DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place Suite 5900 Detroit, MI 48207 (313) 393-8100 Industry Information: www.fda.gov/oc/industry	8/8/16, 8/9/16, 8/10/16, 8/11/16, 8/12/16, 8/16/16, 8/19/16
	FEI NUMBER 3007181436

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anthony S. Kantzavelos, Pharm.D (Owner)

FIRM NAME	STREET ADDRESS
Rx Compounding Inc.	1101 E. 86th St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Indianapolis, IN 46240	Producer of Sterile Drug Products

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

OBSERVATION 1

Equipment, materials, and/or supplies are not adequately disinfected prior to entering the aseptic processing areas.

Specifically,

While loading the items into the pass-through chamber during the aseptic compounding of Vancomycin 25mg/ml prescription number (b)(4), (b) (6) and Tobramycin 14mg/ml prescription number (b)(4), (b) (6) the operator was observed spraying (b)(4) sterile (b)(4) onto the equipment/materials located in the (b)(4). However, the sterile (b)(4) did not make contact with all of the equipment and material surfaces prior to being being placed in the (b)(4) (b)(4) transfer chamber.

OBSERVATION 2

Personnel were observed performing aseptic manipulations that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically,

During the aseptic compounding of Vancomycin 25mg/ml prescription number (b)(4), (b) (6) and Tobramycin 14mg/ml prescription number (b)(4), (b) (6) the operator was observed passing their hands over the open sterile ophthalmic bottles.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Robert M. Barbosa	Robert M. Barbosa (Investigator)	09/16/2016

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Specifically,

1) The gloves [redacted] used during the aseptic compounding of Vancomycin 25mg/ml prescription number [redacted] and Tobramycin 14mg/ml prescription number [redacted] are non-sterile nitrile gloves which are replaced [redacted]

2) The non-sterile nitrile gloves which are changed out [redacted] are not sanitized with sterile [redacted] until after they are exposed to the interior ISO 5 environment. Additionally, during the aseptic compounding of Vancomycin 25mg/ml prescription number [redacted] and Tobramycin 14mg/ml prescription number [redacted] the non-sterile nitrile gloves the operator was using were not form fitting with visible creases and folds in which the non-sterile glove surfaces did not make contact with the sterile [redacted]

OBSERVATION 4
The ISO 5 classified area is located within a non-classified room.

Specifically,

The environment of the curtained anteroom surrounding the [redacted] where all sterile prescriptions are filled is not classified nor was the HEPA filter located in this anteroom certified during your routine [redacted] certifications performed on 1/26/16 and 7/26/16. Additionally, the HEPA filter located in the [redacted] of the anteroom is partially covered by the [redacted]

OBSERVATION 5
Chemical sanitizing agents are not used in your facilities cleanrooms.

Specifically,

The curtained anteroom floor, walls, and surfaces, in which the ISO 5 [redacted] is located, is currently sanitized using a [redacted] only. No sanitizing chemical agents are used during the sanitization of this room.

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OBSERVATION 6

The environmental monitoring is performed is not representative of aseptic conditions.

Specifically,

1) The agar plates used for performing the (b)(4) passive viable air testing are incubated at (b)(4) (b)(4) prior to reading. Due to the excessive incubation time, the agar plates incubated on 7/15/16 were observed on (b)(4) to be completely dessicated and disintegrating. Also this lot of agar plates, lot no. (b)(4) expired on 6/3/15.

2) The test media used with the (b)(4) for performing the (b)(4) fingertip monitoring does not contain any sanitant neutralizing ingredients. Additionally, the (b)(4) incubated on 7/15/16 were observed on (b)(4) to be completely dessicated and disintegrating.

OBSERVATION 7

The certification of ISO 5 classified area is not representative of its condition of use.

Specifically,

The unidirectional airflow studies performed during the certification of the (b)(4) on 1/26/16 and 7/26/16 did not include studies under dynamic conditions.

OBSERVATION 8

Beta-lactam drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

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On 7/20/16 Ceftazidime 50mg/ml prescription no. (b)(4), (b) (6) was filled in your (b)(4) used for filling sterile prescriptions. The (b)(4) was subsequently re-sanitized with (b)(4) and subsequently used to fill Chlorhexidine 0.02% prescription no. (b)(4), (b) (6) on the same day.

Similarly, on 7/15/16 Amoxicillin 52.5mg/ml prescription no. (b)(4), (b) (6) was filled in your non-sterile compounding (b)(4) hood. Subsequently on 7/15/16 Enalapril 5mg/ml prescription no. (b)(4), (b) (6) was filled in this same (b)(4) hood. There was no documented cleaning of the non-sterile (b)(4) hood between the filling of these prescriptions.

Amendment 1.

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