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 CDER-OC-OMQ-International483Response@fda.hhs.gov	09/08/2025-09/19/2025
	FEI NUMBER 3002957541

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Karthik Iyer, General Manager - Operation

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Medicare Ltd.	Survey No. 22 & 24, Village Ujeti, Post Baska
CITY, STATE, ZIP CODE, COUNTRY Halol – 389 350 Gujarat, India	TYPE ESTABLISHMENT INSPECTED 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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, followed, or including adequate validation of the sterilization process. Specifically,

A. On 09/13/2025, I (EL) observed the aseptic assembly, set-up, and filling of [redacted] (b) (4) Injection, U.S. Batch [redacted] (b) (4) in Block [redacted] (b) (4) vial filling line [redacted] (b) (4) Room [redacted] (b) (4) The following deficient aseptic practice was observed.

a) The operator appeared unfamiliar with the sterile connection process. He did not sanitize his hands or use appropriate aseptic technique in performing sterile connections. Specifically,

During the critical S2S (sterile-to-sterile) connection between the sterile product transfer tank (in Grade B) and the filling machine (in Grade A), I observed that without sanitizing his hands, the operator grabbed the sterile connector end (in [redacted] (b) (4) cover) of the manifold tubing from the Grade A filling line. He attempted but failed to hang the tubing over the [redacted] (b) (4) RABS [redacted] (b) (4) He next took the tubing with the sterile connector from the transfer tank. He held both tubing in one hand, using a sterile pair of forceps he removed the [redacted] (b) (4) cover from each connector including the cover he previously handled with his unsanitized hand. He proceeded to use his unsanitized hands opening the [redacted] (b) (4) (cover) from each sterile connector to perform the sterile to sterile connection. He sanitized his hands only after completing

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the S2S connection. Your firm's MF video shows operator sanitized his hands prior to conducting the S2S connection.

b). Items exposed to a less controlled Grade B environment were not sanitized prior to introducing them to a highly controlled (b) (4) RABS Grade A area. Also, operators without sanitizing hands were seen conducting Grade A activities. Specifically,

The (b) (4) were (b) (4) sterilized in (b) (4) bags. During installation of the sterile (b) (4) I observed the (b) (4) wrapper was removed in the Grade B filling room, exposing the (b) (4) wrapper containing the sterile (b) (4) to the Grade B air. I observed that without sanitizing the (b) (4) wrapper surfaces, the (b) (4) bag was transferred into the Grade A filling line area via (b) (4) I observed the operator staged his unsanitized hands (b) (4) (b) (4) to receive the bag, proceeded to open the (b) (4) bag inside the Grade A area, and remove the sterile (b) (4) from the bag. I then observed the operator touched the Grade A side of the (b) (4) with his unsanitized hands in order to find the correct orientation for installation. All (b) (4) for the Grade A filling line were installed this way. Your firm's MF video shows operator sanitized his hands prior to conducting (b) (4) installation.

c). There is a lack of validation for the (b) (4) sterilization cycle. The (b) (4) are cleaned and sterilized between batches. Each (b) (4) receives up to (b) (4) cycles. However, the (b) (4) sterilization cycles are not validated. When watching the (b) (4) installation, I observed some (b) (4) appeared (b) (4) I observed operators having great difficulty (b) (4) SOP 010727, section 5.1.2.9 requires immediate reporting if any abnormality observed during (b) (4) installation. Management confirms there have been no reporting of (b) (4) which indicates possible deterioration of the (b) (4)

d). During the assembly and set-up operations, operators did not sanitize their hands before (b) (4) (b) (4) the Grade A filling area. Hands were sanitized after (b) (4) the (b) (4) RABS (b) (4) while they were already inside the Grade A filling line. Also, during hand sanitization, I observed sterile (b) (4) was

sprayed near the Grade A EM settling plates and active air sampler, possibly contaminating the (b) (4) media.

e). Sterile articles were transferred to the Grade B filling room using a (b) (4) LAF (b) (4) Operators did not sanitize their hands before reaching inside the Grade A (b) (4) LAF (b) (4) Also, the interior Grade A side of the (b) (4) LAF (b) (4) that had been exposed to the Grade B environment was not sanitized before (b) (4)

f). During (b) (4) the stoppers, I observed (b) (4) bags containing sterile stoppers were placed on the Grade B (b) (4) The (b) (4) wrapper of the bag was cut open by (b) (4) operator exposing the (b) (4) wrapper to the Grade B environment. However, without sanitizing the surfaces of the (b) (4) wrapper, the bag was moved into the Grade A filling line (b) (4) During the addition of stoppers, I observed the (b) (4) operator holding the bag directly over the (b) (4) blocking the first air to the (b) (4) containing sterile stoppers.

