

**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 11/26/2018-11/30/2018
	FEI NUMBER 3002806702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mangesh Vaze, Senior Director, Technical Services

FIRM NAME Cipla, Ltd.	STREET ADDRESS Plots D-7, D-22, D-27, M.I.D.C. Industrial Area, Taluka-Daund
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CITY, STATE, ZIP CODE, COUNTRY Kurkumbh Village, Dist. Pune, Maharashtra, 413802 India	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer, API Manufacturer
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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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm lacks adequate cleaning validation data for the (b) (4) ID numbers 1320 and 1330 to support the cleaning procedures for all hardest to clean locations (including the (b) (4) of the (b) (4) and showing removal of the cleaning detergent.

(b) (4) ID numbers 1320 and 1330 were used in the manufacture of (b) (4) Suspension applications: (b) (4) mg (b) (4); and (b) (4) mg and (b) (4) mg (b) (4). They are also shared equipment used in the manufacture of other products: (b) (4)

OBSERVATION 2

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rozelle G Smith, Investigator	Rozelle G Smith Investigator Signed: By: Rozelle G. Smith-S Date Signed: 11-30-2018 00:25:51 X	DATE ISSUED 11/30/2018

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- A. Your firm lacks raw data evidence to support the manufacturing ^{(b) (4)} values, calculated during the ^{(b) (4)} of each of your exhibit batch records (Common Blend (Active) Batches ^{(b) (4)}. Your ^{(b) (4)} 1330 is not capable of capturing the ^{(b) (4)} data directly; therefore, your operator is responsible for manually calculating the ^{(b) (4)} per SOP MT-167, ^{(b) (4)}. According to your Critical Process Parameter record dated 08/18/2017, this manufacturing ^{(b) (4)} represents a critical process parameter.
- i. You were not able to provide any raw data evidence to support the calculated values recorded in these batch records.
 - ii. Your training records are also deficient for the first operator of the process on 24-August-2017 for the calculation instructions, SOP MT-167.
- B. Your firm failed to provide any raw data evidence for the 100% fill weight checks during the packing ^{(b) (4)} for all strengths ^{(b) (4)} of your exhibit batches. Additionally, not all of the in-process fill weight checks (performed at a minimum of ^{(b) (4)} could be verified as there were no printer tapes or other data loggers. Secondary checks were performed only periodically. Out of trend investigations for ^{(b) (4)} for ^{(b) (4)} Suspension ^{(b) (4)} ng investigations, OOT_1015_LAB1/OOT/10/17/01 (opened on 11-Oct-2017) and OOT_1015_LAB1/OOT/10/17/02 (opened on 14-Oct-2017). show the root cause summaries: ^{(b) (4)}.
- C. You have no raw data (actual weight values on printer tape or other data loggers) to support the ^{(b) (4)} Equipment ID 1144 ^{(b) (4)} setup verification for the upper and lower limit tolerances for all strengths of your exhibit batches.
- D. There is no secondary verification of the initial packing machine setup for the critical process parameter of ^{(b) (4)} at the packaging ^{(b) (4)} for all strengths of your exhibit batches. The packaging fill weight tolerances are also a part of the initial setup and were not verified by a second person.

These data values and machine setup verifications were submitted as part of your applications for ^{(b) (4)} ^{(b) (4)} Suspension: ^{(b) (4)} ng ^{(b) (4)}; and ^{(b) (4)} ng and ^{(b) (4)} ng ^{(b) (4)}.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rozelle G Smith, Investigator	Rozelle G Smith Investigator Signed By: Rozelle G. Smith -S Date Signed: 11-30-2018 00:28:01 X	DATE ISSUED 11/30/2018

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