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	11/4/2025-11/14/2025* FEI NUMBER 3010943533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alfonse J. Muto, Owner

FIRM NAME	STREET ADDRESS
Pine Pharmaceuticals, LLC	355 Riverwalk Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tonawanda, NY 14150-5837	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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm fail to adequately evaluate and scientifically justify release of sterile drug products, not limited to but including the following examples,

1) Complaint investigation, COMP-2025-0005, for Vancomycin 10 mg/mL (1mL) single dose vial, lot 79815-C, expiry 1/29/2025, was opened for a cloudy appearance. This investigation confirmed the presence of two cellulose particulates and three unidentified translucent fibers in the four returned vials. These four vials were (b) (4) . Despite the confirmed defects, you concluded that the batch was "essentially free from visible particulate matter" based on inspection of retain samples and characterized this incident as rare (3 particulate complaints in 2024, representing (b) (4)% of distributed units). Furthermore, the visual inspection and AQL performed prior to release and distribution of this lot found zero (0) particles. However, complaint COMP-2025-0005 confirmed there were potentially multiple vials with particulate defects that were missed by your quality team.

   A replacement vial was provided to the complainant, but no corrective or preventative action was implemented. In addition, your firm chose not to identify the three translucent fibers per the analytical lab report.

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2) Your firm released drug products despite failing critical defect limits during 100% visual inspection, basing these release decisions on successful AQL inspections, additional 100% visual reinspections, second 100% AQL reinspections, and removal of affected units. For example,

a) (b) (4) filled Bevacizumab 1.25 mg/0.05 mL injection repackaged into a syringe, lot 83436, expiration 1/15/2026, had an overall critical defect reject rate of (b) (4)% (24/(b) (4) units). Your firm's specification for critical defect limits is (b) (4)%. Your firm performed 100% visual inspection of the batch and found 22 units rejected for container closure integrity issues (loose caps) and 1 empty unit. Your firm investigated this incident under Non-Conformance, NONC-2025-0426, due to the high reject rate and determined that the lot should be reinspected. The second 100% visual inspection performed resulted in 1 additional container closure critical defect found. Your firm determined that the impact of this event was negligible and resulted in a risk rating that required no further investigation because the tightened second AQL and first AQL met acceptance criteria supporting that the batch was essentially free of defects. Your firm released this lot with the justification that the issue was isolated to the identified defective units, which were removed from the batch.

b) Moxifloxacin in Balanced Salt Solution 150mcg/0.1mL 0.5mL vial lot 81919 had an overall critical defect reject rate of (b) (4)% (187/(b) (4) units). Your firm's specification for critical defect limits is (b) (4)%. Your firm investigated this incident under Non-Conformance NONC-2025-0191 due to a high critical defect rate for a container/closure defect (partially crimped seals) on the overall batch. Your firm conducted the initial 100% visual inspection in (b) (4) loads.

Load(b) (4) specifically, failed its initial AQL for major defects (particles). Load(b) (4) then underwent a 100% targeted visual reinspection focused on major defect rejects (particles), as these exceeded the AQL limit during the first inspection. Three major

defects were identified during the initial AQL.

Since the overall batch had a critical defect rate of (b) (4) %, your firm conducted a second 100% visual reinspection, however, this was only performed on loads (b) (4) and (b) (4). Load (b) (4) and (b) (4) underwent 100% targeted visual reinspection for critical defect limits (container/closure) that were exceeded due to an (b) (4) % overall critical reject rate.

Your firm failed to reinspect Load (b) (4) for the reasoning that it had already undergone a full 100% visual reinspection, although the reinspection on load (b) (4) was targeted for particle rejects, not container closure defects. Visual reinspection for container closure defects was never performed on load (b) (4). The batch was subsequently released based on passing results from the second 100% visual reinspection's and targeted AQLs specific to the defects inspected for each load.

