DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/15/2017-9/26/2017* FEI NUMBER 3013030904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nancy J. Costlow, PharmD, RPh, Director

FIRM NAME	STREET ADDRESS
Atlas Pharmaceuticals, LLC	711 E. Carefree Highway Suite 107
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-0101	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm failed to perform and document an investigation into a media fill failure and also determine the root cause of the contaminant. Your firm's first media fill, lot number (b) (4), (b) (6) performed on 06/06/2017 by your Operator, Pharmacy Technician (b) (6), failed. One (1) vial was observed to have growth on 06/12/2017. Your firm identified the contaminant as *Bacillus licheniformis*. Your written procedure titled, "S-09 Media Fill Trial" states that (b) (4) ." Furthermore, you produced Ascorbic Acid, lot number S-60008 (50 ml Amber Vial) on 6/22/2017. You distributed product to a customer on 07/07/2017 and 08/30/2017. This initial media fill failure was repeated multiple times, with the deficiencies listed below.

1. When your firm had Operator, Pharmacy Technician (b) (6)., repeat his media fill as lot number (b) (4), (b) (6) (b) (4) on 06/23/2017, he did not perform a repeat of a full batch size, which consists of filling (b) (4) (b) (4) He repeated only a portion of a batch size in (b) (4) Your written procedure titled, "S-09 Media Fill Trial" does not specify how failed media fill trials are to be repeated.

2. Your Operator, Pharmacy Technician (b) (6) performed a media fill as lot number (b) (4) on 08/30/2017, which had failing results. For media fill lot number (b) (4) , your firm documented that

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growth was observed on Day (b)(4) of incubation and that no growth was observed on Day (b)(4) of incubation. Your firm stated this was because the media fill vial that showed growth on Day (b)(4) was removed, plated, and sent to your contract laboratory for testing. This vial was not allowed to complete a full (b)(4) day incubation before its removal.

B. Your contract service provider performed smoke studies on 05/22/2017, which were captured on video. These smoke studies were documented to pass in the report titled, "Atlas Pharmaceuticals Pharmacy Cleanroom Suite Testing Tour, Project: ATL170522". I reviewed videos of the smoke studies performed on 05/22/2017, which revealed the items listed below.

1. Airflow visualization (i.e. "smoke studies") was not performed under dynamic conditions that accurately represent your firm's aseptic manufacturing procedures.

2. The smoke study videos indicate airflow is not unidirectional. There is apparent turbulence and airflow appears slow in the critical work surface.

C. Your firm's (b) (4) and (b) (4) sterilization validations titled, "VP16-Validation Protocol for the Removal of Endotoxins from Vials, Lids, and Rubber Stoppers" and "VP08-Validation Protocol for Endotoxin Removal and Sterility of Tubing" are deficient in that:

1. Both VP16 and VP08 validation reports only show a (b) (4) of endotoxin and not a (b) (4) (b) (4)

2. There is no apparent determination of "cold spots" by (b) (4) n your (b) (4) (b) (4) chamber.

3. Hold time/expiration dating data of sterilized items are not indicated in your VP16 and VP08 validation reports.

4. (b) (4) cycles parameters used by your firm to (b) (4) glassware are not documented in your glassware (b) (4) batch records, including those that were used to sterilize items used during commercial production of Ascorbic Acid lot number S-60008 on 6/22/2017.

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D. Your media fill qualification program specified in written procedure titled, "S-09 Media Fill Trial" and protocol titled, "Media Fill Procedure", is deficient. Examples included, but were not limited to the items listed below.

1. Your firm does not document how Operators conduct media fills or process simulations under worst-case conditions, including simulations of environmental and personnel monitoring.

2. Your Media Fill Batch Record is deficient in that it does not document how many vials were filled by each Operator during the media fills, if any vials have been rejected, and the final quantity of vials that have been incubated.

3. Media Fill Log sheets are used by your firm to document results of media vial inspections. The log sheets are deficient in that they do not document incubator temperatures. Your firm's procedure specifies the media fill vials are to be incubated at (b) (4) °C for the (b) (4) and at (b) (4) °C for the (b) (4) . The dates of incubation per temperature are not specified in the log sheets. The log sheets also show that a quantity of vials had a result of "G" and "P" (growth and particulates) without full explanation.

