DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	8/3/2026-8/12/2026*
	FEI NUMBER 3014319211

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

FIRM NAME	STREET ADDRESS
Steril-Gene Life Sciences Private Ltd	No.45 Main Road , Mangalam Village, Villianur Commune
CITY, STATE, ZIP CODE, COUNTRY Puducherry, Puducherry, 605110 India	TYPE ESTABLISHMENT INSPECTED 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

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

1. During the set-up and aseptic filling of batch (b) (4) of (b) (4) (US market) on the (b) (4) filling line the following poor aseptic behavior and design was observed:

a. The loading of (b) (4) vials for transfer to the (b) (4) in a (b) (4) laminar air flow (LAF) (b) (4) is a (b) (4) process requiring (b) (4) Grade A area where (b) (4) vials are present.

i. The operators repeatedly reached over (b) (4) vials with their hands and forearms (b) (4)

ii. The operators placed (b) (4) of (b) (4) vials in the (b) (4) LAF in a sequence that resulted in the repeated disruption of the horizontal unidirectional airflow over vials.

b. During the setting of the (b) (4), the hands and forearm of the operator were used directly above the exposed (b) (4), blocking unidirectional airflow.

c. During collection of vials for periodic weight checks, the operator reached their hand and forearm over (b) (4) vials that were not removed.

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	Justin A Boyd, Investigator Martin M Kimani, Investigator X Justin A Boyd Investigator Signed By: 2000358686 Date Signed: 08-12-2026 12:43:15	8/12/2026

d. During unloading of the (b) (4) vial (b) (4) from the (b) (4) LAF to load into the (b) (4):

i. Operators reached over the (b) (4) vials with their hands and forearms.

ii. Operators removed (b) (4) in a sequence that resulted in the disruption of the horizontal unidirectional airflow over vials.

e. During interventions, the (b) (4) blocked unidirectional airflow:

i. Over the (b) (4) during an intervention to adjust (b) (4) tubing.

ii. Over open vials during interventions to remove fallen vials at the (b) (4).

iii. Over stoppers and the stopper bowl during addition of stoppers.

2. The Block (b) (4) filling line is used for commercial aseptic filling of (b) (4) (b) (4) for the US market. During the set-up and aseptic filling of (b) (4) (b) (4) batch (b) (4) on August 5, 2026, the following was observed:

a. There were six (b) (4) interventions to remove stuck bottles at the (b) (4). The operator was seen using their fingers in the conveyor to clear stuck bottles. The operator did not remove the exposed open bottles in the area at the end of the (b) (4) intervention.

b. There were two (b) (4) interventions to free stuck open bottles at the weight check station. No (b) (4) has been installed in this area. During this intervention the exposed open

bottles, including the stuck bottle, were not removed before filling continued. The barrier (b) (4) was (b) (4) an unnecessary amount of time before the intervention.

c. There were four (b) (4) interventions to remove loose (b) (4) caps near the (b) (4) (b) (4) capping station. The (b) (4) reached over open bottles (b) (4) that were not rejected. The (b) (4) was observed to touch the (b) (4) uncapped bottle that was not removed.

d. During the addition of bottles, an operator in the Grade B area hands a bag of bottles to an operator standing in the Grade A area. There is no disinfection of the bag after it is handled by these two operators. (b) (4) are later used to open the bag and pour them into the (b) (4) The operators allowed the outer surfaces of the bag to touch open bottles inside the (b) (4)

e. While securing the (b) (4), the operator used the (b) (4) directly above the (b) (4), disrupting unidirectional airflow.

3. The Block (b) (4) line is used for the commercial aseptic filling of (b) (4) ampules for the US market. During the aseptic filling of (b) (4) Injection batch (b) (4) on the (b) (4) line on August 6, 2026, the operator reached the (b) (4) over open ampules during an intervention to remove fallen ampules at the (b) (4), disrupting unidirectional airflow over the open ampules that were not removed.

