

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 22215 26th Ave SE, Suite 210 Bothell, WA 98021-4421 (425) 302-0340 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 12/6-9; 12/12-12/16/2016
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME First Pharma Associates, LLC dba Riverpoint Pharmacy	STREET ADDRESS 528 E Spokane Falls Blvd, Suite 110
CITY, STATE AND ZIP CODE Spokane, WA 99202	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

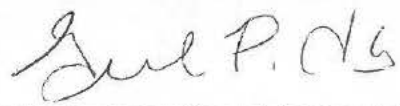
OBSERVATION 1

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, on December 6, 2016 the following was observed during sterile drug production:

- A) The walls inside the Buffer Room, Gowning Room, and Anteroom are composed of a drywall material that has been painted with an epoxy-based paint. A chip exposing the drywall material was observed on the wall between the door and the metal table in the ISO 7 Buffer Room, where sterile drug processing occurs.
- B) The frame surrounding the metal HEPA filter screen installed in the ceiling of the Buffer Room, Gowning Room, and Anteroom is composed of an apparent wood material that has been painted with an epoxy-based paint.
- C) The pass-through box installed between the Buffer Room and Anteroom is composed of a white, laminate wood material that is peeling away from the box frame.
- D) An overhang light with apparent dust buildup was observed installed above a metal table in the Prep Room where in-process drug components are mixed and heated. The Prep Room contains an ISO 5 biological safety cabinet (BSC) in which sterile drug processing occurs.
- E) Wheeled stools observed in use in the Buffer Room and Anteroom has a seat composed of an apparent vinyl material, which appears difficult to clean.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Gerard P. De Leon, Investigator	DATE ISSUED 12/16/2016
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F) Apparent black residue was observed between the seam of the metal workbench and front vent of the Labconco, Model 36209043726D, S/N 020923809E biological safety cabinet (BSC) located in the Prep Room.

G) Apparent orange buildup was observed between the metal frame and window inside the Buffer Room.

H) Apparent buildup was observed on a computer keyboard inside the Powder Hood located in the Prep Room where in-process drug components are prepared for sterile drug production. The computer keyboard was observed in use by an operator on December 6, 2016 during the preparation of in-process drug components.

I) Apparent black staining was observed on the floor of the Buffer Room and Anteroom.

OBSERVATION 2

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

Specifically, a hand wash sink in the Prep Room was observed installed approximately four feet behind a Powder Hood where in-process drug components are weighed. In addition, a biological safety cabinet (BSC) where sterile drug production occurs and a metal table where in-process drug ingredients are mixed and heated are located in the Prep Room.

OBSERVATION 3

The ISO 5 area is located within a non-classified room.

Specifically, the Prep Room, where the ISO 5 BSC is located, is not supplied by HEPA filtered air. The Prep Room is exposed to the surrounding unclassified Laboratory environment that is supplied with air from a floor vent that is not HEPA filtered.

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OBSERVATION 4

ISO 5 classified areas were not certified under dynamic conditions.

Specifically, an in situ air pattern analysis (smoke study) of the following has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions:

- A) The Isolation Tech CAW4, S/N 05-DF08P01 vertical laminar flow hood (LFH) located in the Buffer Room.
- B) The Labconco, Model 36209043726D, S/N 020923809E BSC located in the Prep Room.

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