DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51 Room 4225 Silver Springs, Maryland 20993 (301) 796-3334 Fax (301) 847-8738 Industry Information: www.fda.gov/oc/industry	02/21-03/01/2017
	FEI NUMBER 3005430968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ravindra Kumar Goyal, Plant Head

FIRM NAME	STREET ADDRESS
Cadila Healthcare Limited	Swaraj Majra, Juddi Kalan, Tehsil
CITY, STATE AND ZIP CODE Baddi, Dist. Solan, Himachal Pradesh 173205 India	TYPE OF ESTABLISHMENT INSPECTED Drug Manufacturer

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

Observation 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, not all manufacturing equipment for use in production of (b) (4) Capsules, USP (b) (4) mg and (b) (4) mg has been qualified.

A. The manufacturing area to be used in the commercial production of (b) (4) Capsules, USP (b) (4) mg and (b) (4) mg, referenced in application (b) (4) has not been qualified. Commercial manufacturing will occur on Line (b) (4) in Block (b) (4) Construction is not complete on the (b) (4) line or the opening to the facility and qualification of the area has not been completed.

B. The following equipment to be used in the production of (b) (4) Capsules, USP (b) (4) mg and (b) (4) mg was relocated to Line (b) (4) and has not been qualified:

(b) (4)

C. The following new equipment added to the manufacturing line for (b) (4) Capsules, USP (b) (4) mg and (b) (4) mg has not been qualified:

(b) (4) Line with Counter Material #9400001) including (b) (4)

(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Knowlton Maria Estrella	Nicole E. Knowlton, Investigator Maria E. Estrella, Investigator	03/01/2017

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Observation 2

Master production and control records lack complete manufacturing and control instructions.

A. The batch manufacturing records for (b) (4) Capsules USP (b) (4) mg and (b) (4) mg exhibit batches (b) (4) respectively) and intended batch manufacturing records for (b) (4) Capsules USP (b) (4) mg BMR/ZB/0586-00 and (b) (4) (b) (4) Capsules USP (b) (4) mg BMR/ZB/0587-00 do not include specific instructions describing how to (b) (4) during manufacturing.

Step (b) (4) of the batch manufacturing records state " (b) (4)

Firm management stated during production of the exhibit batches the (b) (4) was (b) (4) manually. There is no documentation of how the manual operation was performed.

B. Firm management stated the filled (b) (4) Capsules USP (b) (4) mg and (b) (4) mg were (b) (4) (b) (4) as a required step in the manufacturing process. There is no instruction for use or reference to the (b) (4) in the batch records for the exhibit batches (b) (4) and (b) (4) or the intended batch manufacturing records BMR/ZB/0586-00 and BMR/ZB/0587-00.

Observation 3

Batch production and control records do not include complete information relating to the production and control of each batch.

A. The batch manufacturing records for (b) (4) Capsules USP (b) (4) mg and (b) (4) mg exhibit batches (b) (4) respectively) and intended batch manufacturing records for (b) (4) Capsules USP (b) (4) mg BMR/ZB/0586-00 and (b) (4) (b) (4) Capsules USP (b) (4) mg BMR/ZB/0587-00 do not include specific instructions describing how to

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(b) (4) during manufacturing.

Step (b) (4) of the batch manufacturing records state (b) (4)
(b) (4)

Firm management stated during production of the exhibit batches the (b) (4) was (b) (4) manually. There is no documentation of how the manual operation was performed.

B. Firm management stated the filled (b) (4) Capsules USP (b) (4) mg and (b) (4) mg were (b) (4) as a required step in the manufacturing process. There is no instruction for use or reference to the (b) (4) in the batch records for the exhibit batches (b) (4) and (b) (4) or the intended batch manufacturing records BMR/ZB/0586-00 and BMR/ZB/0587-00.

C. During the manufacture of the (b) (4) Capsules USP (b) (4) mg exhibit batches the results for theoretical yield were not within the set parameters of (b) (4) (b) (4) %. The results obtained for batches (b) (4) (b) (4) were (b) (4) %, (b) (4) % and (b) (4) %, respectively. A deviation investigation was not initiated and there was no documentation in the batch records regarding this discrepancy.

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