

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>FOOD AND DRUG ADMINISTRATION</b>					
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314		<small>DATE(S) OF INSPECTION</small> 6/21/2016-6/29/2016* <small>FEI NUMBER</small> 3009192575			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Rachel S. Pittman , Pharmacist in Charge/Owner					
<small>FIRM NAME</small> Talon Compounding Pharmacy		<small>STREET ADDRESS</small> 2950 Thousand Oaks Dr Ste 25			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> San Antonio, TX 78247-3347		<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drugs			
<p>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.</p>					
<p><b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b></p> <p><b>OBSERVATION 1</b></p> <p>Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.</p> <p>Specifically,</p> <p>The ISO 5 designated cleanroom is constructed of (b) (4) which (b) (4) of (b) (4). The (b) (4) which measures approximately (b) (4) (b) (4) has several vent like opening approx. (b) (4) that are used allow air out of the cleanroom and are used to (b) (4)</p> <p>A. During the certification of the ISO 5 cleanroom on (b) (4) the room failed to meet the acceptance criteria for ISO 5. Although failing counts were recorded on the test report, the final certification report showed the status of 'PASS'. The firm did not conduct an investigation to determine the root cause of the failed certification and to assess the preventative and corrective action for the failure. Additionally, the firm continued to use the clean room to manufacture and distribute sterile drug products.</p> <p>B. During the certification of the ISO 7 (b) (4) room on (b) (4) the room failed to meet the acceptance criteria for ISO 7. The (b) (4) room is where non-sterile compounding activities are performed and also provides the (b) (4) for the ISO 5 cleanroom. In addition the particle counts in the (b) (4) room where non-sterile powders are weighed also failed to meet ISO 7 requirements when tested on (b) (4).</p>					
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<p>C. The ISO 5 clean room is equipped with HEPA filters that supply filtered air to the area where sterile drug products are produces. These filters have not been leak tested since (b) (4) to confirm the integrity of the filters which ensure aseptic conditions are maintained.</p>						
<p><b>OBSERVATION 2</b> Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.</p> <p>Specifically,</p> <p>A. Your cleanroom practices are deficient to prevent product contamination, from 6/21/2016 to 6/24/2016 we observed the following:</p> <ol style="list-style-type: none"> <li>1. During aseptic processing we observed the technician use expired (b) (4) in the ISO 5 clean room to sanitize gloved hands, wiping down the product contact surface of the pH meter and work surfaces where aseptic operations are performed.</li> <li>2. The technician was observed placing the sterile glove packaging into the trash can located in front of the ISO 5 work area and pushing down the trash with gloved hands before proceeding with performing aseptic manipulations.</li> <li>3. During the stoppering of lyophilized sterile drug product in the ISO 5 cleanroom, we observed the technician (b) (4) with (b) (4) (b) (4) hand was observed moving directly over the top of the open vial.</li> <li>4. Unopened bottles of (b) (4) are stored below the work surface in the ISO 5. During aseptic manipulations the technician was observed reaching below the ISO 5 work surface to retrieve sterile and proceeded to continue processing without sanitizing gloves.</li> </ol>						
