DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 (425)302-0340 Industry Information: www.fda.gov/oc/industry	05/31/2019, 06/03/2019-06/07/2019
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC	1802 N Monroe St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Spokane, WA 99205	Producer of Sterile and Non-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) (WE) OBSERVED:

OBSERVATION 1:
Non-microbial contamination was observed in your production area.

Specifically, upon entering the ISO-7 Buffer room on 03-June-2019, an unidentified object was observed on the floor, in the corner near the wall. This Buffer room contains the ISO-5 Biological Safety Cabinet used for production of sterile drug products.

OBSERVATION 2:
Personnel were observed manually contacting the inner surface of the container or closure.

Specifically, on 05-June-2019, a technician was observed manually stoppering vials of Prostaglandin 20mcg/ml Procaine 0.1% Injection 4/19 Inj, lot #06052019@22, inside the ISO-5 Biological Safety Cabinet.

OBSERVATION 3:
Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. Specifically,

Your firm has not demonstrated that the (b) (4) used to wipe down the hood between uses is capable of deactivating hazardous products between each lot prior to subsequent weighing of non-hazardous products.

A. The (b) (4) hood, Model (b) (4), SN (b) (4), which is located in the ISO-7 Ante room, is used to weigh hazardous and non-hazardous bulk drug substances during production of sterile drug products. It is not possible to determine the daily production sequence in this hood; however, both hazardous and non-hazardous drugs may be weighed during each day.

In this hood, records show production of a hazardous drug product on 30-May-19 followed by production of a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jeffrey P. Raimondi Linda F. Murphy	Jeffrey P. Raimondi, Consumer Safety Officer Linda F. Murphy, Consumer Safety Officer	06/07/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 (425)302-0340 Industry Information: www.fda.gov/oc/industry	05/31/2019, 06/03/2019-06/07/2019
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC	1802 N Monroe St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Spokane, WA 99205	Producer of Sterile and Non-Sterile Drug Products

non-hazardous drug on the subsequent production day without performing a deactivation step:

• On 30-May-19, personnel weighed (b) (4) grams of testosterone cypionate USP, lot 153856/C, during production of Testosterone Cypionate 200mg/Ml Sesame Oil Injection (C3) 1/19 Mdv Inj lot 05292019@4. There was no production between this date and 03-Jun-19.

• On 03-Jun-19, personnel weighed (b) (4) grams of methylcobalamin lot 152056/I during production of Methylcobalamin 10MG/ML Injection 3/19 MDV INJ lot 06032019@19.

B. There are no dedicated hoods or utensils in the non-sterile processing laboratory where non-hazardous drug products are prepared in the same (b) (4) hoods, and with the same utensils, as hazardous drug products. In addition, weighing and mixing utensils are cleaned with (b) (4) between lots of different hazardous products with no assurance the hazardous products have been deactivated.

• On 05-Jun-19, after preparing progesterone/testosterone cream, personnel were observed wiping the mortar, pestle, and other utensils with (b) (4) These same utensils were then used to prepare testosterone cream.

OBSERVATION 4:
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, an in-situ air pattern analysis (smoke study) of the (b) (4) biological safety cabinet (BSC), Model (b) (4), S/N (b) (4) located in the Buffer Room has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions.

This is a repeat observation.

OBSERVATION 5:
Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jeffrey P Raimondi Linda F. Murphy	Jeffrey P. Raimondi, Consumer Safety Officer Linda F. Murphy, Consumer Safety Officer	06/07/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 (425)302-0340 Industry Information: www.fda.gov/oc/industry	05/31/2019, 06/03/2019-06/07/2019
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC	1802 N Monroe St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Spokane, WA 99205	Producer of Sterile and Non-Sterile Drug Products

Specifically, during aseptic compounding of Serum Tears 20% Eye Drops PF solution on 03-Jun-19, during aseptic compounding, the technician's hand was observed blocking the movement of first pass air above or around the sterile caps and tips during manual assembly of the caps and tips used to cover the serum eye droppers.

In addition, a tray of caps and tips were placed directly in front of the return air vents of the ISO-5 biological safety cabinet where the eye drops were being prepared.

