DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	2/12/2018-2/23/2018* FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Pradipta Swain, VP Operations

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

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Aseptic filling lines in Block (b)(4) and (b)(4) show poor design as follows:

A. On 14 February 2018, I observed rough, cracked, and uneven (b)(4) surfaces (with dislodged gaskets) used to create operational barriers separating Grade A filling areas in Block (b)(4) and (b)(4) from the surrounding Grade B environment. These rough surfaces create difficult to clean surfaces in the immediate vicinity of aseptic filling operations. The ceiling above the filling equipment has channels surrounding each of the (b)(4) HEPA filters that are approximately one inch wide by three inches deep that cannot be accessed with a mop used during cleaning/sanitizing. There is extensive use of (b)(4) sealant around all the HEPA filter units and various rough surfaces on the ceiling such as mounting bolts for the filters that create a difficult-to-clean surface in the Grade A environment.

B. Your air-flow visualization studies conducted in April 2017 show upward flow of smoke ((b)(4)) from below waist level up towards the ceiling return grates of Grade B areas immediately adjacent to Grade A areas. These Grade A areas are used for loading a (b)(4) and filling sterile liquid product vials. Videos identified with the following numbers are applicable: 188B

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Scott T Ballard, Investigator Parul M Patel, Investigator - Dedicated Drug Cadre Kellia N Hicks, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 02-23-2018 00:20:08	2/23/2018

and 190A, as well as new videos (not serially numbered) created on 19 February 2018 during the current inspection.

C. On 15 February 2018, I observed the aseptic filling operation for (b) (4) injection batch # (b) (4). During this time and throughout the inspection, I observed operators nearly constantly moving (b) (4) in the aseptic filling room (b) (4) with their gloved hands (and gowned arms) as they moved about. However, environmental monitoring does not include contact plates for the (b) (4) that experience the greatest traffic during production and set-up activities. There is a total of (b) (4) linear meters of (b) (4) in the (b) (4) room and separately (b) (4) linear meters of (b) (4) installed in the Block (b) (4) aseptic filling room # (b) (4). There is no scientific justification for omitting this sampling location.

OBSERVATION 2

Written procedures for cleaning and maintenance fail to include description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically, your equipment is not installed and maintained according to a written procedure to reduce risk to product contact surfaces or process materials.

D. On 12 February 2018, I observed bulk product (b) (4) tanks located in the material prep area labeled as "Cleaned". However, I observed tank #SH159 having a (b) (4) / (b) (4) residue on the (b) (4) gasket. This tank is dedicated to injectable (b) (4) production. I also observed tank #SH412 to have a torn and degraded (b) (4) style gasket installed at the (b) (4). This tank was last used for bulk (b) (4) Injection. The cleaning procedure #PAR-215/05 does not speak directly to cleaning or replacement of the (b) (4)

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gasket.

E. On 14 February 2018, I observed degraded and discolored (b) (4) gaskets on (b) (4) storage tank that supplies (b) (4) to the production area in Block (b) (4). I also observed degraded and discolored gaskets in bulk (b) (4) drug formulation equipment (product contact surface). There is no written procedure with respect to this equipment that specifies service or replacement of gaskets (ENG-020/11).

OBSERVATION 3

Written procedures are lacking which describe in sufficient detail the sampling, testing, approval and rejection of drug product containers and closures.

Specifically, the firm's written procedure "PAR-139/10, Cleaning and Operation of Vial/Ampoule (b) (4) (b) (4) Machine, Effective Date: 11/11/2017" allows the performance of 2 sequential failures without initiation of a deviation investigation. The procedure also states, repeat rejection from the (b) (4) operation as false rejection FR1, FR2, and FR3.

***DATES OF INSPECTION**

2/12/2018(Mon), 2/13/2018(Tue), 2/14/2018(Wed), 2/15/2018(Thu), 2/16/2018(Fri), 2/19/2018(Mon), 2/20/2018(Tue), 2/21/2018(Wed), 2/22/2018(Thu), 2/23/2018(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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