

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER US Food & Drug Administration, CDER/Inspection Assessment Branch White Oak Building 51, Room 4235, 10903 New Hampshire Avenue Silver Spring, MD 20993, Attn: Mr. Concepcion (Coki) Cruz; Telephone 001-301-796-3254; FAX: 001-301-847-8738; E-MAIL: cderosiab@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION April 6, 2017-April 13, 2017
	FEI NUMBER 3004561553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Sanjay Deshmukh, Senior Vice President Operations Region IV**

FIRM NAME Sun Pharmaceuticals Industries Ltd.	STREET ADDRESS Survey No. 259/15
CITY, STATE AND ZIP CODE Dadra, Union Territory of Dadra & Nagar Haveli 396 191, India	TYPE OF ESTABLISHMENT INSPECTED Finished Dosage Drug Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

**Observation 1**

Laboratory records do not include a complete record of all calculations and graphs performed in connection with the test. Specifically,

A) On April 6, 2017, during the walk-through of the quality control laboratory, we observed a torn and discarded graph and data printout sheet generated through the minitab statistical software program for Atomic Absorption Spectroscopy (b)(4) Content test for (b)(4) USP (b)(4) batch (b)(4) dated October 28, 2016.

This discarded graph and data printout sheet was not included in the Atomic Absorption (b)(4) Content test data packet for (b)(4) USP (b)(4) batch (b)(4)

B) On April 6, 2017, during the walk-through of the quality control laboratory, we observed an uncontrolled excel spreadsheet stored on a shared network (M: drive) folder that was used to calculate (b)(4) value of (b)(4)

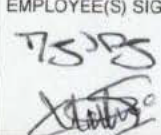
(b)(4) sample content uniformity for (b)(4) batch (b)(4) High Performance Liquid Chromatography data from the Empower system was exported into this excel spreadsheet to calculate the min, max, mean value, standard deviation and %RSD to report as final results for (b)(4) sample content uniformity for (b)(4) batch (b)(4) However, this excel spreadsheet was not included in the data packet.

C) There is no associated raw data for the sample preparation of working reference standard (b)(4) lot (b)(4) that was prepared on November 16, 2016 with expiry of (b)(4) hat is used to

determine related substance by HPLC. The qualification package for this working reference standard shows that (b)(4) of (b)(4) was received at the facility and (b)(4) vials were prepared to create the individual working reference standard vials that are used in the quality control testing laboratory. However, there is no associated sample preparation raw data for these (b)(4) working reference standard vials including the amount and weight dispensed into each of these vials.

**Observation 2**

Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed. Specifically,

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On April 6, 2017, we discovered the following items inside a trash cart located outside the worker change room area: a torn and discarded partially dispensed label for recording the quantity of raw material remaining after use or sampling, stock sticker label that is used to label raw materials in the warehouse, issue sticker coupon that is used to label dispensed materials for use in manufacturing. Furthermore, we also observed three (3) broken tablets and two (2) intact unaccounted for tablets inside a bag that was (b) (4) colored with one side (b) (4) with (b) (4) and plain on the other side that is consistent with the description of (b) (4) ng.

**Observation 3**  
 The quality control unit lacks the authority to review production records to assure that no errors have occurred. Specifically,  
 On April 7, 2017, during a walk-through of the manufacturing and packaging area, we observed stacks of blank and pre-printed logbooks being retained by the production department. In addition, the stamps used for the issuance of these logbooks that are used to record manufacturing data were also retained by the production department. The Quality Unit did not have oversight for the issuance and reconciliation of these logbooks used in the manufacturing area because the issuance and reconciliation of these logbooks were being performed independent of the Quality Unit by each respective production area department head.

**Observation 4**  
 Each lot of drug product is not withheld from use in quarantine before release from the quality control unit. Specifically,  
 On April 7, 2017, we observed five (5) in-process intermediate stage products that were past hold-time expiry in the intermediate storage area that were comingled with other intermediate stage products that were within hold-time expiry. These intermediate stage products that exceeded the hold-time were being stored without any designation or segregation demonstrating that they were past expiry and unacceptable for use for further downstream manufacturing.

**Observation 5**  
 Written records of investigation into unexplained discrepancies or the failure of a batch or its components to meet specification do not always include Conclusion and follow up  
 Specifically, the following lab events were not investigated to assess the Root Cause, also no Corrective and Preventative Action (CAPA) was initiated.

