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	6/2/2025-6/13/2025*
	FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Virang Shah, Vice President - Operations

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Industries Ltd.	Halol - Baroda Highway
CITY, STATE, ZIP CODE, COUNTRY Halol, Gujarat, 389350 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.

Examples of poor aseptic behavior and inadequate environmental monitoring are repeat observations from the December 2022 Warning Letter.

1. During set-up and aseptic filling of [redacted] (b) (4) Injection batch [redacted] (b) (4) (US market) on June 4, 2025, the following was observed:

a. Samples of open vials were periodically collected for filling volume checks by passing a [redacted] (b) (4) using the Grade B operator's gloved hands, from outside the filling barrier under the filling barrier into Grade A. The [redacted] (b) (4) is not disinfected prior to moving it into the filing barrier.

The [redacted] (b) (4) was used near the [redacted] (b) (4) and open vials on the conveyor line. The operator holds the [redacted] (b) (4) with a [redacted] (b) (4) glove above the level of open vials while collecting samples and then passes it back under the barrier to perform volume checks. This check is performed at least [redacted] (b) (4)

Upon exit, the personnel that handle the [redacted] (b) (4) outside the barrier and pass it into the barrier without disinfection are held to Grade B limits during personnel monitoring.

b. During the aseptic connection between the sterilized product tank and the filling machine, the

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operator reached their hand and forearm over the open tank port. [redacted]

During this aseptic connection, [redacted] barrier [redacted] between the Grade A area where the aseptic connection is made and the adjacent Grade B area were left [redacted]

There was no personnel monitoring associated with this Grade A aseptic connection operation. The non-viable particle count probe and settle plate for this area is located behind where the [redacted] operator stands during the aseptic connection because there is not adequate space to collect these samples near the aseptic connection.

c. During set-up, the operator's gloved hand was holding the sterilized stopper chute that contacts stoppers as they move from the stopper bowl to the [redacted] The protective cover had already been removed.

d. During addition of stoppers, the [redacted] gloves were observed over the sterile stoppers and the sterile [redacted] Airflow studies have not thoroughly evaluated the appropriateness of air flow to the exposed stoppers in the [redacted]

e. The sterile product tank is transferred to the filling line using a [redacted] LAF, but due to space limitations, the tank is removed in a Grade B area. The tank was not thoroughly disinfected before transfer into the Grade A area. The tank was placed on a [redacted] that is also transferred from the Grade B area to the Grade A area and was not thoroughly disinfected. The [redacted] was not extended for

disinfection of all areas before transfer into the Grade A area.

f. During installation of the [(b) (4)] the operator removed the protective covering of the [(b) (4)] closest to them first. They then reached over the exposed [(b) (4)] with the [(b) (4)] gloves to remove the coverings for the other [(b) (4)]

g. During set-up and environmental monitoring, personnel left barrier [(b) (4)] to Grade A areas [(b) (4)] unnecessarily while performing activities in other areas.

h. During set-up and filling operations, operators were observed to allow their gowns to touch the Grade A side of a [(b) (4)] glove [(b) (4)] barrier [(b) (4)] and each other due to insufficient space in areas they needed to perform activities.

The Grade A side of the [(b) (4)] glove the operator contacted was not disinfected. When barrier [(b) (4)] are [(b) (4)] Grade B, the barrier is disinfected upon [(b) (4)] but not the [(b) (4)] glove that has been exposed to Grade B.

i. The amount of time between removal of wraps on installed equipment to the start of filling, excluding breaks and environmental monitoring, was approximately 3 hours and 9 minutes. During previous batches this process for the same product was completed in 51 minutes for both batch [(b) (4)] on May 16, 2025, and batch [(b) (4)] on May 25, 2025. Personnel could not explain how the same process using slow and controlled movements on June 4, 2025, could have been completed in these shorter time periods during previous batches.

