DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration; ORA OPQO HQ 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 email: ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	11/17-25/2022
	FEI NUMBER 3014319211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. V. Saravana Kumar, M. Pharm, PhD, General Manager - QA

FIRM NAME	STREET ADDRESS
Steril-Gene Life Sciences Private Ltd.	NO. 45, Main Road, Mangalam Village, Villianur Co,
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Puducherry, IN 605110	Contract Sterile Drug Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1 (Production System)

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance. Specifically,

On 11/17/2022, I witnessed the aseptic filling process of [(b) (4)] injection USP [(b) (4)] % ([(b) (4)] mg/mL); batch # [(b) (4)] This product was filled in the [(b) (4)] filling machine line (Eq. ID: PRD/C/011) located in Plant Block-[(b) (4)] Around 11:35AM, I observed the operators' working practices in the aseptic filling area, while they were doing several filling line interventions (pushing some already filled vials with product from [(b) (4)] to the [(b) (4)] These vials were filled and stoppered but not [(b) (4)] and some of them were laydown on their sides. While stoppered vials (not [(b) (4)] moved from filling line conveyor to the [(b) (4)] machine (both Class A (ISO 5) areas) I noticed that some vials were laydown on their sides and the operator proceeds to open the Restricted Access Barrier (RAB) [(b) (4)] of the [(b) (4)] machine to access the vials [(b) (4)] where the filled [(b) (4)] vials were located. The operator just turn them to the upright position, but failed to document these interventions as part of the batch record activities that may impact product quality. In addition, all vials that were lay down on their sides (product contact with the [(b) (4)] stopper) without [(b) (4)] may leak and compromise the integrity/sterility of the product. The operator just turns the vials to the upright position to proceed with the [(b) (4)] process without having accountability of the number of lay-down vials for further investigation of possible impact in product quality due to filling process discrepancy on this batch.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Dennis Cantellops Paite	Dennis Cantellops Paite, Drug Investigator	11/25/2022