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<p>B. Loyophilization which occurs in the ISO 5 cleanroom requires open vials of sterile drug product (b) (4) located under the main work surface of the cleanroom that lack HEPA filtration (b) (4) for an (b) (4)</p> <p>C. (b) (4) used in the aseptic filling process for sterile drug products is not performed (b) (4). During the inspection we observed the (b) (4) of Lipomax INJ Injectable, Lot # 06212106:51 and MIC 15/50/100mL, Lot # 06222016:89 on 6/22/2016; no (b) (4) tests were performed (b) (4) (b) (4)</p> <p>D. The cleaning process of product contact equipment used in the production of sterile drug products including (b) (4) glassware used to prepare solutions (b) (4) (b) (4) and equipment used to (b) (4) is limited to a (b) (4) (b) (4) in the "ISO 7" (b) (4) room. These pieces of equipment are not sterilized prior to use.</p> <p>E. Media fills performed by your aseptic processing technicians do not represent worst case scenarios nor does it simulate actual production conditions. Your aseptic technician stated that (b) (4) is your firm's largest batch size for aseptic processing. However, your current media fill test consists of (b) (4) (b) (4). You do not dispense any finished "compounded" products (b) (4) (b) (4). Therefore, you are not conducting media fills that mimic your routine worst case production. Moreover, you incubate these (b) (4) at (b) (4) C whereas the package insert states they are to be incubated at (b) (4) (b) (4).</p> <p>F. Your firm uses (b) (4) (b) (4) manufactured by (b) (4) which states in its package insert that it is a (b) (4) (b) (4). Your firm produces "high risk" sterile "compounded" products. In addition, your firm's standard operating procedures entitled, "Compounding Procedures SOP" Version 2 and "Training SOP" Version 2 state that employees involved in sterile "compounding" must complete a (b) (4)</p>						
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<div style="background-color: black; color: white; padding: 10px; text-align: center; font-weight: bold;">(b) (4)</div>			
<b>OBSERVATION 3</b> Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.			
Specifically,			
<div style="margin-left: 40px;"> <b>A.</b> Gowning of operators performing aseptic operations in the ISO 5 cleanroom is inadequate in that:           <ol style="list-style-type: none"> <li>1. Protective gowns, jumpsuits, face masks, shoe covers, and hair nets worn during aseptic processing are not sterile. In addition, jumpsuits stored in the ISO 5 ante room and reused throughout the day.</li> </ol> <p style="margin-left: 40px;"><b>This is a repeat observation from the 483 issued to your firm on 6/24/2015</b></p> <li>2. We observed the technician having exposed skin of the face and neck area while performing aseptic operations in the ISO 5 cleanroom during production of MIC 15/50/100mL, Lot #06222016@89 and Lipomax INJ Injectable, Lot # 06212106:51.</li> <p style="margin-left: 40px;"><b>This is a repeat observation from the 483 issued to your firm on 6/24/2015</b></p> <li>3. The gowning process for entering the ISO 5 cleanroom involved the technician putting on a non-sterile booties, bouffant cap, mask and a previously worn jumpsuit which was hung on a hook in the ISO 5 ante-room; (b) (6), (b) (7)(C) washed (b) (6), (b) (7)(C) hands in the sink located in the ISO 5 ante room and sprayed (b) (6), (b) (7)(C) hands with non-sterile (b) (6), (b) (7)(C) entered the ISO 5 cleanroom with ungloved hands and exposed skin on (b) (6), (b) (7)(C) neck and face. Sterile gloves were put on at the work area. Prior to performing aseptic operations the technician was observed touching the fingertips of (b) (6), (b) (7)(C) gloved hand with (b) (6), (b) (7)(C) ungloved hand during the gloving process.</li> </div>			
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<p style="margin-left: 40px;">4. Non-sterile (red) gloves stored in two zip-lock type bags were observed in the ISO 5 cleanroom which were identified as being used when performing non-aseptic operations including cleaning.</p>					
