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	12/12/2013 - 12/20/2013
	FEI NUMBER 1000138425

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Larketta Jean Scarbrough-Swofford, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Abrams Royal Pharmacy	8220 Abrams Rd
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75231-1402	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

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

Specifically, your firm does not always practice good aseptic techniques while (b) (4)-sterilizing human drug products.

On December 12-13, 2013 we observed your clean room Technicians conducting aseptic fill processes in laminar flow hoods (ISO 5) inside the "Clean Room" (ISO 7) practicing poor aseptic techniques, such as:

1. Touching product contact surface (sterile transfer tubing) with gloved hand after sterile (b) (4)
2. Picking up items (e.g. needle and power cord) off the floor without changing sterile gloves
3. Exposed skin at wrists due to inadequate glove/gown cover
4. Mouth/nose cover sitting below the nose
5. Continuing to (b) (4) and handle products with torn gown at armpit location
6. Opening bench drawers outside of laminar flow hood without sanitizing hands
7. Leaving clean room and returning without changing gloves or gowns
8. Using non-sterile gown clothing

During the time that these conditions were observed, technicians were (b) (4)-sterilizing Glutathione MDV (lot #12122013@52) and Methionin/Choline Blend (lot #12122013@24).

Additionally, Your media fill process (SOP 9.110, ver 5, eff 9/18/2013) does not adequately simulate (b) (4) and filling processes. According to your Pharmacist-In-Charge, the media fill process reflects the highest risk/high volume or the highest risk/low volume preparations performed. Your high risk/high volume media fill consists of transferring non-sterile (b) (4) and filling 1 mL aliquots into 2mL prepared glass vials using a (b) (4). This method does not represent the high risk filling of formulas using the (b) (4) such as the Calcium Edetate (lot #11192013@27) and Glycyrrhizic Acid (lot #11202013@31).

Additionally, the media fill samples are stored in your firm's lab, but not in a controlled temperature incubator and media fill samples are filled in amber vials rather than clear vials for visual inspection of growth.

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OBSERVATION 2

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm does not test and review results for sterility of drug products prior to releasing products for distribution. Also, your firm does not perform (b) (4) test on all batch (b) (4)

On December 13th 2013, We reviewed your firm's written procedure for conducting sterility tests on (b) (4)-sterilized drug products (SOP #9.120; ver 7.0, eff 2/1/2013) which reads in part that randomly selected formulas will be tested for sterility. Your pharmacist stated that batches greater than (b) (4) units in size are sent to a third party lab for sterility testing and the product is not currently released until sterility results are received from the lab. However, your firm does not always wait to release product until sterility testing is complete, for example:

Product	Lot	Test Date	Ship Date
Calcium Chloride solution	05152013@4	7/22/2013	(b) (4) vials on May 23, 2013
Trace Mineral	04302013@21	6/26/2013	(b) (4) vials starting May 2, 2013
Red Block (Lidocaine Blend)	04102013@13	6/14/2013	(b) (4) syringes starting April 18, 2013

On December 16th 2013, your Pharmacist stated it is standard practice to not perform (b) (4) used to (b) (4) sterilize injectable human drug products using the (b) (4). For example, the following batches of product were (b) (4) sterilized, but the (b) (4) in use was not (b) (4) tested:

Stericup	Lot	Date Mixed (b) (4)	Date Shipped
Folic Acid MDV	11142013@8	11/15/2013	20-Nov-13
Calcium Edetate	11192013@27	11/20/2013	5-Dec-13
Glycyrrhizic Acid	11202013@31	11/21/2013	25-Nov-13

Your firm does not peform (b) (4) testing on any of the (b) (4) used. A total of 19 formulas mixed and (b) (4) through aseptic processes area with the (b) (4) were not tested for (b) (4) during November, 2013.

OBSERVATION 3

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 firm's clean room and anteroom are not designed and built to maintain good aseptic processing operations

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and do not have adequate air pressure differential and cascade. Also, your firm has not performed smoke studies to verify unidirectional air flow during static and dynamic conditions in laminar flow hoods (identified as ISO 5).

On December 12th, 2013 we observed the ante-room (identified as ISO 8) does not have air supply ducts installed. The ante-room is separated from the clean room (ISO 7) and the mixing room (ISO 8) by strips of plastic hanging in the intervening doorways. Your firm's procedure (SOP #4.330, ver 1.0, eff 9/25/2013) states that a differential pressure of (b) (4) inches of water is expected to exist between these rooms separated only by strips of plastic that do not create a continuous barrier between the rooms.

