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	1/26/2017 - 3/8/2017
	FEI NUMBER 3006089725

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mrs. Hee Joo Park, RPh, President and CEO, COO, CFO

FIRM NAME	STREET ADDRESS
Puget Sound Drug Corporation dba Key Compounding Pharmacy	530 South 336th Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Federal Way, WA 98003	Producer of sterile and non-sterile drug products

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

OBSERVATION 1

Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action.

Specifically,

Your firm recovered following objectionable microorganisms from the classified areas and failed to conduct a risk/impact assessment on the products produced and distributed from November 2016 to February 2017. During this time when objectionable microorganisms were recovered from your facility, approximately (b) (4) batches of sterile drug products were produced in the ISO 5 hoods from 1/25/17 to 2/28/17.

A. Microorganisms recovered from the ISO 5 hoods:

1) On 1/26/17, in-house surface samples collected from the (b) (4) showed 5 colony forming units (CFUs) per plate from the (b) (4) and 4 CFUs per plate from the (b) (4) (total 9 CFUs). Bacillus horneckiae was identified from these surface samples.

2) Additionally, Bacillus horneckiae was recovered from the in-house surface samples collected on 1/26/17 from the (b) (4) (2 CFUs per plate) and from the (b) (4) on 1/25/17 (1 CFU per plate from the (b) (4) and 1 CFU per plate from the (b) (4)

B. Microorganisms recovered from the (b) (4) are located:

1) On 1/12/17, viable air samples collected from the (b) (4) showed 3 CFUs of gram positive cocci and 1 CFU of Micrococcus spp. during environmental sampling by your third party contractor.

2) On 11/15/16, viable air samples collected from the (b) (4) showed presence of Aspergillus niger (1 CFU), non-sporulating fungi (3 CFUs), Penicillium (5 CFUs), Cladosporium (1 CFU), and Staphylococcus coagulase (-) (4 CFUs).

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OBSERVATION 2

Aseptic practices are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

A. On 01/26/17, the Pharmacy Technician used a small stainless steel hand-held mini mop with a sterile cleaning pad. The technician soaked the cleaning pad with sterile (b) (4) and sanitized the walls of the (b) (4) ISO 5 hood. After cleaning, the technician hung the mop with a dirty cleaning pad inside the hood and filled a sterile injectable drug, TriMix, lot # 01-25-2017@10. The technician completed the sterile filling process, cleaned the ISO 5 hood and did not remove the dirty mop from the hood.

B. On 01/26/17, the Pharmacy Technician failed to clean the ceiling and return grates of the (b) (4) ISO 5 hood with sterile (b) (4) before or after the production of TriMix, a sterile injectable drug product, lot # 01-25-2017@103. Your current practice is to clean these surfaces of the ISO 5 hood (b) (4) during (b) (4) cleaning.

C. On 10/24/16, during (b) (4) cleaning that included cleaning of all surfaces (wall, floors, ceilings, etc.) of the ISO 5, ISO 7 and ISO 8 areas, your firm used (b) (4) that had expired on 9/17/14.

D. Your SOP 3.02 titled: Cleaning and Maintenance of the Clean Room Facility, requires you to perform (b) (4) cleaning with (b) (4) solution. According to your cleaning logs, (b) (4) was made (b) (4) (b) (4) Your firm assigned (b) (4) expiration to (b) (4) There is no documentation that (b) (4) was made for the (b) (4) cleaning and that the work surfaces in the ISO 5, ISO 7 and ISO 8 areas were cleaned with (b) (4) every (b) (4) in November and December 2016, as required by your SOP. Additionally, your SOP does not specify the exposure time of the contact surface with the cleaning/disinfecting solution.

E. On 02/22/17, we observed that the Pharmacy Technician was using non-sterile wipes for disinfecting work surfaces in the (b) (4) ISO 5 hood during production of a sterile injectable, Hydroxo B-12 PBF, 5 mg/mL MDV INJ, lot t02-21-2017@111.

