DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	08/25/2025-09/05/2025
	FEI NUMBER 3004446312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

M. Venkateswar Rao, Senior Vice President - Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd.	Unit XII, Survey No. 314
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bachupally, Hyderabad, 500090, India	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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed, or did not include adequate validation of the aseptic process.

Specifically,

Your firm's (b) (4) Line manufacture sterile drug products for the U.S. market. (b) (4) fill lines are equipped with (b) (4) RABS (b) (4) Restricted Access Barrier System). During the inspection, I (EL) observed the following.

A. The (b) (4) RABS design principle and purpose are not adequately followed to prevent potential microbial contamination of drug products purporting to be sterile. Specifically, excessive (b) (4) (b) (4) interventions were performed that pose significant risks to product quality. For example,

   a) Pe (b) (4) Line, (b) (4) of the (b) (4) Grade A intervention types are (b) (4) interventions. Review of the (b) (4) Injection batch processing records (BPRRs) for U.S. batches (b) (4) revealed that (b) (4) interventions were performed, respectively due to either a lack of (b) (4) or not using the existing (b) (4)

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b) Per (b) (4) Line, (b) (4) of the (b) (4) Grade A intervention types are (b) (4) interventions. Review of the (b) (4) Injection BPRRs for U.S. batches (b) (4) revealed that (b) (4) interventions were performed, respectively due to either a lack of (b) (4) or not using the existing (b) (4) (b) (4)

B. Aseptic processing procedures are not established or followed. During the inspection, I (EL) watched the (b) (4) Line filling videos of (b) (4) Injection U.S. batches (b) (4) with management. We observed the following:

a) General Procedure FU12-PR-INJ-GEN-0057, "Handling of Interventions in (b) (4) (b) (4) Line", section 4.5.12.3 requires to sanitize the external surface of (b) (4) stopper bags completely on all surfaces with (b) (4) before transferring them from the (b) (4) LAF to inside of the Grade A filling line. Review of videos revealed that the above procedure was not followed to prevent microbial contamination. (b) (4) stopper bags were not sanitized prior to moving inside the Grade A filling line.

b) Interventions performed during the vial sealing operations were not documented, evaluated in airflow visualization studies, or simulated during aseptic process simulation. Approximately (b) (4) to (b) (4) seals bags (b) (4) seals per bag) were added via (b) (4) interventions during commercial filling. Your firm's management confirmed stoppered vials are not integral until fully sealed. You lack justification for not documenting, evaluating, or simulating the (b) (4) interventions conducted during vial sealing operations to assure product sterility and quality.

C. Poor aseptic behaviors were observed. During inspection, I (EL) watched the (b) (4) Line filling videos of (b) (4) Injection U.S. batches (b) (4) (b) (4) with management. We observed the following:

a) An operator's whole body was observed inside the grade A fill line space during (b) (4) (b) (4) intervention type (b) (4) "Transfer of sterilized (b) (4) stopper bags" via (b) (4) RABS (b) (4) I observed the operator stepped inside the Grade A fill line from the Grade B area. I observed this operator tossed (b) (4) stopper bags from the (b) (4) (b) (4) The operator did not follow slow and deliberate motion. In addition, per your procedure, a maximum duration of (b) (4) was allowed for this (b) (4) RABS (b) (4) intervention.

b) I observed first air to open vials was blocked during intervention type (b) (4) "Removal of fallen vial at (b) (4)". I observed the operator using a pair of forceps via (b) (4) to remove fallen or tilted vials at (b) (4) I observed the operator placed his hand and forearm over adjacent open vials while conducting intervention (b) (4) The impacted open vials were not rejected or removed.

c) The first air to sterile stoppers was blocked during intervention type (b) (4) "Addition of (b) (4) stoppers to the (b) (4)". After cutting the stopper bag open, I observed the operator touching or handling the bag opening, he then placed the entire bag straight upside down inside the (b) (4) followed by a few hard shakes to dispense the stoppers. The operator's activity blocked first air to the sterile stoppers already inside the (b) (4) I also observed the empty or "dirty" stopper bags were placed on top of the "clean" unopened stopper bags.

