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	4/8/2019-4/15/2019* FEI NUMBER 1818977

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael D. Randolph, Senior Vice President, General Manager

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

OBSERVATION 1

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

Specifically,

Document PAR-ROC-SOP-00231 *Rules for Documentation of Product-Related Documents* allows for the use of documents other than the batch record to complete missing documentation of a critical step or data, however there is no requirement that the supporting document have the specific information missing from the batch record, for example:

A. In the batch record for media fill lot #(b) (4) , page 21 of 41, the verification signature for the count of rejected vials was documented on 30JUL2018 for work performed on 17JUL18 without reference to a document that shows the count of rejected vials. It was stated that rejected vials, if non-integral, are discarded after filling. No deviation was opened for this activity.
B. In the batch record for media fill lot #(b) (4) , page 18 of 41, the signature and date for the activity was recorded on 30JUL18 as being completed on 17JUL18. The referenced document, protocol SA-2018-L1-03, does not specifically show that the steps on page 18 of 41 were completed on 17JUL18, the signature and date in the protocol page 16 of 27 as referenced in discussions, is for the vials being transferred to microbiology for incubation. No deviation was opened for this activity.
C. In the Line Stoppage Form for media fill lot #(b) (4) , the line stoppages were recorded out of order. The second line stoppage on page 1 of 3 is documented as 1158 and restarting at 0021 on 13JUN18, while on page 2 of 3 the first line stoppage is listed as 0855 and restarting on 1111 on 12JUN18. Both stoppages were verified using protocol SA-2018-L1-02 page 13 of 23, which is the list of interventions performed,

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Michael D. Randolph, Senior Vice President, General Manager	
FIRM NAME PAR Sterile Products LLC	STREET ADDRESS 870 Parkdale Rd
CITY, STATE, ZIP CODE, COUNTRY Rochester, MI 48307-1740	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

and does not specifically state the times that the line was stopped. No deviation was opened for this activity.

***DATES OF INSPECTION**

4/08/2019(Mon), 4/09/2019(Tue), 4/10/2019(Wed), 4/11/2019(Thu), 4/12/2019(Fri), 4/15/2019(Mon)

X Shirshendu K Deb
Chemist/Biologist
Signed By: Shirshendu K. Deb -S
Date Signed: 04-15-2019 12:02:22

X Joseph T Madak
Chemist/Biologist
Signed By: 2002428117
Date Signed: 04-15-2019 12:03:01

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Sarah E Rhoades, Investigator Shirshendu K Deb, Chemist/Biologist Joseph T Madak, Chemist/Biologist Amy S Graf, Investigator	X Sarah E Rhoades Investigator Signed By: Sarah E. Rhoades -S Date Signed: 04-15-2019 12:01:51	4/15/2019

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."