DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave,Bldg 51,Rm 4225 Silver Springs, MD 20993 (301)796-3334 Fax:(301)847-8738 Industry Information: www.fda.gov/oc/industry	8/28/2017-9/1/2017
	FEI NUMBER 3004021263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: B. Vijay Mohan Reddy , Head of Operations

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited, Unit VI	Unit 6, Survey No. 329/39 & 329/47, Chitkul Village, Patancheru
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 502307India	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:

Production System

OBSERVATION 1

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Exception no.'s APL-FU6-EXC-15-0031 issued on 5/5/15 and APL-FU6-EXC-15-0031 issued on 5/7/15 in response to customer complaints reporting the presence of black particles in the drug product containers, later determined to be desiccant from the desiccant (b) (4) failed to include adequate detail and instruction for performing the following:

1. The (b) (4)
2. The usage of the (b) (4)
3. 100% Visual inspection for defects of the (b) (4) and adequate operator verification.

Additionally, your firm's investigation into the cause of these complaints identified (b) (4) of the (b) (4) (b) (4) on the (b) (4) equipment as the most likely cause of the damaged (b) (4) Beginning on 5/7/15 this same piece of equipment continued to be used in the (b) (4) of the (b) (4) desiccant (b) (4) as stated in item 2 above followed by a 100% visual inspection. On 12/28/15 a complaint regarding presence of black particles (desiccant) was received for (b) (4) Tablets USP (b) (4) mg lot no. (b) (4) under complaint no. CU06715-U06.

To date, your firm has received a total of 20 customer complaints related to this issue across (b) (4) finished product lots including (b) (4) Tablets USP (b) (4) mg lot no (b) (4) exp. May 2018.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Robert M. Barbosa	Robert M. Barbosa	09/01/2017

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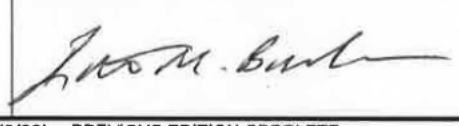
OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Validation of the (b) (4) hold time for (b) (4) Tablets USP (b) (4) mg completed as part of process validation batch numbers (b) (4) reported a maximum (b) (4) hold time of (b) (4) However the (b) (4) hold time of (b) (4) Tablet batches manufactured between September 2015 and April 2017 exceeded this (b) (4) validated (b) (4) hold time.

Similarly, validation of the (b) (4) hold time for (b) (4) Suspension USP (b) (4) mg (b) (4) ml, completed as part of process validation batch numbers (b) (4) reported a maximum (b) (4) hold time of (b) (4) However the (b) (4) hold time of (b) (4) Suspension batches manufactured between September 2015 and August 2017 exceeded this (b) (4) validated (b) (4) hold time.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Robert M. Barbosa	09/01/2017