g). During the (b) (4) intervention for removal of fallen vials from the (b) (4) I observed the operator placed his hand directly over adjacent open vials blocking first air to the vials. The impacted vials were not removed.

h). During the cleaning of the Grade A side of the (b) (4) RABS (b) (4) before (b) (4) the (b) (4) I observed operators using the same side of a wipe up to 3 times. The appropriate technique of using the clean side of a wipe each time to apply parallel unidirectional and overlapping strokes was not observed by the cleanroom operators.

i). I observed aseptic operators using goggles that have holes on top of the frame, allowing exposed skin during aseptic processing. Holes in goggles create pathways for contaminations to enter the cleanroom environment impacting product sterility.

j). There is a lack of procedure providing requirement for operator movement. During the inspection, I observed operators going in and out between the Grade B filling Room (b) (4) and the sterile corridor.

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Personnel movement between the Grade B sterile corridor and the Grade B filling room did not appear carefully controlled to prevent contamination.

B. During review of the airflow visualization studies of Block (b) (4) filling line (Room (b) (4) the lack of adequate smoke coverage, turbulent airflow, or poor aseptic practice were observed. Examples including but were not limited to:

a). Video of Simulation No. (b) (4) -012, "Addition of (b) (4) bottle in (b) (4), showed an operator held the bottle bags directly over the (b) (4) partially blocking the first air to the (b) (4) Also, the (b) (4) bags containing sterile bottles were already staged inside the Grade A area. The video did not show how the bags were moved from a lower grade area to the Grade A location. A strong horizontal airflow was seen coming out of the location where the (b) (4) bags were staged. The airflow during transfer of bags from the (b) (4) to the (b) (4) location and if turbulent airflow was created cannot be assessed.

b). Video of Simulation No. (b) (4) -014, "Addition of cap in (b) (4), showed an operator held the cap bags directly over the (b) (4) partially blocking the first air to the (b) (4) (b) (4) The video showed the (b) (4) bags of sterile caps already staged inside the Garde A area. The airflow of bag movement from a lower grade to the Grade A location cannot be assessed. Also, a continuous swirl of HEPA air or turbulent airflow was observed directly above the left side of the (b) (4) impacting sterile caps inside the (b) (4)

c). Video of Simulation No. (b) (4) -013, "Addition of (b) (4) in (b) (4), showed the dispensing of sterile (b) (4) The video showed a bag of sterile (b) (4) already staged inside the Garde A area. The airflow of bag movement from a lower grade to the Grade A location cannot be assessed. Also, a strong horizontal airflow was seen coming out of the location where the bag was staged. The airflow during transfer of bags from the (b) (4) to the (b) (4) location and if turbulent airflow was created cannot be assessed.

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d). Video of Simulation No. (b) (4)-001, "Loading of filling M/C parts from (b) (4) unloading room to (b) (4) LAF (b) (4)," showed an operator moving sterile machine parts to the (b) (4) Grade A LAF (b) (4) in the (b) (4) unloading Room (b) (4) A horizontal turbulent airflow can be seen blown by the upper right hand side of the (b) (4) There was no assessment of the turbulent airflow and its impact to the sterile items inside the (b) (4) LAF.

C. During review of the aseptic process simulation (APS) or Media Fill (MF) studies, the following was observed:

a). Block (b) (4) vial filling line (b) (4) MF studies did not include simulation of interventions performed during vial sealing operation. This (b) (4) line manufactures commercial products for the U.S. market.

b). Block (b) (4) vial filling line (b) (4) MF studies did not include simulation of interventions performed during vial sealing operation. This (b) (4) line manufactures (b) (4) (b) (4) mg/vial).

OBSERVATION 2
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

During review of the environmental and personnel monitoring (EM and PM), the following was noted:

A. From 01/2023 to date, a total of (b) (4) batches were rejected due to EM or PM excursions. (b) (4) of the rejections involved manufacturing Block (b) (4) PM excursions (Action limits for Grade A: (b) (4) Grade B: (b) (4) cfu/plate or NMT (b) (4) cfu (b) (4) gown locations).

