DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE 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 Industry Information: www.fda.gov/oc/industry	7/23, 7/25, 7/26, and 7/27/2018
	FEI NUMBER 3006456888

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Rana Banerjee, General Manager

FIRM NAME	STREET ADDRESS
Unichem Laboratories Limited	Plot N0. 197, Sector 1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pithampur, Dhar, India	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 (I) (WE) OBSERVED:

1. Cleaning procedures are not validated.

Specifically,
The Unichem Laboratories Ltd. procedure PPQA029/04 is not validated to assure API manufacturing equipment are cleaned to a level that does not impact product quality when employed for the multiple batch campaign process. The cleaning validation protocol did not completely describe the equipment to be cleaned, procedures, materials, acceptable cleaning levels, parameters to be monitored and controlled, and analytical methods. In addition, stability of the worst case condition defined by the completion of a full campaign of (b) (4) batches was not defined, even though finished API has been distributed into the market for years.

2. Test procedures are not scientifically sound and appropriate to ensure that raw materials, intermediates, APIs, and labels and packaging materials conform to established standards of quality and/or purity.

Specifically,
The review of the test results for the finished product testing of (b) (4), USP Batch No. (b) (4) Related Compound (b) (4) (USP limit NMT 0.1%) did not correctly calculate and report a peak matching the location (relative retention time) on the chromatogram for Related Compound (b) (4). The peak matching Related Compound (b) (4) location in the sample sets (b) (4) calculates to be approximately 0.3%, which would be Out Of Specification (OOS). The required investigation and reconciliation by Quality Assurance was not performed for this occurrence of an OOS event.
Further review of Unichem Laboratories Ltd. procedure PPQC141/00, confirmed the company has a policy permitting any response attributed to a blank in HPLC analysis to be (b) (4) without confirming the identity of the compound eluted, investigation, and notification of QA when a possible OOS occurs.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	William Leonard	William Leonard, Investigator	07/27/2018

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3. Laboratory controls were not followed and documented at the time of performance.

Specifically,
Review of Unichem Laboratories Ltd. procedures for Media Preparation and Microbial Limits testing do not provide for an assurance of GMP compliance in the following examples:
a. Media are not placed in a secure, quarantine state pending growth promotion before being released for use in Microbial Limits testing of raw materials, finished goods or stability monitoring.
b. Microbial Limits testing procedures do not require the documentation of the specific incubator used in the performance of testing of raw materials, finished goods or stability monitoring.
c. Microbial Limits testing procedures do not require the documentation of the specific time test media are placed into or removed from the incubator used in the performance of testing of raw materials, finished goods or stability monitoring.

4. There was no record of stability samples stored in containers that simulate the market container.

Specifically,
Review of the Unichem Laboratories Ltd. stability program records for Batch No.'s (b) (4) and (b) (4) found that there was no traceability for the materials of construction of containers used for the units created after the sample of the batch was delivered to the lab. There also was no record of who and when aliquots were created in preparation for stability storage.

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