

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 2/22/2019-3/1/2019*	
		FEI NUMBER 3011905047	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Madan Mohan Reddy, Director			
FIRM NAME Aurobindo Pharma Limited		STREET ADDRESS Unit-XVI, SEZ, Plot No:S-5/A, S-6 & S-7, Polepally (Village), Jadcherla Mandal	
CITY, STATE, ZIP CODE, COUNTRY Mahabubnagar District, Telangana, 509302 India		TYPE ESTABLISHMENT INSPECTED Manufacturer 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 The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, The list of observations noted below document that the Quality Unit has not performed the necessary assessments/reviews to ensure that the objectionable conditions do not negatively affect the aseptic manufacturing processes and Quality Control tests in support of the finished sterile drug products. Specifically, All the deficiencies found during current FDA inspection are indicative that your Quality Unit has not taken the necessary steps with respect to the aseptic manufacturing processes and related systems to adequately assess the CGMPs and the impact on the finished sterile drug products.			
OBSERVATION 2 Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. From September 2017 to April 2018, your firm received 12 complaints regarding particulates found in nine (9) batches of (b) (4) and (b) (4) Injection USP, (b) (4) and (b) (4) g vials. For five (5) of the batches, your firm			
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established that there was no product impact and stated the particles identified were intrinsic to the manufacturing process. However, analysis of two (2) of the returned complaint samples found unidentified material. For example: - According to Investigation Report for Complaint Nos. CUO1217-U16, and CUO1317-U16, titled, <i>Investigation Report for "Little Black Particles Floating Inside the Vial / Black Particulate Matter in (b) (4) Vial"</i>, dated 27-Apr-18, one (1) of the 28 particulates isolated from each of 28 returned complaint sample vials of lot (b) (4) was analyzed by Scanning Electron Microscopy (SEM) and FTIR at an independent laboratory, which reported the sample consisted of heterogeneous material that includes possible silicates, silica, W particles and protein, and nylon. The laboratory was not able to identify the exact nature of the particle. The investigation report's conclusion does not include a probable cause of the unidentifiable material. - According to Investigation Report for Complaint Nos. CU01117-U16, CUO1217-U16, and CUO1317-U16, titled, <i>Investigation Report for Complaints on "Foreign Substance (Tiny Spec of Dark Red / Black Specs Observed in Vials After (b) (4) dated 04-Apr-18, one of the particulates isolated from returned complaint sample lot (b) (4) was analyzed by SEM and FTIR at an independent laboratory, which reported the sample was consistent with kaolin clay, styrene/acrylate ester, and "a small amount of unidentifiable material". The kaolin clay, styrene/acrylate ester were consistent with the (b) (4) stopper of the Active Pharmaceutical Ingredient container. The investigation report's root cause analysis does not include a probable cause of the unidentifiable material.</i> The complaint investigations for the 9 batches resulted in the following conclusions: - Particles in Batch Nos. (b) (4) were attributed to (b) (4) e.g., the complainants (b) (4) selection or user technique caused a portion of the stopper to enter the vial during (b) (4)					
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- Particles in Batch Nos. (b) (4) and (b) (4) attributed the red tint (b) (4) and red particles (b) (4) were due to shredded particles from a gasket located at the API manufacturing site. These batches were recalled. - Particles in Batch Nos. (b) (4) and (b) (4) were attributed due to use of grooved forceps when opening API canisters. - Particles in Batch Nos. (b) (4) were attributed to API material which "could have entrapped between the (b) (4) stopper and rim of the container during filling operations at the API manufacturing site". The established acceptance criterion for particulate matter in constituted solution in (b) (4) and (b) (4) Injection USP, (b) (4) and (b) (4) g finished product states, "the solution is essentially free from particles of foreign matter that can be observed on visual inspection".					
OBSERVATION 3 There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, A. Complaint investigation CU00518-U16 was initiated on 23-Feb-18 due to the collar and stopper coming off three (3) vials of (b) (4) and (b) (4) gm vial, Batch No. (b) (4) Exp. 07/2019. The complainant reported the defect was observed when the caregiver tried to pop off the cap or work with the vial, and noted they had "two (2) vials pop off and one assembled to a (b) (4) plus and start leaking".					
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The investigation report included the following information:

- The initial sealing machine qualification did not include validation of (b) (4) height with respect to vial sizes.
- A malfunction of the semi-automatic visual inspection machine occurred during inspection and was rectified; however, there was no re-inspection of vials.
- Because there was no procedure for reconciliation of vials during initial sealing machine set-up, it was possible that (b) (4) vials used for machine set up could be mixed up with the good vials.

A total of (b) (4) retention samples were visually inspected; however, no retention samples were leak tested. Although a maintenance requisition was issued for adjustment of the semi-automatic vial inspection (b) (4) during processing of this batch (b) (4) personnel did not perform an impact assessment of the equipment malfunction on the vials inspected prior to the breakdown.

Furthermore, the investigation did not include an evaluation of the number of rejects noted during sealing set-up and optical inspection activities as compared with either the typical number of rejects. A comparison of the average number of rejects in (b) (4) and sealing found in the three (3) process validation batches to the number of rejects found in this batch is as follows:

Activity	Reject Type	Average no. rejects from process validation	Number of rejects in Batch No. (b) (4)
Sealing	(b) (4)	12.7	153
	Unsealed / Loose Seal	6.3	96
Optical Inspection	(b) (4)	7.7	315
	Unsealed / Loose Seal	6.7	210

The investigation concluded the complaint defect of “collar and stopper coming off during removal of vial cap” was due to the malfunction of the semi-automatic visual inspection machine. The conclusion also stated

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the (b) (4) on the vial was obvious to health care professionals, the possibility of administration of such a vial is unlikely, and no market action was warranted for the subject batch.

- B. The assay of (b) (4) and (b) (4) injection, lot (b) (4) yielded results of (b) (4) % and (b) (4) %, respectively; the release specification was (b) (4) % to (b) (4) % for both ingredients. The quality control unit has been releasing lots that showed results at the lower end of the release specification. This discrepancy establishes that the current manufacturing process is not sufficiently robust and reproducible to produce predictable results. You did not place this lot on stability; therefore, your stability program does not represent your actual production and distributed batches of this product.

OBSERVATION 4

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

- A. The visual inspection process does not include a 360° inspection of the entire circumference of drug product vials. SOP FU16-PR-GEN-016, titled, *Procedure for Optical Inspection*, instructs personnel to inspect (b) (4) mm containers at a time. On 26-Feb-19, (b) (4) individuals were observed performing visual inspection of (b) (4) Injection USP (b) (4) g, lot (b) (4) and in another room, (b) (4) individuals were observed visually inspecting (b) (4) lot (b) (4) ml vial size). In both cases, personnel picked up (b) (4) vials by their caps, raised them to approximately eye-height, gently shook and inverted the vials against (b) (4). Body mechanics precluded an individual from twisting their wrist in a way to allow for inspection of the back side of the vials, since (b) (4) were held at a time. No employees were observed setting down vials and turning them around in order to examine the full circumference of the vials.

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In addition, the procedure requires personnel to inspect the multiple vials in front of (b) (4) (b) (4) for (b) (4) On 26-Feb-19, an employee located at Inspection Station A was observed inspecting (u) (4) containers against (b) (4) for a total of (b) (4)

B. Personnel are not trained to identify defects in (b) (4) vials such as (b) (4) Product between Vial and Stopper". Neither the visual inspection challenge kit nor the Optical Testing Record (by Manual Inspection) in the (b) (4) and (b) (4) Injection Batch Production Record list (b) (4) Product between Vial and Stopper" as a defect. This defect was identified in the following randomly selected retention samples of (b) (4) Injection (b) (4) g and (b) (4) g:

- Lot (b) (4), Exp. Jun 2019
- Lot (b) (4) Exp. Feb 2020
- Lot (b) (4) Exp. Feb 2020
- Lot (b) (4) Exp. Nov 2020
- Lot (b) (4) Exp. Jan 2021
- Lot (b) (4) Exp. Jan 2021

C. Personnel performing the final visual inspection of finished sterile injectable vials are not challenged on the identification and detection of defects such as red particles, which were found in two (2) complaint samples of (b) (4) Injectable (b) (4) g, which were produced on the (b) (4) Injection (b) (4) Line.

