DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	DATE(S) OF INSPECTION 04/13/2026-04/24/2026 FEI NUMBER 3003999190
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Linda Lin, Vice President Quality and Regulatory Affairs	
FIRM NAME Zhejiang Huahai Pharmaceutical Co., Ltd.	STREET ADDRESS Xunqiao Town, Linhai
CITY, STATE, ZIP CODE, COUNTRY Zhejiang 317024, China	TYPE ESTABLISHMENT INSPECTED 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

Written records are not made of investigations into unexplained discrepancies the failure of a batch or any of its components to meet specifications.

Specifically, no risk analysis exists to determine the root cause of the potential genotoxic and suspected human carcinogenic (b) (4) have been found in your (b)(4) (b)(4) tablets. For example:

A. Your firm sources it's API (b) (4) from (b) (4) manufacturers which are solely determined by the customer. This API is received at the firm with a Certificate of Analysis (COA) from the API manufacturer. In reviewing a total of (b) COA for (b) (4) (b) (4), we observed that testing for (b) (4) are not done by the API manufacturer (b) (4) nor is any (b) (4) analysis conducted by your firm. Since 2024 the firm has accepted (b) (4) batches (b) (4) of (b)(4) (b)(4) to manufacture (b) (4) batches of (b) (4) bulk tablets of which (b) (4) bulk batches (b) (4) tablets) were shipped to the United States. Additionally, while reviewing the firm's documents, it was revealed that the firm requires (b) (4) impurity testing of (b) APIs (b) (4) while (b) (4) APIs (b) (4) (b) (4)

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(b) (4) (b) (4) manufacturers are not required to test for (b) (4) impurities.

B. No final release analyses are done for (b) (4) such as (b) (4) (b) (4) etc. prior to shipment of all batches. The firm manufactures (b) (4) products that are shipped to the United States from Workshop (b) (4) on shared equipment with (b) (4) mg tablets these equipments have direct contact with materials. Examples of such equipment are: (b) (4) (b) (4) (b) (4) The firm manufactured (b) (4) batches and a total of (b) (4) tablets from January 2024 to March 2026 for the United States market from shared equipment in Workshop (b) (4)

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, followed, or including adequate validation of the sterilization process. Specifically,

A. During the inspection, I (EL) watched videos of airflow visualization studies (smoke studies) performed in Formulation Workshop (b) (4) vial filling line in 01/2025. Workshop (b) (4) manufactures (b) (4) for the U.S. market. The lack of adequate smoke coverage, turbulent airflow, or poor aseptic practice were observed. Examples included but were not limited to:

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1. You failed to provide an accurate airflow pattern presentation of your classified cleanroom under both static and dynamic conditions. Specifically, you did not establish study criteria for the smoke generator position or smoke velocity that allow for a comprehensive and meaningful study. Throughout the studies, the smoke generator was placed too far down from the HEPA airflow membrane. Additionally, the smoke velocity appeared high and did not match the HEPA velocity being studied. As a result, the smoke appeared being forced into the air stream leading the airflow instead of being carried by the actual HEPA airflow.

2. Video of static test #4-1 shows clockwise swirl of turbulent airflow on the left side of the smoke stream at the stopper station where a bag of sterile stoppers was staged and waiting to be dispensed.

3. Video of corrective intervention #3 shows multiple updrafts of airflow when the smoke hits the (b) (4) surface on the right side of the smoke stream during rejection of inverted bottles on the (b) (4) You failed to demonstrate that laminar airflow moves down and out to sweep particles away from critical aseptic surfaces.

4. Video of corrective intervention #4 and #5 show that throughout the video, the smoke moves down and inward toward the direction of (b) (4) You failed to demonstrate that clean, laminar airflow moves down and out to sweep particles away from critical aseptic surfaces.

5. Video of corrective intervention #18 shows (b) (4) intervention being conducted in the (b) (4) station. When the (b) (4) RABS (b) (4) all the smoke left the Grade A critical zone and was blown out to the Grade B room leaving the filling station without HEPA

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coverage. You failed to demonstrate that the Grade A critical zone continues to receive HEPA first air coverage during (b) (4) intervention.

6. Video of corrective intervention #13-2 shows the stopper monitoring probe being taken out from the Grade A critical zone and moved to the Grade B room for adjustment during (b) (4) (b) (4) intervention. The probe was later returned to the Grade A area without first been sanitized.