D. Regarding airflow visualization or smoke studies. During the inspection, I (EL) watched the (b) (4) Line static and dynamic smoke studies conducted in Oct and Dec 2023. I (EL) also watched the (b) (4) Line static smoke studies conducted in May 2025. The following lack of adequate coverage or turbulent airflow were noted:

a) Turbulent airflow or swirling of HEPA air was observed in static smoke studies of Grade A vial sealing room for (b) (4) Line. Your firm did not perform dynamic smoke studies of the vial sealing operations for the above fill lines. Thus, the impact of

the turbulent airflow or swirling of the Grade A air to product sterility or quality could not be assessed.

b) A turbulent updraft of airflow was seen above the Grade A (b) (4) conveyor where filled and (b) (4) vials traveled to the (b) (4) in the dynamic studies of the (b) (4) Line.

c) Inadequate coverage of airflow visualization was observed. Specifically, a (b) (4) is being used to hold sterile (b) (4) stopper bags. The size of the (b) (4) is (b) (4) (b) (4) The (b) (4) has (b) (4) When fully stocked, it can hold (b) (4) stopper bags, each containing (b) (4) sterile stoppers. This (b) (4) is staged inside the Grade A fill line space adjacent to the stopper (b) (4) and the (b) (4) conveyor. During active filling, the stopper bags stored on the (b) (4) are used to (b) (4) (b) (4) However, you did not perform dynamic smoke studies to assess impact to HEPA unidirectional airflow by this "wall of bags" inside the Grade A fill line during active filling.

E. Regarding aseptic process simulation (APS) or media fills (MF). Your firm's MF did not include studies of the vial sealing operation for (b) (4) Line where U.S. batches are filled. Your firm's management confirmed vials are not integral until fully sealed. You lacked justification for not simulate the vial sealing activities during MF studies to assure product sterility and quality.

OBSERVATION 2

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

Specifically,

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A. There is a lack of viable EM and non-viable particle count (NVPC) monitoring of the Grade A (b) (4) LAF in (b) (4) Line. The (b) (4) LAF (b) (4) RABS (b) (4) used for the transferring of sterilized machine parts (i.e. (b) (4) (b) (4) and accessories (i.e., forceps and scissors).

B. SOP FU12-QC-MIC-GEN-023, "Personnel Monitoring in Aseptic Area (b) (4) section 4.7.4.2.3 requires that finger dabs monitoring shall be performed for the aseptic operator (b) (4) performing (b) (4) intervention. The above procedure was not always followed. For example, only (b) (4) finger dabs monitoring was performed after conducting (b) (4) (b) (4) RABS (b) (4) interventions of placing viable settle plate at different locations of the (b) (4) Line.

C. Viable surface monitoring results by swab method are unreliable in that the swab test method was inadequately validated. Specifically, the validation conducted in 2016 did not include the study of microbial recovery in the presence of (b) (4) products. The swab test method is used during cleaning validation and to monitor cleanroom equipment surfaces (b) (4) batch production. Currently, a total of (b) (4) Grade A and (b) (4) Grade B equipment surfaces are monitored using this inadequate swab test method (b) (4) batch production in the (b) (4) Line. Also, a total of (b) (4) Grade A and (b) (4) Grade B equipment surfaces are monitored (b) (4) batch in the (b) (4) Line.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and 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,

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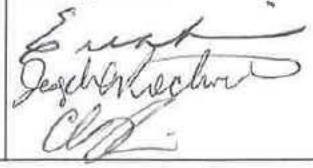
SEE REVERSE OF THIS PAGE		**Eileen A. Liu, Investigator** **Joseph A. Piechocki, Investigator** **Claudia Perez-Kasmarski, Investigator**	09/05/2025

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A. Complaints related to [redacted] (b) (4) tablets received for product defects including, but not limited to discoloration and [redacted] (b) (4) of tablets, were not adequately investigated. For example:

a) [redacted] (b) (4) is a [redacted] (b) (4) drug substance, which requires [redacted] (b) (4) control parameters during manufacturing [redacted] (b) (4) The complaint investigations state that a [redacted] (b) (4) and checked in-process and found satisfactory, and improper handling of production aids (i.e., [redacted] (b) (4) can be ruled out. However, several deficiencies were identified during the inspection with the handling and use of [redacted] (b) (4) which were not included in the evaluation, including, but not limited to, the following:

1. There has been no assessment conducted for the [redacted] (b) (4) components prior to the current inspection to justify that the [redacted] (b) (4) can adequately control [redacted] (b) (4) including all the potential exposures and handling of the [redacted] (b) (4) prior to and during [redacted] (b) (4) throughout the drug product's shelf life.

2. [redacted] (b) (4) used for [redacted] (b) (4) of the drug product can be [redacted] (b) (4) from the vendor's [redacted] (b) (4) Once [redacted] (b) (4) the vendor's [redacted] (b) (4) [redacted] (b) (4) The [redacted] (b) (4) storage location is also not within a [redacted] (b) (4) controlled environment. There has been no assessment of the impact that this [redacted] (b) (4) storage condition has on the [redacted] (b) (4) In addition, the vendor-supplied [redacted] (b) (4) bag could not be located.

