

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**DISTRICT OFFICE ADDRESS AND PHONE NUMBER**

10903 New Hampshire Avenue, Bldg 51 Room 4225  
Silver Springs, Maryland 20993  
(301) 796-3334 Fax (301) 847-8738

**DATE(S) OF INSPECTION**

02/21-03/01/2017

**FEI NUMBER**

3005430968

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED**

**TO:** Mr. Ravindra Kumar Goyal, Plant Head

**FIRM NAME**

Cadila Healthcare Limited

**STREET ADDRESS**

Swaraj Majra, Juddi Kalan, Tehsil

**CITY, STATE AND ZIP CODE**

Baddi, Dist. Solan, Himachal Pradesh 173205 India

**TYPE OF ESTABLISHMENT INSPECTED**

Drug Manufacturer

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) (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:

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)

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**EMPLOYEE(S) SIGNATURE**

*Nicole E. Knowlton*  
*Maria E. Estrella*

**EMPLOYEE(S) NAME AND TITLE (Print or Type)**

Nicole E. Knowlton, Investigator  
Maria E. Estrella, Investigator

**DATE ISSUED**

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**TYPE OF ESTABLISHMENT INSPECTED**

Drug Manufacturer

**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) Capsules USP (b) (4) mg BMR/ZB/0587-00 do not include specific instructions describing how to 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) 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) Capsules USP (b) (4) mg BMR/ZB/0587-00 do not include specific instructions describing how to

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*NEK*  
*me*

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Maria E. Estrella, Investigator

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(b) (4)

during manufacturing.

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

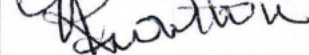
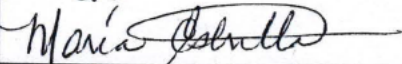
Firm management stated during production of the exhibit batches the (b) (4) was (b) (4) manually. There is no documentation of how the manual operation was performed.

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) 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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