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	10/19/2021-11/3/2021* FEI NUMBER 3012032875

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mrs. Raman Bhaumik, Pharmacist in Charge/Owner

FIRM NAME	STREET ADDRESS
Bhaumik Diversified LLC dba Texas Star Pharmacy	3033 W Parker Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plano, TX 75023-8000	Producer of Sterile and Non Sterile Drug Products

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

You produced hazardous and potent drugs without providing adequate segregation and cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm routinely produces sterile and non-sterile drug products containing hormones such as Testosterone and Progesterone without appropriate controls to prevent cross contamination from these hazardous and/or potent drug products. Your facility has no dedicated rooms, dedicated hoods, or dedicated equipment.

OBSERVATION #2

Smoke studies performed under dynamic conditions are inadequate.

Specifically,

Your firm's smoke study utilizing the (b) (4) is inadequate as it fails to demonstrate unidirectional airflow over and away from the simulated preparation conducted by your firm's pharmacy technician due to the lack of smoke generated from the (b) (4) .

OBSERVATION #3

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	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 11-03-2021 13:22:10	11/3/2021

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Failure to conduct media fills that closely simulates aseptic production operations under the worst case, most challenging and stressful conditions.

Specifically,

Your media fill kit of (b) (4) vials of which (b) (4) are positive controls does not simulate your firm's aseptic production operations under the worst case, most challenging and stressful conditions. For example, the following sterile injectable products were produced by the firm:

- On 8/11/2021, (b) (4) aseptically filled vials of Kisspeptin-10 200mcg/ml, Lot 08112021@9, BUD: 12/09/2021.
- On 10/08/2021, (b) (4) aseptically filled vials of Glutathione 200mg/ml, Lot 10082021@12, BUD: 02/05/2022.
- On 10/14/2021, (b) (4) aseptically filled vials of Nandrolone Decanoate 200mg/ml, 10142021@13, BUD: 04/12/2022.

OBSERVATION #4

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

On 10/19/2021, I observed your sterile technician fail to ensure that the dwell time was reached when using the sporicidal, (b) (4) % solution of (b) (4) to disinfect the surfaces of the ISO5 BSC that was being cleaned for aseptic manipulation activities of Tacrolimus 0.03% Oil Ophthalmic Solution Lot #10182021@12, BUD: 02/15/2022 Eye Drops and/or Glutathione 200mg/ml Injection, Lot #10192021@19, BUD: 02/05/2022.

The Manufacturer's instructions state that a (b) (4) contact time is required to kill *Clostridium difficile* spores however, the sterile technician only allowed a 2-minute contact time. In addition, there was no way contact

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times can be adequately monitored as there was no timer/clock located in the ISO7 buffer room containing the ISO5 BSC.

OBSERVATION #5

Use of non-sterile (b) (4) in ISO-classified areas.

Specifically,

On 10/19/2021, I observed the sterile technician compromise the integrity of the commercially purchased bottle of sterile (b) (4) . (b) (6) removed the spray head to pour the sterile (b) (4) onto sterile wipes in the ISO7 anteroom to disinfect the outside of the totes containing items such as product, (b) (4) and syringes prior to placement on the shelves of the ISO7 buffer room. This practice was observed a second time when (b) (6) was disinfecting the surfaces of the ISO5 BSC in the ISO7 buffer room. However, (b) (6) did not place the spray head properly and left the sterile bottle of (b) (4) partially open to the ISO7 environment until (b) (6) was finished disinfecting the ISO5 BSC. The same bottle of (b) (4) was used to disinfect (b) (6) hands and equipment prior to entry/reentry to the ISO5 BSC.

OBSERVATION #6

Non-sterilized equipment was used in sterile drug production.

Specifically,

On 10/19/2021, I observed your sterile technician using non-sterile scissors and a non-sterile (b) (4) during aseptic activities of Tacrolimus 0.03% Oil Ophthalmic Solution Lot #10182021@12, BUD: 02/15/2022 Eye Drops and/or Glutathione 200mg/ml Injection, Lot #10192021@19, BUD 02/05/2022. The non-sterile scissors

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and non-sterile (b) (4) were stored exposed on a stainless steel shelf located in the ISO7 buffer room where the ISO5 BSC is located.