4. Your firm used amber colored vials for media fills on 06/06/2017, 06/12/2017, 06/15/2017, 06/23/2017, 08/30/2017, 08/31/2017, 09/05/2017, 09/06/2017, and 09/07/2017.

E. On 09/19/2017, I observed Operator, Pharmacy Technician (b) (6) transfer materials for Ascorbic Acid 500mg/mL Injection in 50mL production from an ISO 8 classified area, (ISO 8 Mixing Room and ISO 8 Storage Room) into a purported cleaner ISO 7 classified area. Materials included, but are not limited to, the items that are listed below.

- glassware such as flasks and graduated cylinder
- (b) (4) packets of tubing, forceps, caps, and stoppers
- Ascorbic Acid bulk solution in two (2) large beakers

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I observed Operator(b) (6) gather these items and place them on a cart that was located in the ISO 8 Mixing Room. This cart was transported to the pass-through chamber that leads into the ISO 7 Clean Room(b) (4) Operator(b) (6) placed the items into the pass-through chamber without decontaminating the items before placing them inside of the pass-through.

In addition, I observed that Operator (b) (6) removed the items from the pass-through chamber and placed them directly on shelves and/or on the cart located within the ISO 7 Clean Room(b) (4) without decontaminating the items.

OBSERVATION 2

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

Specifically,

A. There are deficiencies in environmental monitoring, specifically, viable air, surface, and personnel monitoring records. Examples include, but are not limited to, the items listed below.

1. Your "Cleanroom Media Samples" log that is used by your firm to document environmental monitoring results for viable air samples and surface samples does not indicate pass/fail specifications.

2. There are no results for viable air and surface monitoring for the date of production of Ascorbic Acid 500mg/mL Injection in 50mL, lot S-60008 on 06/22/2017.

3. There are multiple instances of poor documentation practices, such as late entries and not indicating the number of days incubated at(b) (4)°C observed on the "Cleanroom Media Samples" log and late entries on the "Routine Fingertip Sampling Form".

4. The(b) (4)fingertip and (b) (4) (b) (4) body sampling forms appear to have missing dates for both sterile production Operators, specifically on 06/06/2017 and on 06/22/2017, when media fill trials and sterile drug production occurred.

5. (b) (4) (b) (4) body sampling is missing multiple weeks in July 2017.

6. Your firm included an "Addendum" to state your employees forgot to enter data on 06/22/2017; however, the log sheets indicate a sampling occurred on 06/23/2017.

B. Your firm's BMS (building management system) is not adequate, because Alert and Alarm settings do not correspond with the established specifications in your written procedures. As such, excursions from specified parameters are not always identified.

Examples of parameters observed to be outside of specifications and the discrepancies between written procedures and BMS settings include, but are not limited to the items indicated in the tables below.

Applicable Written Procedures (Standard Operating Procedures, SOPs)

SOP Number	SOP Title	SOP Version	SOP Date
S-14	Environmental Monitoring of the Sterile Laboratory	2	06/05/2017
S-14	Environmental Monitoring of the Sterile Laboratory	3	07/14/2017
S-13	Sterile Environment and Processing Specifications	2	06/05/2017
Q-13	Monitoring Temperature Controlled Equipment	0	02/02/2017

June 2017 to July 2017; Procedure S-14 Version 2 Was Effective

Examples of Parameters Observed Outside Specifications

Date of Weekly Report	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Reading of Value(s) Outside of Specifications
16 to 22 June 2017	(b) (4) - ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%
24 to 30 June 2017	(b) (4) - ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%
01 to 07	(b) (4) - ISO 7 Clean Room (b) (4)	ISO Class 7 Rooms	(b) (4)°C

