

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 9/8/2020-9/23/2020*
	FEI NUMBER 3013436443

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Ryan D. Oftebro, Principal and CEO

FIRM NAME Kelley-Ross & Associates, Inc. dba Kelley-Ross Compounding Pharmacy	STREET ADDRESS 805 Madison St # 702
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CITY, STATE, ZIP CODE, COUNTRY Seattle, WA 98104-1172	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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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**

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 09/09/20, I observed the sterile production of three lots of Epinephrine/Ketorolac/Ropivacaine 0.0006%/0.03%/0.2%, during which the rubber stoppers on single use vials of Epinephrine, Ketorolac, Ropivacaine, and Sodium Chloride were swabbed with non-sterile (b) (4) prior to (b) (4) in the Biosafety Cabinet (ISO 5 classified Laminar Hood). The material inside each syringe was then (b) (4) with no further sterilization step prior to delivery to patients. These non-sterile (b) (4) wipes were observed in use during the production of lots 6373, 6368, and 6366 of Epinephrine/Ketorolac/Ropivacaine 0.0006%/0.03%/0.2%.

**OBSERVATION 2**

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

Specifically,

- a) The most recent smoke study conducted by your firm to demonstrate the flow of air between the ISO 7 Gowning Room into the ISO 7 Hazard Room, conducted on 07/10/19, showed a stagnant congregation of smoke against the ceiling of the Hazard Room in the area in front of the Biosafety

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Cabinet (ISO 5 classified Laminar Hood), which is used to perform production of sterile drug products.

- b) The most recent smoke study conducted by your firm to demonstrate the flow of air between the Biosafety Cabinet and the surrounding Hazard Room, conducted on 06/12/18, showed smoke flowing from the ISO 7 Hazard Room into the Biosafety Cabinet.

**OBSERVATION 3**

The ISO 5 classified aseptic processing areas had difficult to clean and visibly dirty equipment or surface.

Specifically,

The Biosafety Cabinet (ISO 5 classified Laminar Hood) used to perform production of sterile drug products is located inside the ISO 7 Hazard Room, which is adjacent to the ISO 7 Gowning Room. On 09/11/20, I observed difficult to clean and visibly dirty surfaces in the following areas:

- a) A white residue on the Hazard Room side of the (b) (4) separating the Hazard Room from the Gowning Room, located along the bottom edge of the (b) (4) containing (b) (4) between the rooms.
- b) A white residue on the Hazard Room side of the (b) (4) separating the Hazard Room from the Gowning Room, located along the bottom edge of the (b) (4) next to the left side of the Biosafety Cabinet.
- c) A white residue on the Hazard Room side of the (b) (4) separating the Hazard Room from the Gowning Room, located along the bottom edge of the (b) (4) in the corner of the room opposite the Biosafety Cabinet.
- d) A white residue on the Hazard Room side of the door between the Hazard Room and the Gowning Room, located just above the door handle.
- e) A buildup of dust on the (b) (4) installed in the wall between the Hazard Room and the

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Gowning Room that allows air to flow into the Hazard Room.  
f) A temperature and humidity meter taped to the Hazard Room side of the (b) (4) between the Hazard Room and the ISO 8 Prep Room, with the battery compartment cover missing and the batteries exposed.

**OBSERVATION 4**

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 09/09/20, I observed an employee put on disposable sterile gloves just prior to performing sterile production of Epinephrine/Ketorolac/Ropivacaine 0.0006%/0.03%/0.2% by using the ~~sterile side~~ <sup>outer surface</sup> of one glove to hold onto the ~~non-sterile side~~ <sup>inner surface</sup> of the opposite glove. This practice was observed prior to the production of lots 6373, 6368, and 6366 of Epinephrine/Ketorolac/Ropivacaine 0.0006%/0.03%/0.2%.  
*CAC 01/23/20*

**OBSERVATION 5**

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

Specifically,

Your firm performs non-sterile production of the following cytotoxic drugs using non-product dedicated (b) (4) (b) (4) without ensuring that the method used to clean (b) (4) between production operations effectively removes all cytotoxic material:

- a) Anastrozole/Clomiphene/DHEA 2mg/25mg/50mg capsules
- b) Chlorambucil (vet) Fixed Oil 1.9mg/ml suspension
- c) Fluorouracil (5-Fu)/Salicylic Acid 5%/20% DMSO topical suspension

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- d) Hydroxyurea 100mg Capsule (lactose free) capsules
- e) Mechlorethamine 0.02% (b) (4) ointment

Additionally, your management stated that your firm does not have the ability to track which specific non-product dedicated (b) (4) have been used in the production of which compounded drug lots.

**\*DATES OF INSPECTION**  
9/08/2020(Tue), 9/09/2020(Wed), 9/10/2020(Thu), 9/11/2020(Fri), 9/14/2020(Mon), 9/15/2020(Tue), 9/23/2020(Wed)

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