2. During aseptic filling of [(b) (4)] Injection batch [(b) (4)] on June 2, 2025, on the vial line of Block [(b) (4)]

a. While changing [(b) (4)] air sample using [(b) (4)] glove [(b) (4)] the environmental monitoring

employee used the (b) (4) glove directly above the sterile primary closure stoppers on the stopper track. While passing the completed plate out of the barrier, the employee allowed the (b) (4) glove to directly contact and rest on the sterile stoppers that were in the track that would later be placed on to filled vials.

b. An environmental monitoring operator crossed the filling line in the Grade A through the (b) (4) conveyor and their (b) (4) contacted the Grade A side of the barrier (b) (4) Subsequently, a production operator crossed the Grade A space through the same (b) (4) conveyor. The (b) (4) were then (b) (4) and filling continued without disinfecting the (b) (4) as required by SOP028207. The (b) (4) glove present in (b) (4) the Grade B space is not required to be disinfected.

The sequence of environmental monitoring was not designed to limit crossing through the (b) (4) conveyor area. The environmental monitoring personnel moved through the (b) (4) conveyor with a (b) (4) to change environmental monitoring plates in the Grade A area before returning with the (b) (4) to the other side of the line, and then crossing again to change plates in the Grade B area.

c. Environmental monitoring to change settle and (b) (4) air plates starting at 15:56 on June 2, 2025, took 42 minutes to complete. During previous batches this same process was completed in 15 minutes (batch (b) (4) on May 27, 2025) and 17 minutes (batch (b) (4) on May 25, 2025). Personnel could not explain how the same process using slow and controlled observed movements on June 2, 2025, could have been completed in these shorter time periods during previous batches.

3. For aseptic gowning of operators associated with (b) (4) Injection batch (b) (4) on June 4, 2025:

a. The design of the aseptic gowning space requires the operators to reach over the crossover bench and around a cabinet door that opens towards them to reach aseptic gowning material. This is done while wearing garments from the Grade C (b) (4) This crossover bench is only sanitized (b) (4) according to SOP028811 "Gowning and Degowning Procedure". Operators were observed to place their

feet with the Grade C area coverings on this crossover bench before and during aseptic gowning. Subsequently, operators sat on the same bench after donning their sterile gown.

b. While putting on the aseptic gown, an operator allowed the gown to touch the bag of the trash can. After the gown had been put on, the operator used their hand to push the packaging material in the overflowing trash can down, allowing the arm of the sterile gown to touch the disposed material and trash can.

c. An operator was observed to touch the external surfaces of the aseptic gown with their arm while putting on the aseptic area gown.

d. An environmental monitoring operator inside the filling line was observed with adhered material near the waist of their gown. Personnel from outside the filling area attempted to signal the operator to leave the area, but took no further actions when the person continued their activities without leaving to change their gown.

4. During review of media fills recordings and smoke studies for the vial line in Block (b) (4)

a. An operator reaches over sterile stoppers and the stopper track with the (b) (4) glove during an intervention for elimination of a stopper jam in the (b) (4) in media fill (b) (4) on February 9, 2025. The smoke studies similarly show the (b) (4) glove reaches over the stoppers and stopper track during this intervention. The intervention procedure SOP028207 states the (b) (4) glove should not reach over the sterile part during this intervention.

b. An operator reached over the stoppers and stopper track with the (b) (4) glove and did not move slowly while changing of the (b) (4) air plate using glove (b) (4) during media fill (b) (4) on February 9, 2025.

c. The operator reaches over open vials with the (b) (4) glove while removing fallen vials at the (b) (4) in the smoke studies.

5. During review of media fills (b) (4) and (b) (4) performed on the vial line in Block (b) (4) several deficiencies in aseptic technique were identified:

a. Operator reaching into the Grade A area and remove vials with gloved hands, not using forceps, and discarding vials in a waste bin in Grade B without sanitizing hands between zones.

b. Operator in the aseptic processing area picked up and moved a step stool using gloved hands. The step stool's floor contact points were visibly exposed during this action.

c. Operators failing to disinfect (b) (4) that have (b) (4) into Grade B areas after (b) (4) interventions.

d. A (b) (4) typically stored in the Grade B area, was introduced into the Grade A environment and seen contacting the interior surface of the (b) (4) gloves without undergoing sanitization.