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June 2017	Temperature	(b) (4)°F ((b) (4) °C)	
08 to 15 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) C)	(b) (4)°C
16 to 22 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F (b) (4) °C)	(b) (4)°C
24 to 30 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) °C)	(b) (4)°C
24 to 30 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%
01 to 07 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) C)	(b) (4)°C
08 to 15 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) °C)	(b) (4)°C
16 to 22 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) °C)	(b) (4)°C
24 to 30 June 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) °C)	(b) (4)°C
08 to 15 June 2017	(b) (4) -Incubator (b) (4) in Non-ISO Hallway	Incubator temperatures (b) (4)°C; *however,* media fill sample incubations require (b) (4)°C incubation for (b) (4) days followed by (b) (4)- (b) (4)°C for (b) (4) days	(b) (4)-(b) (4)°C with *neither* incubator set at (b) (4)-(b) (4)°C from (b) (4) June 2017
08 to 15 June 2017	(b) (4) -Incubator (b) (4) in Non-ISO Hallway	Incubator temperatures (b) (4)°C; *however,* media fill sample incubations require (b) (4)°C incubation for	(b) (4) °C with *neither* incubator set at (b) (4)°C from (b) (4) June 2017

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		(b) (4) days followed by (b) (4) (b) (4)°C for (b) (4) days	
16 to 22 June 2017	(b) (4) -Incubator (b) (4) in Non-ISO Hallway	Incubator temperatures (b) (4)°C; *however,* media fill sample incubations require (b) (4)°C incubation for (b) (4) days followed by (b) (4) (b) (4)°C for (b) (4) days	(b) (4) (b) (4) with *neither* incubator set at (b) (4)°C
16 to 22 June 2017	(b) (4) -Incubator (b) (4) in Non-ISO Hallway	Incubator temperatures (b) (4)°C; *however,* media fill sample incubations require (b) (4)°C incubation for (b) (4) days followed by (b) (4) (b) (4)°C for (b) (4) days	(b) (4) °C with *neither* incubator set at (b) (4)°C
01 to 07 July 2017	(b) (4) ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%
01 to 07 July 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F ((b) (4) °C)	(b) (4)°C
01 to 07 July 2017	(b) (4)- ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%
01 to 07 July 2017	(b) (4)- ISO 7 Clean Room (b) (4) Temperature	(b) (4)°F (b) (4) °C)	(b) (4)°C
01 to 07 July 2017	(b) (4) -Incubator (b) (4) in Non-ISO Hallway	Incubator temperatures (b) (4)°C; however, media fill sample incubations require (b) (4)°C incubation for	(b) (4) °C with *neither* incubator set at (b) (4)°C from (b) (4) July 2017

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Date of Weekly Report	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Reading of Value(s) Outside of Specifications
		(b)(4) days followed by (b)(4) (b)(4)°C for (b)(4) days	
01 to 07 July 2017	(b)(4) -Incubator (b)(4) in Non-ISO Hallway	Incubator temperatures (b)(4)°C; *however*, media fill sample incubations require (b)(4)°C incubation for (b)(4) days followed by (b)(4) (b)(4)°C for (b)(4) days	(b)(4) °C with *neither* incubator set at (b)(4)°C from (b)(4) July 2017

Discrepancies Between BMS Settings and Written Procedures

SOP Number and Version	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Setting; Low to High Action Limits; Month in 2017
S-14; Version 2	(b)(4)- ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%; June 2017
S-14; Version 2	(b)(4)- ISO 7 Clean Room (b)(4) Temperature	ISO Class 7 Rooms (b)(4)°F ((b)(4) °C)	(b)(4)°C; June 2017
S-14; Version 2	(b)(4)- ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%; June 2017
S-14; Version 2	(b)(4)- ISO 7 Clean Room (b)(4) Temperature	ISO Class 7 Rooms (b)(4)°F ((b)(4) °C)	(b)(4)°C; June 2017
Q-13; Version 0	(b)(4) -Incubator (b)(4) in Non-ISO Hallway	Incubator temperatures (b)(4)°C; *however*, media fill sample incubations require (b)(4)°C incubation for (b)(4) days followed by (b)(4)	(b)(4)°C; June 2017

