DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OSIAB White Oak Building 51, Room 4316 10903 New Hampshire Ave, Silver Spring, MD 20993 001-301-796-3254 Industry Information: www.fda.gov/oc/industry	02/26/2018 - 03/02/2018* FEI NUMBER 3003510514

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. J. Sambi Reddy, Director Operations

FIRM NAME	STREET ADDRESS
Hetero Drugs Ltd. - Unit 1	Plot Nos. 213, 214, 255, Bonthapally Village, Gummadidala
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mandal, Telangana, Sangareddy District, 502313, India	Active Pharmaceutical Ingredients Manufacturer

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

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. Specifically,

A. OOS investigation OOS-HDL1-17-053 was initiated on 08/10/2017 and closed on 08/11/2017 for (b) (4) (b) (4) Batch No: (b) (4) where it was found out-of-specification for water content by Karl Fischer (KF) replicate -1 ((b) (4) %w/w and the specification (b) (4) %w/w L - (b) (4) %w/w). However, the firm did not extend the investigation to manufacturing.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

Your Quality Unit failed to qualify and perform routine audits of multiple suppliers of computer software used for the GxP computerized systems (Empower 3 Software and Laboratory Information Management System or LIMS) used as data acquisition systems in the testing of raw materials, in-process testing, and API finished materials, and Warehouse Management Portal System (WMPS used as the inventory management system) in your facility as required per Step 20 (Supplier Assessment) of SOP #01-043-00 (Computerized Systems Validation Master Plan) 11/01/2013 effective date. For example, the firm accepted the validation documents of the supplier (Empower 3 Software) and failed to qualify that supplier, LIMS and WPMS suppliers, and has not performed a periodic evaluation of Empower 3 Software.

OBSERVATION 3

Employees engaged in the processing, holding, and testing of a drug product lack the training and experience

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		Yvins Dezan, Investigator	03/02/2018

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required to perform their assigned functions. Specifically, during the walk-through of the Production on 02/26/2018 and QC Laboratory on 02/27/2018, I noticed that several QC personnel interviewed in Unit-I could not explain their assigned functions and processes after repeated opportunities. These personnel are trained based on the review of their training records.

A. The Deputy Manager for Production ((b) (6)) could not fully explain what actions to be taken if metals are found in the (b) (4) located in Room # (b) (4) Unit-I where (b) (4) product is manufactured as part of his assigned functions although he was asked both in native's tongue Telugu and English. He worked on (b) (4) Batch # (b) (4) manufactured for the US Market on 03/12/17 and dispatched on 03/18/2017.

B. The Deputy Manager of Pharma Storage ((b) (6)) could not explain the (b) (4) and staging process of finished materials awaiting QA Release in the Pharma Storage when interviewed although he was asked both in native's tongue Telugu and English. He performed the operation for (b) (4) finished API materials Lots # (b) (4) and (b) (4) and dispatched to US Market on 11/09/2017

C. The Assistant Manager QC ((b) (6)) responsible for receiving finished API materials samples and performing (b) (4) samples of these finished API materials could not fully explain the (b) (4) samples process and cleaning although he was asked both in native's tongue Telugu and English. He performed the (b) (4) sampling operation for (b) (4) Lot # (b) (4) on 01/24/16 and dispatched to US Market on 08/16/2016.

D. The Executive QC in the Instrumentation Laboratory ((b) (6)) could not explain how to operate and standardizing the Malvern Mastersize equipment ID #QCD/225, which he used on 11/24/17 for testing (b) (4) Lots # (b) (4) and dispatched to US Market on 11/30/2017.

E. The Deputy Manager HR ((b) (6)) could not explain how to synchronize analog clocks used in the manufacturing operations and was the author of SOP #55-006-01 (Synchronization of Analog Clocks) 02/22/2018 effective date and the "checked by" person of SOP# 55-006-00 (Synchronization of Analog Clocks) 04/05/2014 effective date.

F. The Sr. Executive Production ((b) (6)) could not explain what actions to be taken if critical step timing for (b) (4) is not met. For example, he was asked if the critical step parameters (# (b) (4)) of (b) (4)

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(b) (4) exceeded the parameter what he would need to do. He stated "if gone over the limit, no problem. However, if gone below the limit, appropriate personnel would be notified and a deviation be raised.

OBSERVATION 4

There is no assurance that the equipment used in the production of (b) (4) API are always maintained and/or kept in/under proper conditions for manufacturing operations and to prevent the contamination of the products handled and/or processed in the equipment. The following conditions were observed on 02/26/2018, during the walk-through the production areas in Unit-I (b) (4) Block (used to produce (b) (4) (b) (4)):

A. Inside of (b) (4) #A (b) (4) 001 for the (b) (4) process was observed dirty (i.e. The gloves used by the Investigator showed a (b) (4) color/stains of the inner surface of the (b) (4) which is used to manufactured (b) (4) products destined for US Market.

OBSERVATION 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding laboratory controls and operations. Specifically, the glassware storage area in your Microbiology laboratory is not well-maintained. Cleaned glassware including vials, flasks, pipettes, etc. were stored uncovered in close proximity to other unclean glassware, cleaning supplies, and the washing sink, which is contrary to Step # (b) (4) of SOP #60-018-01 (Cleaning and Sterilization of Glassware) 08/21/2017 effective date. Additionally, the cleaned glassware was not labeled with current cleaning status.

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