DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	06/15/2015 - 06/24/2015* FEI NUMBER 3009192575

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Wilson M. Shepard, Owner/President

FIRM NAME	STREET ADDRESS
Talon Compounding Pharmacy	2950 Thousand Oaks Dr Ste 25
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78247-3347	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

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

Specifically,

A) During the course of our inspection at your firm, we observed the ISO-5 designated cleanroom has been constructed of (b) (4) openings approximately (b) (4) off the floor, and spaced approximately (b) (4) apart all around the perimeter of the room. These openings are covered by transparent plastic flap coverings. This design renders the plastic flaps as the sole barrier between the ISO-5 cleanroom and the unclassified room. During our inspection, we observed that these flaps had continuous air flow coming out of them from the ISO-5 cleanroom into the unclassified room, causing an open space between the ISO-5 cleanroom and the unclassified area.

B) You have no smoke studies to verify the direction of the air flow in your ISO-5 cleanroom.

OBSERVATION 2

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

Specifically,

Your firm's SOP entitled, "Cleaning and Disinfection", Revised 3/14/14, specifies that "All cleaning activities should take place (b) (4) "; however,

A) On 06/15/2015, during the preparation of BI-MIX PAPAVERINE 30/PHENTOLAMINE 2 INJ INJECTABLE, Lot #06122015:23, Best Used By: 12/09/2015, we observed an operator in the ISO 5 cleanroom using Sterile (b) (4)

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(b) (4) to spray the countertops during API dissolution into solution while a (b) (4) containing the preparation of BI-MIX PAPAVERINE 30/PHENTOLAMINE 2 INJ INJECTABLE, Lot #06122015:23, Best Used By: 12/09/2015BI-MIX was left uncovered and exposed.

B) On 06/16/2015, at approximately 2:05 pm, during the preparation of Testosterone Cypionate 200MG/ML in oil Injectable (lot 06162015:39), we observed an operator in the ISO 5 cleanroom using (b) (4) (b) (4) for facility cleaning during API dissolution into solution. During this cleaning period, six amber vials were found exposed on the counter-top without lids. These amber vials were then utilized to store this sterile injectable product.

C) On 06/17/2015, at approximately 9:30 am, during the observation of (b) (4) cleaning of the ISO-5 cleanroom, we observed the failure of the operator to clean the following surfaces:

1. The exposed surfaces of the (b) (4) refrigerators inside the ISO-5 cleanroom.
2. The second shelf of the table adjacent to the facility's (b) (4).

OBSERVATION 3

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

Specifically, your firm prepares "non-sterile to sterile products" which your firm's owner designated as "High risk compounding category", but, does not have any written procedure for evaluating the "Beyond use date" for the preparations. The products such as Triamcinolone diacetate 40mg/ml (10 ml vial) and Papaverine- 30mg/ml/Phentolamine - 1mg/ml/Prostaglandin -10mcg/ml Injection were found to have "Beyond use date" as five months and six months, respectively, but data to support the BUD was not available. Specifically, sterility tests and endotoxin tests were not performed to support the BUD.

OBSERVATION 4

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

Specifically,

On 06/15/2015, while an operator was gowning in the anteroom, we observed that the sleeve of the operator made contact with the floor of the anteroom. Following contact of the garb with the floor, no corrective action was initiated.
This operator then entered the ISO-5 cleanroom. Subsequently, we asked the firm for information regarding the gowning garb. The firm provided us with boxes of indicated garb. These items, listed below, are non-sterile:

- White Bouffant Caps manufactured by Pro Advantage by NDC (REF P701020)
- Procedure Mask manufactured by 3M (REF 1820)
- Gown manufactured by Medline (Item NONCV700L)
- Basic Shoe Covers, Universal, Nonconductive manufactured by CardinalHealth (REF 2850)

Additionally, when in the ISO-5 cleanroom, the operator had exposed skin surfaces on (b) (6), (b) (7)(C) neck and face area. Furthermore, we did not observe any cleanroom personnel wearing protective eyewear at any time during the inspection.

