DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	November 27 - December 1, 2023
	FEI NUMBER 3008450172

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Girish Arvind Bhunje, Vice President and Head API Operations

FIRM NAME	STREET ADDRESS
Alkem Laboratories Limited	No. 8, Old National Highway, At Naugama, Mandava
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bharuch district, Ankleshwar, Gujarat, 393010, India	API 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:

OBSERVATION 1

Validated methods have not been established for testing of API's.

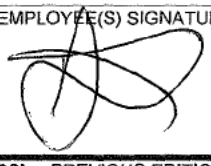
Specifically, your firm does not have a validated method for (b) (4) API's to which the site is used as an alternative testing facility. The site is documented to test for identification of (b) (4) API's by (IR) and water content by (KF). However, during the inspection, when reviewing the method validation and verification documentations, no method verification / validation is established for IR with equipment # MIR1601 and Karl Fisher with equipment # MKF1603, and for (b) (4) (b) (4) API's. According to Sr. General Manager – Quality both methods will be established after (b) (4)

OBSERVATION 2

Investigations are inadequate in that they do not evaluate all potential root causes of unexpected results nor are they adequately extended to potentially impacted API.

Specifically,

A- On December 10, 2022, a fire ensued in Plant-(b) (4) The fire caused damage to all of the technical area of Plant-(b) (4) Your firm investigated the incident through Deviation M/DEV/2022/0031 with closing date of April 20, 2023. In reviewing the deviation, your firm failed to document the final status of approximately (b) (4) of the (b) (4) raw materials that are affected during the fire. The raw materials are listed on Activity PR#103249.
That document states (b) (4) raw materials are "Available", "(b) (4) material kept in Finished goods storage area (b) (4) ", "Not found", or "In process (b) (4) ". Examples of some of the raw materials listed are:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Dipesh Shah, CSO	12/01/2023

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(b) (4)

The report also does not state if the materials are used or disposed. In addition, the document states approximately (b) (4) other raw materials are used.

B- Excursions for Stability Chamber / Cooling Chamber / Deep Freezer are documented on M-QC/0173-F0002-000 under Standard Operating Procedure, M-QC/0173-004, documented titled, 'Operation and Monitoring of Stability Chamber, Cooling Chamber and Deep Freezer (Make: Newtronic) through ICDAS v2.1 Software', with effective date June 1, 2022. On November 29, 2023, I observed 2 excursion reports that are not fully documented.

1- Report for stability chamber MDF1601 with storage condition -20 degrees C +/- 5 degrees, with approve date October 4, 2022. The report states that ice had formed on the coils and the coils needed to be defrosted with hot water. While interviewing Senior Executive Quality Control of the excursion, are the stability samples moved from the chamber MDF1601 during the defrosting of the chamber. He stated that all the samples from chamber MDF1601are moved to a different chamber but that activity is not documented.

2- Report for stability chamber MDF1603 with storage condition 25 degrees C +/- 2, 60% +/- 5%RH degrees, with approve date November 7, 2022. The report states that the humidity is below the set limit for approximately 14 hours. The excursion is corrected by supplying water to the chamber. Senior Executive Quality Control stated that this was corrected by calling the Utility Department to turn on the supply. However, he did not document the activity.

OBSERVATION 3

Employees engaged in the manufacture, processing, packing, holding of finished API's lack the training required to perform their assigned functions. You cannot assure that personnel are adequately trained in order to perform to their assigned duties.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE		Dipesh Shah, CSO	12/01/2023

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Specifically, on December 1, 2023, I reviewed approximately (b)(4) personnel training records through your e-TMS (electronic Training Management System) which included training records from quality management, manufacturing, and contract personnel. I observed employee # (b)(6) is deficient in required trainings such as Awareness Training based on Incident M/LI2021/0056, Change Management for software hardware and network, and Handling of Contract Testing Laboratories.

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		Dipesh Shah, CSO	12/01/2023