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	12/3/2019-12/13/2019*
	FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Pradipta Swain, 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 Sterile and Non-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

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, your Quality Unit failed to implement adequate and validated controls for ensuring that distributed vials of (b) (4) Injection USP (b) (4) mg/mL always comply with the quality they are purported to

(b) (4) release/regulatory specification range is (b) (4) and (b) (4) release/regulatory specification range is (b) (4)

A. On 25 May 2018, assay testing of (b) (4) njection USP (b) (4) mg/mL; Lot (b) (4) Expiration date April 2020 was performed by HPLC. Out-of-specification (OOS) results were observed for content of (b) (4) and (b) (4) with average values of (b) (4) respectively. Your Quality Unit initiated the laboratory investigation PR ID #55524, and no laboratory root cause was identified. Manufacturing investigation PR ID #56109 was also initiated and documented that the source for the OOS results observed were not determined. Approximately, (b) (4) vials of Lot (b) (4) ejected.

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	Kellia N Hicks, Investigator Jose E Melendez, Investigator Dongping Dai, Chemist/Biologist	X Kellia N Hicks Investigator Signed By: Kellia N. Hicks -S Date Signed: 12-13-2019 18:29:10	12/13/2019

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B. On 24 Nov 2018 OOS and Out of trend (OOT) results were also observed for assay testing of (b) (4) Injection USP (b) (4) mg/mL; Lots (b) (4) Expiration Date October 2020. The OOS results for Lot (b) (4) were observed for content of (b) (4) and (b) (4) with average values of (b) (4) respectively. The OOT result (b) (4) was obtained for content of (b) (4) in Lot (b) (4) Your Quality Unit initiated the laboratory investigation PR ID #170804 and documented that based on the preliminary QC laboratory assessment, no assignable cause could be identified for the original OOS/OOT results in Lots (b) (4) and (b) (4)

Your Quality Control laboratory performed additional assay testing for lot (b) (4) Vials from different (b) (4) were analyzed. (b) (4) Injection USP (b) (4) mg/mL; Lot (b) (4) showed results within specifications fo (b) (4) (b) (4), respectively. The (b) (4) sh (b) (4)

Investigation PR ID #170804 revealed the most probable root cause for the OOS in Lot (b) (4) "is the possibility that (b) (4) used for (b) (4) might have not completely (b) (4) and subsequently transferred to filling tank during initial produc (b) (4) . Lot (b) (4) was rejected.

As corrective actions, your Quality Unit implemented the following: (b) (4) (b) (4) (b) (4) Nonetheless, the manufacturing process of (b) (4) Injection USP (b) (4) mg/mL drug product was validated discarding (b) (4) filled vials (b) (4) at (b) (4) line start-up. Your Quality Unit released (b) (4)

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Injection USP(b) (4) mg/mL; Lot(b) (4) even though this lot was manufactured under similar manufacturing conditions as Lot(b) (4)

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, your firm failed to establish and implement controls which ensure data integrity in the use of the environmental monitoring MODA EM PROD version 3.4 computerized system used by your Microbiology Laboratory for all microbiology samples including all sterile environmental monitoring.

A. Your Quality Control (QC) Microbiology Laboratory failed to establish controls which monitor and prevent all environmental monitoring data from being manipulated in the MODA-EM PROD version 3.4 computerized system, in which data from all environmental and personnel microbiology analyses at your facility are entered which are associated with all sterile manufacturing.

Further, your firm failed to establish and implement procedures which require the review and evaluation of quality trends of audit trails in the MODA-EM PROD version 3.4 computerized system from 2016-2019. Hence, your firm failed to perform reviews of audit trails and evaluate quality trends in this computerized system to date, to include, QCU oversight and corrective and preventive actions for minimizing and decreasing the likelihood of reoccurrence of identified trends. Your microbiology laboratory processes approximately(b) (4) and(b) (4) samples per(b) (4) em was

implemented in 2016 in your facility, your microbiology laboratory has processed approximately (b) (4) where audit trails were not reviewed, and the results trended.

For example, MODA-EM operating procedure, "QCM-153/05, Operating procedure for MODA-EM and MODA-FDC system, Effective Date: 23/07/2019" [dd/mm/yyyy], establishes that users, *who are not defined in the procedure*, have access privileges to edit sample information including the following: sample start date (includes time), sample end date (includes time), sampling technician, environment (Dynamic/Static), person sampled, and personnel site (area sampled, such as, (b) (4) . The procedure also does not require prior authorization for such edits from management. All user roles also have the ability to delete information to be printed on the sample labels, such as, plate name, type (b) (4) etc.), plate barcode, vendor, media/Lot, and media used.