4. On the (b) (4) aseptic filling lines used for commercial US market products, the environmental monitoring collected during the batch, including change of settle plates and active air monitoring, is done with (b) (4) interventions. There has been no thorough evaluation to determine whether any of this monitoring could be done using the (b) (4) instead of (b) (4) interventions.

5. The aseptic filling room and equipment were not appropriately maintained:

a. (b) (4) used on the (b) (4) filling line that were cleaned and packaged to go in the (b) (4) on August 3, 2026, were observed with discoloration. Procedure PR/503 requires (b) (4) with discoloration to be discarded.

b. On August 3, 2026, the BMS monitoring device was observed to be taped on the wall in the (b) (4) vial filling room and in the (b) (4) holding tank room. No maintenance work order had been opened for either.

c. The (b) (4) from the floor was peeling at the base of the (b) (4) vial filling machine.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

1. Filling machine pieces that directly contact the sterile (b) (4) packaging components are not sterilized. They are left in place between batches for disinfection on the (b) (4) line that is used to aseptically fill commercial batches of (b) (4) for the US market. These included (b) (4) bowls; the (b) (4) bowl, track, (b) (4) and the (b) (4) bowl.

2. The procedures for performing interventions during commercial aseptic filling lack specific instructions on rejection of potentially impacted containers. During media fills, there is no documentation of the number of containers rejected during interventions, only a total number of rejects during the batch counted from the reject bins. There is no assurance the units rejected during media fills are representative of commercial batches.

Further, during commercial batch (b) (4) of (b) (4) (US market), the interventions were not accurately recorded. There is no assurance that the frequency, duration, and type of interventions performed during the media fill appropriately challenge the aseptic process.

3. For the smoke studies on the (b) (4) aseptic filling line:

a. The smoke study only depicts one operator during loading of (b) (4) vials into (b) (4) into the (b) (4) LAF, while there are (b) (4) people present during commercial activities, with (b) (4) occasionally walking through the area. The camera angles and smoke do not allow for evaluation that air appropriately reaches the (b) (4) vials. The smoke appears to move from right to left across the operator's arm toward the (b) (4) vials when the operator stands on the side closest to the room door and uses the (b) (4) to move vials.

b. The smoke study for transfer from the (b) (4) LAF to the (b) (4) shows smoke that appears to move from the area the operators stand toward the (b) (4) where (b) (4) vials are placed. There is no smoke applied to the laminar flow over the (b) (4) that could demonstrate whether airflow moves across the operator's hands and towards the (b) (4) (b) (4) vials when their hands are in close proximity to the vials while positioning the (b) (4)

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

The batch record for batch (b) (4) of (b) (4) (US market) did not accurately record interventions during the aseptic filling operations. For example:

1. There were two (b) (4) interventions for adjusting the (b) (4). Neither was recorded in the

batch record. This is a new intervention that would require a deviation.

2. The batch record documented (b) (4) instances of the intervention for removal of fallen vial at the (b) (4) with the (b) (4), which is the maximum number allowed before a deviation is required. There were eighteen additional instances of this intervention that were not recorded in the batch record.

3. There was an intervention for adjusting the tubing at the filling station that was not recorded in the batch record. This is a new intervention that would require a deviation.

4. There was an intervention for clearing a jammed, broken vial at the (b) (4) not recorded in the batch record. This is a new intervention that would require a deviation.

