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	05/03/2021-05/21/2021* FEI NUMBER 3013030904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nickolaus R. Banda, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Atlas Pharmaceuticals, LLC	711 E Carefree Hwy Ste 107
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-0103	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, personnel and environmental monitoring specifications for the ISO 5 areas appear inadequate and the approved environmental monitoring procedure does not always require an investigation when viable microorganisms are recovered. The action limit for gloved fingertips of aseptic processing personnel during routine sampling is (b) (4) CFU. A gloved fingertip sample exhibited growth (b) (4) CFU, on 06/17/20 after production of buprenorphine, 0.15 mg/mL injection, lot S-60357, released 07/13/20. This value was below the action limit, and there was no investigation of the potential impact to this lot.

OBSERVATION 2

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

Specifically, the visual inspection procedure and the training of personnel to perform visual inspection appear deficient.

A) One QA specialist identified (b) (4) vials (b) (4) %) contained particulates during visual inspection of dexmedetomidine HCl, 1 mg/mL injection, lot S-60399. This result exceeded the initial inspection action limit specification of less than (b) (4) %. The suspect units were (b) (4) QA specialist identified (b) (4) vials (b) (4) %) contained particulates during the reinspection approximately 15 days

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas L Hunt, Investigator	X Nicholas L Hunt Investigator Signed By: Nicholas L. Hunt -S Date Signed: 06-11-2021 05:44:56	06/11/2021

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later. This was below the reinspection action limit (b) (4)%. QA released this lot without a written investigation of the discrepancy between the (b) (4) inspections performed by qualified personnel.

B) The reinspection process defined in the approved visual inspection procedure, Q-23 Visual Inspection of Sterile Injectable Finished Product, requires QA personnel to (b) (4) The procedure does not ensure all suspect units are segregated from the lot, carefully examined, and excluded from release by QA.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

A) The firm did not conduct media fills prior to resuming sterile production after two extended shutdowns for repairs.

a. There was no media fill prior to reopening the cleanroom to produce sterile drugs on (b) (4)/20. The facility was shut down approximately (b) (4) to repair water damage caused by (b) (4) water system leak on (b) (4)20. There was inadequate assurance production processes were suitable to produce (b) (4) of sterile human drugs and approximately (b) (4) of sterile veterinary drugs prior to completing media fills on 02/03/21.

b. There was no media fill prior to reopening the cleanroom to produce sterile drugs on (b) (4)/20. The facility was shut down approximately (b) (4) to repair drywall and repaint the sterile production suite. There was inadequate assurance production processes were suitable to produce approximately (b) (4) of sterile human drugs and approximately (b) (4) of sterile veterinary drugs prior to completing media fills on 02/03/21.

B) The firm did not perform media fills (b) (4) for all active sterile compounders per the approved

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procedure.

a. There is no media fill documented for (b) (6) between approximately 10/21/19 and 02/03/21. (b) (6) produced approximately (b) (4) sterile lots after 04/21/20.

b. ~~There is no media fill documented for (b) (6) between approximately 12/26/19 and 05/11/21. (b) (6) produced approximately (b) (4) sterile lots after 06/26/20.~~

c. There is no media fill documented for (b) (6) between approximately 09/05/19 and 02/03/21. (b) (6) produced approximately (b) (4) sterile lots after 03/05/20.

C) The firm produced (b) (4) batches of sodium chloride injection 0.9% and 23.4% as an aseptic process verification after the sterile production area was shut down for repairs from approximately (b) (4) until 04/07/20. Sodium chloride injection is (b) (4) sterilized drug and does not appear suitable to verify sterile production and control processes are adequate.

D) On 09/21/20, a contractor tested drywall for moisture content in areas damaged by (b) (4) water system leak on approximately (b) (4) /20. The contractor's report identified the drywall in two shared walls between the non-sterile production area and the ISO 7 Cleanroom (b) (4) had excessive moisture content with values of (b) (4) % and (b) (4) %. The contractor's report indicates excessive moisture/wet are values (b) (4) %. There is no documentation which verifies the moisture content in the drywall was within the relatively dry/normal range of (b) (4) % prior to resuming construction and reopening the cleanroom to produce sterile drugs on (b) (4) /20. There was inadequate assurance sterile production areas were suitable to produce (b) (4) of sterile human drugs and approximately (b) (4) of sterile veterinary drugs prior to completing media fills on 02/03/21.

***DATES OF INSPECTION**

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5/03/2021(Mon), 5/04/2021(Tue), 5/05/2021(Wed), 5/06/2021(Thu), 5/07/2021(Fri), 5/10/2021(Mon), 5/11/2021(Tue), 5/12/2021(Wed), 5/13/2021(Thu), 5/14/2021(Fri), 5/17/2021(Mon), 5/18/2021(Tue), 5/19/2021(Wed), 5/20/2021(Thu), 5/21/2021(Fri)

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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 judgment, 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."