7. During all (b) (4) interventions, the sterile (b) (4) bottle was moved from the Grade A to the Grade B area to sanitize the (b) (4) surfaces of the (b) (4) RABS (b) (4) before (b) (4) of the (b) (4) The sterile (b) (4) bottle was returned to Grade A zone without first been sanitized.

B. On 04/18/2026, I (EL) observed the aseptic filling of (b) (4) Injection, Batch No.: (b) (4) (U.S. batch) in Formulation Workshop (b) (4) The following deficient aseptic practice was observed.

1. During the dispensing of sterile stoppers, I observed an operator positioning a stopper bag directly over the (b) (4) blocking HEPA first air to the (b) (4) and sterile stoppers. The same deficient practice was also observed in MF and smoke study videos.

2. I observed an operator crossing the (b) (4) conveyor to get to the other side of the fill line. After (b) (4) and moving the conveyor to the Grade B area, the operator failed to sanitize the exposed Grade A side of the (b) (4) and the conveyor before (b) (4) I also observed the same operator moved a bottle of sterile (b) (4) from Grade A to Grade B to clean the exposed Grade A surfaces of a (b) (4) on the

opposite side of the conveyor. She later returned the (b) (4) bottle to Grade A area without first sanitizing it.

C. There is a failure to perform adequate (b) (4) integrity testing that can pose critical risk to aseptic manufacturing of drugs purporting to be sterile. Specifically,

You lacked justification for performing Workshops (b) (4) (U.S. fill lines) (b) (4) integrity testing only (b) (4) regardless of multiple batches are being manufactured during that time. Between batches, (b) (4) are visually inspected for damages during cleaning per SOP-F-SP-130.07, section (b) (4) However, you lack written procedures on how to perform visual inspection. Also, you lack documented training to show the operators can adequately identify failures, i.e., (b) (4) (b) (4)

D. During inspection of the (b) (4) mL vial reject kit used to qualify operators performing 100% (b) (4) visual inspection of (b) (4) Injection, it was noted that approximately (b) (4) of (b) (4) defect vials had product on the stopper. The material observed were (b) (4) particles (b) (4) The presence of consistent observation of product on the (b) (4) indicated that during (b) (4) particles of drug product were migrating (b) (4) of the vial and potentially onto the (b) (4) (or (b) (4) potentially). Presence of particles (b) (4) the stopper is a critical defect as it may impact the container closure integrity. Due to the presence of the (b) (4) however, particle intrusion to the (b) (4) cannot be visually assessed without breaking sterility and exposing the (b) (4) to the environment. There is no assurance that container closure of any (b) (4) mL vials used in (b) (4) of (b) (4)

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Injection, are free from stopper contamination that would compromise the container closure integrity. Additionally, product on the stopper, is not a criterion in the 100% (b) (4) visual inspection (b) (4) At minimum, (b) (4) product on the stoppers should be included in the rejects, even as a cosmetic defect, with an appropriate reject limit, as even as a seemingly cosmetic defect, it may impact critical quality attributes of the finished drug product, most distinctly assay due to product loss.

Due to the inability to visually ensure that no migrating particles in the (b) (4) area resulted in a critical defect impacting the container closure integrity, a field alert for (b) (4) Injection was filed on 4/23/2026.

E. Visual inspection defect kits do not contain any examples of turbid solutions of any color, in any sterile solution container closure system (b) (4) Visual inspectors of your firm's (b) (4) injections are not challenged during qualification to ensure that they can readily and consistently identify turbid solutions. Additionally, turbidity is not detected by your (b) (4) visual inspection system or listed as a defect category in the visual inspector qualification.

F. The visual inspection kits for (b) (4) drug products do not include defects or detailed pictures and descriptions of (b) (4) defects (b) (4) are not included as examples in the defect kit or described detail in the written procedure/defect library.

OBSERVATION 3

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

There is a failure to adequately clean (b) (4) RABS Grade A equipment surfaces. For example,

A. SOP-F-SP-105.12, section (b) (4) allows for a single clean cloth (b) (4) to wipe up to (b) (4) (b) (4) of the Grade A equipment surfaces. Therefore, the clean side of each cloth can wipe multiple surface areas until it is obviously dirty. You failed to follow the single-stroke per clean-side technique to prevent carryover of contamination from one area to a different area of the Grade A surface.

