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	8/5/2024-9/30/2024* FEI NUMBER 3010943533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Alfonse J. Muto Jr., 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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

1. On 9/10/24 during the production of Lidocaine HCL 4% Ophthalmic Solution, 3mL bottle, Lot # (b)(4) Exp: March 5, 2025, on the (b)(4) filling machine, it was observed that open bottles containing sterile product being placed in a non-HEPA filtered (b)(4) from the (b)(4) LFH (b)(4) (filling area) to (b)(4) LFH (b)(4) (capping area).

   In addition, no environmental monitoring is being conducted on the (b)(4). Lastly, your firm's smoke study entitled, (b)(4) (2/27/24) demonstrates that the air is flowing from the (b)(4) (capping area) to the (b)(4) (filling area) creating turbulent airflow which can increase the level of particulates during the filling operations.

2. Your firm failed to provide justification to support that air velocity and airflow patterns determined in the (b)(4) Recertification (February 2024) in your (b)(4) flow hoods are adequate to ensure the protection of drug products from turbulent airflow. For example, a maximum air velocity of 189 FPM and a minimum air velocity of 85 FPM was observed in hood (b)(4) and a maximum air velocity of 145 FPM and a minimum air velocity of 38 FPM was observed in hood (b)(4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ucheabuchi C Chudi-Nwankwor, Investigator Simone E Pitts, National Expert Jazmine N Brown, Investigator Lauren H Augustyniak, Investigator	X Simone E Pitts National Expert Signed By: Simone E. Pitts -S Date Signed: 09-30-2024 16:15:21	9/30/2024

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3. The airflow visualization studies used to qualify the (b)(4) with (b)(4) were insufficient in that the airflows studies were not performed under dynamic conditions to determine unidirectionality of the airflow. In addition, during my review of your airflow visualization study for (b)(4) Equipment ID (b)(4) it was observed that turbulent air near the (b)(4) . Lastly, the smoke probe was not positioned at an angle to fully visualize and access the airflow around the (b)(4) in these (b)(4) The smoke was observed to move in an upward direction within (b)(4) and flow into the ISO 7 area.

4. Your firm's dynamic smoke study entitled, (b)(4) , 9/14/23 is inadequate due to the ISO 7 buffer room airflow concerns (b)(4) airflow) during aseptic production, which can potentially cause particle contamination. There have been no changes to the hood design since the last inspection in September 2023. All the (b)(4) Laminar Airflow Workbenches and/or (b)(4) Laminar Airflow Workbenches (b)(4) have the same design in that the air intake is on the (b)(4) of the hood. ***This is a repeated FDA-483 Observation from 09/2023.**

5. On 8/7/24, I observed the following inadequate aseptic technique during production: the operators are still resting their arms on the ISO 5 hood, it appears that the operator standing is working outside of the ISO 5 hood and the person sitting has product to the edge of the hood therefore not working (b)(4) within their (b)(4) hood. ***This is a repeated FDA-483 Observation from 09/2023.**

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Your firm's environmental monitoring specifications were inadequate (alert (b)(4) cfu and action (b)(4) cfu) until December 21, 2023. During that time your firm had one ISO 5 EM failure on 12/5/23, 2 cfu for personnel identified as *Micrococcus luteus* (operators' right glove) during the

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production of Bevacizumab 2.5 mg/0.1mL, lot #(b)(4) EXP: 04/03/2024 within hood (b)(4) located in Suite (b)(4) Buffer Room (b)(4) as documented in NONC-2023-1393. Your firm released the batch based solely on finished product testing and deemed the impact of this event as minor.

In addition, from 12/5/2023 through 08/23/2024 your firm had a total of approximately 16 environmental monitoring failures for personnel, surface and non-viable particulate monitoring within the ISO 5 environment and all batches were released solely based on finished product testing.

2. Your firm failed to conduct environmental monitoring (i.e. swab samples) of critical product contact surfaces within your ISO 5 environment such as the filling needle of your firms (b)(4) filling machine and the filling needle within your (b)(4) aseptic filling process at the completion of the filling operations to ensure it maintained its sterility throughout the production run. In addition, your firm failed to conduct EM on the (b)(4) ISO 5 arm rests as well as the gowning areas that come in contact with these (b)(4).

3. Your firm's non-viable particle (NVP) count monitoring is inadequate as it is not representative of the entire batch instead you conduct NVP at the (b)(4) of a production run therefore missing critical data from the (b)(4) of the production run (total production run is approximately (b)(4)). In addition, your firm allows for repeated NVP testing (b)(4) times if a failure is observed without any scientific justification. As a result, your firm has initiated the following non-conformances for NVP failures: 2024-0272, 2024-0294 and 2024-0353 re-testing was allowed, and batches were released based on other EM data and finished product testing.