Additionally, the, MODA-EM operating procedure, "QCM-153/05, Operating procedure for MODA-EM and MODA-FDC system, Effective Date: 23/07/2019" [dd/mm/yyyy], establishes in section 7.2.3.7.1, "Sample information that has not yet been approved may be edited to correct errors or add information that was not collected earlier in the sample life cycle. The edit sample information for the currently selected sample, the user selects the Edit option on the Operation ribbon menu. Further, global program operating procedure, "Form027545, Computerized Systems Administration Protocol for Lonza MODA, Version 1.0, Effective Date: 24 Dec 2018" establishes in Attachement-3, List of parameters for different authorization level for Lonza MODA, that the Administrator [IT], Functional Admin [QA], and the Supervisor have user access privileges to un-approve samples. Samples can be edited in an unapproved status.

Further, the MODA-EM PROD version 3.4 computerized software system used to manage microbiological environmental monitoring data, establishes via assigned user roles within the program

and procedure, "Form027545, Computerized Systems Administration Protocol for Lonza MODA, Version 1.0, Effective Date: 24 Dec 2018", that all user roles including: Administrator, Lab Approver, and the Site Supervisor, have access privileges to edit all microbiological test results in MODA without prior authorization from management, including, but not limited to, the following names:

- "TestResultEdit"
- "TestResultIncubation"
- "TestResultOrganism"
- "TestResultProduct"
- "TestResultResults"
- "TestResultSampling"
- "TestResultTesting"

There is no oversight of this data to include trending and CAPAs.

B. Trend reports procedure, "QCM-147/03, Trend reports in Quality Control Microbiology, Effective Date: 30/03/2018" [dd/mm/yyyy], fails to establish that all identified microbiological findings must be trended and corrective actions identified and implemented to minimize or correct quality trends in MODA. Currently, your firm trends results data only. For example, your procedure, failed to require the trending of sample edits and edited test results. There is no evaluation with regards to determining the root cause or corrective and preventive actions were taken to control editing, and to address minimizing and decreasing the likelihood of reoccurrence of identified trends.

C. The control procedure SOP-ANA-017/10 entitled "Cleaning and operation of (b) (4) (b) (4) ; effective date 19 Apr 2021 establishes, "if maximum cycle time and (b) (4) value is observed more than established limit for (b) (4) Injection (Non-USA

product), then further data is to be evaluated/investigated, and based on finished product results, batches will be released for commercial purpose."

On 17 Aug 2018, one (1) (b) (4) of (b) (4) AN-026 located at Block (b) (4) was found out-of-limit (OOL) during (b) (4) of (b) (4) (b) (4) mg (b) (4) bags; Lots (b) (4). The (b) (4) showed a value of (b) (4) C (acceptance range limit is (b) (4) (b) (4) to (b) (4) (b) (4)). In addition, the exposure time was (b) (4) (the acceptance limit is (b) (4) (b) (4)). Your Quality Unit initiated the investigation PR ID #103640 which documented a damaged (b) (4) was the most probable root cause of this incident.

Although the (b) (4) cycle for Lots (b) (4) was found out-of-validated range, the lots were sampled by the QA unit and released to QC laboratory for analyses. The failure of the (b) (4) (b) (4) cycle was not reported to the QC Laboratory. On 5 Sep 2018 and 17 Sep 2018, out-of-trend (OOT) (PR ID #115388) and out-of-specification (OOS) (PR ID #123172) results were observed for Related Substance (RS) testing. Lot (b) (4) showed OOT result ~ (b) (4) % and Lot (b) (4) showed OOS result (b) (4) % for (b) (4) impurity. The acceptance limit is NMT (b) (4) %. After completion of Phase-1 and 2 investigations where no laboratory assignable cause was identified, (b) (4) mg (b) (4) Injection (Non-US marketed product); Lots (b) (4) were rejected.

D. Your firm failed to ensure data integrity in raw material dispensing. During a walkthrough of the (b) (4) Block (b) (4) on 03 Dec 2019, we observed that the material dispensed date on the container label for dispensed raw materials of product (b) (4) ablets USP, (b) (4) mg, batch no. (b) (4) was missing on 3 (three) (b) (4) of the same material. Further the "Material Dispensed By" was typewritten and

completed by an employee ahead of time but was not completed contemporaneously. The Employee documented as the dispenser did not dispense the raw material but was the 2nd person verification.

OBSERVATION 3

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.

Your Quality Control Unit (QCU) failed to establish scientifically sound and appropriate analytical test procedures designed to assure that representative sample vials of (b) (4) Injection USP (b) (4) ng/mL filling process are taken for analysis and conform to expected quality attributes.

