



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food & Drug Administration CDER/OC/OMPQ/DIDQ White Oak Bldg. 51, Room 4234 10903 New Hampshire Ave Silver Spring, MD 20993 Tel: 301-796-3206		DATE(S) OF INSPECTION 3/27/2017 - 4/04/2017	
		FEI NUMBER 3002949085	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Arun Gupta, Senior Director and Location Head			
FIRM 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	
DURING AN INSPECTION OF YOUR FIRM(I) (WE) OBSERVED:			
<p>1. Complete records are not always maintained for periodic calibration of laboratory instruments, apparatus, gauges, and recording devices.</p> <p>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.</p> <p>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 (b) (4) USP Batch # (b) (4) manufactured 2/25/2017, # (b) (4) manufactured 2/23/2017 & (b) (4) 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.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  		DATE ISSUED 4/04/2017
	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Gayle S. Lawson, Investigator Kenneth H. Williams, Chemist		