<p><b>OBSERVATION 4</b></p> <p>Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.</p> <p>Specifically,</p> <ul style="list-style-type: none"> <li>A. Between 6/21/16 and 6/23/16 we observed your technician use, a bottle of sterile (b) (4) with an expiration date of 1/2015 during the production of sterile drug products. The (b) (4) was used to wipe work surfaces and product contact equipment such as the pH meter probe in the ISO 5 cleanroom.</li> <li>B. On 6/22/16, we observed your personnel move powders that had been weighed in the ISO 7 (b) (4) room where growing is not required into to the ISO 5 cleanroom without disinfecting the outer surface. The material was used to produce the sterile injectable drug product MIC 15/50/100mL, Lot#06222016:89.</li> <li>C. A sporicidal agent was only used to perform (b) (4) cleaning of the ceiling walls and floors of the ISO 5 cleanroom in (b) (4) between January 2016 to June 2016. Additionally your cleaning procedure "Cleaning and Disinfection", Revision 7/9/14, states these areas should be cleaned (b) (4)</li> <li>D. Your firm failed to conduct disinfectant efficacy studies involving the (b) (4) (b) (4) and other disinfectants in use at the facility. In addition, there is no defined and established contact time for these disinfectants.</li> </ul>					
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<p>E. The Cleaning log for March 2016 to May 2016 lacks documentation of the person performing the actual (b) (4) and (b) (4) cleaning activities; however the initials of the supervisor verifying the cleaning.</p>			
<p><b>OBSERVATION 5</b>            Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.</p> <p>Specifically,</p> <p>A. Your firm has not validated the (b) (4) process used to produce sterile drug products. Between 6/21/16 and 6/24/16 we observed your technician performing (b) (4) of drug products on a (b) (4) basis using (b) (4) including MIC 15/50/100 mL, Lot# 06222016:89.</p> <p>B. The (b) (4) used to sterilize injectable drug products and product contact equipment is deficient in that</p> <ol style="list-style-type: none"> <li>1. The equipment was not qualified prior to use.</li> <li>2. The sterilization (b) (4) used to produce these products has not been validated to demonstrate effective sterilization (b) (4)</li> <li>3. You do not include (b) (4) in each sterilization (b) (4) and (b) (4) has been used since January 2016.</li> <li>4. The processing (b) (4) used to sterilize sterile drug products do not meet the minimum operating (b) (4) defined in the equipment operating manual (b) (4) the sterilization (b) (4) used by your firm is for Medroxyprogesterone Acetate 105mg/ml Suspension is (b) (4)</li> </ol>			
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<p style="text-align: center;"><b>This is a repeat observation from the 483 issued to your firm on 6/24/2015</b></p> <p>C. The (b) (4) used to produce your firms sterile injectable drug products was not qualified prior to use to determine the adequacy of the equipment. In addition you have not validated the lyophilization process to determine if it is appropriate for use in the production of sterile drug products.</p> <p style="text-align: center;"><b>This is a repeat observation from the 483 issued to your firm on 6/24/2015</b></p>							
<p><b>OBSERVATION 6</b></p> <p>Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically,</p> <p>A. Your environmental monitoring procedure "Environmental Testing" is deficient in that there is no scientific rationale to support the frequency and methodology of testing:</p> <ol style="list-style-type: none"> <li>1. Monitoring of sterile compounding personnel is not performed at the completion of each aseptic operation. Gloved fingertip monitoring is only performed every (b) (4)</li> <li>2. The ISO 5 cleanroom is used to produce sterile drug products on a (b) (4) basis; you have not performed viable air monitoring as part of the (b) (4) certification of the ISO 5 cleanroom additionally viable air monitoring is not performed during the production of sterile drug products. Your current viable air monitoring procedure is limited to the use of settle plates (b) (4)</li> <li>3. There is no scientific rationale for the selection of surface and air sampling locations as part of the environmental monitoring program. According to the procedure "... (b) (4)</li> </ol>							
