DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12225 Wilkins Avenue MPN4, Room #107 Rockville, MD 20852 (240)402-5557 Fax:(301)827-1498	12/2/2019-12/10/2019* FEI NUMBER 3014319211

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sulaiman Abdul Hai, Managing Director

FIRM NAME	STREET ADDRESS
Steril-Gene Life Sciences Pvt Ltd	No.45, Mangalam Main Road, Mangalam Village, Villianur Commune
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Puducherry, Puducherry India	Contract Sterile Drug Product 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:
Production Control System

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

On 12/05/2019, I observed (b) (4) employees conducting visual inspection process for (b) (4) mL vials of (b) (4), batch # (b) (4). I found that one (1) of the employees placed five (5) out of (b) (4) vials with what appears to be scratches on the surface of approximately (b) (4) mm on the approved vials bin. Your firm's employee failed to follow procedure #PR/086-09, "Visual Inspection of Filled Ampoules and Vials", effective date 10/22/2019 which establishes that scratches on the top of the surfaces should be rejected because are considered as minor defect.

Facility and Equipment System

OBSERVATION 2

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jose F Velez, Investigator

X Jose F Velez
Investigator
Signed By: 2000547088
Date Signed: 12-10-2019 15:46:57

DATE ISSUED
12/10/2019

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Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use.

Specifically,

During my review of Cleaning Validation Protocol #PR/CV/C/007-01, effective date 08/21/2018, I found that the sampling plan for the manufacturing tank, PRD/C/022 and sterile holding tank, PRD/C/023 were not adequate due to tank sampling drawings were missing the (b) (4) Additionally, there are no instructions to visually inspect the (b) (4) and a (b) (4) sensor (b) (4) of both tanks for residues. My review also found that there is a lack of sound justification for excluding the (b) (4) valve sampling location in the manufacturing tank but including the same sampling point location in the sterile holding tank. These tanks are used in the manufacturing of (b) (4) Solution (b) (4) Your firm failed to establish an adequate sampling plan in the cleaning validation for the manufacturing and sterile holding tanks to assure contact surface equipment are free of active pharmaceutical, chemical and microbial residues.

***DATES OF INSPECTION**
12/02/2019(Mon), 12/03/2019(Tue), 12/04/2019(Wed), 12/05/2019(Thu), 12/06/2019(Fri), 12/09/2019(Mon), 12/10/2019(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jose F Velez, Investigator	X Jose F Velez Investigator Signed By: 2000547088 Date Signed: 12-10-2019 15:46:57	12/10/2019