5. Two interventions for addition of stoppers were not recorded in the batch record.

OBSERVATION 4

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

1. On August 5, 2026, non-dedicated equipment in Block (b) used in the manufacture of (b) (4) (b) (4) Tablets and (b) (4) Tablets for the US market had been cleaned, but was observed with visible residues and maintenance deficiencies:

a. (b) (4) PR/AG/261

i. Visible residues were observed on the (b) (4) in the (b) (4) bowl, on the underside of the (b) (4) bowl, in the (b) (4) duct area, and in the (b) (4).

ii. Sealant on the product contact (b) (4) assembly inside the (b) (4) bowl was missing pieces.

iii. There was damage to the product (b) (4), broken gaskets where the (b) (4) bowl is placed, and the (b) (4) portion of the (b) (4) bowl cover was torn in multiple places.

b. (b) (4) machine PR/530

i. The (b) (4) duct had residues and an unidentified piece of white material.

ii. Visible residues were observed inside the (b) (4) (b) (4), and in a gap in the gasket.

iii. The (b) (4) had visible residues in multiple locations.

c. (b) (4) PR/AR/007

i. There were visible residues on product contact surfaces.

ii. The gasket was damaged.

d. The (b) (4) PR/AG/092 had visible residues on product contact surfaces.

e. (b) (4) PR/AG/063

i. (b) (4) residues were observed around the (b) (4).

ii. The (b) (4) had a build-up of residues. When the equipment was moved, pieces of this residue fell to the floor.

2. On August 6, 2026, the (b) (4) in Room (b) (4) was labeled as "clean" but further review of the (b) (4) unit revealed that the (b) (4) was not clean and contained a (b) (4) (b) (4) residue. This equipment is used in the manufacture of (b) (4) mg (b) (4) for distribution to the US market.

3. On August 4, 2026, during the ongoing manufacture of (b) (4) Tablets batch (b) (4) (US Market), compression machine PR/AG/103 was leaking (b) (4)

4. On August 3, 2026, the cover designed to protect (b) (4) (b) (4) for the (b) (4) vial line was cracked.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

On August 4, 2026, during aseptic filling of batch (b) (4) of (b) (4) (US market):

1. Disinfectant was repeatedly sprayed above and near a settle plate and an active air sampling device.

2. Personnel monitoring of operators performing high risk Grade A activities were not performed immediately after the activities.

a. An operator performed two (b) (4) interventions to adjust the stopper bowl. This is a new intervention that required Grade A hand monitoring according to procedure MI/006, but none were collected.

b. (b) (4) operators performing (b) (4) loading of (b) (4) vials into the (b) (4) LAF left the filling room. Approximately 10 minutes later, they reentered the room, after disinfecting their hands while exiting and reentering. They reentered the Grade A area (b) (4) area where (b) (4) vials are loaded, but performed no more vial loading activities. Their hands were then monitored to be associated with the Grade A vial loading activity.

c. During set-up, the operator performing aseptic connections is not monitored at the end of the aseptic connections. This operator continues the remaining set-up activities before their hands are monitored.

OBSERVATION 6

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

The process validation report for (b) (4) Tablets USP (b) (4) mg (US market) recommended a specification of (b) (4) for compaction force during commercial tableting based on the process validation data. This data is not reflected in the current batch record that lists a compaction force target of (b) (4) and a range of (b) (4) The compression machine batch report for US batch (b) (4) showed the average compaction force was frequently above the range recommended during process validation.

The compression machine uses the target compaction force to reject high and low compaction force tablets. The manufacturing instructions lack instructions on how to set these rejection values. The operators can change the rejection values, but the operators manufacturing (b) (4) could not explain

how the number is set. There is no review of the setting of the reject values, or review of the audit trail that documents changes, as part of the batch record review.

On August 4, 2026, during ongoing manufacturing of (b) (4), (b) (4) of the machine was set with a reject rate of (b) (4) % of the target compaction force, allowing the machine to accept tablets with a compaction force in the range of (b) (4)

OBSERVATION 7

Written production and process control procedures are not documented at the time of performance.

On August 3, 2026, missing signatures and entries were observed in logbooks in the Grade C production areas of Block (b) (4) Deviation DV/C/26/038 was opened and identified missing entries in 47 of the (b) (4) logbooks in Block (b) However, this investigation could not be thoroughly and accurately completed because multiple employees in the area backdated records before they were reviewed during the investigation, obscuring missing entries.

