DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Baltimore District Office 6000 Metro Drive Suite 101 Baltimore, MD 21215 USA Industry Information: www.fda.gov/oc/industry	10/17/2016 - 10/25/2016
	FEI NUMBER 3004021253

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: K. Narasimha Reddy

FIRM NAME	STREET ADDRESS
Aurobindo Pharma, Ltd. Unit 01	Sy. No. 385, 386, 388-396
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Borpatla Village, Medak District, Telangana, India 502296	API 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:

Equipment cleaning procedures are not adequately validated.
Specifically,

a) Equipment cleaning validation studies do not support a validated time period for holding dirty equipment before initiating the cleaning process. The equipment cleaning procedure, SOP AQA-020, effective date January 20, 2016, specifies the establishment of a holding period of (b) (4) before cleaning dirty equipment through the completion of three acceptable cleaning runs; this activity has not been performed for all product-specific equipment trains. Current cleaning procedures rely on an unvalidated holding period of (b) (4)

b) Equipment cleaning validation procedures do not include testing for the efficacy of bioburden or endotoxin removal from those equipment trains where product with a bioburden or endotoxin specification is manufactured.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Steven P. Donald, Investigator	10/25/2016

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."