Your firm's Cleanroom Certification & Biological Sampling Report (dated August 29, 2013) document provided by a third party certifying contractor shows that air pressure differentials between these rooms are 0.0039 inches of water (clean room to ante-room) and 0.0014 (ante-room to mixing room). The mixing room identified as ISO 8 environment has non-filtered air supply moving down the differential into the ante-room represented in the report referenced above. The ante-room is constructed without an air exhaust vent.

Additionally, there have been no smoke studies performed to evaluate the unidirectional flow of ISO 5 hoods, the clean room, or the ante-room. This includes smoke studies in both static and dynamic conditions.

We observed the clean room and ISO 5 hoods used to (b) (4) and fill products intended to be sterile injectable such as Calcium Edetate (lot #11192013@27) and Glycyrrhizic Acid (lot #11202013@31).

OBSERVATION 4

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, your firm does not always investigate testing results that show drug products have failed to meet specifications for sterility. Also, your firm has not performed corrective action for above limit environmental monitoring.

On December 13th, 2013 we reviewed "OOS Checklist" documents that record the investigation of sterility positives occurring during 2013. There are a total of eleven sterility failure results during 2013. Of these reports, six do not include a report that identifies the genus or species of the growth organism. These reports document a review of transport records, environmental monitoring, equipment calibration, and compounding record. For the reports that do identify genus and species of the growth organism, no investigation or corrections are conducted to address common reservoirs of the organism.

On 10/25/2013 and 11/8/2013, the viable air monitoring samples yielded results which were above your established action alert level (b) (4), as written in your standard operating procedure (SOP #3.030, version 3.0, eff 9/12/2013) titled, "Environmental Monitoring of the Clean Room Facility". Samples taken on 10/25/2013 in your horizontal LAF hood, designated as Hood 2, H1A, resulted in 3 Colony Forming Units (CFU). Samples taken on 11/8/2013 in your vertical LAF hood, designated as Hood 1, H2A, resulted in 2 CFU. You did not perform and document an investigation to identify the

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microbial isolates or to the cause. Your SOP states that in addition to identifying the microbial isolate a review of the pressure differential; HEPA and clean room certification; and Logs of Use, Maintenance, and Cleaning will be conducted.

On 10/25/2013, you produced the following:

(b) (4) [redacted]

On 11/8/2013, you produced the following:

(b) (4) [redacted]

OBSERVATION 5

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm does not adequately investigate and document investigations of complaints according to your written procedure.

On December 13, 2013 we reviewed your firm's list and documentation of complaints including reports of corneal edema, fever, swelling, nausea, and headaches. For 2013, your firm has received a total of five complaints where one of those records does not include the lot number of the product in question and two of these records do not document a specific problem or the nature of the complaint.

There is no documented investigation, testing, document review, or root causes identified for these complaints.

OBSERVATION 6

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

Specifically, your firm does not adequately monitor environmental conditions in your ISO 5 laminar flow hoods and and your ISO 7 clean room.

Your firm performs contact plate sampling (b) (4) and air sampling (b) (4) according to sampling logs dated October 11 - November 29, 2013. There are approximately (b) (4) formulas mixed and filled every day of aseptic processing in the ISO 7 clean room where you work in ISO 5 laminar flow hoods.

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Your procedure (SOP #3.030, ver 3.0, eff 9/12/2013) calls for sampling at least every (b) (4) for air sampling and (b) (4) for contact plates.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm does not adequately rotate solutions and using appropriate wipes for cleaning and disinfecting your ISO 5 laminar flow hoods and ISO 7 clean room.

Your firm has used non-sterile wipes (Item (b) (4) non-woven wipes) to clean and disinfect the ISO 5 hoods and ISO 7 Clean room througout 2013. Also, your firm has used sterile (b) (4) throughout 2013 according to cleaning logs dated January to November 2013. Your firm has not rotated solutions to account for sporicidal agents.

OBSERVATION 8

Procedures describing the calibration of instruments, apparatus, gauges and recording devices are deficiently written or followed.

Specifically, your firm's laboratory equipment is not adequately designed and installed for its intended purpose.

Your incubator (b) (4)) used for microbiological culturing of your environmental monitoring (touch plates, air sampling, and surface contact) samples went above the maximum culture temperature range of (b) (4) °C. From 9/3/2013 to 9/19/2013 and on 9/25/2013, the recorded temperature of this incubator ranged from (b) (4)

This incubator has an approximate interior dimension of (b) (4) and is loaded from the top. The door must be fully opened in order to obtain the temperature, which is obtained at most once per (b) (4) from a thermometer that sits at the bottom of the incubator. It does not have a temperature monitoring device on the outside of the unit.

