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 (b) (4) fda.hhs.gov	10/06/2025-10/14/2025 FEI NUMBER 3004713402

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Roger Kuo, Chief Operating Officer

FIRM NAME	STREET ADDRESS
UBI Pharma Inc.	45 Guangfu N. Road, Hukou
CITY, STATE, ZIP CODE, COUNTRY Hsinchu, Taiwan 303036	TYPE ESTABLISHMENT INSPECTED Drug Product 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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, the visual inspection of your (b) (4) Injection (b) (4) mcg/mL (b) (4) mL and (b) (4) mL vials is carried out in (b) (4) The resulting vials then undergo Acceptance Quality Limit (AQL) testing before releasing. You carry out AQL testing via (b) (4) Review of the qualification report of your (b) (4) PQR/GT 2.3.118.03 Version 01 Effective date 11/10/2018 confirmed that the (b) (4) was not qualified for the defect categories for (b) (4) Injection (b) (4) mcg/mL (b) (4) mL and (b) (4) mL vials. The qualification is based on limited number of samples that include (b) (4) defect samples and (b)(4) random samples. Your Production Manager (b) (6) could not produce a list of these vials nor was able to produce any documents with respect to the type of defects that (b) (4) defect samples represented.

You also use (b) (4) defect samples to challenge your (b) (4) prior to (b) (4) VI. According to your Production Manager (b) (6) these (b) (4) defect vials are randomly selected from a pool of (b) (4) defect vials that have been collected from the reject vials during the

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manufacturing. Your Production Manager (b) (6) also stated that periodically the damaged defect vials (from pool of (b) (4) defect vials) are replaced from the defective vials from the manufacturing.

On my request, you compiled a list of your (b) (4) defect vials that represented (b) (4) critical defect (b) (4) vials for glass fragments), (b) (4) major defect (b) (4) vials for low volume), and (b) (4) minor defect (b) (4) vials for bad seal). According to your procedure, SOP No. P3190 Version 07, Operating, Cleaning, and Maintenance Procedure of (b) (4) Effective date 1/8/2024, and Batch Manufacturing Record for Batch No. (D)(4), the defect categories of (b) (4) Injection (b) (4) mcg/mL (b) (4) mL and (b) (4) mL vials include, (b) (4) critical defect (b) (4) major defect (b) (4) and (b) (4) minor defect (b) (4)

You have used your (b) (4) to release > (b) (4) vials of (b) (4) Injection (b) (4) mcg/mL (b) (4) mL and (b) (4) mL vials to the US marker that are still within the expiry date.

OBSERVATION 2

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in process material and the drug product.

Specifically, your procedures SOP No. P3190 Version 07, Operating, Cleaning, and Maintenance Procedure of (b) (4) Effective date 1/8/2024), SOP No. P3109 Version 15 Sterile (b) (4) Liquid Vial Inspection Procedure (Effective date 12/9/2024), and SOP No. P801 Version 5 Sampling Plan and AQL Calculation (Effective date 3/10/2025) fail to ensure your sterile (b) (4) products are essentially free of visible particulates such that;

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A. E.g., for the (b) (4) mL vials, Section (b) (4) of your procedure SOP No. P3190 Version 07 has provision for 100% (b) (4) VI of the batch for a passing specification of (b) (4) (b) (4) This potentially leave at least (b) (4) % of critical defective vials undetected. In the (b) (4) step, you carry out AQL where you inspect (b) (4) vials via (b) (4) VI on (b) (4) (b) (4) Your SOP No. P801 Version 5 for AQL does not specify how to collect these (b) (4) vials, nor you record the locations (b) (4) of the selected vials for AQL. The procedure also does not specify type of inspection (b) (4) for AQL vials.

B. Your procedure SOP No. P3109 Version 15 Sterile (b) (4) Liquid Vial Inspection Procedure (Effective date 12/9/2024) does not ensure that defect vials are created in such a way as to demonstrate qualification of the 100% visual inspection program for (b) (4) You have (b) (4) test kits: (b) (4) (b) (4) Each test kit is comprised of (b) (4) vials including (b) (4) defect vials (Section 5.2.6 SOP No. SOP No. P3109 Version 15). Each vial (including defect vials) is numbered/coded that corresponds to various defects which could allow identification of the defective vials. The procedure did not provide expiration dates or reevaluation frequency of the test kits.

C. Your test kit consists of far exceeding number of defects, (b) (4) %) in a sample of (b) (4) vials. The Inspection of (b) (4) Products for Visible Patriciates Guidance for Industry requires no more than (b) (4) % of defective units in a test kit. Your procedure also does not have representative pictures for the defects. Your Production Manager (b) (6) confirmed that the firm did not have standards for the defects and stated that the samples of the defect kits are periodically replaced from the corresponding reject types from the manufacturing.

