

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404	DATE(S) OF INSPECTION 3/11/2019-4/17/2019*
	FEI NUMBER 3015133983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brandon K. Knott, Pharm.D., Pharmacist / Owner

FIRM NAME Poulsbo Compounding Pharmacy LLC, dba Cascade Specialty Pharmacy	STREET ADDRESS 325 NE Hostmark Street
CITY, STATE, ZIP CODE, COUNTRY Poulsbo, WA 98370-6668	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile and 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 did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

Certification of your firm's ISO-5 biosafety cabinet and ISO-7 labs on 10/11/18 resulted in the following microbial counts below from active air sampling, including 20 CFUs in the ISO-5 biosafety cabinet (BSC), exceeding the (b) (4) CFU allowable limits. These resulted were reported on 10/25/18, but production continued without adequate remediation.

Location	Classification	Limit	Results
Biosafety Cabinet	ISO-5	(b) (4)	20
Sterile clean room	ISO-7		2
Ante-room	ISO-7		9

Environmental monitoring is performed by your firm approximately every (b) (4) weeks using (b) (4) , with (b) (4) cleaning noted on (b) (4). Sterile production

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occurred between 10/11/18 and 10/25/18, the dates of the certification testing and reporting. There was no record of cleaning and disinfection of the new ISO-5 hood between 10/11/19 and the next periodic cleaning on (b) (4), but production occurred on 10/11/18, 10/12/18, and 10/16/18 and throughout the remainder of October 2018. Microbial testing including sterility, total microbial count, and endotoxin are not performed on each batch of sterile product, including during the period from 10/11/18 - 10/25/18.

OBSERVATION 2

Inadequately protected product intended to be sterile was exposed to lower than ISO 5 classified aseptic processing area quality air.

Specifically,

Your environmental monitoring controls are deficient for the following reasons:

- A. A new ISO-5 biosafety cabinet hood was installed on 10/10/18 to replace a laminar air flow hood. A smoke study was not performed for the new ISO-5 hood to demonstrate that the environment is adequately protecting product for (b) (4). Certification of the hood on 10/11/18 revealed 20 CFUs from active air monitoring inside the ISO-5 hood, exceeding the limits of (b) (4) CFU), but effective remedial actions were not taken or not documented, and certification retest was not done.

- B. Media fill and glove fingertip testing does not always represent the worst-case scenario with equipment in the ISO-5 hood for large batch production.

- C. Environmental monitoring is performed by your firm approximately every (b) (4) weeks using

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(b) (4). Settling plates are not used to monitor sterile production. Surface testing tests (b) (4) of the ISO-5 hood but does not include (b) (4) locations to provide test coverage for the entire ISO-5 area used in production.

D. Microbial testing including sterility, total microbial count, and endotoxin are not performed on each batch of sterile product.

OBSERVATION 3

You produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically,

- A. Your firm works with beta-lactam drugs including Amoxicillin, Cephalexin, Ceftazidime, and Ceftriaxone, as well as hormones, antibiotics, and other hazardous compounds in the general non-sterile lab on the main floor and in the upstairs capsule filling lab space and shipping/receiving area.
- B. Your staff use non-dedicated (b) (4) hoods, lab utensils, balances, capsule filling machine, and other lab items in the handling and processing of these materials. There were no procedures provided to designate separate handling, segregation, or cleaning of lab work surfaces or personnel before or after handling beta-lactam products.
- C. Your firm works with (b) (4) beta-lactam products. During inspection of your lab, I observed (b) (4) beta-lactam products stored in more than one drawer of the non-sterile lab and also on the lab benches. Your staff reported that the beta-lactam products are "mostly" used in (b) (4) processing hood that was approximately 10-15 feet away from the drawers where the penicillin materials are kept.

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- D. Your staff do not change lab coats or hair nets between different chemical productions. There are no records of consistent glove changes between production activity involving beta-lactam, other hazardous compounds including hormones, and other chemical types.
- E. Your cleaning procedures do not include cleaning verification to ensure that the cleaning methods are effective to prevent cross contamination.
- F. Air-handling systems for the manufacture and processing of penicillin drug products are not completely separate from those used for other drug products for human use. Your air handling system recycles air from the non-sterile lab, via HEPA filter, to the ISO-7 clean-rooms. Your firm does not use negative-pressure rooms for containment of penicillin or hazardous drug products. There were no procedures or test results available to show that beta-lactam or penicillin derivatives are effectively contained and not contaminating other lab areas.
- G. On 5/10/18 a Class 1 (b) (4) processing hood in the non-sterile lab failed certification: (b) (4) model (b) (4), SN (b) (4). According to your firm's staff, this hood was used for storage of supplies and capsules until the HEPA filter could be replaced on 6/6/18. There were no cleaning and disinfection records for this specific hood and cleaning validation to show that effective measures were taken to prevent cross-contamination of materials stored or worked with in this hood during the hood failure.

