DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	4/5/2023-4/14/2023* FEI NUMBER 1818977

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paula A. Del Papa, Vice President & General Manager Manufacturing Operations

FIRM NAME	STREET ADDRESS
Par Sterile Products LLC	870 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, MI 48307-1740	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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. There is not complete documentation of interventions performed during batch record execution. For example, during video review of the filling operations of (b) (4) Injection, USP (b) (4) Lot #(b) (4), we observed the following:

1. Multiple interventions occurring at the same location where only one intervention was documented;

2. Separate interventions performed at different places on the filling line, where only one intervention was documented—simulation of this practice during aseptic process simulations was unable to be provided; and

3. Interventions performed that are not visualized during airflow visualization studies nor simulated in aseptic process simulations (media fills).

The filling record for (b) (4) lot #(b) (4) was reviewed by Quality on 02/22/2023 and the batch was subsequently released on 04/04/2023.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joseph A Piechocki, Investigator Joohi Castelvetere, Investigator - Dedicated Drug Cadre Jacob G Lutz, Investigator X Joseph A Piechocki Investigator Signed By: Joseph A. Piechocki Jr -S Date Signed: 04-14-2023 14:05:13	4/14/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	4/5/2023-4/14/2023* FEI NUMBER 1818977

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paula A. Del Papa, Vice President & General Manager Manufacturing Operations

FIRM NAME	STREET ADDRESS
Par Sterile Products LLC	870 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, MI 48307-1740	Manufacturer

B. Cleaning operations used to clean and disinfect Line(b) (4) prior to setup did not follow governing procedure VV-SOP-00286, "Environmental Control Sanitation", effective date 01/04/2023. For example, during the cleaning video review of pre-production cleaning and disinfection of Line(b) (4) for (b) (4) Injection, USP (b) (4) Lot #(b) (4), we observed that the disinfection of the (b) (4) within the Grade A area was not performed following the (b) (4) and (b) (4) technique, with (b) (4) strokes, and (b) (4), as required per procedure.

C. Operations related to the setup of filling equipment on Line(b) (4) were not conducted following aseptic practices. For example, during the set-up of filling equipment within the Grade A area of Line(b) (4) for (b) (4) Injection, USP (b) (4) Lot #(b) (4), we observed the following:

1. Previously sanitized (b) (4) surrounding the Grade A area were frequently moved by the operations personnel. The (b) (4) were not subsequently disinfected after manipulation after the setup operations were completed.

2. Non-sterile components, including the Grade B exposed (b) (4) bags containing sterile needle holders, were brought into the Grade A area and placed on the vial in-feed to the filler. These bags were not disinfected prior to their entry into the Grade A area.

In addition, at the completion of setup and prior to exiting Line(b) (4), operators were observed disinfecting their hands with (b) (4) before conducting Personnel Monitoring. According to VV-SOP-00713, "Personnel Monitoring Program", effective date 10/13/2022, gloves are not to be sprayed with (b) (4) prior to (b) (4) sample exposure.

D. Operations related to the filling of (b) (4) lot #(b) (4) on Line(b) (4) were not always conducted

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	4/5/2023-4/14/2023*
	FEI NUMBER 1818977

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Paula A. Del Papa, Vice President & General Manager Manufacturing Operations

FIRM NAME	STREET ADDRESS
Par Sterile Products LLC	870 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, MI 48307-1740	Manufacturer

following aseptic practices. For example, we repeatedly observed filling operators resting forearms and holding hands below the waist, interacting with (b) (4) without disinfection, and moving hands between Grade A and Grade B spaces without frequent disinfection.

***DATES OF INSPECTION**

4/05/2023(Wed), 4/06/2023(Thu), 4/10/2023(Mon), 4/11/2023(Tue), 4/12/2023(Wed), 4/13/2023(Thu), 4/14/2023(Fri)

X Joohi Castelvetere
Investigator - Dedicated Drug Cadre
Signed By: Joohi Castelvetere -S
Date Signed: 04-14-2023 14:10:04

X Jacob G Lutz
Investigator
Signed By: 2002879082
Date Signed: 04-14-2023 14:11:10

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Joseph A Piechocki, Investigator
Joohi Castelvetere, Investigator - Dedicated Drug Cadre
Jacob G Lutz, Investigator

X Joseph A Piechocki
Investigator
Signed By: Joseph A. Piechocki Jr -S
Date Signed: 04-14-2023 14:05:13

DATE ISSUED
4/14/2023

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."