B. During the inspection, I (EL) observed Grade A cleaning after batch production. I noted defined cleaning techniques were not followed. Specifically,

1. On 04/14/2026, I observed Formulation Workship (b) (4) Grade A cleaning after the production (b) (4) Injection, Batch No. (b) (4) (non-U.S.). I observed an operation failed to perform overlapping strokes while cleaning the Grade A side of (b) (4) RABS (b) (4) SOP-F-SP-105.12, section (b) (4) states wiping strokes shall overlap by (b) (4) %. Additionally, while cleaning (b) (4) the operator did not clean (b) (4) or perform visual inspection for damages as required per SOP-F-SP-130.07, section (b) (4)

2. On 04/15/2026, I observed Formulation Workshop (b) (4) Grade A cleaning after the production of (b) (4) Injection, Batch No. (b) (4) (non-U.S.). I observed one operator wiping the (b) (4) surface (approximately (b) (4) in circular motion contradicting requirement per SOP-F-SP-126.02, section (b) (4) where it states to clean the equipment surface (b) (4) (b) (4)

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Additionally, I observed a second operator cleaning (b) (4) However, he did not (b) (4) to ensure thorough coverage as required per SOP-F-SP-130.07, section (b) (4)

C. You lacked adequate justification for washing and sterilizing (b) (4) (b) (4) is used to sanitize (b) (4) pre and post batch production. (b) (4) is used (b) (4) However, at the end of each batch production not all used (b) (4) are monitored; only (b) (4) out of a total (b) (4) in Workshop (b) (4) and (b) (4) out of (b) (4) (b) (4) in Workshop (b) (4) are sampled and tested for microbial contamination. Further, (b) (4) (b) (4) is monitored, and (b) (4) are sampled. You do not sample and test (b) (4) to assure maximum coverage of monitoring.

OBSERVATION 4

Laboratory records do not include complete data derived from all tests, examinations, and assay necessary to assure compliance with established specifications and standards.

A. There is a lack of laboratory data integrity. Bacterial colony growth in media growth promotion test (GPT) is inaccurately recorded to show acceptance result. Specifically,

On 04/20/2026, I conducted a walkthrough inspection of the QC Microbiology Laboratory located in Building (b) (4) I reviewed GPT result for (b) (4) Lot No. (b) (4) (Exp. (b) (4) after (b) (4) incubation (acceptance: colony growth ≤ (b) (4) The (b) (4) is an indicator media used to detect the presence of objectionable microorganism (b) (4) (b) (4) in (b) (4) API, excipients, and FP for the U.S. market. I inspected Lot No. (b) (4) for evidence of microbial growth. I did not see any cfu on tested (b) (4) plates. My finding of no

growth was confirmed by QC Microbiology Supervisor and Deputy Manager of QC Microbiology. However, the laboratory worksheet recorded "B" indicating cfu growth was observed and "Y" indicating the colony morphology is consistent.

B. The Microbial Limit Test (MLT) is used to release all U.S. (b) (4) Your firm's MLT results are not always reliable. (b) (4) drug product particles and actual microbial growth (if present) cannot be adequately differentiated. Specifically,

On 04/13/2026, I conducted a walkthrough inspection of the QC Microbiology Laboratory. I inspected the MLT Total Yeast and Mold Count (TYMC) for (b) (4) batches of (b) (4) (b) (4) Tablets (non-U.S. product). All results were < (b) (4) cfu/g indicating no microbial or (b) (4) cfu recovery. However, I noted widespread (b) (4) dots encased inside the (b) (4) (b) (4) media that cannot be ruled out as real microbial cfu recovery during testing. SOP-F-QC-366.04, "Formulation Microbiological Laboratory Guidance for Enumeration of Colony Forming Units" lacks procedure for identifying and enumerating cfu when growth is encased inside the (b) (4) media. You also lack documented training to ensure your laboratory personnel can adequately recognize and enumerate microbial growth in the above scenario.

OBSERVATION 5

Laboratory Controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

A. Your firm does not have a test method to conduct testing for (b) (4) Therefor the firm is unable to test for (b) (4)

impurities. Upon further review of the firm's other products test methods, it was observed that the firm does not have test methods for detecting (b) (4) impurities after cleaning equipment for (b) (4) out of (b) (4) products.