Following these incidents, the operator produced BI-MIX PAPAVERINE 30/PHENTOLAMINE 2 INJ injectable solution, Lot #06122015:23, Best Used By: 12/09/2015, a sterile injectable.

OBSERVATION 5

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

The product "T3 13.5 mcg / T4 57 mcg Capsule, lot # 11252014:34" was tested for potency (b) (4) (b) (4). The (b) (4) results were reported as 76.1% for ingredient T3 and 80.2% for ingredient T4 and indicated as "Variation of active within formulation observed"; however, at (b) (4), the results were reported as 90.9% for ingredient T3 and 92.3% for ingredient T4. Furthermore, the laboratory results as "Meets USP potency requirements". Your Pharmacist in Charge indicated that this variability in potency test results are routinely observed and may be due to inconsistent mixing. Your firm's owner indicated that the root cause of the inconsistency has not been determined, but continues utilizing similar methods despite the variability.

OBSERVATION 6

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

Specifically,

A) Your firm utilizes (b) (4) to sterilize amber vials and rubber stoppers used to store sterile injectables. On 06/17/2015, we requested your validation for the repeatability and reproducibility of the (b) (4). You provided us with (b) (4) MANUAL". A

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number of sections were highlighted, including suggested (b) (4) . We further inquired about your validation and method for ensuring appropriate functionality of this instrument. You indicated that there was not such documentation. You stated that you use (b) (4) to ensure sterility.

B) Your firm utilizes a (b) (4) (b) (4) for the production of injectables. Your firm did not perform any equipment qualification prior to use to determine the adequacy of the equipment. Additionally, your firm did not perform validation activities to determine (b) (4) for the procedure followed. On 06/17/2015, we observed the contents of the product HCG 10000iu / MIC 0.55%; 1.1%; 1.1% (Lot# 10082014:43; Best used by: 09/30/2015), were sticking to the top and sides of the vial.

C) There is no depyrogenation step included in your sterilization process.

OBSERVATION 7

There was a failure to handle and store components at all times in a manner to prevent contamination.

Specifically,

On 06/15/2015, we observed the following components to be out of the expiration dates:

-(b) (4) , Expiration Date: 03/31/2015.
-(b) (4) , Best Used By 04/30/2015.
(b) (4) , Expiration Date: 03/31/2015.
(b) (4) Best Used By: 5/31/2015 (b) (4)

OBSERVATION 8

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

Specifically,

On 06/15/2015, we observed the preparation of BI-MIX PAPAVERINE 30/PHENTOLAMINE 2 INJ injectable solution, Lot #06122015:23, Best Used By: 12/09/2015, in the ISO-5 room. During operations in this cleanroom environment, we observed a large number of scattered papers on a table adjacent to the facility's (b) (4) Additionally, on the lower shelf of this referenced table, a number of glass and plastic bulk containers were observed.

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OBSERVATION 9

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

Specifically,

Your firm's Facility Maintenance SOP entitled, "Cleanroom Monitoring and Certification", Revised 05/06/14, specifies that "the environment in the cleanroom will be monitored (b) (4) " and the '(b) (4) (b) (4) should be (b) (4) in (b) (4) locations in the cleanroom. Your Pharmacist in Charge also indicated that the (b) (4) are (b) (4) (b) (4) locations as identified on the environmental monitoring records. However, your firm does not have records substantiating (b) (4) testing. The previous three tests were conducted on (b) (4) and (b) (4) .
Additionally, records were reviewed dating back until June of 2013 and the following inconsistencies were observed in the environmental monitoring documentation:
- 12/18/14 – Records indicate only (b) (4) were used and only (b) (4) of monitoring.
- 12/11/14 – Records indicate only (b) (4) were used and only (b) (4) of monitoring.
- 10/13/14 – Only (b) (4) were indicated.

OBSERVATION 10

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

Specifically,

A) You do not have any endotoxin testing performed, and only perform sterility testing on (b) (4)

B) You do not perform (b) (4)

C) There is no validation of your sterilization methods.

*** DATES OF INSPECTION:**
06/15/2015(Mon), 06/16/2015(Tue), 06/17/2015(Wed), 06/18/2015(Thu), 06/24/2015(Wed)

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