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Review of monitoring records from 01/2023 to date showed a negative trend of Block (b) (4) PM where a total of 122 PM Grade B action limit excursions were noted (including 5 Grade A excursions). Microorganisms isolated included Gram positive skin flora species (i.e., *Staphylococcus, Micrococcus*), *Bacillus species*, Gram negative species (i.e., *Pseudomonas, Moraxella, Vibro*), and mold species (i.e., *Aspergillus, Penicillium*). As of to date, an effective comprehensive CAPA has yet to be achieved.

B. There is a lack of adequate justification to classify the manufacturing Block (b) (4) filling line (b) (4) vial sealing (b) (4) RABS as Grade C (Action limits: Passive air (b) (4) cfu/plate, Active air (b) (4) cfu/m³). This (b) (4) line manufactures sterile (b) (4) (b) (4) mg/vial). In addition, you stated that Grade A air is supplied to the (b) (4) RABS and the non-viable particle count (NVPC) is monitored per Grade A standard. However, no NVPC is monitored during batch production. Only pre or post batch NVPC is monitored.

C. There is a lack of adequate justification to classify the manufacturing Block (b) (4) filling line (b) (4) vial sealing (b) (4) RABS as Grade B (Action limits: Passive air (b) (4) cfu/plate, Active air (b) (4) cfu/m³). This (b) (4) line manufactures sterile commercial products for the U.S. market. In addition, you stated that Grade A air is supplied to the (b) (4) RABS and NVPC is monitored per Grade A standard. However, no NVPC is monitored during batch production. Only pre or post batch NVPC is monitored.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy, 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. Specifically,

A. FAR/25/001 was submitted on 01/17/2025 regarding bacteriological contamination observed in the aseptic process simulation (APS) Batch (b) (4) On 01/13/2025, APS Batch (b) (4) was conducted in Block (b) (4) Line (Room (b) (4) On 01/16/2025, positive growth of *Staphylococcus hominis* was observed in all (b) (4) vials before incubation. Deviation was initiated on

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01/16/2025. Your investigation (No. 2061578) identified that (b) (4) integrity failure being the root cause for the APS failure. However, you did not conduct investigation into the reason(s) for the (b) (4) failure, i.e., (b) (4) damage, improper (b) (4) system (b) (4) mimic a failure, or incomplete (b) (4) ranges (b) (4) Your CAPA included the use of (b) (4) Instead of (b) (4) a total of (b) (4) (b) (4) are used.

From 06/21/2024 (last successful APS) to 01/13/2025, a total of (b) (4) batches of aseptically filled (b) (4) Suspension USP were manufactured in Block (b) (4) (b) (4) Line (b) (4) A total of (b) (4) batches are currently in the U.S. market and within expiry. Your investigation is inadequate in that it did not include investigation into (b) (4) integrity failure. Your CAPA is inadequate in that it failed to assure the observed (b) (4) failure will not occur again.

B. The Block (b) (4) vial filling line (b) (4) is used to aseptically fill products for (b) (4) (b) (4) APS requalification Batch (b) (4) was filled on 07/05/2024. After (b) (4) of the incubation, positive growth was observed in (b) (4) container units. After (b) (4) of the incubation, growth was seen in (b) (4) container units. Your investigation identified that incorrect size of (b) (4) stoppers being the root cause for contamination. The contaminating microorganisms included *Kocuria rhizophila, Kocuria palustris, Aspergillus tubingensis/vadensis, Staphylococcus haemolyticus, Staphylococcus epidermidis, Micrococcus luteus, Brachybacterium conglomeratum/paracnglomeratum, and Brachybacterium squillarum.*

Your investigation is inadequate in that you did not look into what caused the ingress of contaminating microorganism. Your management stated the contamination was likely introduced from the Grade C (Action limits: Passive air (b) (4) cfu/plate, Active air (b) (4) cfu/m^3) area surrounding the sealing Grade B (b) (4) RABS. Your CAPA included using the correct size (b) (4) stoppers. However, you failed to thoroughly investigate how the ingress of microbial contamination occurred. In 12/2024, without adequate justification, you downgraded the vial sealing (b) (4) RABS from Grade B to Grade C, further exposing the sealing operation to a lesser controlled environment. Your MF failure investigation and CAPA actions were inadequate to assure product sterility.

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C. Review of MF failure investigations revealed containers that showed positive growth were immediately removed and tested for microbial identification prior to completion of the (b) (4) incubation. Removal of containers prior to the (b) (4) incubation does not allow for the detection of slow-growing microorganisms, damaged microorganisms, or microorganisms having different temperature requirement sufficient time to recover and proliferate.

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