OBSERVATION 2

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

Inadequate media fills is a repeat observation from the December 2022 Warning Letter.

1. Aseptic Process Simulation (media fill) (b) (4) in (b) (4) Parenteral Area, Filling Line (b) (4) for (b) (4) mL vial performed for (b) (4) injection, (b) (4) mg/ml, (b) (4) ml vial does not accurately represent the actual manufacturing process. Deficiencies include but were not limited to:

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Commercial Manufacturing Process	Aseptic Process Simulation
In-process fill checks involve passing a (b) (4) into the Grade A area, holding the (b) (4) above the level of the open vials, then moving the (b) (4) to a Grade B area of the room for volume verification. The (b) (4) is not disinfected when it is passed from Grade B to Grade A.	During media fills the (b) (4) is kept inside the barrier and the vials are lifted and then placed back on the line by the operator. The (b) (4) is never removed from the line and transferred to the Grade B area where the fill volume check is completed.
Aseptic Connection is done by (b) (4) operators positioned on opposite sides of the formulation tank. These operators exchange forceps, used for removing the (b) (4) aseptic connection tubing. This transfer takes place across the top of the tank, directly above its uncovered, open outlet.	Aseptic Connection was conducted by (b) (4) operator eliminating the forceps transfer and need to reach across the tank.
Stopper bag placement is performed by (b) (4) operators who were observed touching the (b) (4) laminar airflow (LAF) unit, (b) (4) (b) (4) gloves, and other operators' gowning.	Stopper bag placement done by (b) (4) (b) (4) operator.
No (b) (4) viable air monitoring was conducted within the Grade A area	(b) (4) Viable Air Monitoring Device is placed on a (b) (4) within

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where the aseptic connection took place during manufacturing of batch (b) (4)	the Grade A area where the aseptic connection took place for Media Fill (b) (4).

2. The qualification process for aseptic personnel does not specify required activities to be performed during a media fill to demonstrate competency. Multiple operators are responsible for setup activities during media fills and routine production, but the specific activities performed by each operator are not documented. As a result, an operator may be qualified to conduct the aseptic connection without ever having performed this task during a media fill.

3. During Block (b) (4) vial line media fills:

a. Media fill procedures do not ensure there are media filled vials present on the line during qualification of interventions that would not require the line to be cleared during commercial batches.

b. There are breaks in which no production personnel are present and there are no media filled vials present on the line, but this is considered part of the media fill filling duration. During routine commercial manufacturing, enough operators will remain in the room for continuous operations.

4. Smoke studies of the aseptic connection and loading of stopper bags on the Block (b) (4) vial line only include one person performing the activity. During (b) (4) Injection batch (b) (4) (US market) on June 4, 2025, there were (b) (4) people performing these activities.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

1. Investigations of environmental and personnel monitoring excursions frequently fail to identify root

causes, thoroughly evaluate potential sources for the identified organisms including Gram negative, spore forming and mold organisms, or implement effective corrective and preventive actions. For example:

a. The vial line in Block (b) (4) and associated (b) (4) have been used for aseptic filling of (b) (4) Injection for the US market. Since January 2024 there have been 3 batch rejections related to environmental monitoring excursions, 30 instances of Grade A recoveries, 76 Grade B action level results, and 56 Grade B alert level results.

b. The vial line in Block (b) (4) has been used for aseptic filling of (b) (4) Injection and (b) (4) Injection for the US market. Since January 2024 there have been 2 batch rejections related to environmental monitoring excursions, 19 instances of Grade A recoveries, 14 Grade B action level results, and 24 Grade B alert level results.

c. The vial line (b) (4) in Block (b) (4) and associated (b) (4) were used for aseptic filling of (b) (4) Injection for the US market, until manufacturing stopped in this area in December of 2024. From January 2024-December 2024 there were 4 batch rejections related to environmental monitoring excursions, 23 instances of Grade A recoveries, 43 Grade B action level excursions, and 39 Grade B alert level results.

d. The vial line (b) (4) in Block (b) (4) was used for aseptic filling of (b) (4) Injection for the US market, until manufacturing stopped in this area in February of 2025. From January 2024-February 2025 there was one batch rejection related to environmental monitoring excursions, 15 instances of Grade A recoveries, 37 Grade B action level excursions, and 34 Grade B alert level results.