OBSERVATION #7

Personnel failed to disinfect or change gloves frequent enough to prevent contamination.

Specifically,

On 10/19/2021, during the set up for aseptic activities of Tacrolimus 0.03% Oil Ophthalmic Solution, Lot #10182021@12, BUD: 02/15/2022 and Glutathione 200mg/ml Injection, Lot #10192021@19, BUD 02/05/2022. I observed your sterile technician on two occasions fail to disinfect or remove (b) (6) gloved hands after touching the garbage can. The sterile technician proceeded to touch supplies (syringes, packages of rubber stoppers, scissors) located on the stainless-steel shelf in the ISO7 buffer room and place (b) (6) hands in the ISO5 BSC.

OBSERVATION #8

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

The following bulk drug substances were used in the formulation of a drug products that are not compliant with a USP or NF monograph, not components of a FDA approved drug and do not appear on the FDA 503A bulk list.

- (b) (4) Lot (b) (4), Exp:04/02/23 was used in Kisspeptin-10 MDV 200mcg/ml (5ml) Injection, Lot #08112021@9, BUD: 12/09/2021
- (b) (4): Lot (b) (4), Exp: 02/28/2021 was used in Bremelanotide (PT-141) 5mg/ml Injectable, Lot #05272021@4, BUD 09/24/2021.
- (b) (4): Lot (b) (4), Exp: 11/30/2021 was used in CJC-1295/Ipamorelin 1mg/1mg/ml,

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Lot #08202021@18, BUD: 12/18/2021.

- (b) (4) : Lot (b) (4), Exp: 11/30/2021 was used in CJC-1295/Ipamorelin 1mg/1mg/ml, Lot #08202021@18, BUD: 12/18/2021.

These sterile injectable drug products made from non-pharmaceutical grade components were distributed to patients.

OBSERVATION #9

Stock solutions are not adequately prepared for use in sterile drug preparations to prevent proliferation of microbes.

Specifically,

Your Pharmacist stated that stock solutions made from non-sterile components are not (b) (4) sterile upon preparation and stored in the refrigerator until needed, though not longer than (b) (4) . For example,

Your firm prepared (b) (4) Stock Solution, Lot # (b) (4) with a BUD of 04/10/2022 that was used in approximately (b) (4) batches of TRIMIX and QUADMIX produced from 10/12/2021 to 10/18/2021, sterile injectable drug products.

Your firm prepared (b) (4) Stock Solution, Lot # (b) (4) with a BUD of 11/15/2021 that was used in approximately (b) (4) batches QUADMIX produced from 05/19/2021 to 09/14/2021, a sterile injectable drug product.

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OBSERVATION #10

You used a non-pharmaceutical grade detergent, non-sterile disinfectant to clean glassware and equipment used in the production of sterile injectable and non-sterile drug products.

Specifically,

Your firm uses a commercial brand "(b) (4)" "(b) (4) " fast dissolving tablets, a non-pharmaceutical grade, non-sterile disinfectant to clean equipment such as glass beakers which is routinely used in the production of your sterile and non-sterile drug products. There is no assurance that detergent residue and residues from hazardous/potent drugs are absent from equipment prior to its use during the production of your sterile and non-sterile drug products.

OBSERVATION #11

Visibly dirty utensils used in the production of non-sterile drug products.

Specifically,

On 10/21/2021, I observed several visibly dirty, discolored and rusty utensils (rubber spatulas, stainless steel spatulas with or without wooden handles) in a plastic storage bin dedicated for clean utensils used in the production of non sterile drug products during the walk through of your firm's non-sterile compounding laboratory.

OBSERVATION #12

Non-microbial contamination was observed in your production area.

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Specifically,

On 10/19/2021, the floor and door of your ISO7 preparation room used to prepare solutions used in the aseptic processing were visibly dirty with brown residue despite (b) (4) cleaning as stated by your Pharmacist.

***DATES OF INSPECTION**
10/19/2021(Tue), 10/20/2021(Wed), 10/21/2021(Thu), 10/22/2021(Fri), 10/25/2021(Mon), 10/26/2021(Tue), 10/27/2021(Wed), 10/28/2021(Thu), 11/03/2021(Wed)

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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."