Logbooks reviewed on August 7, 2026, that contained backdated entries included:

1. Equipment Usage Logbook PR/649/F/01-01 for the (b) (4) integrity tester.

2. (b) (4) Integrity, Cleaning, and Sterilization Record PR/503/F/01-03.

3. Non-Sterile Area LAF Usage Record PR/263/F/01-02 for the solution preparation area.

4. Balance Verification Log QA/096/F/01-03 for balance PRD/C/066.

OBSERVATION 8

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Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

On August 5, 2026, a personnel monitoring plate that had been counted by two different analysts was found to have (b) (4) CFU, but had been reported as no growth "NG". The sample was for the right hand of (b) (6), a microbiology operator working in block (b) (4) area during the (b) (4) trial batch (b) (4). This was a Grade B sample with an action limit of (b) (4) CFU.

OBSERVATION 9

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

1. The (b) (4) integrity tester in Block (b) (4) overwrites the electronic data without being reviewed. Failing and aborted tests appear as alarms, but any operator can clear an alarm and the record will be overwritten due to the limited data storage capacity. A gap assessment performed for this piece of equipment identified no deficiencies.

On August 3, 2026, the software displayed an unacknowledged alarm from July 3, 2026, for a (b) (4) failure. There was no reference in a logbook or the paper printouts to this failure. The electronic data from this time period had been overwritten.

2. There is a shared username and password for operators using the (b) (4). A gap assessment inaccurately stated there were unique usernames and passwords.

3. There is a shared username and password for operators using the (b) (4)
A gap assessment dated January 6, 2023, identified gaps with the software controls, but no remediation activities were identified.

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OBSERVATION 10

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

1. Your firm failed to conduct thorough, scientifically sound investigations to determine the actual root causes of the following out-of-specification (OOS) results: OOS-C-26-002, OOS-C-26-001, OOS-C-26-011, OOS-C-26-005, OOS-C-26-004, OOS-J-26-003, OOS-C-25-034, and OOS-J-26-002.

OOS ID	Product/Test	Root Cause
OOS-C-26-011	(b) (4) Assay	Speculative spillage during standard weighing
OOS-C-26-005	(b) (4) USP Assay	Speculative spillage of material or pipette seepage
OOS-C-26-004	(b) (4)	Cloudy vial headspace = improper handling
OOS-C-25-034		(b) (4) ingress
OOS-J-26-003		Damaged vial cap
OOS-C-26-002	(b) (4) injection	Analyst error
OOS-C-26-001	(b) (4) raw material	Degraded HPLC column

2. Your firm implemented corrective and preventive actions (CAPAs) for out-of-specification results OOS-C-24-012, OOS-C-24-016, OOS-C-24-037, OOS-G-OSD-24-008, OOS-J-24-001, OOS-J-24-002, OOS-C-26-011, OOS-C-26-005, OOS-C-26-004, and OOS-C-25-03 that relied primarily on personnel training without investigating or addressing underlying system design deficiencies, or equipment issues.

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For example the OOS-C-26-001 for (b) (4) raw material (batch # (b) (4) was initiated for the unspecified impurity result (b) (4) % analysis relative to a specification of NMT (b) (4) % by HPLC. This OOS for related substances was invalidated after an "alternative column" was used during hypothesis testing and produced passing results. The original column had (b) (4) cumulative injections and the preventive action was simply "the initial column (b) (4) shall not be used for (b) (4) analysis". There was no CAPA to establish column lifespan limits, evaluate system suitability criteria that failed to catch a degraded column, or assess method robustness. Similar outcomes were observed for other reviewed OOS where no CAPAs were initiated or the CAPAs implemented do not adequately address root causes or prevent recurrence.

