DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Observation 1

The facility design was observed to allow the influx of poor quality air into a higher classified area.

Specifically,

A. Your cleanroom design includes the ISO 5 classified area air exhausts, which vents along the floor into a non-classified/ non differential pressure monitored/ controlled area containing dust particulates on the floor. Your pharmacy has identified this area as an ISO Class 8. Your pharmacy uses this area for storage along with (b) (4) and (b) (4) processing area for (b) (4) and sterilization of aseptic processing utensils and components. The area also has an unrestricted doorway entering your pharmacy’s non-sterile hazardous drug processing area. Your firm’s cleanroom design failed to prevent contamination and lower quality air from entering your ISO 5 sterile drug compounding area from the non-classified area identified as an ISO Class 8 which is assessed (b) (4). There have been no changes made in the cleanroom overall design since the previous FDA inspection. This is a repeat observation.

B. No HEPA filter coverage is available for the (b) (4) located in cleanroom connecting the non-classified area to the ISO 7 Classified cleanrooms containing (b) (4) LAFU built into the room, which may potentially allow the influx of poor quality air into a higher classified area. This is a repeat observation.

C. (b) (4) doors are designed with no safeguard in place to detect and notify of changes in differential pressure in the event (b) (4) along with spaces between the

SEE REVERSE OF THIS PAGE

Cameron E Moore, Investigator

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door edges. Your pharmacy document differential pressures in each classified area within the cleanroom
(b) (4) The (b) (4) has are no inter-locking mechanism to prevent (b) (4)
(b) (4) Additionally, there are no other electronic monitoring systems in place to
detect a change in differential pressure.

D. The area outside your pharmacy's modular cleanroom, identified as an ISO Class 8, your pharmacy failed
to adequately control and monitor the area to ensure it the documented requirements. The area is used
as a storage area, containing both an (b) (4) and (b) (4) . There is a thorough going
doorway which leads to your pharmacy's non-sterile hazardous drug processing area. Your pharmacy
uses a scale on a stainless-steel workbench to weigh (b) (4) drug components which is located
approximately 3 feet from the unrestricted doorway leading into the alleged ISO 8 classified area.

Observation 2
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, during your pharmacy's cleanroom re-certification, unidirectional airflow was not verified under
operational (dynamic) conditions where all equipment (mixers and (b) (4) used during aseptic processing in
addition to pharmacy technician simulating drug product processing was in use and being performed within the
ISO 5 processing area. Your firm's clean room re-certification reports tests dated 8/25/2021, 10/23/2020,
8/19/2020, 8/9/2019 and 4/10/2019 were documented as being performed in dynamic conditions. No aseptic
simulations and equipment were in use and performed at the time of the documented cleanroom. This is a
repeat observation.

OBSERVATION 3
Your firm handled hazardous drug products without adequate containment, segregation, or cleaning of work
surfaces and utensils to prevent cross-contamination.

Specifically, during a walkthrough of your pharmacy's non-sterile hazardous drug processing area, your
pharmacy was observed using an air blower, underneath the table, to dry utensils. At the same time, your
pharmacy technician was in the middle of processing a batch of non-sterile hazardous drug product, ANAS0.07MG/B12-1MG/ B7-10MG/COQ10-100MG/ FINAS2.5MG RESV 200MG/TADAL5MG/ VITD3-4000IU/ZN 30MG K-CAPS #509 Capsules, Lot # 09172021:48, BUD 2/28/2022. Your pharmacy PIC reported no laboratory testing is performed on any processed non-sterile drug products.

*DATES OF INSPECTION
9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu), 10/01/2021(Fri), 10/06/2021(Wed)
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."