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F. Your SOP 3.02 titled: Cleaning and Maintenance of the Clean Room Facility, states that the (b) (4) cleaning will be done with (b) (4) However, for the (b) (4) cleaning performed on (b) (4) and (b) (4), the disinfecting solutions were not (b) (4) and (b) (4) was used (b) (4) for (b) (4)

OBSERVATION 3
Environmental monitoring is not adequately performed in your aseptic areas.

Specifically, your firm performed (b) (4) cleaning and collected environmental samples approximately within (b) (4) of cleaning. For example:

A. Your firm performed (b) (4) cleaning on 3/14/16 and in-house surface samples for environmental monitoring were collected on 3/15/16.

B. Your firm performed (b) (4) cleaning on 1/11/17 and surface samples for environmental monitoring were collected by your third party contractor on 1/12/17.

OBSERVATION 4
There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm failed to conduct adequate investigation regarding sterility assurance of a sterile drug product. On 11/3/16, your firm produced Sodium Phenylbutyrate, Lot t11-02-2016@87 that failed sterility when sent to an outside testing laboratory. The same lot of Sodium Phenylbutyrate, Lot t11-02-2016@87, when tested in-house, passed the sterility test. Your firm opened an investigation, Internal Quality Related Event (QRE) on 01/04/17 approximately two months later. However, the investigation failed to identify a possible root cause and the potential discrepancy between sterility test results for the in-house testing and outside testing laboratory.

OBSERVATION 5
Aseptic practices are deficient regarding the system for maintaining an environment suitable for production of sterile drugs.

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Specifically,
A. On 2/22/17, we observed various examples of paper and cardboard, stored and/or in use, in the ISO 7 "Compounding Room", to include card board boxes containing (b) (4) and a small sign with the Key Compounding Pharmacy name and logo on it.

B. Additionally, on 2/22/17 we observed the Pharmacist Technician and the Lead Pharmacist exchanging a paper note pad back and forth through the (b) (4) where the Pharmacy Technician was observed writing (b)(6),(b)(7)(C) requests for supplies on the note pad while it was in the (b) (4). The Pharmacy Technician remained in the ISO 7 "Compounding Room" and the Lead Pharmacist was in the ISO 8 "Prep Room". We observed this practice 4-5 times within the course of approximately 20 minutes.

OBSERVATION 6
Personnel performing aseptic operations failed to disinfect or change gloves frequently enough to prevent contamination.

Specifically,
A. On 1/26/17, the Pharmacy Technician donned sterile gloves on top of non-sterile gloves. After sanitizing the (b) (4) ISO 5 hood and (b) (4) etc., the technician did not disinfect (b)(6),(b)(7)(C) sterile gloves and started (b) (4) a sterile injectable drug product, TriMix, lot # 01-25-2017@103 (b) (4)

B. On the following occasions microorganisms were recovered from the sterile glove fingertips of the Pharmacy Technician involved in producing sterile drugs:
1) On 1/25/17, 1 CFU was recovered from the (b) (4) fingertip of the technician, (b)(6),(b)(7)(C) The microorganism identified was Bacillus benzoevorans.
2) On 1/26/17, 1 CFU was recovered from the (b) (4) fingertip and 2 CFUs from the (b) (4) fingertip of the technician, (b)(6),(b)(7)(C) The microorganisms identified from the (b) (4) fingertip were Bacillus horneckiae. The (b) (4) fingertip results were examined visually by your consultant microbiologist and the microorganism was considered as spreader, Bacillus.
3) On 1/27/17, 1 CFU was recovered from the (b) (4) fingertip of the technician, (b)(6),(b)(7)(C) Sample was sent to (b) (4)

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(b) (4) for microbial identification.

4) On 2/2/17, 1 CFU was recovered from the (b) (4) fingertip and 1 CFU from the (b) (4) fingertip of the technician, (b)(6),(b)(7)(C) Your firm discarded these samples and no microbial identification was performed.

OBSERVATION 7

The final containers/closures used for drug products intended to be sterile have not been sterilized or depyrogenated.

Specifically, there is no assurance that the container and closures that undergo in-house sterilization or depyrogenation are sterile, as follows:

A. Your firm did not use (b) (4) with every batch of containers and closures that are sterilized in-house using (b) (4). The (b) (4) are used (b) (4). Also, there is no documentation about the (b) (4) when (b) (4) were used.

