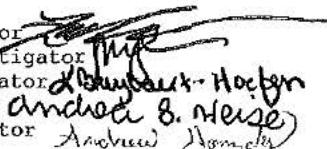


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 08/05/2013 - 08/30/2013* FEI NUMBER 3003240654
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Michael S. Travis, President		
FIRM NAME Front Range Laboratories, Incorporated	STREET ADDRESS 3985 S Lincoln Ave	
CITY, STATE, ZIP CODE, COUNTRY Loveland, CO 80537-2531	TYPE ESTABLISHMENT INSPECTED Testing Laboratory	
<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>		
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:		
OBSERVATION 1		
<p>Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.</p> <p>Specifically,</p> <p>There is no verification of any methods reported to be USP and/or validation of any internal methods for any drugs tested, this is evidenced by:</p>		
<p>1) Sterility (b) (4) Accelerated Sterility Testing and 14-day Sterility Testing</p> <p>a. Your firm has not performed any verification of any methods reported to be USP and/or validation of any internal methods, this includes (b) (4) Accelerated Sterility Testing which has been in place since (b) (4).</p> <p>i. No validation studies have been conducted for the (b) (4) accelerated sterility testing, including studies that demonstrate equivalency to USP <71>. Sterility analysts indicated that approximately (b) (4)% of all sterility testing (according to analysts, approximately (b) (4) sterility samples are received/tested daily) is done using the (b) (4) accelerated sterility testing method. Your firm's "Accelerated Sterility Testing" SOP (MICRO-SOP-024) has no provisions for the microbial growth media to be challenged with Growth Promotion Testing. The reliability of this sterility test has not been shown to be validated with the Bacteriostatic and Fungistasis test; these tests have not been conducted. Additionally,</p> <p>1. No validation studies have been conducted on the (b) (4) (b) (4) flow cytometer used for (b) (4) Accelerated Sterility testing.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachery L. Miller, Investigator Marie B. Buen-Bigornia, Investigator Kimberley A. Hoefen, Investigator Andrea S. Heise, Investigator Andrew J. Gonzales, Investigator <div style="text-align: right;">  </div>	DATE ISSUED 08/30/2013

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2. No verification of microbial growth, such as gram staining, is being performed on (b) (4) or (b) (4) tubes that are resulted as a "fail" by the (b) (4). As part of your process when a (b) (4) "fail" is resulted, a subculture is performed from the broth to a (b) (4) plate. The (b) (4) plate is incubated for (b) (4) under aerobic conditions. Identification is performed if any growth is observed on the (b) (4) plate. Therefore, a verification of microbial growth, such as a gram stain, is needed in order to determine what the expected growth should be on the (b) (4) plates.
3. (b) (4), which is used to culture anaerobic microorganisms, is being used as part of (b) (4) Accelerated Sterility testing and is not incubated under anaerobic conditions per USP <71> to allow for the growth of anaerobic microorganisms.
4. You are not following procedure (MICRO-SOP-024). According to your procedure, the (b) (4) Accelerated Sterility Testing is to be performed using (b) (4) broths. When broths are analyzed using the (b) (4) (b) (4) there are inconsistencies with the number of broths analyzed. In numerous instances, only one broth tube (b) (4) or (b) (4) tubes) was analyzed instead of (b) (4).
- ii. In the event that an (b) (4) sterility test result is found to be a "fail", a (b) (4) of broth tubes and a subculture using (b) (4) plates is performed. When no growth is observed on the subculture plates, a passing result is reported to the customer. For example: sample (b) (4) (Bevacizumab 25mg/mL, expiry 11/5/2013), failed (b) (4) sterility test on 8/14/2013, and was subcultured on 8/16/2013. No growth was found on subculture, and a passing sterility result was reported to the customer on 8/20/2013. There are 33 examples using this same follow-up method for finished products which are still within expiry, between the time period of 5/1/2013 through 8/20/2013. The above follow-up method has not been validated, including demonstration of equivalency to the methods described within USP <71> as required. In addition, your firm does not investigate all (b) (4) sterility failures to determine whether results can be invalidated.

