DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	02/19/2013 - 02/26/2013* FEI NUMBER 3004146124

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Richard E. Rasmuson, Owner/Pharmacist

FIRM NAME	STREET ADDRESS
University Pharmacy, Inc.	1320 East 200 South
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Salt Lake City, UT 84104	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

Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,
On February 19th, 2013, during an inspectional tour of the ISO 5 sterile core, I observed the following inside of the firm's (b) (4) Hood where (b) sterile injectables are produced:

1) Along the front perforated/pored air guard, spills and splatters of amber and white colored residue were observed stuck to/clogged in these perforations. Approximately 1mm of a dusty/fuzzy film was observed suspended/hanging from this residue. Approximately 20% of the (b)(4) by (b)(4) metal guard was observed affected with the same;

2) Below the perforated/pored air guard, multiple spills and splatters of amber, rust, and white colored residue were observed in a drip-like metal pan. More than one of these splattered spots were observed to be approximately 2 inches in diameter and approximately 50% of the metal pan was observed to be affected with the same;

3) Above the work surface and directly below the hood's HEPA filter, multiple white residue splatters were observed attached to this suspended perforated/pored ceiling. One of these splatter marks was approximately 6 inches in diameter and the total splattering covered approximately 15% of the metal ceiling. According to the pharmacy technician, this had never been noticed by him and possibly occured from a misguided stream of liquid ejected from a highly-pressurized syringe;

4) On both sides of the work surface area, in the crevices between the work surface area and the side walls of the ISO 5 sterile hood, spills and splatterings of an amber colored material were observed running along approximately 20% of both of these crevices.

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OBSERVATION 2

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

Specifically,

A. Firm released and dispensed Progesterone/Pregnenolone 50mg/2.5mg injection lot 721372 without test results of sterility, endotoxins and potency. Progesterone/Pregnenolone 50mg/2.5mg lot 721372 was produced 1/22/13 with a bulk yield amount (b) (4) There is no documentation in the Formulation Worksheet of the number of individual (b) (4) vials filled from the (b) (4) bulk batch. Director of Compounding stated they can fill approximately (b) (4) (b) vials.

B. Firm released and dispensed bulk batch of Progesterone/Pregnenolone 50/2.5 mg/ml lot 716184 without performing a potency/assay on both active ingredients. Specification for Progesterone and Pregnenolone is (b) (4) for both actives. Firm stated the contract lab is having a hard time validating a method for Pregnenolone because it is too close chemically to the other active.

C. Firm released and dispensed bulk batch of Progesterone/Pregnenolone lot 711102 without performing a potency test on Pregnenolone. Pregnenolone specification is (b) (4) (b) (4) released which can fill approximately (b) (4) (b) vials.

D. After further manipulations of the bulk sterile drug product (filling of individual product vials), the firm performs a sterility test only and not endotoxins or potency on the finished drug product vial. For example, TRIMIX(Papverine/Phentolamine/Alprostadyl) 17.65/0.588/5.88 injections lot# 720775 (b) (4) bulk batch passed the specifications for sterility, endotoxins and potency. After the test results passed specification, the firm (b) (4) fills the vials from the bulk batch and tests the finished product vials for sterility only. In addition, if less than (b) units of sterile drug product are produced from a bulk batch then no testing is performed per SOP No. 10.009 titled "Sterile Preparation Release Tests- Sterility, Bacterial Endotoxin, and Pyrogen Test".

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,

A. The (b) (4) sterilization process for producing the bulk batches of TRIMIX (Papaverine/Phentolamine/Alprostadyl) 17.65/0.588/5.88 injections, Progestrone 50mg/ml olive oil injections, and Progesterone/Pregnenolone 50/2.5mg/ml sesame oil injections has not been validated. The firm has no documentation to qualify the (b) (4) with regards to bacterial retention, extractables, and hardware compatibility;

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such as the case with the (b)(4) (b) (4) system used on the Progesterone/Pregnenolone 50/2.5mg/ml sesame oil batches. The firm has no documentation to challenge the bacterial retention of the (b) (4) with challenged organisms or bioburden quantity. All (b) (4) ingredients are non-sterile for the TRIMIX injections, Progestrone injections, and Progesterone/Pregnenolone and Hydroxyprogesterone 250mg/ml sesame oil injections. In addition, SOP # 8.012 titled "Compounding of Sterile Solutions"; written procedures established for the (b) (4) does not specify the minimum pressure needed for the (b) (4) integrity test to pass. The (b) (4) sterilization process for producing the bulk batches of Hydroxyprogesterone 250mg/ml sesame oil batches has not been validated. There is no documentation o (b) (4) studies for the volume of Hydroxyprogesterone batches produced by the (b) (4) sterilization process. In addition, the (b) (4) (b) (4) used to sterilize the Hydroxyprogesterone 250mg/ml sesame oil batches has not been qualified for use.

B. The firm uses a (b) (4) (b) (4) system and assembles a non-sterile (b) (4) onto the system. The entire unit is (b) (4) for sterilization with no documentation of time and temperature. A BI indicator is placed in th (b) (4) There are no validation studies to demonstrate the efficacy of the method used to sterilize the (b) (4) unit. This (b) (4) (b) (4) system is used for the Progesterone/Pregnenolone 50/2.5mg/ml sesame oil batches.

