DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/22/2015 - 09/29/2015 FEI NUMBER 3005468616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Thomas C. Reed, Owner

FIRM NAME	STREET ADDRESS
Jones Drug Company, Inc. dba Reed's Compounding Pharmacy	2729 E. Speedway Blvd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tucson, AZ 85716-3800	Producer of Sterile Drugs

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 do not include adequate validation of the sterilization process.

Specifically,

A. The sterile (b) (4) process was validated by conducting media fill studies every (b) (4) . However, the media fill studies were deficient in that,

   a. There was no compounding record generated. Section 9.1.2 of SOP 8.110 version 1.0 titled: Sterile Compounding Process Validation (Media Fills) states "All media fills shall be conducted (b) (4) ." The preparation of media sample; the length of time for the media fill study; and the incubation time and temperature were not documented.

   b. The media fill study did not represent the worst case of your sterile product preparation. For example, the Tri-Mix product batch solution preparation normally uses (b) (4) to complete the aseptic (b) (4) process. In addition, a (b) (4) was also used. Your media fill study did not simulate the use of (b) (4) and the process of (b) (4) process using the (b) (4)

   c. According to SOP 8.110 version 1.0 titled: Sterile Compounding Process Validation (Media Fills) section 9.5 (b) (4) However, there is no record of such (b) (4) done (b) (4) .

   d. The media fill study for Pharm Tech (b) (6) on (b) (4) did not document the media lot number and its expiration date. The record was reviewed and signed off without the deficiencies identified.

   e. The media fill study for Pharm Tech (b) (6) on (b) (4) did not include glove surface microbial testing result. The record was reviewed and signed off without the deficiencies identified.

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	Liming Zhang, Investigator Alan P. Kurtzberg, Investigator	09/29/2015

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B. According SOP 4.040 version 1.0 titled: Use,Verification and Maintenance of the (b) (4), section 9.5.1, "Depyrogenation of glassware must be verified on a (b) (4) basis using (b) (4) vials." However, only the following verification studies were documented.

(b) (4)

Results
Pass
Pass
Pass
Pass
Pass
Pass
Pass
None
Pass
Pass
Pass
Pass

C. On 9/22/2015 upon completing the preparation of Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7, Pharm Tech(b) (6) conducted a (b) (4) to evaluate (b) (4). The test was carried out with a (b) (4) According to SOP 4.170 version 1.0 titled: Use and Maintenance of the (b) (4) section 9.1.18 and 9.1.1.9, the test shall be carried out by (b) (4) The actual (b) (4) test did not follow the SOP procedure.

D. The (b) (4) used for the (b) (4), was not calibrated and did not have any unique identifier such as a serial number.

OBSERVATION 2

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

Specifically,

A. Your SOP 3.030 version 1.1 titled: Environmental Monitoring of the Clean Room Facility is deficient in that it does not require personnel and ISO5 (b) (4) laminar flow hood to be monitored for viable microorganisms on daily sterile product preparation.

B. Sampling plan for the surface monitoring of viable microorganisms in clean room was not established with respect

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to the exact sampling locations. The (b) (4) surface sampling was conducted on only (b) (4)

C. No environmental monitoring of air, personnel, and surface during (b) (4) sterile product preparation inside the ISO 7 buffer room and ISO 5 laminar air flow hood was conducted.

D. The (b) (4) surface monitoring for viable microorganisms was deficient in that the (b) (4) (b) (4) plates used for sampling was not verified through growth promotion testing.

E. There was no record of surface sampling for viable microorganisms from the non-stainless steel chair in the ISO 7 buffer room, the vertical strip curtains separating between ante room and prep room, the vertical strip curtains separating the prep room and the non-classified area, the (b) (4) in the ante room and the prep room, the (b) (4), the (b) (4) non-sterile (b) (4), and the (b) (4) cart used to transport supplies to the ISO 7 buffer room.

F. The (b) (4) clean room facility surface sampling logs from June to September, 2015 did not include media lot number and the media expiration date. The records were not reviewed and not signed off.

G. The (b) (4) clean room facility surface sampling log from January, 2015 did not include media lot number and the media expiration date. The records have been reviewed and signed off without such deficiencies identified.