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Andrew J. Gonzales, Investigator *AG*

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1. In one instance only, a (b) (4) of the broth tubes was performed: Sample (b) (4) (testosterone cypionate 200 mg/mL, expiry 11/3/2013), failed (b) (4) sterility test on 5/14/2013, and no evidence of a subculture result was documented. A passing sterility result was reported to the customer on 5/13/2013; before analysis was completed on 5/14/2013.

Your accelerated testing procedure (MICRO-SOP-024) is inadequate because fastidious growing microorganisms, anaerobes and molds may not be recovered since broths are only incubated for (b) (4). Additionally, (b) (4) plates are being used for sub-culturing and have not been shown to support growth of a wide-range of microorganisms. These plates are only being incubated aerobically for (b) (4). Subsequently, since no verification of microbial growth (such as gram staining), is performed on broths, there is no way to determine if microorganisms should have been recovered.

- iii. When the (b) (4) is reported to not be operational, a (b) (4)

(b) (4)
(b) (4)
(b) (4). For example, a (b) (4) was performed on 6/24/2013, in place of using the (b) (4) for sample # (b) (4) (calcium gluconate 2 gm/100mL, expiry 8/16/2013). A passing result was reported to the customer on 6/24/2013. When the (b) (4) was down on 7/31/2013, a (b) (4) (b) (4) and subculture was performed on 8/5/2013 for sample # (b) (4) (calcium gluconate 1gm PF, expiry 9/27/2013), and a passing result was reported to the customer on 8/7/2013. Neither of these follow-up methods have been validated, including demonstration of equivalency to the methods described within USP <71> as required.

Your accelerated testing procedure (MICRO-SOP-024) is inadequate because fastidious growing microorganisms, anaerobes and molds may not be recovered since broths are only incubated for (b) (4) and (b) (4) plates are being used for sub-culturing. Additionally, the (b) (4) plates are

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only being incubated aerobically for (b) (4). Subsequently, since no verification of microbial growth (such as gram staining), is performed on broths, there is no way to determine if microorganisms should have been recovered.

1. A subculture is not being performed in all cases of (b) (4) at (b) (4)

This deviates from your firm's Accelerated Sterility Testing SOP (MICRO-SOP-024), which requires a subculture from (b) (4).

Potential (b) (4) turbidity in broths may not be observed at (b) (4).

Additionally, (b) (4) plates are being used for sub-culturing and have not been shown to support growth of a wide-range of microorganisms. These plates are only being incubated aerobically for (b) (4).

Subsequently, since there is no verification of microbial growth (such as gram staining), performed on broths, there is no way to determine if microorganisms should have been recovered.

- b. Your firm is without any verification of any methods reported to be USP and/or validation of any internal methods, this includes 14-day USP <71> Sterility Testing.

- i. No Growth Promotion Test and Bacteriostatic and Fungistasis Tests have been conducted in accordance with USP <71> for any drug tested at any time. Sterility analysts indicated that (b) (4) % of all sterility testing is done using the traditional 14-day sterility testing. Your firm's "Sterility Testing via (b) (4)

(b) (4) Method" SOP (MICRO-SOP-009) provides no provisions for Growth Promotion Test and the Bacteriostatic and Fungistasis Test.

1. No verification of microbial growth, such as gram staining, is performed on positive (turbid) results from (b) (4) in order to verify growth and to determine if microorganisms are present. General media plates are used for sub-culturing positive (turbid) results and they are being incubated aerobically. If growth is (b) (4) observed on the (b) (4) plates, identification(s) are performed.
2. No definitive read dates for the sterility tests are recorded on laboratory worksheets indicating when the final read of each individual sample takes place. According to a sterility analyst, there is a final date that represents when all samples on one worksheet were finalized. This includes any culturing due to positive results. In some instances, 14-day Sterility Testing worksheets indicate that the incubation period was less than the required 14-

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day period required by USP <71>. It cannot be verified that samples were run for the specified 14-day period if a final read date is not recorded for every sample.