OBSERVATION 5

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

Specifically,

A. The Performance Qualification Protocol of Laminar Air Flow Unit Filling Area; Doc. Number FU16-PR-LAMAF-016-EQP-PQ-001; dated Dec 15, 2015 documents that all NVP sampling locations under

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Unidirectional Air Flow (UDAF) with Restricted Access Barriers (RABs) (Grade A) in filling Line (b) (4) area "complies" with respect to the observed NVP count (b) (4) and (b) (4) micron / m3). Per this protocol, a total of (b) (4) sampling locations were distributed throughout the LAFs units (i.e. PR-LAMAF-016, PR-LAMAF-017, PR-LAMAF-018, PR-LAMAF-019 and PR-LAMAF-020) ensuring that each LAF unit should get at least (b) (4) sampling location. However, there is no scientific justification to demonstrate that the selected distribution of sampling locations (particle counter probes) produces meaningful result and represents the critical zones of the filling Line (b) (4). Same deficiency was also observed in filling Line (b) (4) Injection area. B. The Report Rationale for Selection of Online Non-Viable Particle Count Location for (b) (4) Filling Line (b) (4) Doc. Number FU16-MIS-VSR-018; dated Dec 03, 2016, concluded that the existing installed online non-viable particle counter locations (b) (4) are adequate to capture the particles from the work/activity site in critical zones of the Restricted Access Barriers (RABs) (Grade A) in filling Line (b) (4) area with respect to the observed NVP count (b) (4) and (b) (4) micron / m3). However, there are no empirical data neither scientific justification, which demonstrate the selected counter locations are suitable enough for the continuous online monitoring of NVP in filling Line (b) (4) area. Your rationale for selecting the current locations of the fixed probes for continuous monitoring of NVP is based solely on the fact that each of the locations is not more than (b) (4) away from exposed vials. Same deficiency was also observed in filling Line (b) (4) Injection area. C. Monitoring of Non-Viable Particle (NVP) of the Grade A interior of the Mobile Transfer Carts (MTC) is not performed during dynamic operations to ensure the Grade A environment is maintained during the manual transferring process of the sterile equipment parts and tools into the aseptic filling zones of the (b) (4) and (b) (4) injectable (b) (4) drug products, respectively. D. The vials of (b) (4) Injection are sealed and capped within a Grade A designated area in manufacturing Room (b) (4). However, there is no NVP monitoring performed to ensure the Grade A environment is maintained during the dynamic operations.					
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Similar deficiency was also found in Line (b) (4) manufacturing Room (b) (4) sealing/capping for (b) (4) Injectable. E. The Protocol for Smoke Study in (b) (4) Injectable Area Line (b) (4) Doc. Number FU16-(b) (4)-AFSP-0005; dated Mar 08, 2018 describes/requires: ➤ Section 1.0 – To describe a procedure to perform the smoke studies in the clean rooms of (b) (4) Injectable Line (b) (4) area. And includes various aseptic process simulations. ➤ Section 5.0 – To simulate the all interventions in dynamic conditions for demonstrating the air flow pattern. Nonetheless, your air flow pattern study conducted during the filling equipment transfer/assembly and process for filling Line (b) (4) in (b) (4) area (Equipment ID PR-VFASM-001), and documented in the DVD (b) (4) Injectable Area Line (b) (4) dated Apr 02, 2018, used to ensure unidirectional airflow during manufacture of aseptically filled drug products, is deficient in that do not demonstrate how the air flow pattern of the RABs (Grade A) area of the vial filling Line (b) (4) is affected by the intervention of two (2) operators simultaneously transferring the forceps and the forceps' stands during set-up process to different locations into the filling zone (b) (4) (b) (4). For example, I noticed Operator #1 was manually transferred the referenced sterilized tools from the Mobile LAF Transfer Cart (MTC) to the stoppering area. Operator #2 was in front of the filling pump, where he was receiving the forceps and the stands from the Operator #1. The (b) (4) of the RABs remained open for up to 20 minutes. In addition, Similar deficiency was also observed in the Protocol for Smoke Study in (b) (4) Injectable Line (b) (4) Area; Doc. Number FU16-(b) (4)-APSP-0003; dated Feb 09, 2018. Specifically, your air flow pattern study conducted during the filling equipment transfer/assembly and process for filling Line (b) (4) in (b) (4) area (Equipment ID PR-PMDME-001), and documented in the DVD (b) (4) Area; dated Feb 09, 2018, utilized to ensure unidirectional airflow during manufacture of aseptically filled drug products, is deficient in that do not demonstrate how the air			