H. According to firm's clean room facility personnel touch plate log, media lot (b) (4) with expiration date of 3/10/2015 was used to test sample personnel gloves on (b) (4). No explanation was documented in the records.

I. The media lot number for employee glove monitoring on (b) (4) was not documented.

J. The personnel touch plate records from March 2015 to September 2015 were not reviewed and not signed off.

K. There was no record of employee glove monitoring after 9/4/2015 while sterile products were prepared on (b) (4) with a total of (b) (4) sterile products prepared during this period.

L. (b) (4) were not incubated according to instruction 9.5.6 ("...(b) (4) at (b) (4) C...") of SOP 3.030 version 1.1, Environmental Monitoring of the Clean Room Facility. The incubator temperature log showed the following temperature deviations for the (b) (4) °C incubator (Incubator (b) (4)

a. June 2015 - 2 of the (b) (4) readings are above the (b) (4) °C range
b. July 2015 - 22 of the (b) (4) readings are above the (b) (4) °C range
c. August 2015 - 13 of the (b) (4) readings are above the (b) (4) °C range

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d. September 2015 - all readings within range, however 3 days are missing information with no explanation given

In addition, the log sheets were not reviewed and did not contain the allowable range.

OBSERVATION 3

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

Specifically,

Gowning for sterile operation is inadequate in that,

A. Non-sterile face mask, hairnet, lab coat, and shoe covers were worn during aseptic preparation of sterile products in ISO 5(b) (4) laminar air flow hood.

B. Gowning was repeatedly used on the same day for different sterile product preparation. On 9/22/2015, Pharm Tech (b) (6) prepared two sterile products at different times. Upon exiting the ISO 7 buffer room after completing the first product preparation,(b) (6) hung (b) (6) lab coat in the ISO 8 ante room with face mask and hairnet stored in lab coat pocket. When (b) (6) was ready for the second sterile product preparation, (b) (6) used the same lab coat, hairnet, and face mask to enter the ISO 7 buffer room.

C. During sterile product preparation on 9/22/2015, part of Pharm Tech (b) (6) facial skin was exposed such as (b) (6) forehead and neck. (b) (6) hair was not completely tucked into the hairnet.

OBSERVATION 4

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

Specifically,

A. The wipes used for wiping down tools, containers, and any items that were transferred into the ISO 7 room/ISO 5 LAHF and for cleaning ISO 5 LAHF bench were not sterile.

B. The (b) (4) non-sterile (b) (4) normally stored in ISO 8 ante room that was used for the (b) (4) of Tri-Mix product inside ISO 5 LAHF was cleaned only on the outside. The inside of the (b) (4) was never cleaned and the (b) (4)

C. There was no record indicating that the vertical strip curtains inside the clean rooms were cleaned and sanitized on a

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regular basis.

OBSERVATION 5

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

A. Weights used for balance calibration are not NIST traceable as required in firm's procedure 4.060 version 1.0, Use Calibration and Maintenance of the (b) (4) Balances.

B. Thermometers used for monitoring temperatures of freezers, incubators, and (b) (4) were not calibrated.

OBSERVATION 6

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. The clean room including ISO 5 LAFH was certified by an outside contractor, (b) (4), on a (b) (4) basis. The (b) (4) from the viable air monitoring were incubated in-house. A result summary sheet was provided to (b) (4) upon completion of the (b) (4) incubation and (b) (4) prepared a certification report using the results provided. There was no record showing who performed the results reading and no record indicating that the results were reviewed. In addition, (b) (4) identification, such as lot number and expiration date, was not recorded.

B. No written procedure has been established to provide a schedule for HEPA filter changes in the ISO classified rooms.

OBSERVATION 7

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

Specifically,

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The laboratory testing is deficient in that,

A. The visual examination of the finished product was not carried out against a black/white background and was not done under sufficient lighting conditions. On 9/22/2015, we observed Pharm Tech (b)(6) visual examination of Ceftazidime 50 mg/mL Ophthalmic product solution lot t09222015@3. (b)(6) held the product container against the (b)(4) in the ISO 8 prep room to examine the content and he shook the container during visual examination.