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<small>CITY, STATE, ZIP CODE, COUNTRY</small> San Antonio, TX 78247-3347		<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drugs			
<div style="margin-left: 40px;"> <p>4. Your firm does not perform non-viable air monitoring in the ISO 5 cleanroom during the production of sterile drug products. During the (b) (4) recertification (b) (4) (b) (4) out of specification particle counts were identified in the area of the room where the lyophilization process is performed and there is no physical separation between this area and the remainder of the room.</p> <p>5. No leak tests have been performed on the HEPA filters located in the ISO 5 cleanroom where sterile drug products are produced.</p> <p>6. From 6/21/2016 to 6/24/2016 we did not observed air monitoring in the ISO 5 cleanroom during aseptic operations or any other environmental monitoring to ensure aseptic technique. Furthermore, there is a lack of personnel monitoring for (b) (4) aseptic operations.</p> <p>B. There is no evidence that smoke studies were conducted under dynamic conditions within the ISO 5 clean room where sterile operations are performed. The sterile production area is not segregated from the rest of the ISO 5 room.</p> <p>C. The pressure differentials between the ISO 5 cleanroom area and the ISO 7 (b) (4) room are not continuously monitored. The pressure differential is only checked (b) (4) by your technician. Additionally, the pressure differential between the gown room and the ISO 5 clean room are not recorded. During observation of aseptic operations the pressure gauge monitoring pressure between the gowning room and the ISO 5 clean room was observed to fluctuate between (b) (4) and (b) (4) w.c.</p> <p>D. Between 6/21/16 and 6/24/16 the air return vents (b) (4) (b) (4) was observed to be partially obstructed by the table which holds the (b) (4) located on the south wall inside the ISO 5 cleanroom. Another cart containing a large number of supplies and containers in the same location on the outside of the wall was also observed partially obstructing air flow out of the ISO 5. Additionally, a shelving unit containing various supplies located on the west wall outside of the ISO 5 was observed in</p> </div>					
<b>SEE REVERSE OF THIS PAGE</b>		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small>            Patty P Kaewussdangkul, Investigator            Lori G Cantin, FDA Center Employee or            Employee of Other Federal Agencies            Hala L Selby, Investigator         </td> <td style="width: 40%; vertical-align: top; border: 1px solid black; padding: 5px;"> <div style="text-align: right; font-size: small;">6/29/2016</div> <div style="text-align: center;"> <b>X</b> Hala L Selby  <small>Hala L Selby Investigator Signed by: Hala L Selby -IS</small> </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Patty P Kaewussdangkul, Investigator Lori G Cantin, FDA Center Employee or Employee of Other Federal Agencies Hala L Selby, Investigator	<div style="text-align: right; font-size: small;">6/29/2016</div> <div style="text-align: center;"> <b>X</b> Hala L Selby  <small>Hala L Selby Investigator Signed by: Hala L Selby -IS</small> </div>
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INSPECTIONAL OBSERVATIONS		PAGE 8 OF 12 PAGES			