B. On 04/17/2026, while observing preparation for (b) (4) microbiological enumeration samples via (b) (4), a microbiologist was observed using a (b) (4) (b) (4) inside the ISO 5, grade A laminar airflow workbench to sanitize the (b) (4) of a (b) (4) manifold, (b) (4) (b) (4) Use of (b) (4) can result in turbulence in laminar airflow of the Grade A workbench, damage to the HPEA filter, and has the potential to contaminate the clean area with (b) (4) (b) (4) No assessment has been carried out to evaluate the impact of the (b) (4) transfer and potential (b) (4) degradation on microbiological analyses, to date. Personnel from your microbiology department did not demonstrate a robust understanding of the (b) (4) (b) (4) process, as they stated that using a (b) (4) to sterilize the (b) (4) holder was necessary to prevent sample contamination. Even when it was explained that a (b) (4) would retain microbiological contaminants on the (b) (4) surface. The (b) (4) manifold (b) (4) (b) (4) "sanitization" is utilized for (b) (4) (b) (4) microbial analysis, and other product specific analyses.

OBSERVATION 6

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Control procedures are not established which 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,

A. The operational parameters of the bottle filling, capping, and labeling operations controlled by the (b) (4) bottling filling and labeling machines, are not recorded during execution of the filling and labeling process. There is no mechanism by which to verify that equipment was operated within the qualified filling and labeling parameters, to ensure adequate filling counts and proper placement, adhesion and legibility of product labels to the exterior of bottles of finished drug products, of any size or configuration (bottle volume, product strength, number of tablets/capsules per bottle).

B. During bottle filling, your firm's packaging batch records indicate that bottles are filled, weighed and counted during set-up of the filling line, to establish upper and lower limits for the bottle filling operation and ensure count accuracy. However, during the inspection it was observed that your firm does not perform or document the count verification during set-up, or at any other time during the bottle filling operation. As such, there is no assurance that bottles of finished drug products (tablets, capsules), contain the labelled quantity of units.

C. According to your firm's packaging personnel, during bottle filling operations (b) (4) rejected filled bottles are collected, the contents are emptied, inspected and, if found conforming, are reintroduced to the (b) (4) of the (b) (4) bottle filling line. On 04/14/2026, a (b) (4) bag containing (b) (4) tablets from Batch No. (b) (4) was observed on the table in Room (b) (4) bottle filling Line (b) (4) When asked as to the identity of the tablets, your firm's packaging personnel indicated that the tablets were rejected in-process and pending visual inspection and re-introduction to the (b) (4) No corresponding entries for tablet inspection were noted during review of the packaging batch record. Your firm's packaging personnel later

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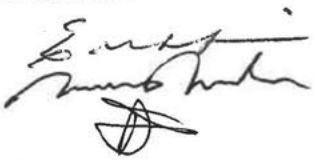
SEE REVERSE OF THIS PAGE		**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

confirmed that the inspection is not documented in the batch record nor anywhere else. During discussion your firm's management team acknowledged that due to the gross container weight upper and lower bottling filling limits, bottles with miscounts may be accepted as adequately filled bottles, due to the margin of error calculation built into the upper and lower weight limit configuration during set up.

Despite receipt of numerous complaints regarding low tablet/capsule counts, foreign, broken, cracked, chipped, disintegrating, off-color, and dusty tablets, your firm's complaint investigations routinely failed to identify the numerous deficiencies in the bottle filling and labeling process as potential root causes. The (b) (4) bottle filling lines have been in use since August 2018.

D. The tablet punch and die inspection process is deficient. The procedural step for punch and die inspection is provided in SMP-F-EN-009.06, "Mould Management Procedure", Step (b) (4), and states "after production the molds shall be dissembled in a timely manner, cleaned in accordance with the equipment cleaning procedure, and inspected for intact appearance. If any defects are found, the workshop supervisor shall be reported to promptly". The procedure does not offer detailed instructions for punch and die inspection and does not include assessment of critical parameters such as the (b) (4) or provide any mechanism to detect non-visible (b) (4) damage. As (b) (4) is not tracked initially or periodically, (b) (4) (b) (4) to minimize non-process parameter-controlled intra-batch variation in (b) (4) (b) (4), is not possible. The procedure also does not require periodic monitoring of critical wear points of dies, specifically, measuring the inner die diameter and the surface area of the die bore. The procedure also does not require inspection of the inner die compression zone, for wear rings (bore sighting), which would necessitate removing the dies from use.

