DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	11/04/2014 - 11/25/2014* FEI NUMBER 3011074473

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Cliffic Guidry, Pharmacy Manager

FIRM NAME	STREET ADDRESS
Walgreens Infusion Services	9030 Kirby Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77054-2504	Producer of 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 WE OBSERVED:

OBSERVATION 1

Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production.

Specifically,

1. On 11/04/2014, we observed there is no positive air flow in the ISO-5 Laminar Air Flow hood #(b) in the ISO-7 cleanroom where drug products are produced. We held up a piece of paper, where air flow should have been and it did not move. We could not feel any movement of air coming out from under the ISO-5 hood, where Cubicin 600 mg/0.9% NaCl 100 mL, (expiration date of 11/18/2014), was being produced, into the ISO-7 buffer room, nor could we feel any movement of air from the ISO-8 ante room into the unclassified area. No smoke studies, under static or dynamic conditions, have been performed.

2. There is no measurable pressure differential between the buffer room (ISO-7), where the ISO-5 hoods are located, and the ante room (ISO-8), and between the ante room (ISO-8), where gowning is performed, and the unclassified area. The pressure gauges intended to measure this differential do not fluctuate when the door is opened. Per your firm's management, the air is kept in continuous operation.

3. The company with whom your firm contracts for the re-certification of the clean rooms, (b) (4) posted a sign outside the ante room indicating the cleanroom does not meet requirements for Walgreen's specs. Your management stated this meant the room specifications were met for the particle counts under the hoods, but the pressure was too low. This was report (b) (4) dated July 22, 2014. In addition, the reports from your contractor for July 22, 2014 and February 13, 2014 both indicate the HEPA Leak was not tested due to low air flows and inaccessible introduction point. There is no documented evidence indicating the last time the HEPA filters were tested, and your firm has not taken any corrective actions or made any repairs to the HEPA filters.

4. The (b) (4) recorded pressure readings for the ISO-8 ante room and ISO-7 buffer room are outside of the acceptable ranges indicated on your form entitled, "FR-P-190 (b) (4) Temperature and Maintenance Record" for the months of June, July, August, September, and October 2014. Your pre-determined acceptable pressure readings should be between (b) (4) inches and readings are recorded as 0.00. In addition, there was no investigation or action taken regarding these out of range readings.

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	Darla J. Christopher, Investigator Jason R. Caballero, Investigator	11/25/2014

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5. The (b) (4) recorded temperature readings for the ISO-8 ante room, ISO-7 buffer room, and ISO-7 chemo rooms are outside of the acceptable ranges indicated on your form entitled, "FR-P-190 (b) (4) Temperature and Maintenance Record" for the months of June, July, August, September, and October 2014. Your pre-determined acceptable temperatures should be maintained at (b)(4) degrees Fahrenheit or lower, and the daily temperature readings were recorded at between 70 and 85 degrees Fahrenheit (b) (4) . In addition, there were no (b) (4) temperatures recorded for the ISO-7 chemo room at all for the month of July 2014.

6. On 11/04/2014, we observed the (b) (4) , located in the ISO-7 buffer room, directly under the ISO-5 Laminar Flow hoods numbered (b) (4) , were cluttered with what appeared to be dust and debris, such as empty vial covers and used (b) (4) . The drug product being produced at the time was Cubicin 600 mg/0.9% NaCl 100 mL., exp. date: 11/18/2014.

OBSERVATION 2

Written procedures for sanitation are not followed.