2. Media failure investigations from the Block (b) (4) vial line, where (b) (4) Injection is aseptically filled for the US market, were not thorough to identify root causes supported by evidence and associated corrective and preventive actions. These included:

a. Media fill failure investigation 1499853 for batch [(b) (4)] initiated June 7, 2023, identified 13 failed vials identifying *Pseudomonas stutzeri* (2 vials), *Bacillus cereus* (1 vial), and species from *Staphylococcus*, *Micrococcus*, and/or *Kocuria* in the other contaminated units. The contaminated vials were spread across [(b) (4)] different [(b) (4)] on [(b) (4)] and one vial from a [(b) (4)] on [(b) (4)] [(b) (4)] The investigation did not thoroughly evaluate these organisms and whether they came from different sources.

One of the probable causes identified during the investigation was improper [(b) (4)] However, improperly [(b) (4)] vials are not detected or removed during routine batches and all of the contaminated vials were ultimately integral following stoppering at the end of the [(b) (4)] simulation.

The investigation describes simulation of [(b) (4)] interventions during [(b) (4)] loading to remove fallen vials that occurred when improperly [(b) (4)] vials were present. However, the images in the investigation and media fill video show the improperly [(b) (4)] vials identified were not present in the [(b) (4)] loading area at the time of these interventions.

The [(b) (4)] from [(b) (4)] were filled on [(b) (4)] from [(b) (4)] to [(b) (4)] at [(b) (4)] The contaminated vials were not reconcilable with the approximate time and the activity occurring during this nearly [(b) (4)] period.

Review of selected portions of the media fill videos showed additional interventions that were not identified in the media fill investigations where intervention procedures were not followed. These included reaching the [(b) (4)] glove over sterile stoppers and the stopper track/bowl during interventions to remove stopper jams and change [(b) (4)] air plate.

b. Media fill failure investigation 1499853 for batch [(b) (4)] (13 contaminated vials) and 1545028

for batch [redacted] (b) (4) (2 contaminated vials) both identified a possible root cause of abnormal events during unloading of the [redacted] (b) (4) that led to the contamination.

Vials are stoppered [redacted] (b) (4) before capping. The contaminated vials were capped and were integral vials. The investigation did not evaluate whether the [redacted] (b) (4) was appropriate to reject vials that were not properly stoppered before capping.

Additionally, process validation of [redacted] (b) (4) Injection product did not include data to demonstrate the vials throughout the batch are stoppered and maintain a vacuum to prevent potential ingress of microorganisms, moisture, or oxygen between the [redacted] (b) (4) stoppering and capping.

c. Media fill failure investigation 1498591 for batch [redacted] (b) (4) identified gross contamination of the bulk product with Bacillus cereus on June 1, 2023. The investigation identified poor aseptic behavior associated with the aseptic connection as a probable root cause. The CAPA actions included implementation of sterile to sterile connections to reduce the risk from the manual aseptic connection on the vial line on Block [redacted] (b) (4) This preventive action was not extended to aseptic filling lines in other blocks to evaluate the use of sterile to sterile connections.