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- PR No#125473/ LE- (b)(4) 2016-0382: An unidentified extraneous peak was observed during the Dissolution of (b)(4) tablet (b)(4) mg (Stability Station 12M LT) Lot # (b)(4)
- PR No#125578/ LE- (b)(4) 2016-0385: An unidentified extraneous peak was observed during the Dissolution of (b)(4) Capsule (b)(4) mg (Stability Station 2M ACC) Lot # (b)(4)
- PR No#125849/ LE- (b)(4) 2016-0387: An unidentified extraneous peak shape was observed during the impurity (b)(4) RS of (b)(4) tablet USP (b)(4) mg (Stability Station 24M LT ) Lot # (b)(4) and Lot # (b)(4)
- PR No#126162/ LE- (b)(4) 2016-0392: An unidentified extraneous peak was observed during the Assay of (b)(4) tablet (b)(4) (b)(4) mg (Stability Station 24M LT) Lot # (b)(4)
- PR No#126673/ LE- (b)(4) 2016-0394: An unidentified extraneous peak was observed during the Assay of (b)(4) tablet (b)(4) (b)(4) mg (Stability Station 24M LT) Lot # (b)(4)
- PR No#126785/ LE- (b)(4) 2016-0395: An unidentified extraneous peak shape was observed during the (b)(4) Dissolution of (b)(4) Capsule (b)(4) mg (Stability Station 2M ACC ) Lot # (b)(4)
- PR No#1267469/ LE- (b)(4) 2016-0401: Empower data was missing during the Dissolution and Assay test of (b)(4) Tablets (b)(4) mg (Stability Station 16M LT ) Lot # (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 and the drug products. Specifically, the firm has been receiving numerous customer complaints regarding over fill and under fill tablets ranging from one to sixty-three since 2015. The firm conducted investigations which include process verifications to assess the root cause and found that the tablet (b)(4) gives anomalies during the tablet (b)(4) process. As a (b)(4) control, the firm has a check weigher in the packaging line. However, this check weigher is not sensitive enough to capture under fill or over fill tablets.

**Observation 7**

Routine checking of electronic equipment is not performed according to a written program to ensure proper performance. Specifically, Computer software related errors were not captured within the quality system. For example, in the quality control laboratory, audit trail errors regarding electronic atomic absorption spectroscopy run files saved in the wrong database folder and (b)(4) instrument communication errors resulting in multiple blank run data files have been observed without any associated incident report or impact assessment by the Quality Unit.

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**Observation 8**  
Employees are not given training in written procedure required by current good manufacturing practices regulation. Specifically,  
A) For PR#84010/OS-(b)(4) 2016-0063 (b)(4) Tablets USP, (b)(4) ng, Batch No: (b)(4) an OOS was observed for Assay test which was initiated on April 1, 2016. The OOS concluded that the most probable root cause identified was due to a dilution error performed by the Analyst. As a CAPA, the analysts were trained for appropriate care for laboratory practices, standard preparation, and dilution. However, For PR# 93116/OS-(b)(4) 2016-0107 (b)(4) Tablets, another OOS was observed for Assay test which was initiated on May 16, 2016. This OOS also concluded by recognizing that the most probable root cause for the OOS result was due to standard dilution error performed by the analyst. As a CAPA, the analysts were again retrained for the same training which was conducted approximately one month prior for a similar issue. Furthermore, the following are a few examples of OOS results that have occurred due to the lack of training or lack of CAPA effectiveness:

- PR# 70399 / OS-(b)(4) 2016-0015; Analyst used improper diluent
- PR# 70621/ OS-(b)(4) 2016-0017; Analyst prepared a wrong standard stock solution.
- PR# 142287/ OS-(b)(4) 2017-0006; Analyst failed to (b)(4) the samples for assay test
- PR# 147750/ OS-(b)(4) 2017-0022; Analyst failed to mix the diluent thoroughly.
- PR# 142243/ OS-(b)(4) 2017-0004; Analyst failed to follow the standard testing procedure (STP)
- PR# 144967/ OS-(b)(4) 2017-0016; Analyst used wrong standard solution.
- PR# 151545/ OS-(b)(4) 2017-0032; quote from report: "Analyst might have done unknown mistake"

B) On April 8, 2017, we discovered training question assessments and answer keys to the training assessment questions on the (M: drive) shared network folder. These training question assessments are used to evaluate the effectiveness of training provided at the facility. However, the answers to these training assessments are accessible to all personnel with access to this shared network drive including quality control laboratory personnel engaged in the testing of drug products as well as production personnel.

C) On January 13, 2017, Quality Control employee (b)(6) performed the secondary Quality Assurance review for Atomic Absorption Spectroscopy (AAS) testing of (b)(4) batch (b)(4) 6 month and (b)(4) (b)(4) batch (b)(4) 36 month stability sample assay and dissolution results. However, this employee that performed the secondary review was not trained in Atomic Absorption Spectroscopy.

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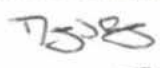
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**Observation 9**  
 Clothing of personnel engaged in the manufacturing of drug products is not appropriate for the duties they perform. Specifically,  
 On April 7, 2017, we observed that employees working in the production area are instructed to gown and then pass through a common unclassified corridor where the waste disposal of packaging material is removed from the facility by un-gowned personnel. In addition, we also observed personnel working in the production area exit the facility to the outside exterior of the building and re-enter the facility with the dedicated production area (b) (4) style slippers.

**Observation 10**  
 Warehouse procedure is not followed. Specifically,  
 On April 7, 2017, we observed (b) (4) lot (b) (4) located at position (b) (4) in the warehouse area. However, when a query was made in the (b) (4) Enterprise Resource Planning electronic system that tracks the location and status of materials located in the warehouse, we discovered that the system showed that the material was located in the wrong location at position (b) (4) in the warehouse.

**Observation 11**  
 Adequate lighting is not provided in all area  
 Specifically during the walk through, we observed the firm's raw material warehouse RM-11 was not adequately lit. Approximately four (4) (b) (4) lights were not in a working condition.

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