DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway #300 Dallas, TX 75204-3128 214-253-5200 Industry Information: www.fda.gov/oc/industry	1/22-24; 27-29/2020; 2/10-11/2020
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. David A. McLennan, Owner

FIRM NAME	STREET ADDRESS
Vita Pharmacy, LLC dba Talon Pharmacy of Boerne	1430 South Main Street, #105
CITY, STATE AND ZIP CODE Boerne, TX 78066-3334	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

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) (WE) OBSERVED:

OBSERVATION #1

In regard to aseptic practice:

A. On 1/23/20, during the aseptic processing of Mic B Complex Injectable, lot #01232020@1, the operator was observed placing his gloved hands outside the ISO 5 workbench area to retrieve supplies. Upon re-entry into the ISO 5 workbench area with the supplies, he failed to re-sanitize his hands.

B. On 1/23/20, during the (b) (4) of Methylcobalamin 1mg/ml for Injection, lot #01232020@2, I (Stephen Brown) noted that the pharmacist was performing the (b) (4) and filling of a vial outside the ISO 5 workbench area.

C. I (Stephen Brown) noted that sterile wipes, stoppers, and vials were stored in the ISO 7 cleanroom in original packaging which was open to the environment.

OBSERVATION #2

The glass beakers used in the production of sterile, injectable drug products are not depyrogenated prior to use. The glass beakers are cleaned with household detergent, washed in a dishwasher, and stored uncovered in a drawer prior to use.

The same beakers are also used in the production of hazardous, non-sterile drug products.

OBSERVATION #3

On 1/24/20, I (Stephen Brown) observed brownish residue on a corner of the HEPA filter located in the ISO 5

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator Clifton L. Randell, Microbiologist Ana-Maria A. Plapcianu, Microbiologist	02/11/2020

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway #300 Dallas, TX 75204-3128 214-253-5200 Industry Information: www.fda.gov/oc/industry	1/22-24; 27-29/2020; 2/10-11/2020
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Mr. David A. McLennan, Owner	
FIRM NAME Vita Pharmacy, LLC dba Talon Pharmacy of Boerne	STREET ADDRESS 1430 South Main Street, #105
CITY, STATE AND ZIP CODE Boerne, TX 78066-3334	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

workbench area.

OBSERVATION #4

In regard to the latest clean room certification dated 10/3/19:

A. The ISO 5 classified area was not certified under dynamic conditions . Specifically, the smoke studies did not include simulation of routine production such as (b) (4) and filling/stoppering of vials.

B. The smoke studies showed slow-moving or turbulent airflow in the ISO 5 classified area.

C. The smoke study did not extend to the rest of the ISO 7 area to show the movement of air from the HEPA hoods to the vents (b) (4) .

OBSERVATION #5

Your firm does not perform environmental monitoring of the (b) (4) (b) (4) .

OBSERVATION #6

In regard to the production of highly potent drugs:

A. Your firm produces hazardous, highly potent drugs without providing proper containment and segregation to prevent cross-contamination. Currently, these drugs are weighed out and mixed on an open countertop in the general pharmacy area (ISO 8).

For example, on 1/22/20, your firm produced Estradiol/Estriol/Testosterone1.5/2/2 mg/gram Cream, lot #01222020@3 which was assigned Rx #(b) (6) for patient (b) (6)

B. Your firm does not use an oxidizing agent to clean the countertop and stainless steel spatulas between

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Stephen D. Brown, Investigator Cliffon L. Randell, Microbiologist Ana-Maria A. Plapcianu, Microbiologist	02/11/2020

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway #300 Dallas, TX 75204-3128 214-253-5200 Industry Information: www.fda.gov/oc/industry	1/22-24; 27-29/2020; 2/10-11/2020
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Mr. David A. McLennan, Owner	
FIRM NAME Vita Pharmacy, LLC dba Talon Pharmacy of Boerne	STREET ADDRESS 1430 South Main Street, #105
CITY, STATE AND ZIP CODE Boerne, TX 78066-3334	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

preparations. In addition, the spatulas are not dedicated.

Currently, your firm uses (b) (4) to clean the countertop and spatulas between preparations. However, your firm has no evidence to show that the use of (b) (4) will effectively remove residues which might be present on the countertop surface or spatulas after production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator Clifton L. Randell, Microbiologist Ana-Maria A. Plapcianu, Microbiologist	02/11/2020