3. Your Quality Unit did not investigate out of trend test results of an annual stability batch at long term stability condition and allowed failing batches of a drug product to remain in the US market. For example,

a. According to section 5.3.2.2 of your Out of Trend (OOT) investigation procedure SOP027983, Version: 7.0, Effective date: 29-Apr-2024 "*For each parameter to be monitored for OOT and at each of the applicable stability station, perform regression analysis using data of 0, 3, 6, 9 month intervals and establish the trend using available statistical software. Start monitoring and reporting of trends from 12th month interval and then subsequently all stations need to be monitored*". However, we observed

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that your Quality Unit allowed annual stability batch of (b) (4) Tablets (b) (4) mg, batch number: (b) (4) to remain in distribution and available to the US customers when this batch continued to show increasing trend and potential for failure for the highest unknown impurity and total unknown impurities from the initial (0) to nine (9) month stability timepoint as follows:

Test	Specification Limit	Long term stability time points (months)/Test Results			
		0	3	6	9
Related Substances (By HPLC)	Highest Unknown Impurities: NMT (b) (4) %	(b) (4) %	(b) (4) %	(b) (4) %	(b) (4) %
	Total Unknown Impurities: NMT (b) (4) %	(b) (4) %	(b) (4) %	(b) (4) %	(b) (4) %

Your Quality Unit performed no OOT investigation to investigate the increasing trend of highest unknown impurity, and total unknown impurities until 9 month stability timepoint for (b) (4) (b) (4) Tablets (b) (4) mg, batch number: (b) (4) This batch failed to meet the specification limit for total unknown impurities at 18 month stability time point. Result: (b) (4) %, Specification: (b) (4) %. As a result, your firm initiated Out of Specification (OOS) investigation PR ID: 1465137 on (b) (4) (b) (4) and closed the investigation on (b) (4) (i.e. over 2 months) confirming the OOS test results as "Valid". This further delayed in taking market action and allowed your failing batch of (b) (4) (b) (4) Tablets (b) (4) mg, batch number: (b) (4) to remain in the US market. Your firm submitted recall notification for this batch to the FDA on (b) (4) when the batch was already expired in the same month i.e. (b) (4)

Furthermore, your firm analyzed 22 month and 24 month stability time point samples which continued to show the increasing trend for total unknown impurities as follows:

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Test	Specification Limit	Long term stability time points (months)/Test Results			
		12	18	22*	24
Related Substances (By HPLC)	Highest Unknown Impurities: NMT (b) (4)%	(b) (4)%	(b) (4)%	(b) (4)%	(b) (4)%
	Total Unknown Impurities: NMT (b) (4)%	(b) (4)%	(b) (4)%	(b) (4)%	(b) (4)%

* (b) (4) station since the batch was (b) (4) on stability with a delay of 2 months.

b. Your Out of Trend (OOT) investigation procedure SOP027983, Version: 7.0, Effective date: 29-Apr-2024 is deficient as there is no criteria established for investigating impurities that are equal to or below (b) (4)%. According to your General Manager of QA, laboratory investigation in the event of impurities equal to or below (b) (4)% is left to the discretion of discussion between QA and QC whether to initiate or not to initiate investigation. We observed the following issues with these practices:

i. There is no documented record of the discussions between QA and QC maintained indicating the rational for not initiating investigation in the event of out of trend test results for total unknown impurities and individual known impurities.

ii. There is no mention of discussions between QA and QC being the formal means of decision making to initiate investigation in your Out of Trend (OOT) investigation procedure.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

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The May 2022 FDA 483 and December 2022 Warning Letter described multiple instances of metal particulate contamination in (b) (4) Injection batches due to damaged (b) (4) and (b) (4) on the filling machine. The risk assessment of equipment suitability across all sterile lines identified similar equipment used in Block (b) (4) however this equipment was not replaced. Subsequently, similar metal particulate contamination instances have been identified in (b) (4) (b) (4) ml manufactured on line (b) (4) and attributed to filling machine damage:

1. Investigation PR1748467 (Date: 05-MAR-2024)
Black particulates containing (b) (4) identified in batch (b) (4) (rejected)
Root cause: Improper dismantling of equipment parts before (b) (4)
CAPA: Revision of SOP and interim training (CAPA PR#1904692)