B. Your firm failed to assign any batch identifiers and did not establish hold times for containers, closures and all re-usable sterilized equipment, after (b) (4) and/or depyrogenation.

C. There is no data to support the continued sterility of various sizes of amber-colored glass vials such as 2mL, 5mL, 10mL, 20mL, 30mL and 50 mL that undergo in-house sterilization and depyrogenation.

D. There is no data to support continued sterility of the (b) (4) stoppers that undergo in-house sterilization.

OBSERVATION 8

Inadequate pressure differentials between lower quality air rooms and higher quality air rooms were observed.

Specifically, on 1/26/17 we observed inadequate pressure differentials between the ISO 8 Ante Room lower quality air room and the higher quality air in the ISO 7 "Compounding Room". Also, the air pressure differential between the unclassified non-sterile compounding area into the ISO 8 "Prep Room" were apparently not working. The following issues were noted:

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A. The Magnehelic gauges did not appear to be registering movement and we did not feel any pressure difference entering in or exiting out of these rooms. Your firm had issues with the air pressure differential since 2015 as evidenced by your HVAC contractor (b) (4) Invoice # (b) (4), dated 5/18/15 which states that the "clean room side tubing in the wall was pinched and folded over itself" and that "the lab side (b) (4) was not engaged fully on the brass barb". Additionally, (b) (4) Work Order # (b) (4) , dated 9/13/16 states that the "pressure in the cleanroom is too low and the belt for the HEPA is making some noises".

B. On 1/26/17, 1/27/17 and 1/30/17, your firm recorded the air pressure for the Ante Room as 0.01 psi which was below the acceptable value of (b) (4) psi for the Ante Room as per your (b) (4) monitoring record. Your firm continued producing sterile drug products during this time when there were issues with gauges and/or air pressure differentials.

OBSERVATION 9
Equipment and tools used are not of appropriate materials for use in sterile drug production.

Specifically, on 1/27/17, during non-sterile to sterile production of a sterile ophthalmic solution, Atropine sulphate 0.5%, lot t01-26-2017@93, we observed that the Pharmacy Technician (b) (4) atropine sulphate in a (b) (4) hood using wooden (b) (4) that is particle generating and difficult to clean. This wooden (b) (4) had visible scratches which do not allow the (b) (4) to be cleaned properly.

OBSERVATION 10
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, smoke studies have not been performed in the ISO 5 hoods under dynamic conditions since (b) (4)

OBSERVATION 11
Highly potent 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 handles potent drug substances including hormones and there are no procedures or controls

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in place to prevent cross-contamination. On 2/1/17, we observed following issues related to the control and potential cross-contamination of hormonal drug substances in the (b) (4) hoods in the non-sterile area:

A. After filling the Progesterone EYM 60mg capsules, lot 1-27-2017@100, the Pharmacy Technician was observed cleaning the equipment by blowing air on the equipment. This resulted spreading of the hormone (b) (4) dust all over the hood. During production of non-sterile Progesterone EYM 60mg capsules, lot 1-27-2017@100, (b) (4) dust accumulation was observed in the hood, on the pre-filters (before HEPA filters), along the seams of the hoods.

B. The Pharmacy Technician did not clean the ceiling of the hood as part of (b)(5),(b)(7)(C) post-production cleaning operations. The hood interior ceilings are cleaned only during (b) (4) cleaning. There were visible particulate residues remaining in the hood after cleaning and proceeding to the next batch.

C. Additionally, the hood was wiped down with a wipe soaked with (b) (4) followed by cleaning with (b) (4) before proceeding production for the next batch of the drug product. However, your firm does not have data to support that cleaning with (b) (4) and (b) (4) will effectively neutralize potent drug residues.

D. The technician's sleeves were observed contacting (b) (4) residues on the Hood #1 bench surface during capsule filling of Progesterone EYM 60mg capsules, lot 1-27-2017@100. The technicians use the same lab coat for approximately (b) (4). The lab coats are not changed between batches of various highly potent drugs products produced.

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