

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 2/17/2020-2/21/2020 FEI NUMBER 3006370533	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Rakesh Tripathi, Vice President - Operations			
FIRM NAME Alkem Laboratories Limited		STREET ADDRESS Village- Thana, Distt. - Solan	
CITY, STATE, ZIP CODE, COUNTRY Baddi, Himachal Pradesh, 173205 India		TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: FACILITIES AND EQUIPMENT SYSTEM</p>			
<p>OBSERVATION 1</p> <p>Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.</p> <p>Specifically, your firm failed to perform a Performance Qualification (PO) of the (b) (4) prior to use in the production of (b) (4) tablets. (b) (4) to ensure the (b) (4) is capable of consistently inspecting (b) (4) drug products. The (b) (4) was used to perform the visual inspection of (b) (4) tablets (b) (4)</p>			
<p>QUALITY SYSTEM</p>			
<p>OBSERVATION 2</p> <p>Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications.</p> <p>Specifically, your firm failed to perform an Out-of-Specification (OOS) investigation when the (b) (4) system had a (b) (4) failure of (b) (4) ppb (specified limit (b) (4)) January 30, 2020.</p>			
<p>SEE REVERSE OF THIS PAGE</p>	<p>EMPLOYEE(S) SIGNATURE Jennifer L Huntington, Investigator - Dedicated Drug Cadre</p>		<p>DATE ISSUED 2/21/2020</p> <p style="font-size: small; text-align: center;"> Jennifer L. Huntington Investigator - Dedicated Drug Cadre Signed By: Jennifer L. Huntington - S Date Signed: 02-21-2020 04:55:06 </p>

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