DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. FDA CDER/OIDA/OMPTO 10903 New Hampshire Ave., Bldg. 51 Room 4234 Silver Spring, MD 20993 Tel. (301) 796-3120 Industry Information: www.fda.gov/oc/industry	6/27/2016 - 7/1/2016
	FEI NUMBER 3004086884

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Govindarajan Naraganan, Managing Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited	Survey No. 10 & 13
CITY, STATE AND ZIP CODE Bachupotharam V. Medak District, Telangana [502 319]	TYPE OF ESTABLISHMENT INSPECTED Human Drug Manufacturer (API)

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

Investigations are inadequate.

Specifically, deviation-DE-HO8-000106 was initiated on 22-JUNE-2015 because none of the following (b) (4) (API) batches were submitted for stability: (b) (4) (b) (4) (b) (4). The deviation record contains field, "Number of previous deviations in this Product/System". This field requires previous deviations of the same product or deviation type to be reported, no previous deviations were reported in this field. Deviation-DE-HO8-000077 was reported approximately 2 months previously for failing to submit batch(es) of (b) (4) on stability.

This is a repeat Observation from the 2014 inspection.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[redacted]	Robert HAM, Investigator	7/1/2016

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