E. During process validation, sampling plans have not been established that would allow for evaluation of variation that could be caused by different parameters used to operate equipment or evaluate variability within a batch. For example:

Different main compression force was assessed for (b) (4) Tablets to establish acceptable ranges for commercial batches. Main compression force has an acceptable range of (b) (4) (b) (4) however during your Process Performance Qualification, only compression forces of (b) (4) (b) (4) were evaluated for adequacy and reproducibility.

This is a repeat observation from your firm's 2025 FDA Inspection.

F. Your firm's (b) (4) process does not operate in a state of control; (b) (4) operations were observed to routinely generate (b) (4) (b) (4) (b) (4) Due to the uncontrolled nature of the (b) (4) operation, it is unknown whether the cleaning procedures currently in use can adequately clean equipment that collects more (b) (4) from the (b) (4) than (b) (4) operations. Your firm does not adequately control (b) (4), do not routinely assess (b) (4) to minimize (b) (4) It is unclear if your firm assesses (b) (4) as a parameter prior to the beginning of each (b) (4) operation, to ensure consistent and reproducible (b) (4) operations.

OBSERVATION 7

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In-process specifications for sampling and testing of in-process materials and drug products were not derived from previous acceptable process average and process variability estimates and were not determined by the application of suitable statistical procedures.

No scientific rationale or justification was provided regarding the limited in-process (b) (4) sampling and testing frequency. Regardless of batch size, (b) (4) samples are only collected (b) (4) times; (b) (4) (b) (4) batch sizes range from (b) (4) to (b) (4) tablets. Only (b) (4) of tablets (on average ~ (b)(4) tablets) are sampled at each time point. When asked, your firm's management team stated that (b) (4) would not change significantly during the (b) (4) operation, and that additional (b) (4) testing was unnecessary as the (b) (4) was monitored (b) (4) Although broadly, (b) (4) correlates to (b) (4) (b) (4), directly impact tablet (b) (4). The limited (b) (4) sampling severely limits the ability to identify and correct sources of intrabatch (b) (4) variation. More directly, tablet (b) (4) is a measure (b) (4), while (b) (4) is an assessment of (b) (4) which despite the inverse relationship, are both critical quality attributes requiring routine monitoring and evaluation.

OBSERVATION 8

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

A. Risk assessments RARF-20190222 and RARF-20180718-1, both dated September 26, 2020 are conducted to determine the root cause of the potential genotoxic and suspected human

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	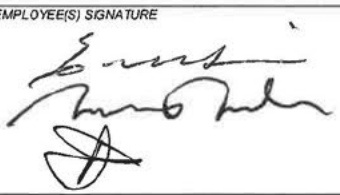	**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

carcinogenic impurities as (b) (4) (b) (4)

1. These investigations failed to extend the investigations into other (b) (4) such as (b) (4) which have been found in your (b) (4) (b) (4) mg tablets.

2. Both the risk assessment only assessed the risk for (b) (4) products and do not assess the risk for all your products that are manufactured in shared equipment such as (b) (4) (b) (4)

3. While conducting the risk assessments, the cleaning of equipment was re-evaluated. After completing the risk assessments another cleaning validation was done under CVF-18136 (R), dated January 8, 2019. That cleaning validation only assessed the cleaning of equipment for the (b) (4) product and did not extend to the other (b) (4) manufactured products in Workshop (b) (4)

B. During our review of your firm's Cleaning Validation, CVF-13051 (R), with approval date June 1, 2015, no Dirty Hold Time (DHT) study is conducted for the (b) (4) used during the manufacturing of batches in Workshop (b) (4)

C. On 04/15/2026, during a walkthrough of the (b) (4) Workshop (b) (4) distribution system, (b) (4) tanks were observed with active leaks from the (b) (4) (b) (4) Upon inspection, leaks were identified coming from the (b) (4) fittings attached to (b) (4) tubing, used to (b) (4) (b) (4) According to the firm's utility management personnel, only (b) (4)

(b) (4) storage tanks were designed to (b) (4). Only the (b) (4) storage tanks with the (b) (4) were observed to have active leaks. The leaks provide a route of ingress for microbiological contamination into to the (b) (4) storage and distribution system.

