

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

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Springs, MD 20993 (301) 796-3334 Fax: (301) 847-8738	DATE(S) OF INSPECTION 9/20/2016-9/29/2016*
	FEI NUMBER 3006370524

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mrityunjay Kumar , VP Operations

FIRM NAME Alkem Laboratories Ltd	STREET ADDRESS 167 Mahatma Gandhi Udyog Nagar Road
CITY, STATE, ZIP CODE, COUNTRY Daman, Daman And Diu, 396210 India	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.


Specifically,

a) your QC laboratory does not report all test results from OOS investigations. CQA/057 Handling OOS Results states to report the average of six results. (b) (4) 1/00S/003/16 initiated for API raw Material (b) (4) USP on January 12, 2016 stated to reported the average of repeat analysis. (b) (4) USP was used in the manufacture of (b) (4) Capsules (b) (4) mg batch numbers (b) (4) and (b) (4) shipped to the US.

b) your QC laboratory does not always report all in-specification test results.

i) You retested (b) (4) and (b) (4) (b) (4) (b) (4) (b) (4) mg/ (b) (4) mg/ (b) (4) ml exhibit batch number (b) (4) for assay after (b) (4) of storage of (b) (4) solution and issued a second CoA reporting only the value of the second test even though the results of the first test were also in specification.

ii) You retested (b) (4) and (b) (4) (b) (4) (b) (4) (b) (4) mg/ (b) (4) mg (b) (4) ml exhibit batch numbers (b) (4) and (b) (4) stability study 25°/60% RH 3 month for assay after (b) (4) of storage of (b) (4) solution as part of (b) (4) 2/OOT/001/14. The incidence summary and final

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conclusion states to report the second test result. The first results were in-specification yet only the second results were reported.

OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your Quality Assurance unit did not ensure you have stability data to support your shelf life dates and storage conditions in that:

a) you do not use the same start date to assign the shelf life for your products as the date you use as day zero for your stability study program. AC/QC/001 Sampling, Testing and Data Compilation for Stability Study defines day zero for the stability study as the date of batch release. AC/QA/032 Assigning of Expiry Date defines the date the API is dispensed as the date/month for assigning the shelf life date.

b) you do not always release batches to establish day zero for your stability studies in a timely manner.

i) Packaging of (b) (4) Tablets USP (b) (4) mg. was completed March 30, 2015. Initial testing was completed March 31, 2015. Final release of the batch, the date used to establish day zero for your stability study, occurred May 14, 2015. Batch release occurred 46 days after final packaging and 56 days from dispensing the API.

ii) Stability Study Summary Reports for (b) (4) (b) (4) Solution (b) (4) mg/mL exhibit batch (b) (4) indicate initial testing for the batch packaged March 01, 2014 was conducted April 21, 2014, 50

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days after packaging. The date in reported on the stability study is March 03, 2014, 18 days after packaging.

c) you did not ensure the container closure system used for (b) (4) Solution (b) (4) mg/mL provides protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product. Both control samples (b) (4) bottles) and stability study samples (b) (4) bottles) of (b) (4) Solution (b) (4) mg/mL batch (b) (4) stored in the (b) (4) position appear to leak drug product.

OBSERVATION 3

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, the container closure system used to package (b) (4) exhibit batch (b) (4) does not prevent product leakage. Both control samples (b) (4) bottles) and stability study samples ((b) (4) bottles) of (b) (4) Solution (b) (4) mg/mL batch (b) (4) stored in the (b) (4) position appear to leak drug product. The (b) (4) of all bottles also appear discolored from the drug product. Four of (b) (4) cartons of control samples showed signs of leakage on the secondary carton and four of (b) (4) cartons of stability study samples stored in the (b) (4) position showed signs of apparent leakage on the secondary carton.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and sampling plans designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

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Specifically; your sampling plans and stability testing timelines are not scientifically sound and changes to in-process and/or finished product specifications are not always scientifically valid in that:

a) you (b) (4) API raw material samples prior to testing:

i) CQA/108 Raw Material, Sampling (Non Sterile) section 5.35 specifies a sample pooling procedure for the (b) (4) sample for API raw material. Samples taken from (b) (4) container are (b) (4) prior to testing.

ii) Section 5.37 specifies material received from other regulatory approved locations of Alkem Group, only description and identification test to be performed and the remaining results shall be entered into LIMS from the CoA received from respective location. Materials received from other Alkem Group facilities include APIs: (b) (4) USP, (b) (4) USP, and (b) (4) USP used in the manufacture of drug products shipped to the US. You do not conduct tests to identify inter and intra batch variation impacting drug product formulation for the above mentioned APIs.