OBSERVATION 4

Your facility design allowed the influx of poor quality air into a higher classified area.

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The ISO-5 biosafety cabinet (BSC) used for sterile productions is contained in an ISO-7 clean-room. The ISO-7 clean-room / buffer room has (b) (4) that connects to the unclassified front receiving desk area. During this inspection, I observed the entrance door between the non-sterile lab and the ISO-7 ante-room left open for several minutes as supplies were brought into the ante-room. These activities may expose the classified air space to lower quality air.

OBSERVATION 5

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

Your firm uses non-sterile (b) (4) cleaning pads and sterile gauze pads to disinfect inside the ISO-5 biosafety cabinet. The cleaning gauze pads used to clean the ISO-5 classified aseptic processing areas are potentially shedding. Fraying of these gauze pads was observed during preparation, cleaning, and disinfection prior to sterile drug production.

The non-sterile (b) (4) cleaning pads and sterile gauze pads are used to clean equipment and working surfaces in the ISO-7 cleanroom/ante-room. The equipment used in the ISO-5 hood include a (b) (4) repeater pump, a stir plate, and a hot plate. These items are stored in a lower shelf under a stainless-steel counter. The disinfection procedure includes wiping the top surface of the equipment. But the equipment is not thoroughly disinfected before being placed in the ISO-5 hood, to include the bottom of the equipment, the electrical cord, and the cracks and hard to reach spaces of the equipment. No data for microbial swabbing of the equipment was available to show that the cleaning and disinfection method was adequate.

OBSERVATION 6

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

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Specifically,

There was a failure to handle and store components and reagents used in non-sterile drug production at all times in a manner to prevent contamination. This includes water, organic solvents, hormones, and other reagents and flavors.

- A. Your firm uses non-pharmaceutical reagents such as (b) (4) water and opened bottles of water labeled sterile (b) (4) that are stored on the lab bench and used in the non-sterile lab for producing non-sterile drug products. The (b) (4) water and (b) (4) containers are opened and used in non-sterile conditions with a labeled 180-day shelf life, but there is no data to support this long of a BUD.

- B. Oil bases, flavors, and drug stocks we observed to be stored in (b) (4) bottles near the windows exposed to sunlight (UV light). These products include organic flavors (pineapple flavor lot (b) (4) and others); and drug stocks such as Testosterone T50 50mg/ml lot (b) (4) Estriol (E3) 20mg/ml stock lot (b) (4) and others. There are no controls or test data to show that these reagents and components used in drug production have not been oxidized, degraded, or decomposed by UV light or heat exposure. Some patient complaints pertain to lack of flavor or ineffectiveness of some drug products.

OBSERVATION 7

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

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Equipment and utensils in the non-sterile lab are not cleaned and maintained adequately to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product. Pharmacy staff did not always change and disinfect gloves between different active and hazardous chemical production operations.

- A. On 3/11-12/19 I observed residue on (b) (4) that were in clean status waiting to be used for production. The residue was evident by visual inspection with natural and fluorescent light. This was described by the PIC as residual cream from a previous production. Hormones such as progesterone, estrogen, and testosterone are used in these (b) (4). According to the PIC, the (b) (4) are difficult to clean and cannot be easily disassembled. The (b) (4) are cleaned with (b) (4).
- B. (b) (4) used in the production of non-sterile drug products were observed to have stains.
- C. On 3/11/19 I observed that the top surface of one (b) (4) processing hood had general dust. This hood had been used for production this day.
- D. The space behind the (b) (4) processing hoods are difficult to reach and difficult to clean. I observed visible residue, debris, powders, and crystalline material on the lab bench space between the hoods and the wall. Residue and crystals were observed on the lab bench under the balances and under other equipment.

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***DATES OF INSPECTION**
3/11/2019(Mon), 3/12/2019(Tue), 3/13/2019(Wed), 3/14/2019(Thu), 3/15/2019(Fri), 3/18/2019(Mon),
3/19/2019(Tue), 3/20/2019(Wed), 3/27/2019(Wed), 3/28/2019(Thu), 4/17/2019(Wed)

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