OBSERVATION 9

Written records of investigation of a drug complaint do not include the follow-up. Specifically,

Since January 2023, your firm has received 939 complaints. Of the 939, only 8 (~0.852%) were deemed to be "serious" complaints, with the rest deemed "not serious". Per SMP-011.19, "Customer Complaint Management Procedure", serious complaints are any "complaint that may possibly result in a product recall, detention, field correction or product notice to Health Authorities because the product defect potentially represents a high patient safety risk, with regard to the following topics: Questions for the sterility of injection products, Reports a product mix-up, cross contamination, mislabeling and misbranding". Per the written procedure, all other complaints are "not serious", which do not specifically require risk assessment, investigation or follow up. During review, "not serious" complaints included foreign tablets found in sealed containers, chipped tablets, broken tablets, empty blisters, crushed tablets, numerous adverse events, dark spots on tablets, wrong color tablets, discolored tablets, (b) (4) compressed into tablets, missing package inserts, rough surface condition of tablets, failed AQL sampling upon receipt of bulk (customers), torn and taped outer shopping bags (customer), metal contamination, OOS assay results, excessive tablet odor, soft tablets, damp tablets, lack of effect, empty product boxes, and incorrect/damaged (b) (4) When investigations are carried out, they lack reasonably expected investigational practices, data and conclusions. For example,

- Complaint CF-23260 (not serious) was initiated for visible metal contamination in batches. Your firm conducted a visual inspection of retain tablets. When asked why a visual inspection would be sufficient to detect metal contamination in compressed tablets, instead of performing (b) (4) (b) (4), your firm's management provided no response. Nonetheless, the complaint was found to be "non-serious" as the visual inspection for metal contamination revealed no defects.

- Complaint CF-23166 (not serious), tablets failing the appearance check, for damage to the (b) (4) were reported by the application holder. The OOS investigation noted that during (b) (4) tablets with "slight damage due to sticking or cracking during (b) (4)" were observed. The investigation appeared to only assess (b) (4) damage due to tablet collision during compression. The investigation concluded that 'considering the damaged area of this complaint tablet is very small, only the (b) (4) is damaged, risk on product quality is under control". No inspection of the (b) (4) was performed to assess potential impact to the generation of the defect, despite the direct correlation between (b) (4) condition and (b) (4) (b) (4).

- Complaint CF-23319 (not serious) was opened for a OOS assay result of (b) (4) %, against the specification of the specification (b) (4) %, reported by the application holder. No documented root cause was determined by your firm or the application holder. However, the OOS was invalidated, finished bulk tablets were subsequently packaged and released for distribution.

- Complaint CF-25076 (not serious), was initiated due to an average OOS stability result (b) (4) % (b) (4) % observed in individual tablets) against the specification of NLT (b) (4) %. The root cause was determined to be usage of (b) (4) sourced from a new supplier, with a higher

(b) (4) The (b) (4) was noted to be (b) (4) %, within the firm's specification for (b) (4), of (b) (4) %. Confusingly, the investigation recommended "that the customer conduct further investigation into the packaging process", despite the assessment of the (b) (4) as the root cause. The stability failure occurred at the 24-month time point, with the expiry period established as (b) (4) Comparative data for the 24-month stability time point resulted in reported results of (b) (4) % (b) (4) % mean). Despite the data confirming the OOS, the OOS, no post investigation actions were taken with respect to the OOS batch distributed.

OBSERVATION 10

Backup data is not assured as exact, complete and secure from alteration, erasure or loss through keeping hard copy or alternate systems. Specifically,

Non-sterile drug manufacturing, packaging and labeling operations are controlled by standalone Programmable Logic Controllers (PLC) accessed via multiple Human Machine Interfaces (HMI). These manufacturing, packaging and labelling processes include (b) (4) (b) (4) (b) (4) which are all controlled by (b) (4) equipment however, none of the systems save data, can export data, and in many cases, critical process parameter data (b) (4) etc.) cannot be saved and are not (b) (4) documented elsewhere.

This is a repeat observation from your firm's 2025 FDA Inspection.

