DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
U.S. Food & Drug Administration ODQ/OC/OMPD/DDA White Oak Bldg. 51, Room 4234 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-795-3206 DATE(S) OF INSPECTION
3/27/2017 - 4/04/2017

FIRN NAME
Dr. Reddy’s Laboratories Limited CTO VI

STREET ADDRESS
APIIC Industrial Estate, Pydibhimavarma (Village)

CITY, STATE AND ZIP CODE
Srikakulam District, Andhra Pradesh, India

TYPE OF ESTABLISHMENT INSPECTED
Drug Manufacturer

DATE(S) OF INSPECTION
3/27/2017 - 4/04/2017

DURING AN INSPECTION OF YOUR FIRM(1) (WE) OBSERVED:

1. Complete records are not always maintained for periodic calibration of laboratory instruments, apparatus, gauges, and recording devices.

For all High Performance Liquid Chromatography systems (HPLC), the firm failed to monitor the lamp hours of their UV detectors. In addition, monitoring of the QC laboratory’s HPLC units does not include a periodic check of the hours of the UV-Vis lamps after 2000 hours of operation as recommended by the manufacturer. For example, six (6) of the HPLC units, QC-170, QC-169, QC-024, QC-026, QC-122 and QC-021, showed operational hours of 13,003 hours, 11,132 hours, 5,106 hours, 3,475 hours, 3,198 hours, and 2,371 hours respectively without the lamps being replaced or being reset to zero after changing of the lamp.

2. Laboratory records do not include a complete record of all data secured in the course of each test, including all chromatograms from laboratory instrumentation, properly identified to show the specific components of the drug substance tested. Specifically, laboratory records do not always contain the HPLC standard and sample chromatograms. For example, the laboratory records for USP Batch #manufactured 2/25/2017, manufactured 2/23/2017 & manufactured 2/22/2017, did not include the HPLC standard and sample chromatograms for Assay and Related Substances instead only results summary reports are attached. The chromatographic data was limited to calculated results for last 3 months.

<table>
<thead>
<tr>
<th>SEE REVERSE OF THIS PAGE</th>
<th>EMPLOYEE(S) SIGNATURE</th>
<th>EMPLOYEE(S) NAME AND TITLE (Print or Type)</th>
<th>DATE ISSUED</th>
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<tbody>
<tr>
<td></td>
<td>Gayle S. Lawson</td>
<td>Kenneth H. Williams, Chemist</td>
<td>4/04/2017</td>
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