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	08/13/2015 - 09/21/2015* FEI NUMBER 3004599113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph E. Grasela, Owner

FIRM NAME	STREET ADDRESS
University Rx Specialties Inc	1875 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92101-2604	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 I OBSERVED:

OBSERVATION 1

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

Specifically, monitoring of the firm's ISO 5 areas and ISO 7 area used to produce sterile drug products is not done during actual production. For example:

1. Lack of active monitoring of differential pressures in the ISO 5 environment. There is no monitoring of the cleanroom pressure differential during aseptic processing of drug products in ISO 5 (b) (4). Differential pressures of the ISO 7 Cleanroom and ISO 8 formula/gowning room are (b) (4) (b) (4) (b) (4) There is no further monitoring of the cleanroom pressure differential gauges either manually or by electronic devices during production.
2. Lack of routine viable particulate air monitoring in the ISO 5 environment. There is no routine monitoring of the viable air particulates during aseptic processing of drug products in the ISO 5 (b) (4). The viable air particulate is conducted (b) (4) (b) (4) (b) (4).
3. Insufficient frequency of environmental monitoring of the ISO 5 environment surfaces. Surface sampling is conducted (b) (4) (b) (4) (b) (4) (b) (4) There is no environmental monitoring surface sampling for the aseptic processing of each lot of drug production.
4. Lack of active non-viable particulate air monitoring of the ISO 5 environment. There is no monitoring of the non-viable air particulates during aseptic processing of drug products in the ISO 5 (b) (4).
5. Lack of viable particulate air monitoring in the ISO 7 environment. There is no monitoring of the viable air particulates during aseptic processing of drug products in the ISO 7 environment. The viable air particulate is conducted (b) (4) (b) (4) (b) (4) The ISO 5 (b) (4) laminar air flow hoods are located within ISO 7 environment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Linda Thai, Investigator	09/21/2015

6. Insufficient frequency of environmental monitoring of the ISO 7 environment surfaces. (b) (4) surface samples are collected (b) (4) at the (b) (4) and in the (b) (4) at (b) (4) . The ISO 5 (b) (4) laminar air flow hoods are located within ISO 7 environment.
7. Lack of active non-viable particulate air monitoring of the ISO 7 environment. There is no monitoring of non-viable air particulates during production of drug products in the ISO 7 environment. The ISO 5 (b) (4) laminar air flow hoods are located within ISO 7 environment.
8. Lack of routine personnel monitoring for operators conducting compounding operations of aseptically processed drug products. Sampling of personnel gloves is not routinely conducted after daily operations. Sampling of personnel gloves is conducted (b) (4) (b) (4)

OBSERVATION 2

There is a failure to thoroughly review 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.

Specifically, failure to thoroughly conduct out of specification investigations with respect to the sterility failure found in three different batches of drug products. The root cause and the source of these contaminations were not thoroughly investigated by your firm. For example,

1. Glycerin 72%/Lidocaine 1% with Epinephrine 1:100000 2:1 injectable, Lot 562655, that was prepared on 5/19/2014 failed sterility. This lot was discarded.
2. Heparin/Lidocaine Irrigation 50,000U - 325mg/25 mL Solution packaged in syringe, Lot # 593202, that was prepared on 10/30/2014 failed sterility. This lot was discarded.
3. Testosterone 100 mg pellet, Lot # 618513, that was made on 3/25/2015 failed sterility. This lot was discarded.

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	08/13/2015 - 09/21/2015* FEI NUMBER 3004599113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph E. Grasela, Owner

FIRM NAME	STREET ADDRESS
University Rx Specialties Inc	1875 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92101-2604	Producer of Sterile Drug Products

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

1. Media fills conducted by the firm (b) (4) are inadequate. For example:
   a. The firm (b) (4) but fails to perform growth promotion on the media fills to ensure that the media supports growth.
   b. The firm's media fills do not simulate the batch processes in which up to (b) (4) (b) (4) mL or (b) (4) mL vials. The firm's current media fills for a "(b) (4) (b) (4)
   c. The media fill record does not include sufficient details to establish that the conditions mimic the actual activities that occur during routine production, (such filling time, number of individuals in the room, (b) (4) equipment placement, doors opening and closing). In addition, the total time for completion of the media fills and the incubation temperature are not recorded.
2. The firm has not performed clean hold time studies for the (b) (4) sterilization glassware (i.e. (b) (4)) used for preparation of sterile drug productions.