4. Your firm failed to follow your procedure in conducting adequate personnel monitoring. SOP-135 "Environmental Monitoring Technique", version 12, dated 19 Feb. 2024, section 6.5.2.1 states "(b)(4) . On 8/7/2024, Technician (b)(6) was observed aseptically filling Bevacizumab 1.25mg/0.5ml Injection, Lot (b)(4)

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in (b)(4). At the end of the filling process, the technician removed her gloved hands from the ISO 5 to disinfect with (b)(4). A then placed her gloved hands back into the ISO 5 (b)(4) to perform Personal Monitoring of the left and right fingertips which fails to provide meaningful data and is not considered representative of actual production.

OBSERVATION 3

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

Specifically, on 9/10-9/11/2024 improper aseptic technique was observed during the production of the following Lidocaine HCL 4% Opthalmic Solution, Batch (b)(4) EXP: March 5, 2025 in Suite (b)(4) and batches produced in Suite (b)(4) Buffer Room (b)(4) Tropicamide Phenylephrine Inj. 15mL, Lot (b)(4) EXP: March 5, 2025 in (b)(4) Avastin Pooling IV bag, Lot (b)(4) Exp: January 16, 2025 in (b)(4) Povidone-Iodine Opthalmic 1mL, Lot (b)(4) Exp: February 8, 2025 in (b)(4) and Bevacizumab Inj. 1.25MG/0.05 ML, Batch (b)(4) EXP; January 9, 2025 in (b)(4)

1. The operators utilize goggles that have holes across the top allowing for egress of potential particulates from the operators' exposed skin. The goggles are part of the sterile gowning used for operators in Suites (b)(4)

2. The operator wiped down the tip/cap, (b)(4) tray bags, syringes, and IV bags with a sterile wipe and placed them in the ISO 7 area instead of wiping and immediately placing in the ISO 5 hood. The operator failed to re-sanitize those components before entering them into the ISO 5 hood. This was observed during production runs of drug products in Suites (b)(4).

3. An operator was observed unwrapping the pre-sterile (b)(4) bottles within trays for ophthalmic product in the (b)(4) ISO 5 (b)(4) filling hood, removing the nested bottles from the side allowing the top of the bottle to come into contact with the edge of the bag instead of removing/opening the entire cover from right to left thereby reducing the risk of potential

particulate contamination.

4. In Suite (b)(4) flow hood), during the production run, Rows (b)(4) trays (b)(4) for a total of (b)(4) droptainers) were not receiving first air.

5. During the filling process the operator was utilizing scissors to grip the (b)(4) which was attached to the filling needle to dispense the drug product, but their gloved hands and sleeves remained directly over the open sterile drug products and blocked first air.

6. The operator was observed picking up the droptainer caps with their gloved hand potentially touching the inside of the cap where the sterile tip is placed, (b)(4) tightening the cap on the droptainers and then utilizing the capper equipment to apply the final torque on the cap.

In addition, from September 2023 to present your firm has received approximately 29 complaints categorized as ADEs for Bevacizumab 1.25MG/0.05 ML relating to Endophthalmitis. Moreover, your Quality Unit has not initiated a corrective and/or preventative action to address these adverse drug events, determine a root cause of the adverse event, and implement an adequate control strategy to mitigate patients from developing Endophthalmitis in the future.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

1. Your firm's SOP, SOP-OO7 titled "Facility Cleaning/Disinfecting", revision 35 dated 10 April 2024, had instructions for (b)(4) contact time when using (b)(4) and (b)(4) in the disinfection of your classified areas including the ISO 5 (b)(4) Your firm failed to document contact times in your Room and (b)(4) cleaning logbooks to ensure your

procedure was followed.

For example, during the inspection, I reviewed the following cleaning logbooks and observed there was no documentation and evidence of the (b)(4) contact time in your:

a. (b)(4) Cleaning (b)(4) logbook; LOG-329; dated 12/30/2023 covering cleaning for all ; cleaned between 01/04/2024 to 08/08/2024.

b. Cleaning Log of Aseptic Compounding Clean Room Suite (b)(4) LOG-385; dated 03/14/2024 covering cleaning of the ISO 7 clean room from 03/14/2024 to 08/08/2024.

2. Your firm failed to adequately clean and sanitize your capper which is utilized in your (b)(4) aseptic filling process inside your ISO5 laminar flow hood. Your firm only sanitizes the exterior portion of the capper with a sterile wipe and fails to clean the interior metal portion that comes in direct contact with the cap. This inadequate cleaning and sanitization can allow for potential residues from friction to enter the trays containing sterile drug product. During production runs, the position of the capping equipment was observed to be placed (b) (4) of the hoods over either open containers or open caps requiring the operators to reach over open containers and/or caps.

