DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	07/27/2015 - 07/31/2015* FEI NUMBER 3011656880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Cecilia R. Ventura, CoOwner/Executive Director

FIRM NAME	STREET ADDRESS
PCP LV LLC dba Pinnacle Compounding Pharmacy	4445 S Eastern Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89119-7851	Outsourcing Facility

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

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

Specifically, your firm uses non-sterile gowning components for the aseptic operation performed in the Cleanroom.

On 07/29/2015, an operator was observed aseptically processing your sterile drug product, Gentamicin Irrigation Solution, in the ISO 5 Hood within the ISO 7 Clean Room, with exposed skin on the face and neck. In addition, non-sterile Tyvex coverall and non-sterile dust mask were worn by the operator.

According to your Pharmacist, your firm's gowning practices for aseptic operation includes:

A. Employees' street clothes and street shoes are worn directly underneath the non-sterile Tyvex coverall.

B. Operators (b) (4) (b) (4) to minimize skin exposure in the ISO 5 hood when performing aseptic compounding operations.

C. Non-sterile Tyvex coveralls (b) (4) (b) (4) when exiting and re-entering the Cleanroom. The (b) (4) coverall will be hung on the hook against the wall in the Anteroom (ISO 8).

OBSERVATION 2

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

Specifically, your firm has not established any written procedures for your sterile operation which include but are not limited to the following:

A. Validation studies of the (b) (4) sterilization and/or depyrogenation cycles using the (b) (4)

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(b) (4) have not been performed for your sterile product, Testosterone Cypionate 200 mg/mL in Grapeseed Oil Injectable. Your formula worksheet for Testosterone instructs at Step (b) (4) "(b) (4) (b) (4) (b) (4)." Your firm has processed and distributed (b) (4), Lot 05062015@4 (200 mL) and 07132015@5 (200 mL).

- In addition, your firm does not use (b) (4) for production runs in the (b) (4) to monitor the effectiveness of the method of (b) (4) and depyrogenation. According to your Pharmacists, the depyrogenation cycle for glassware is (b) (4).
- Your firm does not maintain a Use-log for the (b) (4) to document (b) (4) of the sterilization (b) (4).
- Per your Pharmacist, utensils such as tongs and forceps used for capping the (b) (4) sterilized Testosterone vials were not sterile and were only wiped with (b) (4) prior to use.

B. Written procedures for your firm's media fill program have not been established to assess the state of process control for your sterile operation. According to your Pharmacist, each operator that works in the Cleanroom is required to perform media fills (b) (4). Each media fill consists (b) (4) from (b) (4). This process does not simulate the actual processing of your two sterile products.

- For example, your aseptic process for Testosterone requires (b) (4) (b) (4). Your media fills do not simulate the same process manipulations for this product. Your firm placed the media from the completed media fills in an (b) (4) for (b) (4) days.

C. Written procedures for gowning qualification of operators for the Cleanroom have not been established. According to your Pharmacist, each operator that works in the Cleanroom is required to gown successfully (b) (4) times prior to performing sterile operations. However, the gowning qualification is deficient in that there is no meaningful data supporting the personnel monitoring results. Your firm placed the media from personnel monitoring in an (b) (4) for (b) (4) hours.

D. Written procedures for (b) (4) (b) (4) have not been established. Your firm uses (b) (4) compounded drug products in the ISO 5 Hood. However, we did not observe documentation of (b) (4) (b) (4) for the majority of your sterile product batches. Additionally, there are no training records for operators performing the (b) (4) (b) (4) to demonstrate that they have been adequately trained and competent in performing the task.

E. One (b) (4) was observed in the Cleanroom in addition to one non-classified (b) (4) hood located approximately (b) (4) from the ISO 5 Hood. Operators weigh out and dissolve non-sterile ingredients in the (b) (4) hood.

F. There is no documentation of smoke studies being performed in the ISO 5 Hood under dynamic conditions.

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OBSERVATION 3

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

Specifically, your firm has not performed environmental and personnel monitoring during production of the two sterile products, Testosterone Cypionate 200 mg/mL in Grapeseed Oil Injectable and Gentamicin 80 mg/1 Liter 0.9% Sodium Chloride (vial) Aqueous Solution. The environmental and personnel monitoring program provides information which shows the quality of the aseptic processing environment in which your sterile products are processed.

A. Your firm does not conduct air, or surface, sampling for viable, or non-viable, particles during the aseptic operation of every batch, or at least once per production day in which drug product(s), intended to be sterile, are aseptically processed in your ISO 5 Hood.

B. Personnel monitoring of the operator's gloves and coverall has not been performed post aseptic processing of every batch, or prior to exiting the Cleanroom.

C. Written procedures have not been established for environmental and personnel monitoring in ISO 5 Hood, ISO 7 Cleanroom, and the Anteroom (ISO 8) used for sterile gowning.

OBSERVATION 4

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

Specifically, finished product certificates of analysis from your contract laboratory reference Sterility and Bacterial Endotoxin USP <85> tests. These procedures and associated data could not be evaluated and verified for adequacy and reproducibility because your contract laboratory refused to provide any analytical worksheets, documentation, procedures, or methods associated with their reported results.