B. On 9/22/2015 before preparing the Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7, Pharm Tech (b)(6) calibrated the portable (b)(4) pH meter using (b)(4) . (b)(6) started calibration by (b)(4) .
According to SOP 4.081version 1.0, titled: Use, Calibration and Maintenance of the (b)(4) pH Meter, section 9.2.3 and 9.2.4, the pH meter shall be calibrated by (b)(4) " The (b)(4) calibration was not done using (b)(4) standard solution first.

OBSERVATION 8

Batch production and control records do not include a description of drug product containers and closures used for each batch of drug product produced.

Specifically,

Executed logged formula worksheet (LFW) did not document critical information related to the primary container closures used for the sterile product. For example,

A. There was no record of expiration date documented for the (b)(4) 1 CC syringes used to contain Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7.

B. There was no information documented for the syringe cap used for the same product described in item A. above.

C. There was no information documented for the 2 mL clear serum vials used for Tri-Mix product lot 06262015@5.

D. There was no manufacturer and expiration date documented for the droptainer used for Ceftazidime 50 mg/mL Ophthalmic solution lot t09222015@3.

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OBSERVATION 9

Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed.

Specifically,

A. The following deviations from the approved Logged Formula Worksheet (LFW) for the preparation of Phenylephrine HCl (PF) 1.5% Injectable lot 09222015@7 on 9/22/2015 were observed,

   a. Pharm Tech (b) (6) deviated from the product preparation instruction. Instead of (b) (4) . No documentation of such deviation and explanation was recorded in the LFW.
   b. The LFW showed that the lot number of (b) (4) was (b) (4) . However, the actual lot of (b) (4) used was (b) (4) . The (b) (4) lot actually used in the preparation was not documented on the LFW. No explanation was provided on LFW on the deviation.
   c. The LFW instructed to use (b) (4) sterile (b) (4) lot (b) (4) However (b) (4) was actually used for the product. No explanation was provided for such deviation.

B. The following deficiencies were observed from the approved LFWs for Tri-Mix batch solution,

   a. The Tri-Mix lot 06262015@5 used (b) (4) and Tri-Mix lot 03242015@1 used (b) (4) . There was no expiration date documented for the (b) (4) . In addition, there was no record of a (b) (4) being conducted. According to the Pharmacist in Charge, she was not aware that the (b) (4) was used for the Tri-Mix product.
   b. The LWF for lot 03242015@1 of Tri-Mix documents an expired lot of prostaglandin E1 API (lot # (b) (4) expired 10/13/2013) used during compounding. Technician (b) (6) stated that (b) (4) lot of API (b) (4) and provided contract lab testing for a lot (b) (4) that (b) (6) stated was the lot used for the batch. The contract lab results indicate a potency of (b) (4) mcg/mL. The LWF has the API potency as (b) (4) (units not included). The Pharmacist in Charge stated that this was probably a transcription error. The LWF was reviewed without any mention of these discrepancies.

OBSERVATION 10

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

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A. According to SOP 8.110 version 1.0 titled: Sterile Compounding Process Validation (Media Fill), section 9.5.6, "All (b) (4) data shall be documented on the (b) (4) form, Attachment 1." During (b) (4) media fill studies, no such form was used and no (b) (4) were recorded.

B. SOP 3.030 version 1.1 titled: Environmental Monitoring of the Clean Room Facility, section 9.2.1 instructs to "Document receipt of the media on the Receipt (b) (4) Plates form (Attachment 1) and place the form along with the manufacturer's certificates in a designated EM binder." There was no such form generated to keep track of the received media plates. Per Pharm Tech (b) (6) only certificates were kept.

C. SOP 3.030 Environmental Monitoring of the Clean Room Facility, section 9.4.4 instructs to "Record viable air sampling results on Attachment 2, and file all completed documents in the EM binder." The form requires the following information to be documented: (b) (4) . No such form was used.

D. SOP 4.040 version 1.0 titled: Use,Verification and Maintenance of the (b) (4) section 5.1 requires the verification of (b) (4) be documented on the (b) (4) Verification Log. The (b) (4) done on (b) (4) , and (b) (4) did not document the following critical information: (b) (4) Vial Size, Number of Vials, Liquid Volume (b) (4) . In addition, there was no conclusion whether the verification met the acceptance criteria. Furthermore, the field of Verification Performed by was not documented. However, the log was signed off by reviewer.

