DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, ORA OPQO HQ 12420 Parklawn Drive, RM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	09/24/2018-09/28/2018
	FEI NUMBER 3004081307

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ashwin Upasane, Site Head

FIRM NAME	STREET ADDRESS
Cipla Limited	Verna Industrial Estate
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Verna, Salcette, Goa 403722, India	Drug Manufacturer

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

Observation 1
The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing. Specifically,

The proposed commercial master batch record for the production of [(b) (4)] Tablets, [(b) (4)] ([(b) (4)], version 01, does not provide written instructions for the removal of the [(b) (4)] from a [(b) (4)] bag inside your IPCs (In Process Containers) and the subsequent pouring of this [(b) (4)] back into the same IPC as needed for docking with your compression systems.

Observation 2
Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up. Specifically,

A change to production instructions was implemented prior to completion of all corrective action changes related with a deviation. Namely, as part of Deviation DEV-1006-2017-00073 for [(b) (4)] Tablets, USP [(b) (4)] ng lot [(b) (4)] (AQL non-compliance for minor defects), a Remedial Action item was initiated for the revision to the "Inspection by Attributes for Inprocess Checks of [(b) (4)] Tablets" form to modify defect type "Minor spots" to "Minor spots (Other than [(b) (4)] Spots)".

This Remedial Action was completed with revised form implemented on Nov. 21, 2017, and before the approval of the concurrent proposal under Change Request 1006-P-18-00004 (initiated on January 10, 2018) for the change in the product labeling (Pack Insert) for [(b) (4)] Tablets, USP to include "Due to inherent nature of formulation, occasionally, [(b) (4)] spots may be present on tablet surface. This does not affect efficacy of the product".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Nicole E. Knowlton, Investigator Rebecca Dombrowski, Consumer Safety Officer Pei-I Chu, Chemist	09/28/2018