Your firm does not test for sterility and endotoxin on every batch of sterile products produced. For example, your firm did not conduct sterility or endotoxin testing on Testosterone Cypionate 200mg/mL in Grapeseed Oil injectable lot 07132015@5. This lot was dispensed to patients on 07/13/2015.

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OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, there is no written procedures describing the responsibilities and roles of your Quality Control Unit. The Pharmacist-in-Charge was identified as the Quality Control Unit. There are no written procedures to approve or reject all components, drug product containers, closures, and drug products by your Pharmacist-in-Charge.

OBSERVATION 6

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, your firm failed to thoroughly investigate the following:

A. The Formula Worksheet for Testosterone Cypionate Injectable, Lot (b) (4) (b) (4) was documented as "Void Testing (b) (4)". According to your Pharmacist, this batch failed the (b) (4) test. There was no documentation of the test results from this lot and no investigation has been performed.

B. The Formula Worksheet for Testosterone Cypionate Injectable, (b) (4) (b) (4) was documented as "Void Void Contamination Void". According to your Pharmacist, this batch was spilled in the ISO 5 Hood. There was no documentation of the incident from this lot and no investigation has been performed.

OBSERVATION 7

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

Specifically, written procedures for cleaning and disinfecting ISO-classified areas have not been established.

According to your Pharmacist, cleaning of the ISO 5 Hood, work surfaces, chair, and floor in the Cleanroom is performed (b) (4) sterile operation. Cleaning of the Cleanroom (b) (4) can cause airflow turbulence and compromise the sterile garb of the operator within the Cleanroom.

- On 07/29/2015, your operator stated that (b) (4) did not change (b) (4) sterile gloves (b) (4) (b) (4). (b) (4) continued with the aseptic processing of your sterile drug product after sanitizing (b) (4) gloved hands

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with sterile (b) (4) but [redacted] did not change [redacted] gloves.

- Two cleaning mopsticks were observed stored in the Cleanroom.
- Your firm uses (b) (4) to clean the Cleanroom. The labeling of the (b) (4) specifies contact time (b) (4). According to your Pharmacist, the firm is unable to follow this instruction due to the extended contact time needed for cleaning at (b) (4) C or being able to increase the Cleanroom temperature to (b) (4) C or above.

OBSERVATION 8

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

Specifically, your firm lacks a system of monitoring pressure differential limits in the Cleanroom to detect atypical changes in air pressure that can compromise the Cleanroom environment when not in use and during production. The pressure differential limits for the Cleanroom and Anteroom are checked and recorded (b) (4).

According to the Pharmacist, your firm (b) (4) (b) (4) for the Cleanroom and (b) (4) the ISO 5 Hood (b) (4) The Cleanroom and the ISO 5 Hood are (b) (4) at least (b) (4) (b) (4)

OBSERVATION 9

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

Specifically, your firm has no scientific data to justify the assigned Beyond Use Date for the following sterile products:

- 90 day Beyond Use Date for Testosterone Cypionate Injectable
- 30 day Beyond Use Date for Gentamicin Irrigation Solution

OBSERVATION 10

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and

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503B(a)(10)(B) BL 7/31/15
(B).

Specifically,

The following information is not found on some of your drug product labels:

1. The statement "This is a compounded drug."
2. The name, address and phone number of the outsourcing facility.
3. The date that the drug was compounded.
4. The expiration date
5. The storage and handling instructions.
6. The statement "Not for resale."
7. A list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

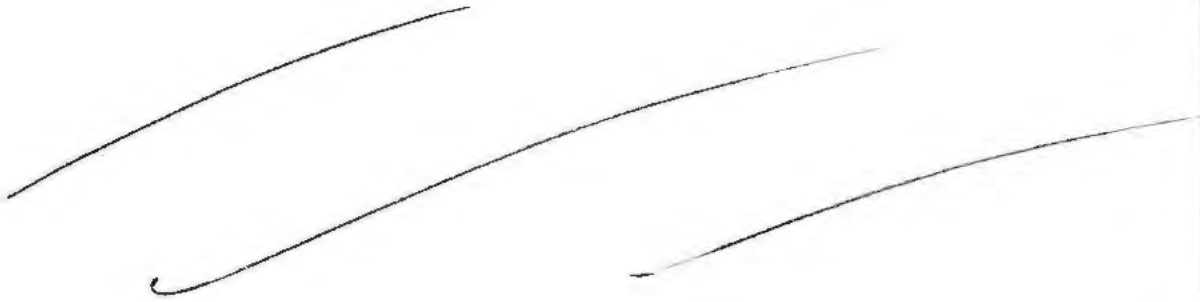
Furthermore, the following information is not found on the container labels for some drug products you produce:

8. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088

Examples of drug product labels that do not contain this information include:

- Gentamicin 80 mg/0.9% Sodium Chloride 1000 mL
- Testosterone Cypionate/Grapeseed Oil 200 mg/mL (10 mL)

*** DATES OF INSPECTION:**
07/27/2015(Mon), 07/28/2015(Tue), 07/29/2015(Wed), 07/31/2015(Fri)



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