Your firm validated analytical procedure entitled "(b) (4) Injection USP (b) (4) mg/mL, (b) (4) mL" specification number (b) (4) effective on 28 Aug 2019, for the determination of (b) (4) (b) (4) ontent in (b) (4) Injection USP (b) (4) mg/mL drug product. Per test procedure (b) (4) the assay sample requires the transfer of (b) (4) g (b) (4) g) of finished product in (b) (4) ml volumetric flask. Per your Deputy General Manager QC, the laboratory receives sample vials representative from (b) (4) of the filling process. Nonetheless, your firm only uses (b) (4) drug product vials for preparing the sample. In addition, there is no documented evidence to show at which (b) (4) f the filling process (i.e (b) (4) the vials analyzed. This practice also impacts the analytical testing of the following US marketed products:

- (b) (4) (b) (4) Injection USP, (b) (4) /vial;
- (b) (4) Injection, (b) (4) mg/vial;

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- (b) (4) Injection USP (b) (4) cg/mL, (b) (4) L/vial;
- (b) (4) Injection (b) (4) mg/mL, (b) (4) mL and (b) (4) mL;
- (b) (4) Injection (b) (4) mg (b) (4) mL (b) (4) mL (b) (4) vial;
- (b) (4) (b) (4) mg (b) (4) Injection, (b) (4) mL/vial;
- (b) (4) Injection USP (b) (4) mg/mL, (b) (4) mL/vial;
- (b) (4) Injection USP (b) (4) mg/mL, (b) (4) mL/vial;
- (b) (4) Injection (b) (4) mg/vial;
- (b) (4) Injection (b) (4) mg/vial, (b) (4) ml/vial

OBSERVATION 4

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

****REPEAT OBSERVATION****

There are no written control procedures that describe, in sufficient detail, the instructions a microbiology analyst must follow during the sampling process for (b) (4) located in the filling machine/(b) (4) (b) (4) loading/(b) (4) room manufacturing ar

Per Senior Executive QA-Microbiology, a swab sample is collected from the (b) (4) that is used in critical operations such as; handling interventions near opened vials or near product exposure zone at the end of the filling process. However, there is no mechanism in place which defines the sampling procedure and the (b) (4) areas that should be sampled at the end of the filling process. Therefore, there is no assuran rent surface monitoring (i.e. swab sampling) is sufficiently robust and can

be used to detect potential microbiological contaminants. This discrepancy impacts the filling lines located in Blocks (b) (4)

OBSERVATION 5

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

Specifically, The Online Particle Count Sampling Location Risk analysis of Room (b) (4) SVP Filling Room; Document No. SPIL (b) (4) NVPC-RA01; approved on 06 Sep 2016 was found to be inadequate in that:

- There is no documented evidence in the report that describes the conditions in which the study was carried out (i.e. dynamic/static conditions);
- There is no documented evidence in the report that describes how the critical operations (e.g. operator's interventions, set-up activities and exposition time of open containers) were evaluated to consider the current (b) (4) locations as sampling critical locations;
- The original risk analy nsidered (b) (4) sampling locations (between (b) (4) area and (b) (4) area) during the assessment. No evaluation was carried out near the (b) (4) (b) (4) even though several operators interventions/process activities (e.g. stopper movements, stopper jams and pick and place movements) are carried out within this critical zone.

There is no documented empirical data which demonstrates that the selected sampling locations in filling Line (b) (4) produces meaningful results and represents the all critical zones of the Grade (b) (4) illing

area. This failure also impacts the following plastic bottle and vial filling lines: Block (b) (4) Block (b) (4) Block (b) (4)

OBSERVATION 6

Control procedures are not established which monitor the output of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, your firm's current procedures fo (b) (4) and sterile current manual visual inspection qualification:

- "SUN/NS-SP/623/02, Protocol for Qualification of Visual Inspector for Inspection of Tablets/Capsules, Effective Date: 06/06/2019 [dd/mm/yyyy]
- "SUN/S-SP/083/01, Protocol for Qualification of Visual Inspector for (b) (4) Effective Date: 06/06/2019" [dd/mm/yyyy]

used for qualifying/ re-qualifying personnel performing the visual inspection of finished drug products manufactured of the following types of drug products, including but not limited to:

- Tablets
- Capsules (b) (4))
- (b) (4)
- Liquid Ampoules
- (b) (4) Vials

- Plastic Bottles
- Suspension Vials
- Liquid Vials
- (b) (4)
- (b) (4)
- Colored Liquid Vials
- (b) (4) Bags

does not require the use of a visual inspection kit, which includes physical samples of all critical defect in different ampoule/bottle sizes or variations of types and sizes of particulates and different types of product formation defects that may be found in batches the Inspectors would be required to inspect in real-time for visual inspector training or qualification, including, but not limited to the following critical defects:

- Tablets not in uniform size
- Missing de-bossing
- Abnormal discoloration of product
- Removal of stopper from the bag
- Stopper quality

The (b) (4) and sterile Inspectors ability (Inspector Fatigue) to identify the above-mentioned defects at the beginning of a (b) (4) ersus the (b) (4) has not been evaluated during the qualification of the Inspectors. None of the Inspectors were originally qualified on all critical defects.

