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	6/3/2019-6/11/2019*
	FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pradipta K. Swain, Vice President of Operations

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

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Production

OBSERVATION 1

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

The Aseptic Process Validation Master Plan was not followed during execution of media fill run (b) (4).

Specifically,

A media fill failure on line (b) (4) for the (b) (4) resulted in media fill failure with over (b) (4) % media batch contamination in the filled, incubated units. An investigation into the media fill failure determined that several 'new' operations occurred during this media fill run. These included the following that were either not recorded in detail as performed or not performed per written batch instructions:

AMENDMENT 1

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	Farhana Khan, Investigator Monica C Burgos Garcia, Investigator Kejun Cheng, FDA Center Employee or Employee of Other Federal Agencies Rebecca E Dombrowski, FDA Center Employee or Employee of Other Federal Agencies	6/11/2019

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- Removal of the (b) (4) to the aseptically sealed tank containing sterile (b) (4) media.
- Maintenance Activity to repair/reset the (b) (4) of the filling station and bevel gear due to reversal of (b) (4) movement resulting in intake of air instead of delivery of media.
- Quality Assurance Impact Evaluation as part of the 'Breakdown Maintenance Report' regarding the filling station reversal (Sr. No. (b) (4)).

Laboratory

OBSERVATION 2

Established laboratory control mechanisms are not documented at the time of performance.

The assurance of the data from the all analytical testing data is not provided

Specifically,

Environmental monitoring of plates on June 5, 2019 included review of more than (b) (4) sample sets. In my review of the data in support of the EM review, it was noted that in selected examples, the primary reviewer performed the plate analysis almost 2 hours prior to the witness review. As explained by your EM QC staff and detailed in written procedure SOP QCM-042, the witness is to perform the witness review of the reading of the EM plates at the same time as the primary review.

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For example, and as noted in the MODA system for EM data:

a) sample plate (b) (4) initial read/results entry: 10:09:05, review: 12:05:17

b) sample plate (b) (4) initial read/results entry: 10:09:05, review: 12:05:17

Device Observations

OBSERVATION 3

Design plans that describe or reference the design and development activities and define responsibility for implementation have not been adequately established.

Specifically, your design plan for (b) (4) Injection, (b) (4) ncg/mL, (b) (4) mL & (b) (4) mL (b) (4) (b) (4) associated to (b) (4) was approved on May 2019. However, your firm began the design activities associated to this product on August 2012. Additionally, your firm did not have an established device history file that demonstrated conformance to an established design plan.

OBSERVATION 4

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the requalification of your (b) (4) (ID:240) conducted on 6/29/2017 under Protocol No.: QUA-S/0253 Requalification Protocol/Report for (b) (4) (b) (4) (equipment ID:240) does not demonstrate that the air supply, assembly air, and

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clamp air pressures required per your reference document, were challenged to determine optimal production parameters. According to your reference document, (b) (4) (b) (4) Instruction approved on 12/07/2019, the pneumatic assembly machine requires an air supply of (b) (4) psi, assembly air cylinders require (b) (4) ± (b) (4) psi and clamp air cylinders require (b) (4) ± (b) (4) psi. During the review of Protocol No.: QUA-S/0253, it was noted that the air supply pressure was recorded as (b) (4) (approximately (b) (4) psi). However, no other data was documented for the assembly air cylinders, the clamp air cylinders, and for the tolerances provided by your supplier.

Moreover, the pneumatic assembly machine (ID:240) was used to assemble exhibit lots associated to (b) (4) (b) (4) (b) (4).

***DATES OF INSPECTION**

6/03/2019(Mon), 6/04/2019(Tue), 6/05/2019(Wed), 6/06/2019(Thu), 6/07/2019(Fri), 6/10/2019(Mon), 6/11/2019(Tue)

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Annotations to Observations

Observation 1: N/A

Observation 2: N/A

Observation 3: Promised to correct

Observation 4: Promised to correct

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