- ii. Anaerobic microorganisms may not be recovered using (b) (4) plates that are incubated aerobically. The 14-day sterility sample analyses are set up in the clean room using (b) (4). The (b) (4) that was used for 14-day sterility testing is incubated for 14 days. Any positive (turbid) growth is subcultured to a (b) (4) plate. The (b) (4) plates are not incubated under anaerobic conditions according to sterility analysts.

2) Endotoxin

- a. Your firm has not performed any verification of any methods reported to be USP and/or preparatory studies of any internal methods, this includes Endotoxin Testing.
- i. No preparatory testing has been done for any drug at any time with respect to endotoxin (b) (4) testing. Your firm's "Bacterial Endotoxin Testing (BET) Utilizing a (b) (4) for Routing Sample Analysis" SOP (MICRO-SOP-020) does not provide any provision for preparatory testing studies.
- ii. From May 2013 to August 2013, (b) (4) endotoxin (b) (4) raw data results were reviewed and 83 results indicated negative result(s) for positive control(s). There is no documentation of your firm retesting these samples. For example, sample (b) (4) (Midazolam PF 50mg/mL Inj., exp. 11/21/2013) was analyzed on 7/29/2013, a single negative result was recorded for both the sample and positive control. A retest was never documented and passing results were sent to the customer on 7/30/2013. Fifty of 83 positive controls that resulted as negative in the analyst's lab notebook (between May 2013 and August 2013) were reported to the customer as passing. There is no assurance the test is valid if the positive control yields a negative result. Failure of the positive control to have a detectable level of endotoxin (for a number of reasons, including those that could be detected by performing the "preparatory testing") will result in a false negative for the sample.
1. In some instances, raw data results indicate only one (b) (4) result for both the sample and positive control, rather than two results. According to USP <85>Endotoxin (b) (4) testing for the sample and the positive control