Additionally,

(b) (4) of the (b) (4) Inspectors in the cohort with qualifications dated 20 Apr 2018- 20 Apr 2020 are still currently employed as Inspectors by your firm have been trained on additional defects with pictures, but the training was not verified for critical defects with qualification to ensure their ability to identify the additional three (3) defects added to the Defect Albums since they were updated in October 2018 (Change Control - PR ID#139557 dated 10 Oct 2018) and December 2018 (Change Control- PR ID#188252 dated 18 Dec 2018), which is 14 months and 12 months respectively to date.

OBSERVATION 7

Written procedures are not established and followed that describe the examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

A. Your firm lacks written procedures describing, in sufficient detail, the visual examination of sterile and (b) (4) finished products, such as, tablets and capsules.

For all (b) (4) finished products, the amount of tablets and capsules, the time spent examining the tablets and capsules, as well as, the different steps the operator must follow are not established in the BMR or in tablet and capsule visual inspection procedure, "TAB-063/20, Inspection of Tablet and Capsule Dosage Form, Effective Date: 28 Jun 2019" [dd/mm/yyyy].

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For example, I, Investigator Hicks, observed (b) (4) visual inspection of (b) (4) Capsules (b) (4) (b) (4) ng Batch number (b) (4) (non-US product) on 11 Dec 2018. During my observation one (1) Inspector performed manual visual inspection in the following way 1) Take a handful of (b) (4) capsules from a pile of (b) (4) capsules on a table, in which your Vice President Operations, (b) (4) reported were approximatel (b) (4) capsules per (b) (4) The operator examined, approximately (b) (4) capsules, in approximately (b) (4) before discarding, rejects, if any, and placing the inspected capsules in a plastic bag. In (b) (4) one (1) operator inspects (b) (4) g of capsules which is approximately (b) (4) capsules. None of the tablets were carefully examined during the manual visual inspection process that I observed.

B. The amount of time spent by Inspectors examining all sterile finished liquid and (b) (4) products is not consistent. Means of tracking time are not provided to each Inspector to ensure the consistency of the manual visual inspection amongst all visual inspectors.

For example, I, Investigator Hicks, observed sterile visual inspection of (b) (4) (b) (4) ng/(b) (4) ml Solution (b) (4) Injection batch number (b) (4) (US product) on 11 Dec. 2018. I observed Inspectors to be performing manual visual inspection from (b) (4) each on the (b) (4) and the (b) (4)

Visual inspection for parenteral products procedure, "PAR-013/25, Visual Inspection of Parenteral Products, Effective Date: 27/06/2019" [dd/mm/yyyy] section 7.11.1 establishes, "Each container shall be observed in reference time of minimum (b) (4) (b) (4) to enhance the detection of particulate

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OBSERVATION 8

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

Specifically, Your Quality Control Unit (QCU) did not conduct a thorough evaluation and implement appropriate and effective corrective actions in a timely manner for the high number of critical alarms (i.e. compressor failure and PLC and PC/communication) observed in (b) (4) M570 and M578 located in Block (b) (4) area.

Specifically, control procedure SOP-PAR-237/04 entitled, "Recording and evaluation of alarms generated during batch manufacturing", effective date 14 March 2019, defines critical alarms as "Alarms that have significant impact on the product (strength, identity, safety, purity and Quality". During (b) (4) trending of alarm evaluation (b) (4) your production department reported 64 (b) (4) M570) and 43 (b) (4) M578 ompressor failure and PLC/PC/communication during manufacturing. Nonetheless, your firm has not carried out a comprehensive assessment to identify the source for the alarmed events (e.g. current equipment preventative maintenance) and established actions for minimizing reoccurrence.

*DATES OF INSPECTION

12/03/2019(Tue), 12/04/2019(Wed), 12/05/2019(Thu), 12/06/2019(Fri), 12/09/2019(Mon), 12/10/2019(Tue), 12/11/2019(Wed), 12/12/2019(Thu), 12/13/2019(Fri)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: Not annotated

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