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SOP Number and Version	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Setting; Low to High Action Limits; Month in 2017
		(b)(4)°C for (b)(4) days	
Q-13; Version 0	(b)(4) -Incubator (b)(4) in Non-ISO Hallway	Incubator temperatures (b)(4)°C; *however*, media fill sample incubations require (b)(4)°C incubation for (b)(4) days followed by (b)(4) (b)(4)°C for (b)(4) days	(b)(4)°C; June 2017

July 2017; Procedure S-14 Versions 2 and 3 Were Effective

Examples of Parameters Observed Outside Specifications

Date of Weekly Report	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Reading of Value(s) Outside of Specifications
08 to 14 July 2017	(b)(4) ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%
15 to 21 July 2017	(b)(4) ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%
08 to 14 July 2017	(b)(4)- ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%
15 to 21 July 2017	(b)(4)- ISO 7 Clean Room (b)(4) Humidity	ISO Class 7 Rooms (b)(4)%	(b)(4)%

Discrepancies Between BMS Settings and Written Procedures

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SOP Number and Version	Facility Location/Description	SOP Established Specification; Low to High Action Limits	BMS Setting; Low to High Action Limits; Month in 2017
S-14; Version 3	(b) (4) ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%; July 2017
S-14; Version 3	(b) (4) ISO 7 Clean Room (b) (4) Temperature	ISO Class 7 Rooms (b) (4)°F (b) (4) °C)	(b) (4)°C; July 2017
S-14; Version 3	(b) (4)- ISO 7 Clean Room (b) (4) Humidity	ISO Class 7 Rooms (b) (4)%	(b) (4)%; July 2017
S-14; Version 3	(b) (4) ISO 7 Clean Room (b) (4) Temperature	(b) (4)°F ((b) (4) °C)	(b) (4)°C; July 2017

C. Your firm does not have established records that your employees use to document and show that they actively monitor the BMS at specified times and frequencies. Your firm relies fully on the BMS and queries reports from the system.

OBSERVATION 3

There is a lack of written procedures describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically,

A. Your firm's written procedure titled, "S-10 Sterile Lab Cleaning Version 1" and the firm's "Cleaning Log(s)" for the Non-Sterile Compounding (production) Room; ISO 8 Areas; and ISO 7 Areas are deficient. Deficiencies include, but are not limited to the items listed below.

1. Specific details regarding your cleaning method are not included in procedure S-10. Examples include, but are not limited to: how a (b) (4) is performed; how cleaning agents are (b) (4); the specific

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contact time for each cleaning agent; and how large of an area can be cleaned before (b) (4) (b) (4) the (b) (4) and in which order the cleaning agents are to be used.

2. The Cleaning Logs do not specify the following: the room(s) and/or locations in the ISO 7 areas that were cleaned; the lot number(s) and expiration date(s) of cleaning agents that were used; and (b) (4) cleaning as required per procedure S-10 was not always performed and/or documented.

B. Your firm performed an inadequate disinfectant testing effectiveness study for each disinfectant for its intended use. The study titled, "2017 Cleaning Validation" performed in May 2017, failed to specify facility cleaning procedures that were used during this study.

C. The (b) (4) Cleaner" used by the firm is not a sterile cleaning agent and it is used to clean the ISO 7 Clean Rooms, including wall surfaces. I observed this practice on 08/17/2017 inside of Clean Room (b) (4)

OBSERVATION 4

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, there are deficiencies in your firm's employee training. Examples include, but are not limited to the items listed below.

A. Training was deficient for a Quality Assurance employee. Your firm's Quality Assurance Technician performed her duties prior to receiving and completing cGMP and Quality training courses. It was also observed that the Quality Assurance employee signed off and approved documents despite multiple failures to meet specifications. Examples include, but are not limited to: environmental monitoring records and media fill records.

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B. Your firm stated that Operators were trained by an external company to conduct (b) (4) testing. However, as late as 08/25/2017, Operators who conduct (b) (4) testing did not have documentation to show that this training was completed.

