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	9/6/2016-9/16/2016* FEI NUMBER 3008461619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Madan Mohan Reddy , Director

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Limited - Unit IV	Unit IV, Plot No. 4, 34-48 EPIP, APIIC, IDA-Pashamylaram, Pantancheru Mandal
CITY, STATE, ZIP CODE, COUNTRY Medak District, Hyderabad, Telangana, 502307India	TYPE ESTABLISHMENT INSPECTED Human 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 OBSERVED:

OBSERVATION 1

An (b) (4) Field Alert Report was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product.

Specifically, your firm has received six complaints pertaining to four separate batches of the sterile human drug (b) (4) Injectable (b) (4) mg (b) (4) mL that describe the (b) (4) stopper pushing into the vial upon spiking with infusion sets. Complaints were received between March and September 2016. No Field Alert has been filed for this issue by your firm.

Additionally, you're own investigation (report "Final Investigation Report" dated September 1, 2016 and report #PRD-INV-0001-16-00) verified that the (b) (4) stoppers can be pushed into the vials, thus making the drug product un-usable.

OBSERVATION 2

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

Specifically, your written test procedures for assay and related substances for all sterile injectable drug products intended for the US market utilize (b) (4) of (b) (4) unit containers in sample preparation (b) (4) HPLC analysis with the justification that (b) (4) reduces the variability of results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Scott T Ballard, Investigator	DATE ISSUED 9/16/2016

X Scott T Ballard
Scott T Ballard
Investigator

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The following examples from (b) (4) total US products and associated test methods are affected:
1. (b) (4) Injection - (b) (4) vials used - STP #(b) (4)
2. (b) (4) Injection – (b) (4) vials – STP #(b) (4)
3. (b) (4) Injection – (b) vials – STP #(b) (4)
4. (b) (4) Injection – (b) vials – STP #(b) (4)

OBSERVATION 3

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, the qualification of equipment is not adequate for its intended purpose including (b) (4) vial stoppering machine, and (b) (4) equipment.

A. The Line # (b) (4) stoppering equipment qualification document # SH1026OQ Rev 1.0 and FU4-PN-(b) (4)-001-EQP-PQ-002 does not include a quantitative evaluation of the (b) (4) (b) (4) for products intended for (b) (4). During the inspection on September 7, I observed a large number of product vials with dislodged and variable (b) (4) (b) (4) during production of (b) (4) Injection (batch (b) (4).

B. The (b) (4) (b) (4) 002 re-qualification document FU4-PN (b) (4) 002-EQP-RQ-001 and product validation reports such as FU4-SIPO-PVR-004) do not speak to the (b) (4) pressure needed to (b) (4) (b) (4) up to (b) (4) vials in a single load occupying (b) (4). This operation is currently controlled by visual indication of (b) (4) through (b) (4) approximate (b) (4) (b) (4) as instructed by SOP #FU4-PR-MF-OPI-090.

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C. The drawing of (b) (4) -40 #L11008Ca-001-01-03 revision 1, provided by the supplier, indicates the equipment should be installed with a (b) (4) unit connected to the (b) (4) valve connection (b) (4) 315. This (b) (4) item is not installed on the equipment.

D. (b) (4) system drawing #APL-IV/EN/(b) (4)/002-14 does not show installed equipment such as (b) (4) in Line #(b) (4) compounding area. This (b) (4) system is used to operate (b) (4) valves and (b) (4) media through equipment during simulations.

E. (b) (4) tank drawing #APL-IV/EN (b) (4)/001-07 and (b) (4) tank drawing # APL-IV/EN (b) (4)/002-01 are inaccurate with respect to the order and location of piping such as (b) (4) and (b) (4) The (b) (4) in these tanks is used for (b) (4) equipment and compounding of drug products (respectively) such as injectables and (b) (4) products.

OBSERVATION 4

The use of instruments and recording devices not meeting established specifications was observed.

Specifically, the "Indu Softweb Studio" SCADA electronic recording system for temperatures found in the micro lab rooms for incubating Environmental Monitoring, Reference Cultures, and other media incubation shows multiple out-of-specification temperatures and loss of communication errors through June, July, and August 2016.

As evidenced by repeated communication failures and out-of-specification data within a three month period, this equipment is not functioning adequately and has not been maintained to the criteria set in the qualification protocol #10443-01.

*DATES OF INSPECTION

9/06/2016(Tue),9/07/2016(Wed),9/08/2016(Thu),9/09/2016(Fri),9/12/2016(Mon),9/13/2016(Tue),9/14/2016(Wed),9/15/2016(Thu),9/16/2016(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Scott T Ballard, Investigator

X Scott T Ballard
Scott T Ballard
Investigator

DATE ISSUED
9/16/2016

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 judgment, 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."