D. You qualify your visual inspectors based on a single inspection report contrary to the Section 5.3.2 of SOP No. P3109 Version 15 that requires inspectors to carry out (b) (4) inspections. On

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10/8/2025 upon a reassessment, your operator (b) (6) failed to correctly identify critical defects and needed training and requalification. It was also noted that the operator did not set up the (b) (4) correctly and measured the light intensity by placing the (b) (4) and not (b) (4) as described in Section 5.4.6 of SOP No. P3109 Version 15. This confirmed that the operator carried out the (b) (4) VI in light intensity < (b) (4) lux (Specification (b) (4) lux). The (b) (4) light intensity set up was also verified by Production Manager (b) (6)

You recorded at least 15 complaints for (b) (4) Injection (b) (4) mcg/mL (b) (4) mL vial for low fill, empty vial, and crack/leak (**Table 1**). You investigated only three (3) of these complaints: (b) (4) (Batch No. (b) (4) Expiry date (b) (4) (Batch No. (b) (4) Mfg. date 11/1/2023 Expiry date (b) (4) (Batch No. (b) (4) Mfg. date 12/3/2023 Expiry date (b) (4) You invalidated all these complaints without determining roots causes.

OBSERVATION 3

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

Specifically, Protocol PQ/GT2.3.224 Version 01 Performance Qualification Protocol of Laminar Flow Hood for (b) (4) Machine (b) (4) ID # (b) (4) Effective date 4/18/2023 and the Version 02 (Effective date 4/12/2024) provide procedure for performing and evaluating the air flow of (b) (4) Line (b) (4) in Room (b) (4) through smoke studies. For example, video recorded of the air flow studies performed (b) (4) and (b) (4) were deficient in the following ways.

A. In multiple (b) (4) intervention simulation studies, the purpose of the smoke study was not clearly defined. E. g. (b) (4) intervention simulation for the (b) (4) Section (Document No. PQ/GT2.3.224 Version 01, Section 4.7.4 pages 20 and 21), the videos were evaluated for "***The Air does not flow from operator to the filling area***" and "The air outside the LFH does not return to the LFH***". Your Production Division Director (b) (6) acknowledged that the

observations were not relevant and were incorrectly populated from the earlier (b) (4) interventions.

B. In one of the (b) (4) intervention, Place and take Out Settle Plate (Document No. PQ/GT2.3.224 Version 01, Section 4.7.4 pages 20 and 21), operator was seen to stretch out the hand over the almost entire length of the (b) (4) blocking the air over the vials. In another similar intervention, Adjust parts' angel/position (PQ/GT2.3.224 Version 02, (b) (4) Section), operator was seen hastily moving hands over the open vials and pushing the vials into the (b) (4) line back onto the (b) (4) Your SOP No. P366 Version 14 Intervention Procedure for Grade A and Grade A Air Supply Area During the Aseptic Filling Process and Operation Procedures for Grade B Area (Effective date 1/15/2025) do not discuss the disposition of the vials with interrupted/blocked laminar air flow.

C. Section 5.1.1.1.1 of your SOP No. P366 Version 14 requires that "before any aseptic operation, both hands to the operator from fingertip to elbows should be disinfected (b) (4) times by using disinfectant spray (b) (4)". At least in one of the (b) (4) interventions, Clean the (b) (4) or Parts (PQ/GT/2.3.224 Version 02 Filling Section 1), operator was observed spraying only the palms of both hands and then contacting the interior of the (b) (4) RABS) and cleaning the (b) (4)

D. Section 5.1.2.3.2 of your SOP No. P366 Version 14 requires that "the hand should not pass over the stoppered containers". However, at least in one of the (b) (4) interventions, Place and take out (b) (4) (PQ/GT/2.3.224 Version 02 Filling Section 2), operator was seen hovering his hands over the stoppered vials.

A similar behavior was seen on 10/8/2025 during the manufacturing of (b) (4) injection (b) (4) mcg/mL (b) (4) mL in (b) (4) mL vial Batch No. (b) (4) on Line (b) (4) During intervention # (b) (4) "Remove or straighten stuck vials, breakage", the operator was seen moving hands over the

stoppered vials. The operator removed broken/stuck vials leaving behind multiple vials that were compromised because of obstruction of first air (laminar air flow LAF) over the stoppered vials from the hand movements. The operator was also seen moving hands hastily inside the LFH potentially causing turbulence.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and /or fully followed.