c) (b) (4) filled Bevacizumab 1.25 mg/0.05 mL injection repackaged into a syringe, lot 83478, expiration 1/17/2026, had an overall reject rate of (b) (4) % (16/(b) (4) units) for critical defects. Your firm's specification for critical defect limits is (b) (4) %. Your firm investigated this incident under Non-Conformance, NONC-2025-0432. The first 100% visual inspection identified 6 container closure defects for a dislodged cap. The first AQL identified an additional 6 container closure defects for a dislodged cap being found. A second, targeted, 100% visual inspection was performed with an additional 4 container closure defects for a dislodged cap found. A second AQL was performed on this second 100% visual reinspection, and received a passing result. Your firm stated in the risk assessment for NONC-2025-0432: "Despite the

initial AQL failure due to visual detection of dislodged (unseated) caps, the subsequent focused reinspection was successfully completed with no defects observed during the tightened AQL, demonstrating that the batch meets the required quality standards. Additionally, there have been no customer complaints or events indicating defects identified after AQL, and corrective actions, such as targeted operator training and updates to the (b) (4) and (b) (4), have been implemented to prevent recurrence. Impact to product SQuIPP has been mitigated and the batch is suitable for release." Ultimately, your firm released this lot with the justification that the issue was isolated to the identified defective units, which were removed from the batch.

OBSERVATION 2

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

Specifically,

1) On 11/4/2025, during the aseptic repackaging of Bevacizumab 1.25 mg/0.05 mL injection, batch 84058, we observed your operator resting their arms on the ergonomic support bars outside the ISO (b) (4) area and then extending their arms and sleeves into the ISO (b) (4) critical zone during the aseptic processing without sanitizing their sleeves, as required by SOP-229, "Cleanroom Behavior and Aseptic Technique," Rev. 04.

2) During video review on 11/12/2025, we observed poor aseptic technique by your operator during the production of Calcium CL 20 mg/mL (500 mL) inj, lot 83663, exp 04/04/2026, produced on (b) (4). For example,

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a. Your operator grabbed transfer tubing from ISO (b)(4) space, brought it into ISO (b)(4) space, and failed to sanitize the tube or their hands upon entry into ISO (b)(4).

b. While preparing the viable air monitors, your operator wiped the monitor with an (b)(4) wipe, set it back onto the table in ISO (b)(4) space, and brought it into ISO (b)(4) space without sanitizing again.

c. Your operator rested their hands and wrists on the ergonomic support bar located within the ISO (b)(4) area. The operator did not perform hand sanitization after this contact and before handling items within the ISO (b)(4) area, including the wipes used to clean the (b)(4) port, a test beaker, and the (b) (4).

3) Your firm does not conduct routine environmental monitoring of trays used to stage materials, including container closures, which are (b) (4) before being placed into the ISO (b)(4) classified area. The current procedure MWA-041, "Aseptic Processing Suite (b)(4) Batch Specific Sample Locations," Rev. 08, fails to establish sampling requirements for these trays.

OBSERVATION 3

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

Specifically,

Your manual visual inspection personnel are not adequately qualified. Your firm implemented changes to your SOP-155, "Training and Qualification of Qualified Visual Inspectors for Compounded Products", Revision 9, for visual inspection qualification which included (b) (4) after (b) (4) (b) (4). Your firm failed to retroactively review your inspectors' previous qualifications to

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see if they align with the new procedure and/or requalify your visual inspectors based on the new criteria.

For example, review of one inspector's qualification revealed that, under the current criteria, the result would constitute (b) (4) due to (b) (4) (b) (4). The inspector was qualified on the (b) (4) visual inspection process in March of 2025, and has continued to perform visual inspections on these products since then, although the governing SOP was revised in August of 2025.

OBSERVATION 4

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of processing of the drug product.

Specifically,

Visual inspection reject limit calculations do not include all units rejected by qualified visual inspectors. For example, your procedure, "Visual Inspection of Finished Product" SOP-061, rev. 23 states that defects will be verified by MQA and all falsely rejected units will be removed from the batch, however, defect rates will be based on quantity of confirmed defective units. The detection of particulate matter can vary between operator, color of fiber, size, and type of particle found.

OBSERVATION 5

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

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Your firm does not have validation performed for (b) (4) mixing and (b) (4) of Tropicamide 1% and Phenylephrine HCL 2.5% Sterile Ophthamic Solution (15mL multi-use dropper). Your firm's mixing instruction include only directions for mix time and do not include mixing speeds. In addition, your firm relies on operator training and QA verification to assure that mixing is adequately performed. (b) (4) (b) (4) are not documented in the batch record and have not been validated.

***DATES OF INSPECTION**
11/04/2025(Tue), 11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri)

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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."