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<p style="text-align: center;">is performed in duplicate. Therefore, two results for the sample and two results for the positive control are required.</p> <p>3) Potency (Assay)/Beyond Use Dating</p> <p>a. Your firm has not performed any verification of any methods reported to be USP and/or validation of any internal methods, this includes potency (assay) and Beyond-Use-Date (BUD) studies (b) (4) BUD studies have been performed since 2011).</p> <ul style="list-style-type: none"> i. No additional spikes, standards or studies are used to determine accuracy, precision, linearity, specificity, limit-of-detection/quantitation, or any other qualities to produce robust, reproducible, accurate results for all methods. ii. There are no written test methods. Your firm cannot ensure that potency analyses are performed the same way every time. iii. Your firm is not fully following USP monographs that are being used as your analytical methods, for example: 1) standards/samples are run at 100 ug/mL for all samples and standards; 2) system suitability injections are not run; 3) USP requirements are not used to determine system suitability (resolution, % RSD, etc.). 											
<p>OBSERVATION 2</p> <p>There is no quality control unit.</p> <p>Specifically,</p> <p>Your firm is without a Quality Management System, evidenced by:</p> <ul style="list-style-type: none"> 1) According to your Quality Management System Policy (SOP ADM-P-003, Revision .3, Section 4.1), your Quality System is established and outlined in the Quality Management System Manual; however, your Quality Management System Manual has not even been created. 											
SEE REVERSE OF THIS PAGE		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 5px;">EMPLOYEE(S) SIGNATURE</th> <th style="text-align: left; padding: 5px;">DATE ISSUED</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Zachery L. Miller, Investigator </td> <td rowspan="5" style="padding: 5px; vertical-align: middle; text-align: center;">08/30/2013</td> </tr> <tr> <td style="padding: 5px;">Marie B. Buen-Bigornia, Investigator </td> </tr> <tr> <td style="padding: 5px;">Kimberley A. Hoefen, Investigator </td> </tr> <tr> <td style="padding: 5px;">Andrea S. Heise, Investigator </td> </tr> <tr> <td style="padding: 5px;">Andrew J. Gonzales, Investigator </td> </tr> </tbody> </table>		EMPLOYEE(S) SIGNATURE	DATE ISSUED	Zachery L. Miller, Investigator	08/30/2013	Marie B. Buen-Bigornia, Investigator	Kimberley A. Hoefen, Investigator	Andrea S. Heise, Investigator	Andrew J. Gonzales, Investigator
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<p>2) Your quality control unit does not have the responsibility for approving or rejecting specifications through validation of internal laboratory methods or verification of methods reported to be USP, which may impact the results you provide to your customer who depend on them to verify the identity, strength, quality, and purity of your products.</p> <p>3) There is no assurance that your laboratory facilities are adequate for the testing and approval (or rejection) of drug product sterility results;</p> <p style="margin-left: 40px;">a. During the sterility testing observed on 8/14/2013, there was no dynamic environmental monitoring being conducted. Environmental monitoring of the clean room is conducted (b) (4), (b) (4) occurring before any sterility analyses. The environmental monitoring consists of using settling plates and a few touch plates under static conditions only. No active or dynamic air sampling has taken place at your firm. Your firm has no assurance that microbial contamination is not occurring under operational conditions.</p> <p style="margin-left: 40px;">b. There is no documentation that your (b) (4) - your only sterilizing agent being used) has been shown effective in eliminating spore forming bacteria and other resistant organisms in your testing laboratory, as evidenced by:</p> <p style="margin-left: 80px;">i. Organisms identified from environmental sampling data of the clean room include numerous bacillus species (spore forming microorganism), staph species and also included gram negative rods and gram negative diplococci. Some of the organisms recovered from environmental monitoring of the clean room identified as <i>Staphylococcus aureus</i>, <i>Staphylococcus haemolyticus</i>, <i>Staphylococcus lugdunensis</i>, <i>Aeromonas-salmonicida</i>, <i>Pseudomonas stutzeri</i>, <i>Acinetobacter lwoffii</i>, <i>Bacillus cereus</i>, <i>Moraxella catarrhalis</i>, <i>Neisseria sicca</i>, <i>Pseudomonas putida</i>, <i>Aeromonas hydrophilia</i>, <i>Pseudomonas syringae</i>, <i>Serratia odoriferae</i>, <i>Pseudomonas aeruginosa</i>.</p> <p style="margin-left: 40px;">c. There is no assurance that your cleaning procedures are adequate:</p> <p style="margin-left: 80px;">i. Your entire cleaning and sterilization process is not documented. The cleaning and sterilization of the clean room, which supports your sterility testing, is conducted (b) (4) with only (b) (4)</p> <p style="margin-left: 80px;">ii. No grid/disinfectant efficacy monitoring has ever been conducted in order to validate the cleanliness and sanitization of the clean room and laminar flow hood.</p> <p style="margin-left: 80px;">iii. It was observed on 8/15/2013, equipment such as a manifold, tubes of media, pliers, and outer packaging of sterile equipment were not sanitized prior to being placed into the laminar flow hood during the sterility analysis testing.</p> <p style="margin-left: 40px;">d. Your firm's (b) (4) flow cytometer (an open system, particulate</p>			
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detecting device), which is used to perform sterility testing on customer samples, is located in an environmentally uncontrolled, unclassified area.

- e. The laminar flow hood, which is situated inside the sterility suite, is not currently assessed for particulates, velocity flow rate, and no smoke studies have been conducted. Your laminar flow hood is a critical piece of equipment, as it is used to stage and set up sterility tests and prevent laboratory contamination of product under sterility testing. No studies concerning, particulate, smoke, flow rate and grid monitoring, have been conducted.
 - f. Your firm does not monitor pressure differentials between areas of cascading air quality. Your firm does not have any monitoring parameters in place to determine how long or how often the doors between classified areas can remain open or if there are any positive pressure drops during sample analysis in the aseptic clean room.
- 4) Your firm is without complete procedures describing the quality control unit's responsibilities and authority to approve and reject all quality control testing results, and the authority to review laboratory records to assure no errors have occurred, or if errors have occurred that they have been fully investigated, for example:
- a. All generated laboratory results are reported to your customers without review and approval from the quality assurance department;
 - b. During the inspection, Investigators documented multiple occasions over the past four months, where your firm's Chief Financial Officer, Deputy Assistant Lab Director, and Data Technician exercised the authority to review and approve sample results and final reports that were sent to customers. These employees are not identified in your firm's QCU, nor do they have the educational background for the authority of approving and rejecting scientific data.
 - i. Below are specific examples where an OOS was created and an investigation was left open for a sterility failure. The above employees approved the failing laboratory results and the final reports. There was no QCU review or Lab Director review of the OOS and the analyst's data, as described in your firm's Out-of-Specification (OOS) Investigation Standard Operating Procedure (ADM-SOP-006):

