DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	08/26/2014 - 09/09/2014* FEI NUMBER 3011000002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dena K. Perry, R.Ph., Pharmacist in Charge and Owner

FIRM NAME	STREET ADDRESS
Perry Drug Inc.	12200 W. 106th Street Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Overland Park, KS 66215	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 I OBSERVED:

From 1 MAY through 26 AUG 2014, your firm has produced (b) (4) sterile drugs from non-sterile powders and distributed them to your customers. These drugs include but are not limited to 17-α Hydroxyprogesterone Caproate injection; "Tri-Mix" Alprostadil (Prostaglandin E1), Phentolamine Mesylate, and Papavarine HCl injection; and HCG (human chorionic gonadotropin) injection. The following observations relate to your general compounding practices of these sterile drugs.

OBSERVATION 1

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

Specifically,

a. The technician, "(b) (6)", performing the sterile production says she has not performed a (b) (4) since she began working at Perry Drug in (b) (6). She is solely responsible for all sterile produced material since June 2014. On 26 AUG 2014, I observed "(b) (6)" producing Testosterone Cypionate, Lot 140826A, 200 mg/ mL. She did not perform a bubble point test.

b. You have not performed any media fills since you began sterile production in 2010.

c. You have not conducted smoke studies, dynamic and static, to verify airflow patterns where you produce sterile drug products.

d. You do not document the sterilization cycle of the (b) (4) used to sterilize the vials and stoppers used during sterile drug production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michele L. Obert, Investigator Michele L Obert, Investigator	DATE ISSUED 09/09/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	08/26/2014 - 09/09/2014* FEI NUMBER 3011000002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dena K. Perry, R.Ph., Pharmacist in Charge and Owner

FIRM NAME	STREET ADDRESS
Perry Drug Inc.	12200 W. 106th Street Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Overland Park, KS 66215	Producer of Sterile Drugs

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,

a. You have no assurance the "stock" vials are sterile, contamination free, and within potency when you fill prescriptions up to 60 days after the drug was produced.

b. You do not routinely perform sterility testing of your sterile drugs. The last record avilable for sterility and endotoxin testing was from March 2013.

OBSERVATION 3

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

Specifically,

a. You do not have written procedures that describe how cleaning will occur in the ISO 5 Clean Room where sterile drugs are produced.

b. You do not use a sporicidal agent in your cleaning processes.

c. You did not document the cleaning of the compounding suite from 10-7-2013 until 5-8-2014.

d. You do not have a procedure for bringing cleaning supplies and utensils into the cleanroom / ISO 5 area.

OBSERVATION 4

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

Specifically,

a. You do not have an Environmental Monitoring program. You have not conducted any environmental monitoring in the cleanrooms / ISO 5 area or on the personnel when sterile drugs are produced.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michele L. Obert, Investigator	09/09/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	08/26/2014 - 09/09/2014* FEI NUMBER 3011000002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dena K. Perry, R.Ph., Pharmacist in Charge and Owner

FIRM NAME	STREET ADDRESS
Perry Drug Inc.	12200 W. 106th Street Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Overland Park, KS 66215	Producer of Sterile Drugs

b. You have not conducted any surface sampling of the ISO classified areas to monitor the bioburden or to determine if your cleaning is adequate.

c. You do not monitor pressure differentials in the cleanrooms / ISO 5 area during production.

OBSERVATION 5

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

a. You do not have a documented procedure for gowning

b. Personnel producing sterile drug products are not gowned with sterile gowning items. Your employees use non-sterile gowns, shoe covers, masks, hair net, and gloves in the areas where you produce sterile drug products.

c. Your personnel have exposed skin around the eyes, neck, and head area in your ISO 5 clean producing sterile drug products. They do not wear safety glasses or sterile goggles.

d. On 26 AUG 2014, technician (b) (6) was observed wearing her shoe covers and gown in the uncontrolled pharmacy area then entering the ISO 7 room. She wore these same shoe covers and gown into the ISO 5 clean room without any additional protective equipment where she produced Testosterone Cypionate, Lot 140826A, 200 mg/ mL.

e. On 29 AUG 2014, technician (b) (6) stated they had a new unwritten, gowning procedure. She donned shoe covers, gown, mask, hair net, and gloves in the ISO 7 area. In the ISO 6 area, she degowned to her street clothes and put on new, non-sterile shoe covers, gown, mask, hair net, and gloves before entering the ISO 5 clean room.

f. On 26 AUG 2014, employee, (b) (6) was performing sterile compounding of Testosterone Cypionate, Lot 140826A, 200 mg/ mL, in the ISO 5 area wearing makeup. In addition, her mask did not cover her nose and her bangs were not inside her hair net.

OBSERVATION 6

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

Specifically,

You have not performed any stability testing on your sterile drug products. You do not have any data to support your labeled Beyond Use Date (Expiration Date). Your Leuprolide Injection Solutions, Testosterone Cypionate Oil

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	08/26/2014 - 09/09/2014* FEI NUMBER 3011000002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Dana R. Perry, R.Ph., Pharmacist in Charge and Owner

FIRM NAME	STREET ADDRESS
Perry Drug Inc.	12200 W. 106th Street Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Overland Park, KS 66213	Producer of Sterile Drugs

Injection Solutions, and 17-α Hydroxyprogesterone Caproate Oil Injection Solution have a 90 day Beyond Use Date.

*** DATES OF INSPECTION:**
08/26/2014(Tue), 08/27/2014(Wed), 08/28/2014(Thu), 08/29/2014(Fri), 09/04/2014(Thu), 09/09/2014(Tue)

MLO 9 Sept 2014

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michele L. Obert, Investigator Michele L Obert, Investigator	09/09/2014