E. Critical sterile product preparation related activities were not recorded in a contemporaneous manner. For example,

a. According to the Pharmacist in Charge, the (b) (4) viable sampling of employee glove was not documented at the time of taking the sample, rather the record was generated when the (b) (4) were observed after completing the incubation period.
b. During the preparation of Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7 on 9/22/2015, (b) (4) by Pharm Tech (b) (6) inside ISO 5 LAFH. However, the (b) (4) was not documented at the time (b) (4) was later recorded in the Quality Assessment Log in ISO 8 prep room.
c. After completing the (b) (4) for the preparation of Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7 on 9/22/2015, Pharm Tech (b) (6) did not record the (b) (4) . When (b) (6) was asked by the FDA investigator why (b) (6) did not record the (b) (4) test result (b) (6) then documented the (b) (4) onto the LFW.

OBSERVATION 11

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

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A. Lot 03182014@22 of Tri-Mix was OOS for high assay. No investigation was performed. A similar incident happened with lot 11042014@32 of Tri-Mix. The report for this incident indicates use of the (b) (4) to accurately measure the component as corrective action. This report was not approved by the Pharmacist in Charge nor did it result in any procedural change/documented training.

B. During incubation of viable samples taken from (b) (4) certification of clean room by (b) (4) four of the bacteria total count samples showed condensation and you concluded that the tests were corrupted. No explanation was provided for the cause of such condensation. The test was repeated on (b) (4).

C. Two of the firm's three recall records provided for the last two years (lot #s 03192015@20 and 07222015@16) were not reviewed.

OBSERVATION 12

Employees are not given training in the particular operations they perform as part of their function.

Specifically,

Your employee training program is deficient in that there was no critical SOP training record and lack of verification on the effectiveness of training. For example,

A. While Pharm Techs (b) (6) and (b) (6) performed critical environmental monitoring work, there was no record in their training file indicating that they were trained to the SOP 3.030 Environmental Monitoring of the Clean Room Facility. According to the clean room facility personnel (b) (4) log, both (b) (6) and (b) (6) performed personnel monitoring test on (b) (4) using media lot (b) (4) which was expired on 3/10/2015. In addition, there was no media lot information used for test performed on (b) (4)

B. On 12/5/2014, Pharm Tech (b) (6) received (b) (4) training that was documented in LFW for Naltrexone HCl 2.3 mg Cap with lot t12032014@57. There was no reviewer initial or signature indicating that the (b) (4) had been verified for correctness.

C. On 7/28/2014, Pharm Tech SN received (b) (4) training related to the preparation of Vancomycin HCl 250 mg/5 mL suspension product with lot t07262014@5. There was no reviewer initial or signature indicating that the (b) (4) had been verified for correctness.

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OBSERVATION 13

Records of the calibration checks of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

No records are kept of daily balance checks for the balance in the hood of the ISO 8 prep room.

OBSERVATION 14

Written procedures are lacking for the use of insecticides designed to prevent the contamination of equipment and drug products.

Specifically,

There was no pest control program established at the firm. No preventive measures such as insect traps or bait stations were used. On 9/23/2015, three dead bugs (one of them was a cockroach) were observed inside the patient consultation room along the display window. The patient consultation room is located about (b)(4) feet from the clean room where the sterile products are prepared. The clean room does not have airlock and the door in ISO 7 buffer room has multiple open slots on the bottom of door panel that can serve as an entry way for insects.

OBSERVATION 15

The flow of components though the building is not designed to prevent contamination.

Specifically,

On 9/22/2015, Pharm Tech, (b)(6) prepared Phenylephrine HCl (PF) 1.5% Injectable product lot 09222015@7. During the initial preparation, (b)(6) placed (b)(4) bottles of (b)(4) solution bottles on the (b)(4) cart without wiping down the bottles first using (b)(4) In addition, (b)(6) placed the (b)(4) containing the (b)(4) onto the same (b)(4) cart without wiping down the (b)(4) first. The (b)(4) cart was later moved into the ISO 7 buffer room.

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OBSERVATION 16

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically,

A food item and food processing equipment were located in the same area where finished sterile products are stored and media samples were incubated. For example, two coffee makers, one microwave oven, and a one gallon soft drink bottle were observed on a bench countertop in the close vicinity of three freezers used to store patient specific products and two incubators used for environmental testing.

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."