3. (b) (4) used for aseptic preparation of sterile drug products are not pharmaceutical grade.

OBSERVATION 4

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

Specifically,

1. No goggles are worn during the preparation of sterile drug products which allows exposed skin around the eyes and neck area in the cleanroom ISO 7 environment in which the ISO 5 (b) (4) are located.
2. Non-sterile gowning materials (shoe covers, hair covers, face mask donned to cover bridge of

nose, (b) (4) coverall) are worn in the cleanroom ISO 7 area. The operator's forearms which enter into the ISO 5 environment to perform aseptic operations are covered with non-sterile gowning which is not adequate to protect from contamination during preparation of sterile drug products.

3. The firm's SOP No. 9.100, Required Garb For Clean Room Facility Access, Version 1.1, Section 9.3.4.5 allows the gown (b) (4) . In addition, on 8/19/15 in the ISO 8 cleanroom, the operator was observed removing the scrub jacket leaving only a street tank top on, proceed with hands and forearms washing, and then don a coverall over a street tank top which was not part of the gowning procedure.

OBSERVATION 5

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

Specifically,

1. (b) (4) and (b) (4) (b) (4) used to clean the aseptic area are not rendered sterile prior to use.

2. The firm uses non sterile (b) (4) (lint-free) and sprays with sterile (b) (4) (b) (4) to be brought into the ISO 5 (b) (4) and to clean the surface of the (b) (4) where the drug products are prepared.

3. The firm uses non sterile disposable cleaning pad for cleaning the cleanroom floor and wall. The mop is damped with cleaning detergent ((b) (4) or (b) (4) (b) (4)) before mopping. The firm has not performed disinfectant efficacy studies to ensure that the cleaning procedure is effective.

4. The firm has not performed disinfectant efficacy studies on the ISO 5 (b) (4) surfaces and ISO 7 cleanroom working surfaces to ensure that the cleaning procedures using (b) (4) or (b) (4) (b) (4) is effective in removal or inactivation of microorganisms, such as bacteria, yeasts, fungi, viruses, molds, and mycoplasmas.

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	08/13/2015 - 09/21/2015* FEI NUMBER 3004599113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph E. Grasela, Owner

FIRM NAME	STREET ADDRESS
University Rx Specialties Inc	1875 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92101-2604	Producer of Sterile Drug Products

OBSERVATION 6

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, the firm does not routinely perform identity and potency test for each drug product. Only (b) (4) (b) (4) is tested for potency for (b) (4) and this (b) (4) In addition, a drug batch size (b) (4)

OBSERVATION 7

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

1. Smoke studies conducted on (b) (4) to determine unidirectional airflows in ISO 5 (b) (4) were not performed under full dynamic conditions and do not provide assurance that the HEPA-filtered unidirectional downward air covers the working area under working conditions. The smoke studies only demonstrated (b) (4) (b) (4) (b) (4) The smoke studies failed to demonstrate the unidirectional downward air without turbulence during a large volume drug aseptic processing where the repeater pump, filling vials, IV bag, and other components are inside the (b) (4).

2. The (b) (4) certifications for ISO 7 and ISO 8 area conducted on (b) (4) failed to include HEPA filter leak testing for the one filter located in ISO 7 and ISO 8 room.

3. You have not established a limit for the number of people that can be in the cleanroom.

4. The differential pressure from the ISO 8 compounding/gowning area to prep room (unclassified area) did not meet your firm's specification of (b) (4) inches of water gauge from 7/11/15 to 8/19/15. Positive pressure differential readings of the ISO 8 Compounding/Gowning Room to the unclassified prep-room were mostly from 0.00 to 0.02 inches of water gauge. No investigation was performed for these of out specifications.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Linda Thai, Investigator LT	09/21/2015

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	08/13/2015 - 09/21/2015* FEI NUMBER 3004599113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph E. Grasela, Owner

FIRM NAME	STREET ADDRESS
University Rx Specialties Inc	1875 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92101-2604	Producer of Sterile Drug Products

*** DATES OF INSPECTION:**
08/13/2015(Thu), 08/14/2015(Fri), 08/17/2015(Mon), 08/18/2015(Tue), 08/19/2015(Wed), 08/20/2015(Thu), 08/24/2015(Mon), 09/21/2015(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Linda Thai, Investigator	09/21/2015