OBSERVATION 6:
The facility is designed and/or operated in a way that permits poor flow of personnel or materials.

Specifically, gowning to enter the ISO-7 Buffer room requires personnel to don sterile gowns inside the adjacent ISO-7 Ante room. This is performed by removing the disposable lab coat in the ISO-7 Ante room, exposing technicians' outer wear clothing to the classified area prior to donning the sterile garments. The disposable lab coat was originally donned in the ISO-8 Gowning room. The Anteroom, which is used to weigh, compound, and (b) (4), non-sterile (b) (4) prior to (b) (4), is expected to have positive pressure as compared with the ~~ISO-5~~ ISO-7 Buffer room. JPR 06/07/19

This gowning practice was observed on 03-June-2019, when sterilizing and filling of Chorionic Gonadotropin 2,000/ML PF Injection 3/19 PF SOLN, Methylcobalamin 10MG/ML Injection 3/19 MDV INJ, and Serum Tears 20% Eye Drops PF 4/19 SOLN occurred.

OBSERVATION 7:
The facility design was observed to allow the influx of lower quality air into a higher classified area.

For example, after technicians wash their hands in the gowning room, the dirty water flows into an uncapped carboy under the sink, where the pooled water sits until it is emptied. Firm management stated this carboy is emptied about (b) (4).

The cleanroom module is designed with (b) (4) which (b) (4)
(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Jeffrey P. Raimondi Linda F. Murphy	Jeffrey P. Raimondi, Consumer Safety Officer Linda F. Murphy, Consumer Safety Officer	06/07/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 (425)302-0340 Industry Information: www.fda.gov/oc/industry	05/31/2019, 06/03/2019-06/07/2019
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC	1802 N Monroe St.
CITY, STATE AND ZIP CODE Spokane, WA 99205	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

(b) (4) The ISO-8 classified (b) (4) maintains positive pressure to the adjacent ISO-7 classified (b) (4) . The (b) (4) maintains positive pressure to the adjacent ISO-7 classified (b) (4) .

A negative pressure gradient from a room with a higher allowable particulate concentration (ISO-8) to a room with lower allowable particulates (ISO-7) may result in ingress of particulates.

OBSERVATION 8:
Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed. Specifically,

During weighing operations on 03-Jun-19, the following air pressure differentials were displayed on the magnehelic gauges:
- (b) (4) to (b) (4) : (+) 0.025 inches of water
- (b) (4) to (b) (4) : (-) 0.01 inches of water
- (b) (4) to (b) (4) needle between 0.00 and (-) 0.01inches of water

OBSERVATION 9:
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, media fills are not performed in a manner that simulates challenging production practices such as the maximum number of vials or syringes filled, maximum number of people in the room, or the duration of aseptic production.

OBSERVATION 10:
The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

A) The (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jeffrey P. Raimondi Linda F. Murphy	Jeffrey P. Raimondi, Consumer Safety Officer Linda F. Murphy, Consumer Safety Officer	06/07/2019

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 (425)302-0340 Industry Information: www.fda.gov/oc/industry	05/31/2019, 06/03/2019-06/07/2019
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Catherine M. Hudek, RPh, NCMP, Director of Pharmacy

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC	1802 N Monroe St.
CITY, STATE AND ZIP CODE Spokane, WA 99205	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

(b) (4) was observed to have a reddish discoloration on the bottom, even after cleaning with sterile (b) (4) JPR 06/07/19

Additionally, although your firm stated the (b) (4) is made of (b) (4) in both the Buffer and Anteroom, the exterior of this (b) (4) was observed to have exposed exterior edges with non-smooth surfaces.

B) Apparent white residue was observed inside the (b) (4) Hood and on the keyboard located in the ISO-7 Anteroom.

C) Each light fixture in the ISO-7 buffer room where the ISO-5 Biological Safety Cabinet is located, has an open slit in them. These slits are not sealed to prevent anything from coming into the ISO-7 buffer room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Jeffrey P. Raimondi Linda F. Murphy	Jeffrey P. Raimondi, Consumer Safety Officer Linda F. Murphy, Consumer Safety Officer	06/07/2019