2. Investigation PR1864871 (Date: 29-JUL-2024)
Black particulates containing (b) (4) found in batch (b) (4) (rejected)
Root cause: Wavy structure on the surface of (b) (4)
CAPA: Replacement of all existing (b) (4) and product contact parts and implement usage of a (b) (4) for (b) (4) storage/holding (CAPA PR#1923446)

3. Additional Finding During PR1864871
Similar black particulates containing (b) (4) identified in batch (b) (4) (rejected) during repeat visual inspections

4. Investigation PR1915854 (Date: 24-AUG-2024)
Black particulates containing (b) (4) detected in batch (b) (4) (rejected)
Root cause: Scratches on (b) (4) and (b) (4) likely due to friction between (b) (4) and (b) (4)
CAPA: Discarding all (b) (4) and replacing with (b) (4)

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Throughout this series of investigations, manufacturing and filling of (b) (4) continued. Batches of (b) (4) were filled on line (b) (4) and released to the US market include but are not limited to:

Name of the Product	Lot No/Batch No	SFG Batch No	Quantity	Mfg.Date	Exp.Date	Country	Release date
(b) (4)							

Replacement with (b) (4) were not implemented until September 2024, despite the same root cause attributed to (b) (4) in Block (b) (4) in 2020.

OBSERVATION 5

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.

1. Multiple black particles, difficult to see and appearing after a period of settling, resulted in the rejection of four (b) (4) Injection batches (b) (4) (b) (4) The source of these particles was determined to be filling equipment. The firm failed to:

a. Change the visual inspection process to avoid "jerking" or shaking the inspection vial until after the vial has been checked for sedimentation of black particles.

b. Update their visual inspection (VI) procedure (SOP #030508, v 12.0, effective 15-May-2025) and challenge kit (Kit ID # (b) (4) last updated 26-Feb-2025) to include these newly identified defects.

c. Include instructions in the current VI procedure for detecting or classifying these small, difficult-to-see particles.

d. Include samples representative of these newly identified defects in the challenge kit used for training and qualifying visual inspectors.

e. Provide documented evidence of retraining or requalification of visual inspectors to detect this new defect type.

2. The established allowable reject percentages for compression force used during tablet manufacturing are not supported by the individual tablet weight data and do not consider other parameters, including hardness. This resulted in the approval of wider ranges that could permit the acceptance of tablets that would otherwise be rejected. For example:

a. For (b) (4) mg tablets, the (b) (4) weight control study used batch (b) (4) for calculating the lower tolerance weight tablets with a compression force of (b) (4) kN. This was used to calculate the low reject rate of not more than (b) (4) %. The in-process data showed (b) (4) of (b) (4) individual tablets were below the weight minimum of (b) (4) mg. Hardness data was not considered in the study, but (b) (4) of (b) (4) individual tablets were below the hardness minimum of (b) (4) kp.

Batch (b) (4) was used for the high tolerance weight tablets with a compression force of (b) (4) kN to calculate a high reject rate of (b) (4) %. The in-process data showed (b) (4) of (b) (4) individual tablets exceeded the upper limit for tablet weight of (b) (4) mg.

b. For (b) (4) mg tablets, the (b) (4) weight control study used batch (b) (4) for the lower tolerance weight limit with a compression force of (b) (4) kN on the (b) (4) (Station (b) (4) This was used to calculate the lower reject rate limits in the batch record of not more than (b) (4) %. The low tolerance in-process data for (b) (4) had (b) (4) of (b) (4) individual tablets below the minimum tablet weight of (b) (4) mg. Hardness data was not considered in the study, but showed (b) (4) of (b) (4) individual tablets below the tolerance limit of (b) (4) kp. The (b) (4) (Station (b) (4) had a compression force of (b) (4) kN and similarly had individual out of limit tablets for weight and hardness.