<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>FOOD AND DRUG ADMINISTRATION</b>			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314		<small>DATE(S) OF INSPECTION</small> 6/21/2016-6/29/2016* <small>FEI NUMBER</small> 3009192575	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Rachel S. Pittman, Pharmacist in Charge/Owner			
<small>FIRM NAME</small> Talon Compounding Pharmacy		<small>STREET ADDRESS</small> 2950 Thousand Oaks Dr Ste 25	
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front of an air return vent also partially obstructing the air flow out of the ISO5.			
<b>OBSERVATION 7</b> The written stability testing program is not followed.  Specifically,  Your firm's Standard Operating Procedure entitled, "Compounding Procedures" Version 2 states that for "high risk" sterile "compounds" in absence of stability data, the beyond use date (BUD) cannot be more than 24 hours if stored at room temperature, not more than 3 days refrigerated and not more than 45 days in the freezer. However, there is no documentation to justify the following BUDs placed on the following injectable drug products prepared by your firm: <ol style="list-style-type: none"> <li>1. All lots of MIC B Complex Injections given a BUD of 90 days.</li> <li>2. HCG 20,000 IU/B12 Vial Lot #06022016:66 given a BUD of 180 days</li> <li>3. Methylocobalamin 1mg/ml (1000mcg/ml) Injection Lot # 01082016:10 given a BUD of 90 days.</li> </ol>			
<b>OBSERVATION 8</b> Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.  <b>This is a repeat observation from the 483 issued to your firm on 6/24/2015.</b>  Specifically,  A. Your firm produces sterile injectable drug products however; you do not routinely test for			
<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Patty P Kaewussdangkul, Investigator Lori G Cantin, FDA Center Employee or Employee of Other Federal Agencies Hala L Selby, Investigator		<small>DATE ISSUED</small> 6/29/2016  <div style="border: 1px solid black; padding: 5px; width: fit-content;">             X Hala L Selby  <small>Hala L Selby</small>  <small>Investigator</small>  <small>Signed by: Hala L Selby</small> </div>
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<p>sterility and endotoxin. Your firm is extending the Beyond Use Dates (BUDs) for several of these sterile injectable drug products but you are not ensuring that the sterility is maintained for the extended BUD dates given to your sterile injectable drug products.</p> <p>There is no scientific data to support the sterility of the following products with extended beyond use dates (BUDs) and no endotoxin tests were conducted for the following products:</p> <ol style="list-style-type: none"> <li>1. All lots of MIC B Complex Injections given a BUD of 90 days.</li> <li>2. HCG 20,000 IU/B12 Vial Lot #06022016:66 given a BUD of 180 days</li> <li>3. MIC 15/50/100ml (No B12) Injection given a BUD of 90 days.</li> </ol> <p>B. Your firm does not test the following sterile injectable preserved products for suitability and antimicrobial effective tests:</p> <ol style="list-style-type: none"> <li>1. All lots of MIC B Complex Injections given a BUD of 90 days.</li> <li>2. All lots of HCG 20,000 IU/B12 Vial including Lot #06022016:66 given a BUD of 180 days</li> <li>3. All lots of Methylcobalamin 1mg/ml (1000mcg/ml) Injection including Lot # 01082016:10 given a BUD of 90 days.</li> <li>4. All lots of MIC 15/50/100ml (No B12) Injection given a BUD of 90 days.</li> </ol> <p>Your firm's Pharmacist In Charge stated that they have never sent any sterile injectable products with preservatives for suitability and antimicrobial effective tests.</p>			
<b>OBSERVATION 9</b> Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.			
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<p>Specifically,</p> <p>On 6/24/16, we observed a (b) (4) containing a clear free flowing liquid labeled Testosterone (b) (4) placed on the (b) (4) table in the ISO 5 clean room. The product observed in the cleanroom was Testosterone (b) (4) Lot (b) (4) that was produced on (b) (4). Testosterone (b) (4) Lot # (b) (4) was used to dispense (b) (4) (b) (4) prescriptions on 6/15/16, 6/16/16, 6/20/16, 6/21/16, 6/22/16, 6/23/16, 6/27/2016 and 6/28/16. According to your Pharmacist In Charge, no hold time study was conducted to ensure that the Testosterone (b) (4) are stable, potent and sterile (b) (4) for distribution to patients.</p>			
<p><b>OBSERVATION 10</b></p> <p>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.</p> <p>Specifically,</p> <p>A) Your firm has no documentation of an investigation being conducted when Methylcobalamin 1mg/ml Injection, Lot #01082016:10 failed potency testing on 01/21/2016. The test revealed that the product had a potency of 51.8 % which is below potency requirements as stated on the lab report provided by your contract laboratory. This lot was distributed to your customers.</p> <p>B) Your firm has no documentation of an investigation being conducted when Testosterone Bi-Blend 125/125mg/ml Injection, Lot #10022015:28 consisting of Testosterone (b) (4) and Testosterone (b) (4) tested superpotent on 11/10/2015. Both actives ingredients were above USP potency requirements according to the lab report issued by the firm's contract laboratory. This lot was also distributed to your customers.</p>			
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

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**\*DATES OF INSPECTION**

6/21/2016(Tue),6/22/2016(Wed),6/23/2016(Thu),6/24/2016(Fri),6/28/2016(Tue),6/29/2016(Wed)

6/29/2016

☒ Patty P Kaewussdangkul

Patty P Kaewussdangkul  
Investigator  
Signed by: Patty P. Kaewussdangkul -S

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EMPLOYEE(S) SIGNATURE

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Hala L Selby, Investigator

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Hala L Selby  
Investigator  
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6/29/2016

DATE ISSUED

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