DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	4/11/2018-4/26/2018* FEI NUMBER 3010943533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Alfonse Muto, RPh, Owner	
FIRM NAME Pine Pharmaceuticals, LLC	STREET ADDRESS 355 Riverwalk Pkwy
CITY, STATE, ZIP CODE, COUNTRY Tonawanda, NY 14150-5837	TYPE ESTABLISHMENT INSPECTED Outsourcing 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 I OBSERVED:

OBSERVATION 1

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically, your firm lacks a specific training and verification schedule to evaluate the skills and expertise needed for personnel engaged in the visual inspection of finished drug products. Currently, according to SOP #4125, entitled "Visual Inspection – Finished Product," Version 1.1, effective date 3/22/18, an eye exam is to be completed (b) (4) for personnel responsible for the inspection of finished drug products. Yet, your firm does not have any written procedures that establish a requirement for personnel performing visual inspection to complete an eye exam, which tests for color-blindness and/or the ability to distinguish color. Moreover, eye exams testing for color-blindness and/or the ability to distinguish color are not collected or documented for personnel engaged in visual inspection.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rachael A Moliver, Investigator	X Rachael A Moliver Investigator Signed By: Rachael Moliver -S Date Signed: 04-26-2018 12:37:55	4/26/2018

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a) You have not adequately qualified the (b) (4) Building Monitoring System used to monitor pressure differentials between rooms within the aseptic processing suite, temperature of aseptic processing areas and room temperature drug storage areas, relative humidity of aseptic processing areas, temperature of refrigerated and frozen drug storage areas, temperature within incubators, and (b) (4) temperature. Currently, you have only performed installation qualification (IQ) and operational qualification (OQ) of the (b) (4) System. You have not completed the evaluation/summary report of the IQ/OQ, as well as the performance qualification (PQ) for the (b) (4) System prior to its use in monitoring aseptic operations and storage areas.

b) Your firm is not using (b) (4) during your (b) (4) sterilization of goggles, stir bars, stir bar retrievers, metal instruments, and vial trays. Currently, your firm is exclusively using an (b) (4), for each (b) (4) load to indicate whether a certain temperature has been reached, specifically (b) (4) °C, for (b) (4) (b) (4). Additionally, your firm has only used (b) (4), for the (b) (4) validation runs conducted during your firm's (b) (4) validation study.

c) Your firm reuses compounded sterile (b) (4) solution multiple times without storing the sterile (b) (4) solution in an ISO-classified area.

OBSERVATION 3

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

a) Product and container labels are generated electronically using your firm's (b) (4) software and (b) (4) software, which are not validated systems.

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b) Strict control is not exercised over labeling issued for use in drug product labeling operations. Currently, all operators have access to the (b) (4) software to generate and print prefilled syringe labels.

c) Examination of packaging and labeling materials for suitability and correctness before packaging operations is not documented in the batch production records. Specifically, product syringe labels, which are printed by an operator "on-demand" in the ISO 7 Packaging Room, are examined by the same operator and then electronically sent to a pharmacist via (b) (4) (not a validated system) to be examined before the product syringe labels are released for labeling operations. However, the results of these printed product syringe label examinations are not recorded.

d) Records do not include the disposition of rejected labeling. The practice of the disposition of rejected labels due to the operator's and/or pharmacist's initial label review of printed product labels is not specified in any procedure. Printed labels that are determined to be defective are discarded; this is not documented anywhere.

***DATES OF INSPECTION**

4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed), 4/19/2018(Thu), 4/24/2018(Tue), 4/26/2018(Thu)

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