Sample #	Product	Expiry	Remarks	Customer Report (P/F) and Date
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(b) (4)	Sodium Citrate 4% Soln. for Inj. MDV OUO	1/6/2014	sample setup 7/12, final report 7/24, not retested	Passes on 7/24/13
(b) (4)	EDTA Disodium 150 mg/mL Sterile Inj. MDV	1/2/2014	sample setup 7/11, final report 7/30, not retested	Passes on 7/30/13
(b) (4)	Sodium Thiosulfate 25% 250 mg/mL (12.5g/50 mL) Sterile Soln for Inj. SDV OUO	1/13/2014	sample setup 7/22, final report 7/30, not retested	Passes on 7/30/13
(b) (4)	Sodium Thiosulfate 25% 250 mg/mL (12.5g/50 mL) Sterile Soln for Inj. PF SDV OUO	1/5/2014	sample setup 7/11, final report 7/19, not retested	Passes on 7/19/13

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

- 1) Personnel gowning qualification and personnel monitoring has never occurred. Your firm's SOP's including "Gowning" (MICRO-SOP-008) does not provide any provisions to do so.
 - a. The attire for drug product testing performed in the laminar flow hood and clean room is inadequate for operations within an ISO 5 clean room (ISO 14644-1 cleanroom standards) or a Class 100 (FED STD 209E equivalent).
 - i. Sterility analysts clean room attire consists of shoe covers, a disposable gown (which is re-used), hair bouffant, safety glasses, face particle mask and a sterile double set of gloves. No sterile sleeve covers are used. Skin was exposed on the sides of the mask, neck and forehead. Street clothes and shoes were also used in the cleanroom. Pant legs were visible as well. Skin and street clothes shed viable and non-viable particulates and can lead to the contamination of the aseptic cleanroom and subsequently the sample.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Zachery L. Miller, Investigator *ZLM*
Marie B. Buen-Bigornia, Investigator *MBB*
Kimberley A. Hoefen, Investigator *KAH*
Andrea S. Heise, Investigator *ASH*
Andrew J. Gonzales, Investigator *AG*

DATE ISSUED

08/30/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 08/05/2013 - 08/30/2013* <hr/> <small>FEINUMBER</small> 3003240654	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> TO: Michael S. Travis, President		
<small>FIRM NAME</small> Front Range Laboratories, Incorporated	<small>STREET ADDRESS</small> 3985 S Lincoln Ave	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Loveland, CO 80537-2531	<small>TYPE ESTABLISHMENT INSPECTED</small> Testing Laboratory	
OBSERVATION 4 <p>The written stability program for drug products does not include reliable, meaningful, and specific test methods.</p> <p>Specifically,</p> <p>Your firm is offering stability study or beyond-use-dating (BUD) data as a service to your customers without validating/verifying your methods to determine if they are stability indicating. The only data to support a customer's product expiry date is potency results obtained from non-validated/non-verified USP methods and there is no data that any of these methods are stability indicating. Methods evaluating related compounds, degradation, and impurities are not used. There is no assurance of the related compound/degradation compound concentrations within the BUD study time. For example out of 10 BUD potency lab analyses reviewed the following was found:</p> <ol style="list-style-type: none"> 1) Customer order received 6/7/13 requested Prednisolone Suspension, 20 mg/mL (sample # (b) (4), expiry 12/2/13) to be analyzed for "BUD" at the following time points (initial, 1 month, 2 month, 3 month, 4 month, 5 month, 6 month). The initial and 1 month analytical "BUD" (potency) testing was completed using non-validated internal firm methods. No related compound/degradation products test was performed. There is no assurance of a positive identification of prednisolone in the sample, for example: <ol style="list-style-type: none"> a. On 6/10/13 (initial time point) assay/potency was analyzed using internal methods. <ol style="list-style-type: none"> i. The USP standard, used to calculate the area/potency, (5th injection) retention time was at 2.974 min. ii. The sample retention time was at 2.132 min (replicates 1 and 2). iii. The sample peak was outside of the industry standard ID limit range of $\pm 5\%$ (2.825-3.123 min). b. On 7/17/13 (1 month time point) assay/potency was analyzed using internal methods. <ol style="list-style-type: none"> i. The USP standard (5th injection) retention time was at 2.314 min. ii. The sample retention time was at 1.777 min (replicates 1 and 2). iii. The sample peak was outside of the industry standard ID limit range of $\pm 5\%$ (2.198-2.430 min). 2) Customer order, dated 12/21/12 requested Atropine Sulfate, 0.1 mg/mL (sample # (b) (4), expiry 		
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Zachery L. Miller, Investigator <i>ZLM</i> Marie B. Buen-Bigornia, Investigator <i>MBB</i> Kimberley A. Hoefen, Investigator <i>KAH</i> Andrea S. Heise, Investigator <i>ASH</i> Andrew J. Gonzales, Investigator <i>AGJ</i>	<small>DATE ISSUED</small> 08/30/2013

