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	03/18/2013 - 03/20/2013
	FEI NUMBER 3006311680

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jan Robinson, Vice President of Operations

FIRM NAME	STREET ADDRESS
IV Solutions of Lubbock	3706 - A 20th St
CITY, STATE, ZIP CODE, COUNTRY Lubbock, TX 79410	TYPE ESTABLISHMENT INSPECTED 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

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm uses non-sterile hair covers, mouth covers, and gowns as clothing for personnel who aseptically process drug products in the clean room.

On March 18 and 19, 2013, a technician, (b) was observed aseptically processing drugs in the ISO 5 Hood, within the ISO 7 clean room, with exposed skin on the face and neck and exposed hair not fully covered by the technician's hair cover. Additionally, clothing worn by the personnel outside the clean room in unclassified areas was not completely covered by the gowning around the neck area, below the knee, and around the backside of the operator . The operator observed was aseptically processing prescriptions for the following aseptically processed drug products:

1. Vancomycin - 250mL, (b total elastomeric pumps
2. Vancomycin - 100mL, (total eslastomeric pumps
3. Ceftriaxone - 100mL, (total elastomeric pumps

OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, your ISO 7 Clean Room, where your (b)(4) ISO 5 hoods reside, and where aseptic processing of sterile drugs occurs, has the exhaust air vent (b) (4) , rather than below the ISO 5 work bench level, potentially putting the ISO 5 hood at greater risk for turbulent, non-laminar, air flow. You have never conducted smoke studies to verify that you are, in fact, getting non turbulent, laminar air flow within your ISO 5 Hoods where aseptic processing of drugs intended to be sterile, occurs.

Additionally, HEPA filters in your ISO 7 clean room and ISO 8 ante-room are not regularly leak tested during (b) (4) (b) (4) clean room certifications. According to clean room test reports, only a visual check and total air flow is measured for the HEPA filters supplying air to the ISO 7 clean room and the ISO 8 ante-room. You have no written procedure/protocol

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for how to conduct HEPA filter certifications or the frequency of these certifications.

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, on 3/18/2013 and 3/19/2013, a technician, (b) , was observed aseptically processing prescriptions for Vancomycin and Ceftriaxone within your (b) (4) ISO 5 hood, which has a work bench made of a wood laminate type material with a stainless steel cover that does not completely overlay the wood laminate work bench. A small amount of wood laminate material is exposed around the outer edges of the work bench. This wood laminate material is harder to disinfect than a completely stainless steel work bench.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, you do not conduct air, or surface, sampling for viable, or non-viable, particles during the aseptic processing of every batch, or at least once per shifts in which drug products, intended to be sterile, are aseptically processed in your ISO 5 hoods. The Pharmacist in Charge stated that the firm aseptically processes (b) (4) of Tobramycin Ampules for Inhalation, (b) (4) , and that each batch of this drug product consists of (b) boxes (each box containing (b) ampules), depending on the volume needed. Your firm does not conduct environmental monitoring of any kind on a frequency of at least once per shift when aseptic processing of any drugs intended to be sterile, occurs.

Your firm has no written procedure which delineates the frequencies of environmental monitoring in ISO 5 and ISO 7 workstations, and the gowning room. For example, written standard operating procedure (SOP) #8, entitled, *Process for personnel fingertip monitoring with contact plates*, does not provide a frequency for collecting fingertip samples and does not call for sampling other parts of the personnel clothing or gown. Additionally, SOP #10, entitled, *Surface cleaning and disinfection sampling assessment procedure*, does not specify a frequency for collecting samples.

OBSERVATION 5

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

Specifically, the (b) media fills you perform do not represent worst case aseptic processing conditions in terms of batch size and length of aseptic processing. You aseptically process batches of Tobramycin Ampules for Inhalation which consists of (b) (4) ampules; yet, according to SOP #12, entitled, *Aseptic Technique Validation*, in your media fills you only

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aseptically process (ampules.

Addtionally, you do not include positive controls, or conduct growth promotion testing, for microbiological media used for media fills for operators who engage in aseptic processing, nor for growth media used for environmental monitoring. According to the Surface Contact Sampling log, your firm uses (b) (4) contact plates for sampling surfaces inside ISO 5 laminar air flow hoods. For media fills, your firm utilizes (b) (4) (b) (4) as part of the (b) (4) Aseptic Technique Validation System.

OBSERVATION 6

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your firm lacks a system of continuous monitoring of positive pressure differential limits during aseptic processing of drugs intended to be sterile. Your current practice is to log the differential pressure readings from your positive pressure differential pressure gauges, representing the differential pressure across your clean room and adjacent gowning room, (b) (4) . Because these gauges are located outside of the clean room itself, if a loss of positive pressure in the clean room occurred during aseptic processing, you may not notice until the clean room differential pressure gauges are read again (b) (4) . Your current clean room differential pressure system has no audible alarm; thus, transient excursions of (b)(4) positive pressure would not be observed or recorded.

OBSERVATION 7

Reserve samples for drug products are not retained for one year after the expiration date of the drug product.

Specifically, you fail to retain and store reserve samples for each batch of aseptically processed Tobramycin 150mg/3ml Ampules for Inhalation you produce and distribute.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."