b) you (b) (4) samples. AG/PV/14-021 Process Validation Protocol for (b) (4) ded (b) (4) samples of the bulk solution before testing (b) (4) samples were also (b) (4) prior to testing including microbial sam

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c) CQA/098 Sampling Plan for Tablets (b) (4) includes (b) (4) samples obtained from the (b) (4) (b) (4) and (b) (4) after packaging for microbial testing prior to testing.

d) A/DQ/15/006 deviation for stability sample analysis not completed within the timelines specified, initiated September 07, 2015, stated the root cause as a lack of manpower and a schedule. The investigation listed as a corrective action to change the timeline to test stability samples stored 40°/75% within (b) (4) and the remaining stability samples within (b) (4) to (b) (4). No scientific rationale was provided for changing the stability testing timelines.

e) you changed the in-process and finished release (b) (4) content specification for (b) (4) tablets (b) (4) (US market) from NMT (b) (4) % to NMT (b) (4) % after an in-process sample out of specification result. No scientific rationale was provided for changing the specification.

f) you changed the release and shelf life (b) (4) content specification for (b) (4) tablets USP (b) (4) mg and (b) (4) mg after a finished product sample out of specification assay result. For (b) (4) Tablets USP (b) (4) mg, and (b) (4) mg the released specification was changed from NMT (b) (4) % to NMT (b) (4) % and the shelf life specification was changed from NMT (b) (4) % to NMT (b) (4) %. No scientific rationale was provided for changing the specification.

OBSERVATION 5

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, you did conduct torque testing or leak tests as part of your equipment qualification AG/P13Q-014 Performance Qualification Protocol for (b) (4) and (b) (4) Capping Machine. (b) (4) (b) (4) Solution (b) (4) mg/mL exhibit batch (b) (4) manufactured using this equipment appears to leak as observed in control samples and stability study samples stored in your control sample room and stability chamber.

OBSERVATION 6

Deviations from written production and process control procedures are not justified.

Specifically, you do not always record and justify deviations in that:

a) expiration dates for APIs used in the manufacture of (b) (4) and (b) (4) (b) (4) (b) (4) mg (b) (4) mg / (b) (4) ml exhibit batch numbers (b) (4) (b) (4) (b) (4) and (b) (4) were not recorded on the batch record. No explanation was provided for not recording the expirations dates.

b) there is no written indication in the batch record for (b) (4) and (b) (4) (b) (4) (b) (4) mg (b) (4) mg / (b) (4) ml exhibit batch number (b) (4) the assay after (b) (4) of storage of (b) (4) solution was retested and a second CoA was issued. The second CoA reported the value of the second test only. The results of the first test and the second test were both in specification.

c) you do not include an original or a copy of the original CoA with batch records, (b) (4) and (b) (4) (b) (4) (b) (4) mg (b) (4) mg / (b) (4) ml exhibit batch number (b) (4) included copy 1 of the

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CoA for this batch dated July 31, 2014. A second copy 2 CoA for this batch dated September 09, 2014 reported a different result for the assay after (b) (4) of storage of (b) (4) solution. The date of copy 2 CoA was used as the stability study time zero date. Both results were in specification.

OBSERVATION 7

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary.


Specifically, September 24, 2016 your SAP inventory system still showed an inventory of (b) (4) bottles of (b) (4) (b) (4) Solution (b) (4) mg/mL. The Batch Packaging Record for (b) (4) (b) (4) Solution (b) (4) mg/mL indicated (b) (4) bottles were transferred to the warehouse after packaging on March 01, 2014. Your SAP inventory records show (b) (4) bottles of (b) (4) (b) (4) Solution (b) (4) mg/mL were received in the warehouse March 06, 2014. On September 21, 2016 I observed the actual count of bottles of (b) (4) (b) (4) Solution (b) (4) mg/mL in your warehouses is (b) (4) bottles. The SAP inventory system had (b) (4) of (b) (4) bottles moving out of the warehouse either September 21, 2016 or September 24, 2016.

OBSERVATION 8

Procedures describing the warehousing of drug products are not established and followed.

Specifically, your warehouse SAP system does not always contain up-to-date and accurate information. A/WH/108 Bonded Store Room does not specify a time frame for updating the warehouse inventory system. On September 21, 2016 your SAP system showed (b) (4) bottles of (b) (4) (b) (4) Solution (b) (4) mg/mL in inventory. The SAP system showed no movement of (b) (4) (b) (4) Solution (b) (4) mg/mL from June 10, 2016 to September 24, 2016. The actual quantity in inventory on September 21, 2016 was (b) (4) bottles. The SAP inventory system had no record of (b) (4) bottles moving out of the warehouse.