This incubator is used to store personnel touch plates that are obtained (b) (4) environmental surface sampling plates that are obtained (b) (4) and viable air samples for environmental monitoring that are obtained (b) (4) throughout 2013. These samples are intended to monitor and ensure aseptic conditions in the clean room used for (b) (4) all injectable human drug products.

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OBSERVATION 9

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

Specifically, your firm does not test injectable human drug products for potency or preservative effectiveness at the time of mixing/filtration and throughout the "Beyond Use Date" of the products.

On December 19th, 2013 your pharmacist stated your firm has conducted assay or potency testing on only one formula (Injectable Vitamin C from Tapioca 500mg/mL) out of over (b)(4) different injectable human drug formulas made in batches larger than (b)(4) units. Product formulas without stability data include:

Product	Lot #	Mixing Date	Beyond Use Date	Shipping Date
Hydroxycobolamin	09162013@61	9/30/2013	3/15/2014	6-Nov-13
Pyridoxine HCl	10282013@94	10/30/2013	4/6/2014	5-Nov-13
Folic Acid	11142013@8	11/15/2013	5/13/2014	20-Nov-13

Your pharmacist stated all products have "Beyond Use Dates" according to written procedure (SOP #9.050, ver 1.0, eff 11/29/2007) which are based on literature references rather than stability studies executed by your firm (with the exception of the Vitamin C product referenced above). Also the data for stability of the Injectable Vitamin C does not include sterility testing. Beyond use dates extend up to six months from the date of mixing and (b) (4)

OBSERVATION 10

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm does not perform growth promotion testing on media used to culture microorganisms for sterility testing, environmental monitoring, media fills, or personnel monitoring.

On December 18th, 2013 your pharmacist stated your firm does not perform growth promotion testing, using a known quantity or identity of organisms on (b) (4) used for sterility testing of (b) (4) sterilized human drug products. For example, this cassette was used to test sterility of Molybdenum MDV (lot #11212013@27). Also, sterility testing performed by your firm includes only an aerobic media (Tryptic Soy Agar) and does not include an anaerobic media such as Fluid Thioglycollate Medium.

Your pharmacist stated your firm does not perform growth promotion testing using a known quantity or identity of organisms on Tryptic Soy Broth (item # (b) (4) ; used for conducting media fill simulations of mixing and filling operations. For example, tryptic soy broth was used to conduct a media fill (dated 10/24/2013) according to your written procedure (SOP #9.110, ver 5).

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Your firm relies on the manufacturers certificate of analysis for growth promotion data.

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm's quality control unit does not document the visual inspection of aseptically processed drug products.

On December 12th, 2013 we reviewed formulation documents executed by your pharmacy technicians for mixing ingredients and (b) (4) sterilizing human drug products intended for sterile injection. These formulation documents lack documentation of a visual inspection conducted according to SOP #9.120 - "Sterile Compounding Finished Preparation Testing" (ver 7.0, eff 2/4/2013). For example, your firm has not documented that visual inspection has been conducted for the following human drug products:

Product	Lot #	Mixing Date	Beyond Use Date	Shipping Date
Hydroxycobolamin	09162013@61	9/30/2013	3/15/2014	6-Nov-13
Pyridoxine HCl	10282013@94	10/30/2013	4/6/2014	5-Nov-13
Folic Acid	11142013@8	11/15/2013	5/13/2014	20-Nov-13

Your firm's pharmacist stated that she and the other pharmacists supervising the pharmacy technicians are preforming the visual inspection for every lot to look for visually apparent problems or contamination, but it is not always documented for the up to (b) (4) formulas mixed and (b) (4) each day in the aseptic filling area.

OBSERVATION 12

There was a failure to handle and store drug product containers at all times in a manner to prevent contamination.

Specifically, your firm does not always store drug product containers off the floor that are used in aseptic processing procedures.

On December 12th 2013, we observed more than three packages of glass serum vials that were designated for sterile filling stored on the floor of the Ante Room. The vials were packaged in foil and placed in a plastic tote. The tote was placed on the floor of the ante room adjacent to the door leading to the mixing room. Additionally, there were vials stored on the bottom shelf of a rolling cart, less than six inches off the floor in the ante room. This rolling cart has items used in the clean room for aseptic processing and must be passed by technicians passing through the ante to enter the clean room.

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