DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 ORAPHARM4_RESPONSES@fda.hhs.gov	3/16/2020-3/20/2020
	FEI NUMBER 1643045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan D. Shoemaker, VP / GM

FIRM NAME	STREET ADDRESS
OSO BioPharmaceuticals Manufacturing, LLC (AMRI)	4272 & 4200 Balloon Park Rd NE and 4401 Alexander Blvd NE
CITY, STATE, ZIP CODE, COUNTRY Albuquerque, NM 87109-5801	TYPE ESTABLISHMENT INSPECTED Parenteral Drug Manufacturer

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.

For Example:

a) Operators were observed with goggles having (unprotected) holes in the top and bottom. Goggles used by operators to protect against exposed skin while working in the grade (b) (4) areas during aseptic operations having unprotected holes creates a lack of defense against a source of particles generated by, and microorganisms shed from, the face.

b) Operators reach above shoulder and head level to gather items stored on shelving within Filling Room (b) (4), actions which may generate particles bellowing from beneath gowning. Operators were observed reaching above head height (observed 3/16/2020 Filling Line (b) (4)) to sanitize (b) (4) doors after interventions, actions which may generate particles bellowing from beneath gowning.

c) Operators were observed sanitizing gloves with sterile (b) (4) and then immediately conducting aseptic operations without pausing for a specific amount of pre-determined contact time (observed 3/16 & 3/18/2020) in Filling Rooms (b) (4) and (b) (4). No contact time has been developed by your firm in a program to determine efficacy

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michael A Charles, Investigator - Dedicated Drug Cadre	X Michael A Charles Investigator - Dedicated Drug Cadre Signed By: Michael A. Charles -S Date Signed: 03-20-2020 15:52:25	3/20/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 ORAPHARM4_RESPONSES@fda.hhs.gov	3/16/2020-3/20/2020
	FEI NUMBER 1643045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan D. Shoemaker, VP / GM	
FIRM NAME OSO BioPharmaceuticals Manufacturing, LLC (AMRI)	STREET ADDRESS 4272 & 4200 Balloon Park Rd NE and 4401 Alexander Blvd NE
CITY, STATE, ZIP CODE, COUNTRY Albuquerque, NM 87109-5801	TYPE ESTABLISHMENT INSPECTED Parenteral Drug Manufacturer

in removing microbes from the surfaces of (b) (4) gloves, (b) (4) and (b) (4) surfaces (utilizing sterile (b) (4) solution) found in the aseptic core.

d) Operators were observed on 3/16/2020 in Filling Room (b) (4) re-using the same surface of wipes when cleaning (b) (4) surfaces after interventions. For example, one Operator was observed wiping an entire (b) (4) inner door with the same folded surface of a single wipe.

e) Operators in aseptic areas may change gloves routinely, but environmental sampling of these gloves is not always conducted to collect complete environmental monitoring data. (b) (4) the filling room, for example, and (b) (4), but not in the case of all routine glove changes.

f) In Filling Line (b) (4), Operators may fully sit on a bench located in the grade (b) (4) area adjacent to the filling operation located in grade (b) (4). Also, Operators fully sit down in a chair at a desk in the grade (b) (4) area while conducting paperwork associated with fill checks.

g) Detachable gloves from (b) (4) (i.e., (b) (4) gloves) in the (b) (4) are (b) (4) of sterile drug product in Filling Line (b) (4).