OBSERVATION 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically,

Your firm failed to have separate dedicated facilities to prevent cross contamination of non-penicillin beta-lactam drug products that are repackaged in the same facility as non-beta-lactam drug products. For example.

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a. The entry and exit for the non-penicillin beta-lactam suites (#148) share the same corridor ((b) (4)) with the entries (#156) and exit (#161) to the other non-beta-lactam drug products manufacturing suite. You produce the following but not limited to non-beta-lactam products; Bevacizumab 2.5 mg/0.1mL, Vancomycin 1mg/0.1Ml, LIDO-PHEN 1%-1.5%(1mL) in Suite(b)(4) (Buffer(b)(4) with entry through door #156 and exit through door #161.

b. The airflow flows from your non-penicillin beta-lactam suites #148 and 149 into corridor (C05) which is shared with the non-beta-lactam manufacturing suites.

In addition, your firm does not have containment control procedures for your non-penicillin beta-lactam drug product manufacturing processes with specifics on how to handle the (b)(4) drug (b)(4) in the commercially available vials used in the manufacturing of your non-penicillin beta-lactam drug products.

OBSERVATION 6

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

1. Your firm conducted inadequate investigations as root causes were not supported through scientific rationale when the following(b) (4) flow hoods failed their performance tests due to media or gasket leaks for the following: Buffer Room(b)(4) , Model # (b)(4) and Buffer Room (b)(4) Model (b)(4) , Buffer Room (b)(4) Model (b)(4) , Buffer Room (b)(4) Model (b)(4) , Buffer Room (b)(4) , Model #(b)(4) . Approximately (b)(4) batches, dating back to the previously passed certification, August 2023 were released based on environmental monitoring results which is determined to be inadequate as critical product contact surfaces are not being assessed, non-viable particulate monitoring is only being conducted at the

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(b)(4) of the production run and finished product testing.

The following batches that have not been adequately evaluated and are on the market within expiration include the following:

- CALCIUM GLUCONATE 2.5% (5ML), lot #(b)(4) (QTY: (b)(4) EXP: 10/5/2024 (b)(4)
- CALCIUM GLUCONATE OPH 1% (500ML), lot #(b) (4) (QTY: (b) (4), EXP: 09/21/2024 ((b)(4)
- CALCIUM GLUCONATE OPH 1% (500ML), lot (b) (4) (QTY: (b) (4)), EXP: 09/22/2024 ((b)(4)
- CALCIUM GLUCONATE OPH 1% (500ML), lot (b) (4) (QTY: (b) (4)), EXP: 09/23/2024 (b)(4)

In addition, your Quality Unit lacked sufficient oversight in that the non-conformances were opened approximately 2-months late and multiple non-conformance reports were created for the same HEPA filter certification failures that occurred in February 2024 over multiple hoods as indicated in the table below:

NONC #	Buffer Room (b)(4)	Date of Incident	NONC Initiated the 1st Time	NONC Initiated the 2nd Time.
2024-0442	(b)(4)	14 FEB 2024	30 APR 2024	06 SEP 2024
2024-0441		10 FEB 2024	30 APR 2024	06 SEP 2024
2024-0440		14 FEB 2024	29 APR 2024	06 SEP 2024
2024-0444		15 FEB 2024	30 APR 2024	06 SEP 2024
2024-0445		15 FEB 2024	30 APR 2024	06 SEP 2024

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2. Your firm-initiated non-conformance 2024-0444 on 4/30/24 for a HEPA Leak in (b)(4) (Room 143, Suite(b)(4) Buffe(b)(4) that occurred on 2/15/24 (approximately 2-months late) and determined the root cause of the failure to be dried product from a previous batch. Your firm failed to evaluate what the dried product was, and the potential cross contamination risk of other batches produced within the ISO 5 hood.

OBSERVATION 7

Your firm failed to establish 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,

1. Your firm's Procedure titled, SOP 061,"Visual Inspection Finished Products", vs. 18 dated 27 May 2024 is deficient as you failed to implement adequate specifications to prevent significant product quality issues from occurring. You have been producing and releasing several lots of Bevacizumab drug products with extremely high levels of visible particulates.

2. You failed to adequately investigate and determine the root cause of too many inherent/intrinsic visible particulates defects contamination in multiple batches of Bevacizumab 1.25mg/0.05mL found out of limit or above alert limits after your first 100% visual inspections. Without identifying a root cause, you conducted successive visual inspections of batches (2nd 100% re-inspection) until inherent/intrinsic visible particulates were within specification and then released batches of Bevacizumab 1.25mg/0.05mL injection, even though there were potential to inherent/intrinsic visible particulates. You have used AQL inappropriately to re-examine the 1st failed 100% without scientific justification by inappropriately using (b)(4) to justify first VI and AQL failures.