OBSERVATION 5

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically, the alert and action levels specified in your written procedure titled, "Q-17 Testing and Release Criteria for Sterile Products" were established per the recommendation of your consultant and not according to any additional statistical basis or scientific rationale. Procedure Q-17 states that (b) (4) . If (b) (4) % of finished product vials in a lot fail visual inspection, procedure Q-17 requires your firm to perform a (b) (4)

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm does not have an established written procedure to define solution expiration dating.
In the ISO 8 Mixing Room on 09/19/2017, I examined (b) (4) and (b) (4) solutions which are used to adjust the pH of drug product bulk solutions. Each solution had different lengths assigned for expiration dating. There were examples of (b) (4) , (b) (4) (b) (4) expiration dates assigned to different lots of these solutions that are prepared at the firm. Examples included, but were not limited to the solutions listed below.

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(b) (4)

OBSERVATION 7

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Your firm's written procedure titled, "E-01 (b) (4) Use, Cleaning and Maintenance" requires that maintenance and cleaning of the (b) (4) is to be performed (b) (4), (b) (4), (b) (4), (b) (4), and (b) (4). Your firm has no documentation to show that such maintenance and cleaning activities are performed per procedure E-01.

B. Your firm has a pH meter located in the ISO 8 Mixing Room. This pH meter is documented as calibrated (b) (4) however, your calibration log does not specify which pH reference standards are used or include calibration reading results.

OBSERVATION 8

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephanie A Slater, Investigator	DATE ISSUED 9/26/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/15/2017-9/26/2017* FEI NUMBER 3013030904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Nancy J. Costlow, PharmD, RPh, Director	
FIRM NAME Atlas Pharmaceuticals, LLC	STREET ADDRESS 711 E. Carefree Highway Suite 107
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-0101	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing and holding.

Specifically, there are deficiencies in the "Master Formulation Record" (batch record) for the Ascorbic Acid 500mg/mL Injection in 50mL drug product, lot number S-60008 dated 06/22/2017 and for the Media Fill Challenge (media fill batch record) dated 06/06, 12, 15, and 23/2017. Examples of batch record deficiencies included, but were not limited to the items listed below.

- Missing equipment lot numbers;
- Missing lot numbers and missing expiration or use by date for sterilized items, such as (b) (4) containers and closures;
- No documentation by Operator(s) to show that each step was completed; and
- No documentation of the product (b) (4) test.

OBSERVATION 9

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically, on 8/15/2017, I observed vials of Ascorbic Acid lot number S-60008 that were stored as "Released" (by Quality) product in your firm's Active Stock and Shipping Area. The product label on Ascorbic Acid lot # S-60008 instructs users to store the product at 2°C to 8°C; however, these vials were being stored at ambient temperature.

OBSERVATION 10

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephanie A Slater, Investigator	X Stephanie A Slater Investigator Signed By: Stephanie A Slater -S Date Signed: 09-26-2017 11:06:52	9/26/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/15/2017-9/26/2017*
	FEI NUMBER 3013030904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Nancy J. Costlow, PharmD, RPh, Director	
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CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-0101	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, your firm has sent "stability samples" to your third party laboratory to test container/closure, identity, and potency. However, no protocols or documents exist to indicate parameters, including, but not limited to: dates when samples were placed on stability; dates when samples were pulled for stability; or stability sample storage conditions.

OBSERVATION 11

The labels of your outsourcing facility's drug products are deficient.

Specifically,

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

- The statement, "Not for resale," is not on your drug product labels. Labels for the following drug product do not contain this statement:
    - Ascorbic Acid Injection 500 mg/mL, 50 mL vial

*DATES OF INSPECTION

8/15/2017(Tue), 8/16/2017(Wed), 8/17/2017(Thu), 8/18/2017(Fri), 8/21/2017(Mon), 8/22/2017(Tue), 8/23/2017(Wed), 8/24/2017(Thu), 9/18/2017(Mon), 9/19/2017(Tue), 9/20/2017(Wed), 9/26/2017(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephanie A Slater, Investigator	X Stephanie A Slater Investigator Signed By: Stephanie A. Slater -S Date Signed: 09-26-2017 10:00:52	9/26/2017