3. Your firm received market complaint MC-B-26-011 (FAR #26786736) on May 13, 2026, from (b) (4) (b) (4) regarding a bottle of (b) (4) Capsules, (b) (4) mg, (b) (4) ct, Lot (b) (4) , that was reported to contain foreign unidentified material, described as fiber/hair and grime material. A preliminary investigation was not initiated to identify the identity of these foreign materials upon receipt of the complaint samples on June 2, 2026. Instead, the investigation was only commenced after the investigators inquired about the status of the foreign fiber analysis during the course of this inspection. The foreign fiber/hair material was confirmed to be hair as of the time of the inspection. Analysis of the grime material identified in the complaint remains pending as of August 11, 2026. Your firm has not identified the sources of the foreign materials found in a bottle of (b) (4) Capsules (b) (4) mg, (b) (4) ct, Lot (b) (4) . No source determination has been documented to support the identification of potential root causes and implementation of appropriate corrective actions.

4. An OOS-J-25-007 investigation was initiated on August 23, 2025, due to the presence of white particles and fibers in (b) (4) solution USP (b) (4) mL) batch number (b) (4) (b) (4) This investigation to date has not determined the identity or source of the white particles and fibers to aid in the determination of potential root causes and implementation of appropriate corrective actions.

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OBSERVATION 11

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Your firm relied on certificate of analyses (COA) for incoming shipments of high-risk component (b) (4) from your supplier. You have not tested each lot and container of (b) (4) upon receipt to detect and quantitate (b) (4) is used in the manufacture of (b) (4) mL). In the last (b) (4) your firm has manufactured (b) (4) batches of (b) (4) containing (b) (4) for distribution. The product has an expiration date of (b) (4)

OBSERVATION 12

Written procedures are not followed for the testing of components.

The written FTIR analytical method, titled "(b) (4) USP (b) (4) ", requires evaluation for the presence of (b) (4) absorption bands in the spectral range of (b) (4) cm^{-1} to (b) (4) cm^{-1} using scale expansion, as specified in the method procedure. The FTIR instrument scan parameters are configured with a minimum of (b) (4) cm^{-1} and a maximum of (b) (4) cm^{-1} thus excluding the (b) (4) cm^{-1} spectral window necessary to detect (b) (4) absorption bands. As a result, the evaluation for the presence of (b) (4) has never been conducted on any (b) (4) USP lot tested using this method. Review of laboratory records confirms that (b) batches of (b) (4) USP, with Sample ID's (b) (4) were analyzed using this method over the past (b) (4) , none of which included a (b) (4) absorption band evaluation. The affected lots were used in the manufacture of (b) batches of (b) (4) tablets USP (b) (4) mg and (b) (4) batches of (b) (4) tablets (b) (4) mg. These products have an expiry period of (b) (4)

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The data was reviewed and approved to comply with the specifications, even though the data reviewer could not have verified the (b) (4) cm^{-1} as required by the test method.

OBSERVATION 13

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

The firm does not perform performance verification on the FTIR instruments QC/4/304, QC/4/379, and QCD/D/022 prior to their use for raw material identification and finished product testing. No documented performance verification records were observed for the past 3 years. These instruments have been used in identity verification of the following APIs and excipients that are used to make finished drug products for the US market: (b) (4)

The firm's SOP Numbers QC-060-12, titled "Operation, calibration and cleaning procedure for Fourier Transform Infra-red spectrophotometer and attenuated total reflectance with lab solution IR software" and QC/529-02, titled "Operation, calibration and cleaning procedure for Fourier Transform Infra-red spectrophotometer" do not specify the need and required frequency for conducting FTIR performance verification testing to ensure the instrument is operating within established performance parameters.

***DATES OF INSPECTION**

8/03/2026(Mon), 8/04/2026(Tue), 8/05/2026(Wed), 8/06/2026(Thu), 8/07/2026(Fri), 8/10/2026(Mon), 8/11/2026(Tue), 8/12/2026(Wed)

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