3. The vendor's [redacted] (b) (4) for the [redacted] (b) (4) contains a [redacted] (b) (4) which will [redacted] (b) (4) There is no procedural requirement to assess this [redacted] (b) (4) and the potential

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impact on the [(b) (4)] prior to [(b) (4)] Furthermore, during the walkthrough of the [(b) (4)] area on 02Sep2025, vendor [(b) (4)] [(b) (4)] bags had a puncture with no integrity assessment requirement.

b) Retain samples were not adequately assessed. Study FU12-MIS-VSP-0692 showed samples without [(b) (4)] failed [(b) (4)] assay [(b) (4)] %) at [(b) (4)] despite meeting appearance specs. Complaint investigations for [(b) (4)] tablets did not consistently require chemical analysis for [(b) (4)] assay.

Since 2022, approximately 96 complaints have been received related to discoloration of [(b) (4)] Tablets, with approximately 76 complaints identifying that the patient had mishandled the drug product. Since [(b) (4)] corrections were implemented in August 2024, 14 additional complaints have been received for discoloration, disintegration, and broken tablets.

B. In 2025, four non-conformances were initiated for a total of [(b) (4)] batches of [(b) (4)] Tablets USP [(b) (4)] mg not meeting the CpK acceptance criteria of ≥ [(b) (4)] for the [(b) (4)] assay in labelled amount.due to process capability (CpK) and process performance (PpK). Three of the investigations concluded no root cause was found. However, investigation APL-FU12-PNC-25-0106 concluded that the root cause for being outside the CpK acceptance criteria could have been attributable to lower assay values (e.g., [(b) (4)] % and [(b) (4)] %) included in the process capability evaluation. You failed to provide additional assessment in non-conformance APL-FU12-PNC-25-0106 to assess these batches and determine if there were any anomalies that could have led to the lower observed assay values.

Since 2022, there have been approximately 60 non-conformances initiated due to not meeting the acceptance criteria for CpK and PpK with either no root cause found or the root cause of the non-conformances being attributed to the variability in the results obtained during the assessment.

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OBSERVATION 4

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,

A. Process validations do not ensure critical parameters are challenged and validated ranges are not incorporated into batch records. For example:

a. The process validation summarized in FU12-PPQ-R-0230 for (b) (4) Suspension USP (b) (4) mg (b) (4) mL (b) (4) was conducted to optimize the (b) (4) time for (b) (4) number of (b) (4) used and quantity in each (b) (4) due to an OOS (b) (4) Unit (b) (4) INV/087/23) related to an elevated impurity during the 9 month stability interval, where the root cause was determined to be higher (b) (4) with longer (b) (4) times (b) (4) leading to an increase in (b) (4) impurities in the drug substance and subsequent reaction with (b) (4) in the excipients. The batch record allows (b) (4) but validation used (b) (4) and did not demonstrate impact of high/low (b) (4) settings during (b) (4)

b. Samples were obtained from the (b) (4) during the process validation summarized in FU12-PPQ-R-0230 from (b) (4) There was no testing of these samples, nor was there (b) (4) testing of (b) (4) in the (b) (4) to ensure (b) (4) According to the validation protocol, over (b) (4) of the drug substance may lead to dissolution problems, and the (b) (4) is considered a critical step.

c. The batch production record implemented based on the above process validation incorporated a total (b) (4) time of NLT (b) (4) and allows a (b) (4) of

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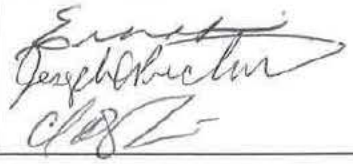
SEE REVERSE OF THIS PAGE		Eileen A. Liu, Investigator Joseph A. Piechocki, Investigator Claudia Perez-Kasmarski, Investigator	09/05/2025

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(b) (4) The batch record does not adequately incorporate the findings of the process validation, as the (b) (4) was only challenged at (b) (4)

B. The (b) (4) hold time studies conducted are not adequately designed to ensure (b) (4) For example, during the (b) (4) hold time study conducted for (b) (4) (b) (4) Tablets USP (b) (4) mg (b) (4) mg, the (b) (4) was off-loaded from the (b) (4) into (b) (4) bags. (b) (4) samples (b) (4) were selected from (b) (4) on (b) (4) of storage for (b) (4) There is no scientific justification for the sampling of (b) (4) bag for (b) (4)