OBSERVATION 6

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

The procedure SOP028225 relating to the transfer of analytical test methods from your offsite facilities (Transferring Unit (TU)) to your Quality Control Laboratories at the site (Receiving Unit (RU)) are deficient. According to section 5.6.6.3 "Direct Transfer - Two-Way Approach" of SOP028225, Analyst from TU analyzed sample at RU laboratory utilizing the same equipment, reagents, reference standards, and HPLC column that were later utilized by Analyst of your RU laboratory. There is no variable involved in analysis conducted by both the Analysts to ensure transfer of method is accurate and reliable. Your transfer of analytical methods resembled like analyst qualification and retest analysis that normally involves the use of same sample, reagent, equipment, column, and reference standard. This was observed relating to the transfer of the following analytical test procedures:

1. Product: (b) (4) Injection, (b) (4) mg/mL, (b) (4) mL and (b) (4) mL, Test: Related

Substances by HPLC. AMT Report No.: CAL/AMTR/17/002/00

2. Product: [redacted] Tablets, [redacted] mg and [redacted] mg, Test: Related [redacted] Impurities by HPLC, Dissolution by HPLC, and Assay by HPLC. AMT Report No.: AM18-09.20/TR/00

3. Product: [redacted] Tablets [redacted] mg, and [redacted] mg, API: [redacted] USP, Test: Residual Solvent Method III by GC, AMT Report No.: CAL/AMTR/17/0231/00

4. Product: [redacted] Tablets, [redacted] mg and [redacted] mg, API: [redacted] USP, Test: Assay by HPLC, Related Substances by HPLC, Residual Solvent by GC, AMT Report No.: AM18-09.19/TR/00.

OBSERVATION 7

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

On 12-Jun-2025, we observed [redacted] like liquid dripping from the cracks of the ceiling of your 2 to 8°C [redacted] stability chamber ID: QCC-587. The [redacted] sealant that covered the cracks at the leaking areas appeared broken and missing sealant. We also observed potential growth of bacterial, fungal, and mold in dark black to brown to reddish and off-white color colonies. The liquid was dripping from the cracks through these colonies on the top of stability samples that were stored underneath on the racks inside this stability chamber. This stability chamber is used for the storage of sterile [redacted] drug products for the US and other than the US markets.

OBSERVATION 8

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

The procedure for documenting visual inspection results during media fills is inadequate to ensure the

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	6/2/2025-6/13/2025*
	FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Virang Shah, Vice President - Operations	
FIRM NAME Sun Pharmaceutical Industries Ltd.	STREET ADDRESS Halol - Baroda Highway
CITY, STATE, ZIP CODE, COUNTRY Halol, Gujarat, 389350 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

accuracy and integrity of batch records.

During the review of media fill [redacted] (b) (4) eff. 17-Mar-2025 and subsequent interview, it was observed that the [redacted] (b) (4) labels used to record initial visual inspection results were discarded after the results were transcribed into the batch record. The firm's Standard Operating Procedure for Visual Inspection of Media Fill Containers (SOP032025, v. 2.0, eff. 26-Feb-2024) does not require the retention of these [redacted] (b) (4) labels or provide an alternative method for verifying the accuracy of transcribed data. In addition, there is no documented second-person verification process to ensure the accurate transfer of inspection results from the [redacted] (b) (4) labels to the batch record.

***DATES OF INSPECTION**

6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu), 6/06/2025(Fri), 6/09/2025(Mon), 6/10/2025(Tue), 6/11/2025(Wed), 6/12/2025(Thu), 6/13/2025(Fri)

X Lisa L Flores
Office of Global Policy and Strategy Employee
Signed By: 2001625756
Date Signed: 06-13-2025 13:12:00

X Pratik S Upadhyay
Investigator - Dedicated Drug Cadre
Signed By: PRATIK S. UPADHYAY -S
Date Signed: 06-13-2025 13:12:35

EMPLOYEE(S) SIGNATURE
Justin A Boyd, Investigator
Pratik S Upadhyay, Investigator - Dedicated Drug Cadre
Lisa L Flores, Office of Global Policy and Strategy Employee

X Justin A Boyd
Investigator
Signed By: 2000358686
Date Signed: 06-13-2025 13:11:34

DATE ISSUED
6/13/2025