For example, your firm did not adequately investigate the failures of the 100% Visual Inspection for the following but not limited to lots of Bevacizumab 1.25mg/0.05mL for inherent/intrinsic visible particulates defects:

Lot (b)(4) Exp. 08/17/2024 with 208 inherent/intrinsic visible particulates defects and also with 1st and 2nd AQL failures. (b)(4) of the batch size).

Lot (b)(4) Exp. 07/10/2024 with 336 inherent/intrinsic visible particulates defects. ((b)(4) of the batch size)

These product lots were released by your Quality Assurance for distribution on 6/06/2024 and 07/22/2024 respectively without expanding your investigation to your production processes.

3. Your firm failed to provide adequate production process controls to protect the following sterile drug products (b) (4) as indicated on the production batch instructions as (b)(4) ": Moxifloxacin 125MCG/0,1 ML Inj, Lot (b)(4) EXP: 09/22/2024, Bevacizumab 1.25 MG/0.05 ML Inj, Lot: (b)(4) EXP: 09/20/2024, Lidocaine HCL 4% (3ML) Ophthalmic, Lot: (b)(4) EXP: 12/10/2024, and Povidone – Iodine 5% (1ML) Ophthalmic, Lot:(b)(4) EXP: 07/18/2024.

OBSERVATION 8

Written procedures are not established that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

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1. Your firm failed to adequately demonstrate that your process is reproducible and can produce products that consistently meets predetermined specifications for Bevacizumab 1.25mg/0.5ml Injection. For example, your firm lacks in-process weight or volume verification utilizing a calibrated instrument. Since September 2023, you have received approximately 260 complaints for either: empty syringe/air pocket (air bubble), depressed syringe/underfilled and insufficient fill volume. Furthermore, your Quality Unit has not initiated a corrective and/or preventative action to address these complaints and a possible plan to mitigate complaints such as these in the future.

2. Your firm's Defect limit working document titled, MWA-048,"Percentage Defect Alert and Action Limit", rev.3 dated August 27, 2024 governing the conduct of 100% (b)(4) visual inspection of your finished sterile drug products lack action levels for significant individual defects which will require investigations. You do not have proper specifications / defect limits for all your drug products for significant defects subject to identification and rejection during 100% (b)(4) visual inspection. For example, you have not set an appropriate defect limit for all defect categories for visual inspection of your drug products in vials, bottles droptainers; to include the following but not limited sterile drug products:
   a. Lido-Phen 1%-1.5% (1mL) SDV ((b)(4))
   b. LIDO-OXYMET 2%-0.025% (20 ML) NASAL SOL ((b)(4)
   c. MOXIFLOXACIN IN BSS 100 MCG/0.1 ML SYR ((b)(4)
   d. LIDOCAINE HCL 4% (3 ML) OPHTH ((b)(4))
   e. TROPI-PHEN 1% - 2.5% OPHTH SOL (5 ML) ((b)(4))

   You have not categorized the alert and action limit for all particulates as Critical or Major despite the defect category for all your sterile drug products.

3. Your firm's in-process specifications, with respect to visible particulates, are clearly not consistent with the drug product final specifications. You have not appropriately validated your 100%

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visual inspection process to determine a suitable statistical procedure for your defect category limits. You rely on historical data rather than final specifications derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate.

OBSERVATION 9

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

Specifically, your firm failed to adequately calculate the actual and theoretical yields at each phase of production. For example, your firm is inappropriately calculating batch yields by leaving out all Visual Inspection defects which potentially account for up to (b) (4) % loss of the batch. There is no scientifically sound justification for the failure of reporting Inherent/Intrinsic visible particulate defects and there is no scientific justification for the (b)(4) inherent particulate rejects for Bevacizumab 1.25mg/0.05mL Inj., Lot (b)(4) EXP:8/17/24; as they were not considered in neither the percent defect calculations nor the yield calculations (actual versus theoretical yield).

*DATES OF INSPECTION

8/05/2024(Mon), 8/06/2024(Tue), 8/07/2024(Wed), 8/08/2024(Thu), 8/09/2024(Fri), 8/13/2024(Tue), 8/15/2024(Thu), 8/16/2024(Fri), 8/30/2024(Fri), 9/06/2024(Fri), 9/10/2024(Tue), 9/11/2024(Wed), 9/12/2024(Thu), 9/13/2024(Fri), 9/27/2024(Fri), 9/30/2024(Mon)

X Jazmine N Brown
Investigator
Signed By: Jazmine N. Brown -S
Date Signed: 09-30-2024 16:15:51

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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."