h) Your SOP, Cleaning/Decontaminating and Sanitization of the Aseptic Filling Areas and Controlled Support Areas, for disinfecting the aseptic processing areas used in manufacturing of sterile drugs, does not ensure validated disinfectant contact times are achieved.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michael A Charles, Investigator - Dedicated Drug Cadre	X Michael A Charles Investigator - Dedicated Drug Cadre Signed By: Michael A. Charles -S Date Signed: 03-20-2020 15:52:25	3/20/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 ORAPHARM4_RESPONSES@fda.hhs.gov	3/16/2020-3/20/2020 FEI NUMBER 1643045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan D. Shoemaker, VP / GM	
FIRM NAME	STREET ADDRESS
OSO BioPharmaceuticals Manufacturing, LLC (AMRI)	4272 & 4200 Balloon Park Rd NE and 4401 Alexander Blvd NE
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Albuquerque, NM 87109-5801	Parenteral Drug Manufacturer

i) Parts that are (b) (4) (sterilized) for use in Filling Rooms (b) (4) &(b) (4) where sterile drugs are aseptically filled are packaged in containers that are (b) (4) instead of using hermetically sealed containers, therefore not assuring continued sterility of the equipment prior to opening and use on the filling line after transfer of these materials from the (b) (4) through Grade (b) (4) areas and into the Grade (b) (4) areas in the filling rooms.

j) (b) (4) monitoring (b) (4) in the aseptic filling lines are not completely and ideally situated in order to fully represent filling conditions, i.e., they are not entirely positioned in locations to optimize detection of potential product contamination. (b) (4) and (b) (4) monitoring is conducted in aseptic Filling Lines (b) (4) & (b) (4) *except* that (b) (4) air monitoring (i.e., (b) (4)) in aseptic filling lines (where sterile drug products are aseptically filled) is not conducted in locations within the airflow and immediately adjacent of (b) (4) loading intervention activities (within the filling line) in order to optimize detection of potential (b) (4) environmental contaminants in Lines (b) (4) & (b) (4). And, in Line (b) (4), there is no (b) (4) air monitoring in the immediate vicinity where (b) (4) and in the vicinity where interventions are conducted by operators within the grade (b) (4) area where (b) (4) may fall down on the (b) (4) and have to be removed. Also, (b) (4) air monitoring is not conducted where (b) (4) travel from (b) (4) to the point of being removed from the filling line for (b) (4), which is a distance of approximately (b) (4), on Filling Line (b) (4).

OBSERVATION 2

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

For example:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael A Charles, Investigator - Dedicated Drug Cadre X Michael A Charles Investigator - Dedicated Drug Cadre Signed By: Michael A. Charles -S Date Signed: 03-20-2020 15:52:25	3/20/2020

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 ORAPHARM4_RESPONSES@fda.hhs.gov	3/16/2020-3/20/2020
	FEI NUMBER 1643045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jonathan D. Shoemaker, VP / GM

FIRM NAME	STREET ADDRESS
OSO BioPharmaceuticals Manufacturing, LLC (AMRI)	4272 & 4200 Balloon Park Rd NE and 4401 Alexander Blvd NE
CITY, STATE, ZIP CODE, COUNTRY Albuquerque, NM 87109-5801	TYPE ESTABLISHMENT INSPECTED Parenteral Drug Manufacturer

a) Investigations for dead insects found in manufacturing areas continues without verification that actions to prevent bugs from entering production areas is accomplished. For example, Deviation Report 673649 created 13 June 2019 reported multiple dead moths found in Filling Room (b) (4). Deviation 679496 created 12 August 2019 reported a dead insect in Filling Room (b) (4). Deviation Report 682187 created 27 August 2019 found a dead spider in Filling Room (b) (4). Deviation 14979 created 30 January 2020 found a dead spider in the grade (b) (4) space of Filling Room (b) (4).

b) When particles are found during 100% visual inspection processes for parenteral drugs, investigations are not opened to determine root cause and implement corrective and preventative actions to insure that operations that generate inclusion of visible particles are prevented. For example, the visual inspection of (b) (4) from lot (b) (4) produced in (b) (4) found one black particle, one black fiber, and one red particle which were not required to be fully identified and investigated as a deviation.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Michael A Charles, Investigator - Dedicated Drug Cadre

X Michael A Charles
Investigator - Dedicated Drug Cadre
Signed By: Michael A. Charles -S
Date Signed: 03-20-2020
15:52:25

DATE ISSUED
3/20/2020

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."