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	2/26/2018-3/6/2018* FEI NUMBER 3009883410

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Naveen Kumar Jain, Plant Head

FIRM NAME	STREET ADDRESS
Auronext Pharma	A-1128, Riico Industrial Area, Phase - Iii, District Alwar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bhiwadi, Rajasthan, 301019India	Manufacturing Facility

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:

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, the firm has unsubstantiated ranges in reference to a critical process parameter for their Vial Sealing Machine (Equipment ID PF/VSM-01), in their manufacturing batch records, which is not supported by process development and/or process validation data. The batch record has a Vial Sealing Machine Operation Speed Range of (b) (4) - (b) (4) vials per minute. The firm never processed at the worst case processing speed, (b) (4) vials per minute, during process development or manufacturing process validation.

OBSERVATION 2

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

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EMPLOYEE(S) SIGNATURE
Anastasia M Shields, Investigator
Carrie A Hughes, Investigator

X Anastasia M Shields
Investigator
Signed By: Anastasia M. Shields -S
Date Signed: 03-06-2018 03:51:32

DATE ISSUED
3/6/2018

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FIRM NAME Auronext Pharma	STREET ADDRESS A-1128, Riico Industrial Area, Phase - Iii, District Alwar
CITY, STATE, ZIP CODE, COUNTRY Bhiwadi, Rajasthan, 301019India	TYPE ESTABLISHMENT INSPECTED Manufacturing Facility

Specifically, The current procedure for qualifying/requalifying personnel performing the 100% visual inspection of sterile drug products for injection, entitled, SOP#PF071-07, "Visual Inspector Qualification/Requalification", does not sufficiently challenge personnel with the full range of visual particulate contamination (in terms of variations of types and sizes of particulates) that they may find in batches they would be required to inspect. The visual inspection kit used for training and testing of visual inspectors, for both the manual and semiautomatic visual inspection processes, only contains (b) (4) glass vial containing a piece of (b) (4) particulate, and (b) (4) glass vial containing a relatively large piece of (b) (4) particulate.

OBSERVATION 3

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit.

Specifically,

Your firm's (b) (4) Microbial Identification System (QC/VMI-01) was installed on 01/10/2011 with (b) (4) SW software version (b) (4). Since the installation, the (b) (4) SW was updated at least twice:

- From version (b) (4) to version (b) (4) with no documentation to indicate when the update(s) occurred;
- From version (b) (4) to version (b) (4) (current version) on 18/06/2014 during a service call by the vendor.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Anastasia M Shields, Investigator Carrie A Hughes, Investigator	X Anastasia M Shields Investigator Signed By Anastasia M. Shields - S Date Signed 03-06-2018 03 51 32	3/6/2018

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These (b) (4) SW software updates were installed without a qualification protocol pre-approved, reviewed, or approved by your Quality Unit.

While Auronext maintains a service agreement with (b) (4) for Preventive Maintenance at (b) (4) (b) (4) intervals, your firm has failed to:

- Retain preventative maintenance reports and service reports provided by the vendor at each visit since the system was installed;
- Assess the impact of items on the 21-point checklist (provided by the vendor at each service call) to the qualification status of the system.

The (b) (4) Microbial Identification System (QC/VMI-01) is used to identify microorganisms isolated from samples collected from: sterile finished drug products; sterile finished bulk; the environmental monitoring program, including personnel monitoring; and the (b) (4) monitoring program.

***DATES OF INSPECTION**
2/26/2018(Mon), 2/27/2018(Tue), 2/28/2018(Wed), 3/01/2018(Thu), 3/05/2018(Mon), 3/06/2018(Tue)

X Carrie A Hughes
Investigator
Signed By: Carrie A. Hughes -S
Date Signed: 03-06-2018 03:52:03

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