C. The controls established for handling (b) (4) and drug products containing this drug substance, including (b) (4) tablets, do not ensure that there is no negative impact on the assay and impurities of the drug product. For example:

a) Drug product tablets containing (b) (4) are (b) (4) (b) (4) in (b) (4) rooms (b) (4) There has been no adequate study to determine the amount of time the (b) (4) tablets can remain exposed to (b) (4) (b) (4) without impacting the assay and impurities of the drug product.

b) The (b) (4) tablets containing (b) (4) drug substance are stored within (b) (4) (b) (4) bag. (b) (4) During the walkthrough on 02Sep2025, (b) (4) storage bags had unsealed corners and ripped seams despite documentation stating integral seals. (b) (4) areas are not fully sealed, and the (b) (4) procedure does not ensure consistent use or seal integrity.

c) The (b) (4) is used throughout the manufacturing unit operations, and the (b) (4) are stored within (b) (4) bag (b) (4) (b) (4) The (b) (4) bag is not (b) (4) when the (b) (4) are not in use, and during the walkthrough on 02Sep2025, the (b) (4) were being stored in an

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	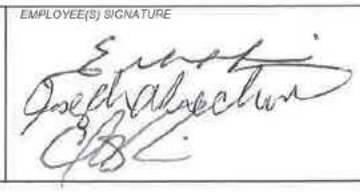	Eileen A. Liu, Investigator Joseph A. Piechocki, Investigator Claudia Perez-Kasmarski, Investigator	09/05/2025

area with (b) (4) No study has been provided which justifies the storage of the (b) (4) in this area under these storage conditions.

d) During the walkthrough on 25Aug2025 while observing the (b) (4) of (b) (4) (b) (4) USP tablets, at least (b) (4) drums of tablets that did not have container labels attached were observed. In addition, a (b) (4) container of tablets from the same lot was identified, which is used to (b) (4) (b) (4) This extra container did not have any (b) (4)

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

A. (b) (4) equipment parameter changes are not always recorded and there are no established procedures related to the appropriate checks required to be conducted when parameters are changed after set-up. For example, the following batch records were reviewed in which parameters were changed, and no procedures were provided which indicated the in-process checks required to be conducted:

a) During the manufacture of (b) (4) Tablets USP (b) (4) mg (b) (4) mg Batch (b) (4) after setup was completed, the (b) (4) (b) (4) were changed from the original approved set-up parameters according to the operating history obtained from the (b) (4) equipment. The batch record did not indicate these changes.

b) During the manufacture of (b) (4) Tablets USP (b) (4) mg Batch (b) (4) after setup was completed, the (b) (4) and individual lower and upper limits were changed from the original set-up parameters according to the Catch Report obtained from the (b) (4) equipment. The batch record did not indicate these changes.

c) During the manufacture of (b) (4) Tablets USP (b) (4) mg Batch (b) (4) after setup was completed, the (b) (4) was changed from the original set-up parameters according to the Batch Report obtained from the (b) (4) equipment. The batch record did not indicate these changes.

B. Batch record review procedures do not ensure that the process parameters established within the batch record are adequately verified. For example, during the review of the change report associated with the (b) (4) of (b) (4) Tablets USP (b) (4) mg Batches (b) (4) and (b) (4) the individual value limit upper percent (b) (4) and individual value limit lower percent (b) (4) which when the (b) (4) for (b) (4) is above or below these limits will reject that individual tablet, were not set at the approved set point of (b) (4) as established in the associated batch production record and summarized below.

(b) (4)

According to the operator and Quality Assurance personnel, the adjustments were made because the equipment was rejecting the tablets after setup. Both operations and quality assurance personnel stated that the tablets were verified to pass all in-process checks (including (b) (4) (b) (4) prior to running the batch, however the in-process checks

described above were not documented. Furthermore, in both batch production records, all operations and in-process Quality Assurance checks recorded this value throughout the batch production record as (b) (4) even though the change report shows that the parameter was not set at this value. In addition, a non-conformance was not opened to document the incorrect set point.

