DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration, 22215 26th Avenue, Suite 210 Bothell, WA 98021 Phone: 425-302-0340 Industry Information: www.fda.gov/oc/industry	05/30/2017 to 06/15/2017
	FEI NUMBER 3013401760

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Troy D. Langdon, Executive Vice President and Chief Operating Officer

FIRM NAME	STREET ADDRESS
Shiraz Specialty Pharmacy, Inc. dba Axis Pharmacy Northwest	6007 244th St. SW, Suite A1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mountlake Terrace, WA 98043	Producer of non-sterile drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Both highly potent drugs and beta-lactam containing drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, your firm is producing drugs that fall into the following categories: highly potent, hazardous, non-hazardous and beta-lactam. The production of all of these drugs occurs in your non-sterile production and processing areas. These drugs are produced without adequate process controls to prevent cross-contamination. For example:

A) On 3/30/17, your firm produced a refill for a product referred to as Magic Mouthwash, Log # 6471, Prescription# (b) (6), (b) (7)(C). Penicillin is listed as one of the drug components on the batch records and this drug was prepared in the (b) (4) hood that is used to produce other highly potent and non-hazardous drug products. The batch production records further indicate that the Pharmacy Technician crushed (b) (4) penicillin tablets 500mg ((b) (4) Units) in the hood using a non-dedicated (b) (4) that is used to compound other drug products. The other drugs that were produced on 3/30/17 include: Anastrozole, 0.5 mg capsules; Progesterone 12.5 mg/ 0.1 mL topical cream; Testosterone 100 mg troches; Tadalafil 20mg troche; Ranitidine 15 mg/mL oral suspension; Guanfacine 1mg/5 mL oral suspension; and, Bi-Est 0.5 mg/ mL topical cream. The aforementioned drugs were produced in the same hood where Magic Mouthwash was produced and shared the same equipment as the beta-lactam containing products.

Further, no testing of compounded drugs is performed to ensure there is no potential cross-contamination with the beta-lactam containing product.

B) Additionally, we observed that the Pharmacy Technician did not demonstrate adequate techniques on how to handle beta-lactam drugs in a way that minimizes the risk of potential cross-contamination. Particularly, on

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5/31/17, during production of Progesterone 200 mg capsules, Log# 6888, we observed that the sleeves of Pharmacy Technician's lab coat were in direct contact with the progesterone (b) (4) spilled in the (b) (4) (b) (4) hood. The technician stated that (b) (6), (b) uses the same lab coat for approximately (b) (4). The lab coats are not changed between batches of various highly potent drugs products produced, or when beta-lactam containing products are produced.

OBSERVATION 2
Cleaning of production and processing areas, equipment and utensils used for the production of highly potent and beta-lactam containing drugs is inadequate to prevent potential cross-contamination.

Specifically, your firm is using highly potent drug substances including hormones and penicillin in the production of various non-sterile drug products. The following issues were noted:

A) Your current practice is to wipe down work surface of the (b) (4) hood with (b) (4) (b) (4), after drug production of both highly potent and beta-lactam containing drugs. Your firm does not have data to support that cleaning with (b) (4) is effective in removing and neutralizing potent drug residues. For example: On 5/31/17, we observed the production of Progesterone 200 mg capsules, Log # 6888 in the (b) (4) hood. After filling the Progesterone capsules, the Pharmacy Technician cleaned only the work surface of the hood where hormonal (b) (4) was spilled with (b) (4). The technician did not clean other surfaces of the hood including the walls and ceiling of the hood. We observed production (b) (4) residue accumulation in the hood, on the pre-filters (before HEPA filters) and along the seams of the hood.

B) Your firm does not have data to support that (b) (4) and (b) (4) dish washing soap or (b) (4) are appropriate cleaning agents to eliminate drug residues on the equipment surfaces used to produce highly potent drug substances including hormones and penicillin containing drug products.

OBSERVATION 3
Non-pharmaceutical grade components are used in the production of non-sterile drug products.

Specifically, your firm is using non-pharmaceutical grade water ((b) (4) brand) as a

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component during production of non-sterile drug products such as:

1) Lidocaine 4% nasal spray, BUD 30 days at room temperature.
2) Ketamine 100mg/ mL nasal spray, BUD 30 days refrigerated.
3) Tranexamic Acid 4.8% Rinse, preservative free, BUD 30 days at room temperature.
4) Diph/Peni/Nyst/Lido/HC suspension, preservative free, BUD 30 days refrigerated.
5) Potassium bromide 300mg/mL suspension, preservative free, BUD 30 days at room temperature.

OBSERVATION 4
Drug components used in the production of highly potent, hazardous and non-hazardous drug products are not adequately stored.

Specifically, on 6/6/17 we observed unlabeled syringes attached to the top of the drug component bottles. Your firm discards these syringes only when the material is finished. We also observed that many of those syringes still had liquid remaining in the syringe. The following drug components were observed to have syringes attached on the bottles: bulk solution of (b) (4) Lot (b) (4), expiration 7/31/18; (b) (4) solution (b) (4) Lot (b) (4), expiration 11/13/18; (b) (4) Lot (b) (4), expiration 1/31/19; (b) (4) Lot (b) (4), expiration 2/3/18, (b) (4) Lot (b) (4), expiration 11/30/17.

OBSERVATION 5
Equipment and tools used are not of appropriate materials for use in drug production.

Specifically, (b) (4) spatulas that had apparent discoloration were used on 5/30/17 during production of Progesterone 50 mg/mL topical cream, Log # 6883 and HCG 500 IU troche, Log # 6884.

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