C. There is no validated sterilization process for sterilizing an eye drop tip package component. I observed the firm produce a patient prescription ophthalmic sterile drug called Pilocarpine 1% Ophthalmic gel eye drops lot 722604. The drug was (b) (4) with a BI and (b) (4) a (b) fo (b) minutes. The non-sterile Ophthalmic eye drop tip was immersed in a beaker of (b) (4) for no specified time or a procedure stating the time for soaking the eye drop tip. After the drug was (b) (4) the eye drop tip was assembled onto the drug vial (b) (4) and dispensed to the patient.

OBSERVATION 4

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

Specifically,
On February 19th, 2013, while witnessing the pharmacy technician's sterile aseptic technique, in producing Pilocarpine 1% Opthalmic eye gel lot #722604 and TRIMIX(Papaverine/Phentolamine/Alprostadyl) 17.65mg/0.588mg/5.88mg. lot # 722609, I observed the following:

1) The technician's hands and arms were observed inside of the ISO 5 hood without sterile sleeve covers;

2) The technician's movements in the ISO 5 hood were observed to be too fast.

3) At one point during sterile compounding, the technician left the ISO 5 hood with collected wrappers/trash, passed through the ISO 7 buffer zone, the ISO 7 ante/gowning room, and into the ISO 8 prep room to discard collected trash without removing gowning materials/sterile gloves. He immediatley returned to the ISO 7 buffer room, through the ISO 7

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ante/gowning room, and reached inside the ISO 5 hood for the sterile (b)(4) to sanitize his gloves.

OBSERVATION 5

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. There is no environmental monitoring or personnel monitoring (viable, non-viable and total particulates) in the ISO 5 Class 100 Laminar flow hood during or immediately after producing sterile injectable drug products. The pharmacy technician stated they conduct viable air monitoring and surface samples when they are not in operation in the ISO 5 hood producing sterile drug products. For example, "The Environmental Air Sample Log" shows viable air samples were collected in the ISO 5 hood on the following dates: 2/13/13, 11/29/12, 10/12/12, 8/9/12, 6/5/12, 2/23/12. The frequency of the viable air sampling is not consistent and it is not defined in a procedure. Surface samples are collected every (b) (4) in the ISO 5 hood; last collected March and September of 2012. Personnel monitoring is only conducted during (b) (4) to qualify personnel.

B. (b) (4) is the only disinfectant used to clean and disinfect in the ISO 5 Class 100 Laminar flow hood. There are no disinfection studies to demonstrate the (b) (4) is effective against bacterial spores or fungi.

C. We observed the inadequate disinfection of the ISO 5 Laminar flow hood used for aseptic processing of sterile drug products. The Pharmacy technician was observed only wiping the table top work surface with a sterile wipe and the (b) (4) disinfectant. He did not remove the stored items ((b) (4) bulk batch of Progesterone, eye drop solution, sterile eye drop assemblies) in the hood and did not wipe down the sides or the back of the hood for preparation of sterile compounding of injectables. In addition, the SOP titled, "Sterile Compounding Room Cleaning and Disinfecting", No. 5.003 Revision 01 does not describe in detail how to clean the ISO 5 hood. It reads: 1. Remove items from area 2. Clean surface.

D. There is no rotation of disinfectants used in the ISO 7 and ISO 8 buffer room, ante room and preparation rooms. (b) (4) which is used as a sporicide for the cleaning of the non-sterile preparation area outside the clean room and outside the ISO 5 hood area.

E. We observed pharmcy technician weigh non-sterile dry active ingredients on weigh paper but did not disinfect scales in between weighing the actives for two separate formulations (b) (4) (b) (4). We observed debris in crevices of weigh scales and pink dry powder residue which; had accumulated in the back of the exhaust intake inside this containment where non-sterile dry ingredients are weighed.

F. No smoke studies are performed in the ISO 5 Hood in dynamic conditions to determine unidirectional airflow or air turbulence over sterile drug product. In addition, there is no monitoring of the magnehlic pressure in the ISO 5 Hood.

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OBSERVATION 6

Results of stability testing are not used in determining expiration dates.

Specifically,

A. There is no stability data to support the sterility or potency of Progesterone/Pregnenolone vials beyond Use Date (BUD) of 6 months. For example, Progesterone/Pregnenolone 50mg/2.5 mg lot 716184 produced on 9/21/12 has a beyond use date of 3/20/13.

B. There is no stability data to support the potency of the TRIMIX(Papaverine/Phentolamine/Alprostadyl) 17.65mg/0.588mg/5.88mg injections, Progesterone 50mg/ml olive oil injections, refrigerated drug vials BUD of 90 days. TriMix lot 720775 batch produced and refrigerated on 1/8/13; BUD of 4/8/13.

C. There is no stability protocol to evaluate each of the drugs for physical stability, chemical stability, and microbiological stability throughout the shelf life claimed and storage conditions.

*** DATES OF INSPECTION:**
02/19/2013(Tue), 02/20/2013(Wed), 02/21/2013(Thu), 02/22/2013(Fri), 02/26/2013(Tue)

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