A review of additional batches manufactured during this campaign showed that at least (b) (4) additional batches did not have these settings correctly set during manufacturing, and these batch production records also recorded the (b) (4) checks as (b) (4)

OBSERVATION 6

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. The campaign length cleaning studies conducted for (b) (4) and (b) (4) equipment to establish the number of days or number of batches before a Type C cleaning needs to be performed are not scientifically justified or defined. For example:

   a. From (b) (4) for the (b) (4) PR/SD (b) (4) 08 (within (b) (4) which is used for the (b) (4) of (b) (4) used in the manufacture of (b) (4) Tablets USP, the number of batches executed between Type C cleaning ranged from (b) (4) batches. The campaign length study used to support the number of days/batches within a campaign challenged the (b) (4) however did not document the rationale for not including the (b) (4) (b) (4) within the room.

b. From [redacted] for [redacted] Equipment PR/SD [redacted] (within [redacted] which is used to manufacture [redacted] Tablets USP, the number of batches executed between Type C cleaning ranged from [redacted] batches. No data was provided to support the campaign length of the maximum number of batches.

B. Equipment used for the manufacture of drug products intended for the US market are not appropriately cleaned. During the walkthrough on 26Aug2025 of the [redacted] after a Type C cleaning, apparent [redacted] (later identified as [redacted] was found on the [redacted] In addition, standing [redacted] was observed within the [redacted] line for the same [redacted] identified during the inspection as incorrect [redacted] of the [redacted] line.

OBSERVATION 7

Buildings used in the manufacturing, processing, packing, and holding of a drug product are not maintained in a good state of repair.

Specifically,

A. On 27Aug2025, during the walkthrough inspection of the Packing Material Storage Area [redacted] Warehouse located [redacted] of the warehouse building were observed in a state of disrepair. I (CPK) observed leaky, corroded, and perforated ceilings and rainwater seeping through the shipping doors and ceiling tiles. As I (CPK) walked throughout the storage, I (CPK) observed puddles of water accumulated and a plastic bag collecting rainwater near entry doorways. In addition, rainwater from leaks was observed in the following areas:

a. [redacted] Packing Materials Storage
b. [redacted] Packing Materials Storage

c. [redacted] (b) (4) Finished Products Storage above [redacted] (b) (4)
d. Receiving Entrances [redacted] (b) (4)
e. Piping above [redacted] (b) (4)
f. Coming through a hole in ceiling above [redacted] (b) (4) Lot [redacted] (b) (4) labeled "Keep Dry".

There was noticeable corrosion in the [redacted] (b) (4) tiles lining that could potentially harbor moisture-loving bacteria, mold, and other pathogens that may contaminate packaging materials and finished drug products.

B. Records for [redacted] (b) (4) Sensors lack traceability in Building Management System (BMS) Reports. The [redacted] (b) (4) readings fail to adequately identify the independent [redacted] (b) (4) monitors by equipment ID numbers [redacted] (b) (4) [redacted] (b) (4)

C. On 01Sep2025, during the walkthrough inspection of [redacted] (b) (4) area and [redacted] (b) (4) of [redacted] (b) (4) Suspension, USP [redacted] (b) (4) mg, Batch [redacted] (b) (4) I observed the [redacted] (b) (4) in [redacted] (b) (4) monitor [redacted] not reading the [redacted] (b) (4)

OBSERVATION 8

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. During the review of the cleaning and sanitation of the [redacted] (b) (4) Systems, passivation report of storage tanks and loop distribution system performed on 08Dec2024 shows that the [redacted] (b) (4) was [redacted] (b) (4) and out of specification. According to SOP FU12-EN-CLN-008, the loop must be [redacted] (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International1483Response@fda.hhs.gov	08/25/2025-09/05/2025
	FEI NUMBER 3004446312

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

M. Venkateswar Rao, Senior Vice President - Quality

FIRM NAME	STREET ADDRESS
Aurobindo Pharma Ltd.	Unit XII, Survey No. 314
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bachupally, Hyderabad, 500090, India	Drug Manufacturer

(b) (4) he system until the (b) (4) reads within acceptance criteria (b) (4) and measure the same. However, on 09Dec2024, Quality Control Unit reviewed and approved the (b) (4) for use including a potential risk for chemical contamination.

B. I (CPK) reviewed the (b) (4) calibration results for multiset point micropipette Eppendorf #32, report QCMCMP32/12, dated 31Dec2024. I (CPK) observed that the calibration was performed using a scale that did not have the sensitivity (nearest thousandths) to measure 10 microliters (uL) ± 0.12 (nearest hundredths) accurately and precisely. Instead, the 10 uL pipette was measured as a 20uL pipette and averaged the results for the 10uL micropipette. The analyst performing the calibration wrote the balance was unstable, however, the Quality Control Unit approved the micropipette for analysis.

9/5/2025
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Eileen A. Liu, Investigator Joseph A. Piechocki, Investigator Claudia Perez-Kasmarski, Investigator	09/05/2025