DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/23/2021-10/6/2021*
	FEI NUMBER 3009192575

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gary M. Huddleston, Pharmacist-In-Charge (PIC)	
FIRM NAME Vita Pharmacy, LLC dba Talon Compounding Pharmacy	STREET ADDRESS 2950 Thousand Oaks Dr Ste 25
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78247-3347	TYPE ESTABLISHMENT INSPECTED Sterile and Non-sterile Drug Producer

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 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 dusk 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	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 10-06-2021 17:06:20	10/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/23/2021-10/6/2021* FEI NUMBER 3009192575
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gary M. Huddleston, Pharmacist-In-Charge (PIC)	
FIRM NAME	STREET ADDRESS
Vita Pharmacy, LLC dba Talon Compounding Pharmacy	2950 Thousand Oaks Dr Ste 25
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78247-3347	Sterile and Non-sterile Drug Producer

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 are 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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 10-06-2021 17:06:20	10/6/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	9/23/2021-10/6/2021*
	FEI NUMBER 3009192575

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Gary M. Huddleston, Pharmacist-In-Charge (PIC)	
FIRM NAME Vita Pharmacy, LLC dba Talon Compounding Pharmacy	STREET ADDRESS 2950 Thousand Oaks Dr Ste 25
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78247-3347	TYPE ESTABLISHMENT INSPECTED Sterile and Non-sterile Drug Producer

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)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 10-06-2021 17:06:20	DATE ISSUED 10/6/2021

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."