

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION														
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 12420 Parklawn Drive, Room 2032 Rockville, MD 20857			<small>DATE(S) OF INSPECTION</small> 1/27/2025-1/31/2025 <small>FEI NUMBER</small> 3014255847											
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Satyanarayana Chava, Chief Executive Officer														
<small>FIRM NAME</small> Laurus Labs Limited		<small>STREET ADDRESS</small> Plot No 25, 25A to 25K, APSEZ Denotified Area, Lalamkoduru Village, Rambilli Mandal												
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Anakapalli District, Andhra Pradesh, 531011 India		<small>TYPE ESTABLISHMENT INSPECTED</small> API 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 WE OBSERVED:</p> <p>Written procedures, including changes thereof, are not drafted, reviewed and approved by appropriate organization units, and approved by the quality control unit.</p> <p>Specifically,</p> <p>You failed to ensure that equipment qualification protocols are reviewed and approved by the quality unit. During the inspection, we observed multiple equipment used for the manufacturing of multiple active pharmaceutical ingredients (i.e., (b) (4) qualified without an approved protocol. Examples of these manufacturing equipment include:</p>														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Equipment ID</th> <th style="width: 25%;">Equipment Name</th> <th style="width: 20%;">Installation Qualification Document #</th> <th style="width: 20%;">Operational Qualification Document #</th> <th style="width: 20%;">Performance Qualification Document #</th> </tr> </thead> <tbody> <tr> <td colspan="5" style="height: 100px;">(b) (4)</td> </tr> </tbody> </table>					Equipment ID	Equipment Name	Installation Qualification Document #	Operational Qualification Document #	Performance Qualification Document #	(b) (4)				
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SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Jessica S Estriplet, Investigator Olumide A Akinyemi, Investigator		<small>DATE ISSUED</small> 1/31/2025 <div style="text-align: center;"> <small>Jessica S Estriplet Investigator Signed By: Jessica S. Estriplet -G Date Signed: 01-31-2025 07:19:29</small> X </div>										

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