DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT 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	4/10/2017-4/18/2017* FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Venkateswar Rao , Associate Vice President Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit III, Survey No. 313-314, Bachupally, Quthubullapur (M), RR District.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 500090India	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 WE OBSERVED:
LABORATORY SYSTEM

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,
a) you (b) (4) microbial samples prior to testing, including excipients utilized in the manufacture of drug products shipped to the U.S. For example, you (b) (4) samples taken of (b) (4) tested for TAMC, TYMC, and specific microbial species. (b) (4) is used in the manufacture of drug products shipped to the U.S. including but not limited to: (b) (4) Tablets USP (b) (4) mg (b) (4) mg/ (b) (4) mg and (b) (4) Tablets USP (b) (4) mg (b) (4) mg (b) (4) mg.

b) you conduct microbial testing on (b) (4) samples for the following finished dosage drug products destined for the U.S. market: (b) (4) Tablets USP (b) (4) mg (b) (4) mg (b) (4) mg, (b) (4) Solution USP (b) (4) mg (b) (4) ml, (b) (4) Solution (b) (4) mg (b) (4) ml. (b) (4) Solution USP (b) (4) mg/5 mL, (b) (4) Solution USP (b) (4) mg (b) (4) mL, (b) (4) Solution USP (b) (4) mg (b) (4) mL, (b) (4) Solution USP (b) (4) mg (b) (4) mL, (b) (4) Solution USP (b) (4) mg/mL and (b) (4) mg (b) (4) mL, (b) (4) mg/mL, (b) (4) Suspension USP (b) (4) mg per (b) (4) mL. (b) (4) Suspension USP (b) (4) mg/mL and (b) (4) mg/mL. (b) (4) Solution USP (b) (4) mg (b) (4) mL. (b) (4) Solution USP (b) (4) mg/mL, (b) (4) Solution (b) (4) mg (b) (4) mL, and (b) (4) Solution USP (b) (4) mg/mL.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Angela E Glenn, Investigator Cheryl A Clausen, Generic Drug User Fee Amendments (GDUFA) 4/18/2017 X Angela E Glenn Angela E Glenn Investigator Signed by: Angela E. Glenn -S	4/18/2017

DISTRICT 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	4/10/2017-4/18/2017* FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Venkateswar Rao , Associate Vice President Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit III, Survey No. 313-314, Bachupally, Quthubullapur (M), RR District.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 500090India	Drug Manufacturer

This is a repeat observation from the 2015 inspection.

OBSERVATION 2

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically,

a) you do not always identify a root cause for non-conformance or OOS results and you do not always have data or documentation to support the identified root cause.

b) you do not always take appropriate corrective and preventive actions in response to laboratory incidence and OOS investigations. For example, OOS investigation of (b) (4) Suspension USP (b) (4) mg/mL batch (b) (4) you hypothesized the particle size distribution in the (b) (4) was changed due to an operator adding material from rejected bottles obtained during line start-up back into the (b) (4) Your corrective and preventive action did not include testing for variation in particle size distribution from the (b) (4) and finished drug products produced in the subsequent validation batches.

c) your Reporting and Monitoring of Process Non-Conformance in Automated QMS Software procedure defines quality impacting events as occurrences or errors which will affect the quality, purity, and strength of drug products and safety of the patient. However, your written procedure for Event Classification categorizes a deviation with a serious or hazardous effect, which is highly likely to occur but detectable, as non-quality impacting.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Angela E Glenn, Investigator Cheryl A Clausen, Generic Drug User Fee Amendments (GDUFA) 4/18/2017 X Angela E Glenn Angela E Glenn Investigator Signed by: Angela E. Glenn -S	4/18/2017

DISTRICT 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	4/10/2017-4/18/2017* FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Venkateswar Rao , Associate Vice President Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit III, Survey No. 313-314, Bachupally, Quthubullapur (M), RR District.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 500090India	Drug Manufacturer

Specifically,
a) your QA Administrator regularly restarts your U3EMP3APP server to lock laboratory projects prior to data back-up, a practice not specified in your written procedure for Empower data back-up.

b) your QA Administrator regularly records no errors after reviewing the system log for your Empower server even though the log lists errors.

OBSERVATION 4

Deviations from written test procedures are not recorded and justified.

Specifically, your written procedure for Microbial Examination of Non-Sterile Products does not instruct analysts to (b) (4) which is the actual practice when conducting microbial testing of excipients and (b) (4) used in the manufacture of drug products shipped to the U. S., as well as testing of finished dosage drug products shipped to the U.S.

OBSERVATION 5

The sensitivity of test methods have not been.

Specifically, the sensitivity of your cleaning validation test method is not scientifically sound in that, as part of validation testing for your cleaning test method and cleaning procedures for (b) (4) (b) (4) content you inhibited integration for all but about (b) (4) of a (b) (4) analysis for system precision and about (b) (4) for sample analysis, potentially failing to identify and quantify impurities.

OBSERVATION 6

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

DISTRICT 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	4/10/2017-4/18/2017* FEI NUMBER 3004021229

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M. Venkateswar Rao , Associate Vice President Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd	Unit III, Survey No. 313-314, Bachupally, Quthubullapur (M), RR District.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hyderabad, Telangana, 500090India	Drug Manufacturer

Specifically,
a) you do not provide a reason for modifying the specified quantities listed on your analytical worksheets, nor do you provide data to verify the modifications produce results at least as accurate and reliable as the original quantities specified on the analytical worksheet.

b) you do not always contemporaneously document laboratory observations, errors and incidences.

***DATES OF INSPECTION**
4/10/2017(Mon),4/11/2017(Tue),4/12/2017(Wed),4/13/2017(Thu),4/14/2017(Fri),4/17/2017(Mon),4/18/2017(Tue)

4/18/2017

X Cheryl A Clausen
Cheryl A Clausen
Generic Drug User Fee Amendments (GDUFA)
Signed by: Cheryl A. Clausen -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Angela E Glenn, Investigator Cheryl A Clausen, Generic Drug User Fee Amendments (GDUFA)	4/18/2017

4/18/2017
X Angela E Glenn
Angela E Glenn
Investigator
Signed by: Angela E. Glenn -S