

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Denver Federal Center-Building 20 6th Ave. and Kipling St. PO Box 25087 Denver, CO 80225-0087 Phone: 303-236-3000 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 5/8/2017-5/23/2017*
	FEI NUMBER 3004995630

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Joe D. Wise, Owner

FIRM NAME Joe Wise Pharmacy, Inc.	STREET ADDRESS 6179 S. Balsam Way, Suite 150
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CITY, STATE AND ZIP CODE Littleton, CO 80123	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs
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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) (WE) OBSERVED:

Observation 1
 Disinfecting agents and wipes used in the ISO 5 zone are not sterile.

- Specifically,
- A. The wipes used with the (b) (4) to sanitize the "(b) (4)" are not sterile.
 - B. The (b) (4) disinfectant used inside of the "(b) (4)" is not sterile.

Observation 2
 Personnel engaged in aseptic processing were observed wearing non-sterile gloves.


Specifically,

The (b) (4) assembly within the '(b) (4)' are not identified as sterile, and there is no sporicidal treatment of the (b) (4) prior to sterile drug production in the "(b) (4)".

Observation 3
 Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically,

On 5/9/2017, we observed sterile drug production pharmacist clean the "(b) (4)", located in an unclassified drug production room, with (b) (4) then replace the refuse bag located inside the ISO 5 zone. This exchange of the bags exposed the ISO 5 zone to the unclassified air. No air pressure monitoring is conducted to assure unclassified air did not ingress into the ISO 5 zone.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jamie L. C. Dion, Investigator Tenzin Jangchup, Investigator	DATE ISSUED 05/23/2017
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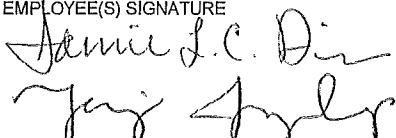
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Observation 4
 The ISO 5 classified area is located within a non-classified room.

Specifically,
 The "(b) (4)" used for aseptic filling of sterile products is located in an unclassified room.

Observation 5
 Sinks or drains are present in the cleanroom where the ISO 5 zone is located.

Specifically,
 There is a sink and dishwasher located in the unclassified room where the "(b) (4)" is located.

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