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flow pattern of the RABs (Grade A) area of the vial filling Line (b) (4) is affected by the open (b) (4) intervention of removing fallen vial from the (b) (4) area.					
OBSERVATION 6 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed. Specifically, A. Your control procedure FU16-MIS-VSP-036 Aseptic Process Simulation Validation Plan (b) (4) Line; dated Feb 04, 2018 and the Protocol Aseptic Process Simulation By Media Fill (b) (4) Injectable Section; Doc. Number FU16-(b) (4)-APSP-002; dated Feb 04, 2018 were found inadequate. Specifically, these control procedures do not require a periodic simulation of new intervention (RABs open (b) (4) intervention) observed during the routine commercial filling process of (b) (4) drug products. During the inspection, I randomly selected 34 lots of (b) (4) products to evaluate the routine and non-routine interventions performed during the commercial aseptic filling process. From my review, I found that 85% of the selected lots show a new open (b) (4) RABs intervention that is identifies as "removal of fallen vial from (b) (4) area". However, your Quality Unit did not initiate an assessment of this new open (b) (4) intervention to evaluate its impact over the (b) (4) aseptic filling operations. B. There is no assurance that your process simulation studies (media fills) performed in the filling Line (b) (4) (Equipment ID PR-VFASM-001) and filling Line (b) (4) (Equipment ID PR-PMDME-001) for (b) (4) injectable (b) (4) drug products respectively are truly representative of the conditions observed and/or that might occur during routine aseptic filling operations of vials. This is evidenced in that, although routine and non-routine operator's interventions are simulated during the media fills, the frequency and the duration at which these interventions are simulated are not established on a historical and/or retrospective evaluation of the filled commercial batches.					
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CITY, STATE, ZIP CODE, COUNTRY Mahabubnagar District, Telangana, 509302 India		TYPE ESTABLISHMENT INSPECTED Manufacturer of Sterile Drug Products	
For example, Aseptic Media Fill Validation; Protocol FU16-(b) (4) -APSP-001; dated Jan 18, 2019, requires that "removal of fallen empty vials at (b) (4)" should be simulated (b) (4) in total) during the aseptic process simulation. Subject intervention is classified as a routine intervention and is carried out through (b) (4). However, during my review of the commercial batch records for (b) (4) Injection (b) (4) g; Lot (b) (4) I found that "removal of fallen empty vials at (b) (4) intervention was carried out approximately twenty (20) times during the aseptic filling process of commercial Lot (b) (4). No assessment of the filling Line (b) (4) or the components were performed although the frequency of this intervention is more than the validated (b) (4) times that media fill Protocol FU16-(b) (4) -APSP-001 requires. C. The filling Line (b) (4) equipment set-up is not optimized to prevent contamination from occurring during routine aseptic filling operations. Specifically, On Feb 23, 2019, I witnessed the equipment transfer and set-up process of filling Line (b) (4) in (b) (4) area. The line was in preparation for aseptic filling process of (b) (4) Injection (b) (4) g; Lot (b) (4) Around 12:45 pm, I observed two (operators) working simultaneously in the Grade A area of the aseptic filling line, transferring the forceps and the forceps' stands to different locations into the filling line (b) (4). Operator #1 was manually transferred the referenced sterilized tools from the Mobile LAF Transfer Cart (MTC) to the stoppering area. Operator #2 was in front of the filling pump, where he was receiving the forceps and the stands from the Operator #1. The (b) (4) of the Restricted Access Barriers (RABS) remained open for up to 20 minutes (13:05). Meanwhile, the empty glass vials that were going to be used in the aseptic filling process of Lot (b) (4) were on the (b) (4). Moreover, there is no documented evidence in the batch records of (b) (4) Injection (b) (4) g; Lot (b) (4) which describes the manual transferring process of the forceps and the stands from the MTC and into the aseptic filling zone, was carried out during the set-up activities for filling Line (b) (4).			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Linda F Murphy, Consumer Safety Officer Jose E Melendez, Investigator - Dedicated Drug Cadre Walden H Lee, Chemist/Biologist Linda F Murphy Consumer Safety Officer Signed By: Linda F. Murphy-S Date Signed: 03-01-2019 09:57:36 X	
		DATE ISSUED 3/1/2019	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 2/22/2019-3/1/2019*
	FEI NUMBER 3011905047