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

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6/19/2013) to be analyzed for potency. An E-mail update from the customer dated 2/8/13 requested additional "BUD" analysis at the following time points, 45 days and 90 days. The analytical "BUD" (potency) 45 day (2/8/13) and 90 day (3/21/13) testing has been completed and analyzed by using a purported "USP" method. All sections of the USP monograph are not followed. Your firm cannot assure a failing result was not reported as passing, for example:

- a. The standard/samples were run at a concentration of approximately 100 ug/mL atropine sulfate, the official USP monograph used 80 ug/mL atropine sulfate.
- b. No system suitability injection was prepared and injected.
- c. The system suitability resolution limits were not evaluated since the system suitability injection was not performed.

- 3) Customer order received 5/10/13 requested Diazepam/Amitriptyline, 5/10 mg suppository (sample # (b) (4) expiry 06-11-2013), to be analyzed for "BUD" at the following time points (initial, 90 days, 180 days and 270 days). Only the initial analytical "BUD" (potency) testing has been completed. On 5/13/13 (initial time point) and 5/20/13 (retest for initial time point) assay/potency was analyzed using non-validated internal methods. Your firm cannot assure a failing result was not reported as passing, for example:

- a. There is no validated sample preparation method to ensure the solid sample goes into solution.
- b. Between the original and retest, there were changes to the analytical method.
 - i. The organic solvent used to dissolve the sample was changed from (b) (4) to (b) (4).
 - ii. The HPLC mobile phase ratio and organic solvent were changed from (b) (4) to (b) (4).

OBSERVATION 5

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

Specifically,

Your firm does not require, on a continual frequency, training for your laboratory analysts necessary for

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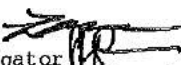
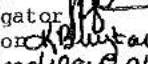
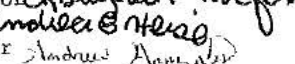
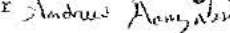
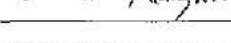
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them to carry out their assigned responsibilities. Your firm does not require your analysts to read in its entirety and/or train on any of the USP procedures even though you report laboratory testing according to USP <85> BACTERIA ENDOTOXIN TEST and USP <71> STERILITY TESTS.

*** DATES OF INSPECTION:**

08/05/2013(Mon), 08/06/2013(Tue), 08/07/2013(Wed), 08/08/2013(Thu), 08/13/2013(Tue), 08/14/2013(Wed), 08/15/2013(Thu), 08/16/2013(Fri), 08/19/2013(Mon), 08/20/2013(Tue), 08/21/2013(Wed), 08/22/2013(Thu), 08/23/2013(Fri), 08/24/2013(Sat), 08/30/2013(Fri)

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	Andrew J. Gonzales, Investigator 	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."