OBSERVATION 9

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Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, you do not evaluate the quality standards of each drug product in that Annual Product Quality Reviews do not include year-to-year trending of critical processing parameters.


OBSERVATION 10

The quality control unit lacks the responsibility and authority to approve and reject all drug products.

Specifically, your Quality Assurance unit has not established, documented, and implemented an effective system for managing quality in that:

a) REG/006 Field Alerts does not specify to evaluate the need to extend complaint investigations to other products. The procedure does not include a definition establishing day zero for complaints received.

b) A1/MC/15/003 Market Complaint Investigation Report investigating complaints for (b) (4) (b) (4) (b) (4) mg/mL for batch numbers (b) (4) and (b) (4) contains results from testing batches of the same product manufactured in a previous campaign. The report did not include extending the investigation to other products using the same equipment.

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OBSERVATION 11

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, digital counters tag no. (b) (4) missed (b) (4) calibration according to the (b) (4) instrument calibration calendar for (b) (4) and Injection area. AC/EM/027 Calibration Schedule for Gauges and Instruments states that calibration can be done ± (b) (4) from planned due date. The planned date for the (b) (4) calibration for Digital Counters tag no. (b) (4) was listed as September 2, 2016 on the instrument calibration calendar and the status date was not recorded.

OBSERVATION 12

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used.

Specifically, revalidation of the initial cleaning validation of (b) (4) and (b) (4) tablets manufactured in the (b) (4) facility of (b) (4) block (b) (4) Block) was not performed as required by your written procedure. AC/QA/073 Cleaning Validation states revalidation shall be performed for periodic cleaning verification every (b) (4). The most recent Cleaning Validation Report for (b) (4) and (b) (4) Tablets (b) (4) mg was approved on 04/29/2015.

OBSERVATION 13

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

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a) CQA/005 Vendor Qualification of Raw Material does not specify how APIs are evaluated against the manufacturer's CoA, what if any tests listed on the manufacturer's CoA are conducted and if test methods used to verify the results on the manufacturer's CoA are the same test methods used by the manufacturer.

b) A/QC/105 Handling of Reference Standards, Preparation and Handling of Working Standards section 6.3.5 specifies all reference standards are stored in a refrigerator/incubator 2° – 8 ° C; section 6.5.18 specifies the current stock of reference standards is verified and documented (b) (4); and section 6.5.19 specifies expired reference standards are destroyed. On September 20, 2016 I observed expired USP reference standard (b) (4) Related Substance Compound (b) (4) used for method transfer testing HPLC impurity testing of (b) (4) stored in freezer QC/340 at (b) (4) - (b) (4) C. This expired standard was not discarded as required by your procedure and it was not listed on the Verification of Reference Standards Lots Updated List as required by your procedure.

c) Written procedures, such as A/QC/117 Operation and Calibration of Dissolution Tester Make-Electrolab (TDT-08L), do not contain sufficient detail to ensure consistent performance of procedures. Dissolution testing is conducted on tablets and capsules such as (b) (4) (b) (4) and (b) (4) shipped to the U.S. On September 20, 2016 I observed dissolution testing for (b) (4) Tablets (b) (4) mg (b) (4) count batch number (b) (4) stability study 3 month on instrument QC/010 and determined samples were neither added nor (b) (4) in a consistent and reproducible manner.

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d) Written procedures such as A/QC/115 Operation and Calibration of HPLC Systems with UV & PDA Detectors (Waters Make) and A/QC/141 Operation and Calibration of Gas Chromatograph, do not specify the criteria for activities such as creating methods and making single injections, do not specify what approvals are needed before conducting such activities, and do not specify when change control must be initiated prior to conducting such activities. HPLC testing for Assay and Inorganic Impurities is used to release drug products such as (b) (4) and (b) (4) shipped to the U.S.

e) Responsibilities for the review of pest control records in the manufacturing block where (b) (4) products are manufactured are not clearly defined or followed. Pest control records are both checked and verified by a Housekeeping employee as both the Head of Human Resources and the Personnel and Administration Representative. Pest control records are not reviewed by the quality unit.

***DATES OF INSPECTION**

9/20/2016(Tue),9/21/2016(Wed),9/22/2016(Thu),9/23/2016(Fri),9/24/2016(Sat),9/26/2016(Mon),9/27/2016(Tue),9/28/2016(Wed),9/29/2016(Thu)

Verifying...

Tiara N Brown-Crosen
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