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Madan Mohan Reddy, Director

FIRM NAME Aurobindo Pharma Limited	STREET ADDRESS Unit-XVI, SEZ, Plot No:S-5/A, S-6 & S-7, Polepally (Village), Jadcherla Mandal
CITY, STATE, ZIP CODE, COUNTRY Mahabubnagar District, Telangana, 509302 India	TYPE ESTABLISHMENT INSPECTED Manufacturer of Sterile Drug Products

OBSERVATION 7

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and sampling plans designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

- A. According to In-House procedure GTP/RF/031/03, titled, *Test for Particulate Matter*", the required sample size for (b) (4) and (b) (4) products such as (b) (4) and (b) (4) Injection and (b) (4) and (b) (4) Injection is (b) (4) vials. The standard batch size for (b) (4) and (b) (4) Injection USP (b) (4) g, is (b) (4) vials, and the standard batch size for (b) (4) and (b) (4) Injection USP (b) (4) grams/vial is (b) (4) vials.

According to the Microbiology Laboratory Manager, (b) (4) vials are selected at random from a group of (b) (4) vials collected every (b) (4) throughout production and then tested according to GTP101-05, titled, *Particulate Matter (By light obscuration method)*. He acknowledged the sample size was not based on a statistical rationale.

- B. The assay of (b) (4) and (b) (4) injection, lot (b) (4) yielded results of (b) (4) % and (b) (4) %, respectively; the finished product specification was (b) (4) % to (b) (4) % for both ingredients. The control alert limits established by your firm for (b) (4) were (b) (4) % to (b) (4) % and for (b) (4) % to (b) (4) % which were outside the finished product release specification, and no assessment was performed.

- C. The uniformity of dosage by weight variation of (b) (4) and (b) (4) injection, yielded the results for the following released US lots:

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FIRM NAME Aurobindo Pharma Limited		STREET ADDRESS Unit-XVI, SEZ, Plot No:S-5/A, S-6 & S-7, Polepally (Village), Jadcherla Mandal			
CITY, STATE, ZIP CODE, COUNTRY Mahabubnagar District, Telangana, 509302 India		TYPE ESTABLISHMENT INSPECTED Manufacturer of Sterile Drug Products			
OBSERVATION 9 Written procedures are lacking which describe in sufficient detail the sampling and testing of components. Specifically, Control procedure CQA-CP-GEN-050, titled, <i>Supplier Qualification Program for Raw Materials</i>; which is used to monitor suppliers of Active Pharmaceutical Ingredients (APIs), requires your firm to consider disqualifying suppliers due to issues including, but not limited to receipt of contaminated material which has adverse impact on product quality. On 01-May-18, your firm initiated a recall of (2) lots of (b) (4) and (b) (4) Injection USP (b) (4) g. Batch Nos. (b) (4) manufactured in September 2017, due to Market Complaint Nos. CU01517-U16 and CU01617-U16, which were received regarding red tint (Batch (b) (4) and red-colored particulates in (b) (4) solution (Batch (b) (4)). The complaint investigations attributed the particles to gasket material at the API supplier in two (2) different batches of API. In addition, Complaint No. CU01217-U16 was received due to black particles found inside a vial of (b) (4) and (b) (4) Injection USP (b) (4) g., Batch (b) (4) and the particles were attributed to the filling operations at the API manufacturer. Your firm did not disqualify the supplier, or otherwise require additional evaluation of incoming batches after these events in order to prevent reoccurrence.					
OBSERVATION 10 The records for components do not include the identity and quantity of each shipment of each lot, name of the supplier, supplier's lot number and date of receipt.					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Linda F Murphy, Consumer Safety Officer Jose E Melendez, Investigator - Dedicated Drug Cadre Walden H Lee, Chemist/Biologist </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 3/1/2019 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Linda F Murphy, Consumer Safety Officer Jose E Melendez, Investigator - Dedicated Drug Cadre Walden H Lee, Chemist/Biologist	DATE ISSUED 3/1/2019
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		Linda F Murphy Consumer Safety Officer Signed By: Linda F. Murphy-S Date Signed: 03-01-2019 09:57:36 X			

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Specifically, According to SOP CQA-CP-GEN-043, titled, <i>Sampling of Raw Material</i>, your firm receives "tailgate" samples of sterile Active Pharmaceutical Ingredients (API) from which samples are collected for raw material analytical and microbiological testing. Records are not available showing the receipt date, quantity, supplier's name, supplier's lot number, or temperature log for incoming tailgate samples. For example, records dated 30-Aug-17 show receipt of (b) (4) batches of sterile (b) (4) and (b) (4) Injection USP, supplier batch numbers (b) (4) and (b) (4). These records showed (b) (4) of each batch were received; however, this information did not account for receipt of any tailgate samples.			
OBSERVATION 11 The accuracy, sensitivity and specificity of test methods have not been documented. Specifically, A. The test method, (b) (4) was used to determine the (b) (4) of (b) (4) raw materials. It was also used to determine the (b) (4) of the drug products (b) (4) Injection, (b) (4) Injection, (b) (4) Injection and (b) (4) Injection during finished product and stability testing. This method has not been verified by the quality control laboratory. B. The test method, GTP013-06 Heavy Metals Method-E, was used to determine the heavy metal content of (b) (4) USP and (b) (4) USP. This method was adopted from USP <231> Heavy Metals, Method II which was removed from the USP January 2018.			
*DATES OF INSPECTION			
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2/22/2019(Fri), 2/23/2019(Sat), 2/25/2019(Mon), 2/26/2019(Tue), 2/27/2019(Wed), 2/28/2019(Thu),
3/01/2019(Fri)

X Jose E Melendez
Investigator - Dedicated Drug Cadre
Signed By: Jose E. Melendez -S
Date Signed: 03-01-2019 09:58:08

X Walden H Lee
Chemist/Biologist
Signed By: 1300071161
Date Signed: 03-01-2019 09:59:06

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

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Jose E Melendez, Investigator - Dedicated
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Walden H Lee, Chemist/Biologist

Linda F Murphy
Consumer Safety Officer
Signed By: Linda F. Murphy -S
Date Signed: 03-01-2019 09:57:36

X

DATE ISSUED

3/1/2019