) where sterile products are open to the environment during compounding manipulations inside the LF<sup>(b)(4)</sup>.
- c. The February 2021 cleaning log of the ISO 5 LF<sup>(b)(4)</sup> indicated that no cleaning was performed from 2/23/2021 to 2/28/2021. The (b)(4) operation checklist indicated that the (b)(4) was not in use during this period. However, your prescription records show that Atropine Ophthalmic Solution, 0.01%, Lot 022621A was compounded on 2/26/2021 using the LF<sup>(b)(4)</sup>.

**OBSERVATION 3**

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

Specifically,

Your firm compounds sterile/non-sterile drug products such as, but not limited to beta-lactams, opioids, antineoplastic, and hormonal products. However, no cleaning agent is currently utilized that would render these compounds inactivated and removed from product contact surfaces. In addition,

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cleaning activities after compounding operations are not documented and cannot not be verified.

**\*DATES OF INSPECTION**

6/09/2021(Wed), 6/10/2021(Thu), 6/14/2021(Mon), 6/21/2021(Mon), 6/22/2021(Tue), 6/25/2021(Fri),  
6/29/2021(Tue), 7/01/2021(Thu), 7/02/2021(Fri), 7/14/2021(Wed), 7/26/2021(Mon)

Jessica S Estriplet  
Investigator  
Signed By: Jessica S. Estriplet-S  
Date Signed: 07-26-2021 09:48:10  
X \_\_\_\_\_

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Unnee Ranjan, Investigator Jessica S Estriplet, Investigator	Unnee Ranjan Investigator Signed By: 2001555336 Date Signed 07-26-2021 09:47:35 X _____	DATE ISSUED 7/26/2021

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."