DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg. 51 Room 4225 Silver Springs, Maryland 20993 (301) 796-3334 Fax (301) 847-8738 Industry Information: www.fda.gov/oc/industry	3/2, 3, 6, 7, 8, 9, 10/2017
	FEI NUMBER 3006370533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bhapinder Singh Grover, Vice President-Quality

FIRM NAME	STREET ADDRESS
Alkem Laboratories Limited	Village- Thana, Nalagarh,
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Baddi, Solan Himachal Pradesh 173205 India (IND)	Drug Manufacturer

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

OBSERVATION 1

The written testing stability program is not followed.

The required stability testing on numerous drug products (over approximately 1,000 individual samples) was not completed within the time frames established in procedure Stability Management QC/063/07, current at the time the samples were due for testing.

Deviation B/DQ/15/014 was opened November 13, 2015 and CAPA B/CAPA/15/122 was opened December 15, 2015 to address missing the analysis time frames. Over two hundred and fifty samples were identified beyond their required analysis time frames. A target date of December 31, 2015 was set to complete the analysis on these samples. There is no documentation to show this target date was met.

Deviation B/DQ/15/015 was opened December 18, 2015 to address the increase of stability samples outside their required analysis time frames. Over five hundred samples were identified beyond their required analysis time frame and a target date of February 25, 2016 was set to complete these samples. There is no documentation to show this target date was met.

OBSERVATION 2

Master production and control records lack complete manufacturing and control instructions and special notations.

A. Procedure QC/082, Operation, Cleaning and Calibration of (b) (4) (Revision 07), does not contain instructions for the use of (b) (4) to complete the validated load pattern in the (b) (4) (G/QC/099). Firm management stated (b) (4) is used to fulfill media loads to be sterilized: however, this is not fully

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Knowlton Maria Estrella	Nicole E. Knowlton, Investigator Maria E. Estrella, Investigator	3/10/2017

documented.

B. Performance Qualification PQ_WIHC_01 Revision 1 covering (b) (4) Humidity Chambers G/QC/465 and G/QC/370 does not contain detailed information regarding the load. Firm management confirmed all of the chambers were qualified the same way.

For example, Chamber G/QC/465 was qualified for the 40±2°C/75 RH ±5% setting and is intended for stability management of US product, including but not limited to, (b) (4) Tabs (b) (4) mg ((b) (4) (b) (4) ng Tablets (b) (4) and (b) (4) Tablets (b) (4) mg ((b) (4)

Chamber G/QC/370 was qualified for the 25±2°C/60 RH ±5% setting and is intended for stability management of US product, including but not limited to (b) (4) Tablets (b) (4) mg ((b) (4) (b) (4) Tablets (b) (4) mg ((b) (4)), and (b) (4) Capsules USP (b) (4) mg ((b) (4) (b) (4)

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the 100% visual inspection of filled capsules conducted in Block (b) (4) prior to packaging, is performed manually on a (b) (4) There is no written procedure describing this process, training specific to this manual operation, lighting requirements, capsule rotation, and control of the volume of capsules on the (b) (4) Manual inspection was observed on March 2, 2017 for (b) (4) Capsules USP, (b) (4) Lot (b) (4)