Specifically,

Per your Standard Operating Procedure, Pharmacy P-125, entitled, "Sterile Compounding Environment Procedures," with the effective date of 02/01/2008, there is no written documentation of the (b) (4) cleaning of the exterior workbench surfaces, shelves, tables, bins, totes, stools, cabinet surfaces, and LAF hood exteriors in the ISO-7 buffer room having been performed for the month of October 2014. There are no sporicidals being used and no instructions of dwell time for cleaner on the surface being cleaned to be effective. The (b) (4) your firm uses to clean the cleanrooms do not contain sporicidal agents and are non-sterile.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

On 11/04/2014, we observed an employee working under the ISO-5 number (b) hood drop a sterile glove on the floor of the ISO-7 buffer room, pick it up, put it on her hand, and then proceed to produce drug product without sanitizing the glove. A few moments later, after she changed gloves, this same employee wiped sweat from the brow of her exposed face with her sterile gloves and then continued to produce drug product without changing or sanitizing gloves. This same employee used a gloved hand to ring a table bell that appeared to be corroded or pitted, in the pass through area, and proceeded to produce drug product (Cubicin 600 mg/0.9% NaCl 100 mL, exp. date: 11/18/2014) without changing or sanitizing gloves. (b) (4)

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OBSERVATION 4

Established sampling plans are not followed and documented at the time of performance.

Specifically,

1. Your Standard Operating Procedure, entitled, "Sterile Admixture Quality Control," dated 07/22/2014, states that environmental surface samples will be collected from the (b) (4) ISO-5 Laminar Air Flow hoods in the ISO-7 buffer room, the ISO-5 (b) (4) hood in the ISO-7 chemo room, the (b) (4) stainless steel tables in the ISO-7 buffer room, the stainless steel cart in the ISO-8 ante room, the ISO-8 ante room door, and the ISO-8 ante room wall on a (b) (4) basis; however, the most recent dates of sampling were 10/14/14, 06/14/14, and 02/28/14, indicating they are only performed once every 4 months.

2. Your Standard Operating Procedure, entitled, "Sterile Admixture Quality Control," dated 07/22/2014, states the surface samples collected quarterly from the (b) (4) ISO-5 Laminar Air Flow hoods located in the ISO-7 buffer room and the ISO-5 (b) (4) in the ISO-7 chemo room, and from various points in the ISO-7 buffer room and ISO-8 ante room, will be incubated for (b) (4), followed by (b) (4) . The Environmental Monitoring Results Form FR-P-165c for these routine plate samples only lists one date for sampling conducted 10/14/14, 06/14,14, and 02/28/14, and does not indicate if this is the date the sample was collected, (b) (4)

OBSERVATION 5

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

1. On 11/04/2014, the face mask utilized by an employee working under the number (b) (4) ISO-5 Laminar Air Flow hood in the ISO-7 buffer room failed to cover her entire face. This employee, producing the drug product, Cubicin 600 mg/0.9% NaCl 100 mL, exp. date: 11/18/2014, had exposed body areas such as neck, forehead, eyes, ears, and cheeks.

2. Your firm does not require, nor does it provide sterile gowns, facial masks, or any kind of protective eye wear to employees.

OBSERVATION 6

Production personnel were not practicing good sanitation and health habits.

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On 11/04/2014, we observed an employee, after gowning in the ISO-8 ante room, and entering the ISO-7 buffer room, proceed, with gloved hands, to reach through the plastic curtains dividing the two rooms and transfer an unsanitized stainless steel shelving unit, which held medical and gowning supplies, from the ISO-8 ante room into the ISO-7 buffer room. Her gloved hands were observed making contact with the plastic curtains. Another employee was observed transferring an unsanitized stainless steel cart and a waste receptacle from the ISO-8 ante room into the ISO-7 buffer room on the same date. The drug product being produced at the time of these observations was Cubicin 600 mg/0.9% NaCl 100 mL., exp date: 11/18/2014.

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm does not perform any stability testing on drug products, such as Cubicin 600 mg/0.9% NaCl 100 mL, exp. date: 11/18/2014, to determine Best Used By Dates (BUDs) and storage conditions of the product.

*** DATES OF INSPECTION:**
11/04/2014(Tue), 11/05/2014(Wed), 11/06/2014(Thu), 11/13/2014(Thu), 11/17/2014(Mon), 11/19/2014(Wed), 11/20/2014(Thu), 11/25/2014(Tue)

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