DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center- Bldg. 20 6th Avenue and Kipling St. PO Box 25087 Denver, CO 80225 Industry Information: www.fda.gov/oc/industry	6/12/2019, 6/13/2019, 6/17/2019, 6/18/2019, 6/21/2019
	FEI NUMBER 3004995630

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Joe D. Wise, Jr., Owner

FIRM NAME	STREET ADDRESS
Joe Wise Pharmacy, Inc. DBA Wise Pharmacy	6179 S. Balsam Way Ste 150
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Littleton, CO 80123	Producer of Sterile and Non-Sterile Drug Products

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

OBSERVATION 1

The classified ISO 5 aseptic processing area was located within a non-classifed room (segregated production area).

Specifically, the ISO 5 certified (b) (4) used for aseptic filling of sterile drug products is located within a non-classified room which is not HEPA filter equipped. Additionally, pharmacy personnel move in and out of the unclassified Compounding Room, and conduct non-sterile compounding operations in the same room where the "(b) (4) " is located.

The "(b) (4) " is opened and exposed to the non-classified environment during (b) (4) cleaning. On 6/13/2019, I observed the Sterile Pharmacist open the front panel on the "(b) (4) " and clean the interior of the (b) (4) with (b) (4) and sterile water.

Furthermore, there is an approximate 3" crack on the front panel of the "(b) (4) ", located in the upper right corner of the front panel, appearing to originate from a plastic screw-like piece that tightens the panel door (the front panel of the door (b) (4) , allowing the operator to open it for cleaning). The Sterile Pharmacist stated the crack has been there since he started on 4/1/2019.

(This is a Repeat Observation from the previous inspection in 2017)

OBSERVATION 2

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jamie L. C. Dion	Jamie L. C. Dion, CSO	06/21/2019

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Sinks or drains were present in the cleanroom where the ISO 5 classified aseptic processing area was located.

Specifically, there is a sink and dishwasher located in the non-classified Compounding Room approximately 10' from where the ISO 5 certified (b) (4) is located.

(This is a Repeat Observation from the previous inspection in 2017)

OBSERVATION 3

You produced hazardous drugs without providing adequate containment and cleaning of work surfaces to prevent cross-contamination.

Specifically, a deactivating agent is not used for cleaning non-sterile hoods in the non-classified Compounding Room. (b) (4) is used to clean (b) (4) hoods (Make: (b) (4) (b) (4) , Models: (b) (4) , IDs: (b) (4)) located in the non-classified Compounding Room and utilized for the weighing of hazardous and non-hazardous bulk drug substances. It is not possible to determine daily production sequence in these hoods; however, both hazardous and non-hazardous drugs may be weighed and mixed in each of the (b) (4) hoods during each day, including opioid and hormonal powders.

OBSERVATION 4

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

Specifically, your firm does not use pharmaceutical grade water to produce human drug products including: nasal solutions, suspensions, oral solutions, and ointments.

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	J. D.	Jamie L. C. Dion, CSO	06/21/2019

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OBSERVATION 5

ISO 5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.

Specifically, an in-situ air pattern analysis (smoke study) of the ISO 5 certified (b) (4) has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions.

OBSERVATION 6

Environmental monitoring was not performed in your aseptic processing areas.

Specifically, (b) (4) environmental (b) (4) ((b) (4)) touch plate samples collected from inside of the ISO 5 certified (b) (4) are incubated at uncontrolled room temperatures on the counter of the non-classified Compounding Room. The sterile pharmacist stated this is the process he has been following since he started on 4/1/2019.

Further, the firm's certified (b) (4) incubator (Model: (b) (4), S/N: (b) (4)) is not used to incubate environmental (b) (4) touch plate samples.

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