Specifically,

A. You manufacture (b) (4) injection (b) (4) mcg/mL for the US market under a contract for your US customer (b) (4) You do not have a Quality Agreement with your US customer (b) (4) The initial QA was signed on 5/20/2019 and was effective for five years until 5/19/2024. You did not review/renew the QA with your customer, (b) (4)

B. Your initial QA did not have a provision for timely submission of Field Alert Reports. Section 25.3 of Complaint Handling requires Acknowledgment of receipt of the complaint and notification within (b) (4) Section 26.1 Adverse Event requires investigation should happen within (b) (4) after the notification (b) (4) Section 4.1 of your procedure, SOP No. P091 Version No. 04 The Procedure for Field Alert Report (US) requires submission of FAR within 3 business days of problem being identified.

C. Section 4.2 of SOP No. P091 Version No. 04 requires submission of FAR for drug product that fails to meet the specification established for it in the application. Since June 2023, (b) (4) injection (b) (4) mcg/mL (b) (4) mL in (b) (4) mL vial recorded at least 15 complaints for underfill vials, empty vials, and at least one complaint for crack/leak (**Table 1**). Your customer, (b) (4) decided not to investigate and file FAR. According to your (expired) QA, you are

responsible for complaint investigation. You did not investigate at least 12 complaints and FAR was not submitted based on the market complaints that suggested that the drug product failed to meet the specification established for it in the application.

Table 1. List of market complaints for June 2023 - September 2025

Entry	Complaint No. (b) (4) (b) (4)	UBI	Batch No.	Defect	Notes
1		complaints received from (b) (4) but not investigated by UBI	(b) (4)	Empty vial	
2				Empty vial	
3				Underfill	
4				Crack/Leak	
5				Underfill	
6				Underfill	
7				Underfill	MedWatch
8				Underfill	
9			Not available	Underfill	
10		(b) (4)	(b) (4)	Underfill	MedWatch
11				Empty vial	
12				Underfill	
13		complaints received from (b) (4) but not investigated by UBI		Underfill	
14				Underfill	
15			Not available	Underfill	

D. You did not follow your procedure SOP No. P034 Version No. 09 Change Control (Effective date 4/30/2025 and did not create a change control when you replaced (b) (4) of the capping machine ID # 74.51.00 on Filling Line (b) (4) The (b) (4) was changed under CAPA 25020 to address Deviation # DR250402 (recorded on 4/4/2025) for (b) (4) injection (b) (4)

mcg/mL (b) (4) mL in (b) (4) mL vial Batch No. (b) (4) that exceeded the design operation time of media fill of vial filling line (b) (4) vs (b) (4) The aging (b) (4) caused cracked on the (b) (4) caps. However, the CAPA was not effective since a similar deviation DR250504 was recorded on 5/15/2025 for Batch No. (b) (4) You amended the initial CAPA 25020 and dedicated the (b) (4) for Product # (b) (4) injection (b) (4) mcg/mL (b) (4) mL in (b) (4) mL vial on Line (b) (4) to prevent excessive adjustment during the capping. You did not carry out any product quality impact as a result of installing new (b) (4)

OBSERVATION 5

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, you manufacture (b) (4) injection (b) (4) mcg/mL (b) (4) mL in (b) (4) mL vial as (b) (4) (b) (4) drug product. You received at least 15 market complaints for partially filled vials, empty vials, and crack/leak vial (**Table 1**). You investigated only 3 (three) of these market complaints; (b) (4) (Batch No. (b) (4) Expiry date (b) (4) (Batch No. (b) (4) Mfg. date 11/1/2023 Expiry date (b) (4) (Batch No. (b) (4) Mfg. date 12/3/2023 Expiry date (b) (4) Section 5.1.2 of SOP No. P818 Version 08 Handling of Product Complaints (Effective date 12/13/2024) requires, "QA supervisor should acquire the complaint sample(s) from the customer to facilitate the investigation". You do not have any documentary evidence for acquiring the complaint samples. You conducted the investigation without the complaint sample and based on the manufacturing records, invalidated the complaints.

Section 5.2.1.1 of SOP No. P818 Version 08 requires checking the complaint sample for counterfeit. It is not clear, how you determined that the complaint samples were not counterfeit without acquiring the complaint samples or pictures of the complaint samples.

Review of the (b) (4) visual inspection reports for the three implicated batches confirmed presence of

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underfill vials: (b) (4) Batch No. (b) (4) vials, (b) (4) Batch No. (b) (4) vials, (b) (4) Batch No. (b) (4) vials. Your batch record suggested that you sample (b) (4) (b) (4) at filling rate of (b) (4) This is equivalent to (b) (4) at the filling stage.

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