OBSERVATION 11

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		**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	04/13/2026-04/24/2026 FEI NUMBER 3003999190

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Linda Lin, Vice President Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Zhejiang Huahai Pharmaceutical Co., Ltd.	Xunqiao Town, Linhai
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Zhejiang 317024, China	Drug Manufacturer

Equipment for adequate control over air pressure, microorganisms, dust, humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product. Specifically,

A. Your firm's Grade D production rooms (nonsterile production blocks (b) (4) are not adequately qualified. During review of qualification data, it was noted that dynamic non-viable particle counts, (b) (4) monitoring data, (b) (4) monitoring data, active air and settle plate recoveries were arbitrarily low. For example, with no (b) (4) (b) (4) your firm's (b) (4) used to clean equipment in Grade D areas has routinely reported zero CFU/mL. Routine microbiological sampling of your firm's (b) (4) point of use locations, routinely returned 0 CFU/mL, across numerous Point-Of-Use (POU) locations over the review period, despite active leaks in (b) (4) storage tanks at the time of this inspection. During dynamic NVP monitoring of Room (b) (4) sampled locations reported zero particle counts. When the improbability of these sustained environmental monitoring results was discussed with your firm's microbiologists, they responded that the data is reflective of the current conditions captured at the time. Comparative sampling performed on 4/24/2026 in (b) (4) in static conditions, was unable to replicate the data collected during the qualification.

B. (b) (4) Facility Management System used for monitoring of Temperature, Humidity and Differential Pressure does not require documented written approval or justification, prior changing environmental monitoring limits and alarm criteria. It was observed that your firm's personnel have changed specific area limits, based on verbal requests from production staff. Additionally, your FMS has (b) (4) modes, each with specific limits and Air Handling Unit (AHU) workloads. It is unclear whether each mode has evaluated for adequacy, or that the current system settings are in-line with area limits and specifications, at the time the system was qualified. At the time of the inspection the firm was unable to provide audit trails for the (b)(4) system, despite requests.

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	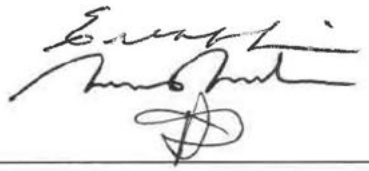	**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

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C. Dead legs were observed in Room (b) (4) rooms). "(b) (4) pipes enter each room vertically, and end directly with no avenue for redirection. The (b) (4) in these pipes remains stagnant until use for (b) (4) (b) (4) When asked for a point-of-use identification number, your firm's production personnel responded that the (b) (4) pipes have no ID and are identified by name only. No data could be provided indicating the specifications (b) (4) from these (b) (4) pipes is held to. According to the firm's production personnel none of the (b) (4) pipes" have been sampled for (b) (4) microbiological content, or Bacterial Endotoxin.

D. Your firm's (b) (4) Distribution Systems are not continuously monitored/monitored (b) (4) for (b) (4) Your firm was unable to provide any rationale for only performing (b) (4) analysis (b) (4) content in (b) (4) can change rapidly, however, (b) (4) analysis represents the momentary (b) (4) at the time the sample is taken, and is prone to environmental sample contamination, resulting in artificially high results or "false positives".

OBSERVATION 12

You do not have written procedures and process control procedures to ensure and document that all key process parameters are controlled and any deviations from the procedures are justified. Specifically,

The (b) (4) Non-Viable Particle Counters (NVPC) were not appropriately qualified. During qualification, the accuracy and completeness of the saved and printed audit trail data was not verified. Complete data including records of manual sample collection abortions, alarms and user log-ins were not accurate and complete, at the time the NVPCs were qualified. Furthermore, there

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	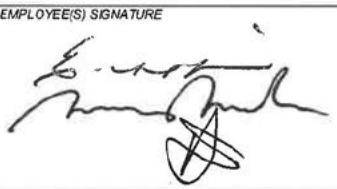	**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

is no periodic review of the NVPC audit trails. Additionally, NVPCs without audit trail functionality remain in use in the non-sterile production blocks, despite the inability to meet current regulatory expectations for (b) (4) computerized systems that generate electronic data, being well understood and acknowledged by the firm's management team.

OBSERVATION 13

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

A. Your firm was notified by your customer that (b) (4) batches (b) (4) (b) (4) mg tablets (Batches: (b) (4) exceeded the (b) (4) limit of not more than (b) (4) for (b) (4) During the inspection we asked to review the batch manufacturing records for the batches. According to Technology Director, the firm's role for the manufacturing of the (b) (4) mg tablets is that of a contract manufacturer and the batch numbers that are provided are the customer's batch numbers. Technology Director further stated that "they do not have any idea on how to track their batch numbers to the site". When asked if this is the case for all customers that the firm contract manufactures for, the Quality Assurance Manager stated that all bulk batches manufactured for contract manufacture products cannot be traced back to the firm's respective batches. The firm has a total of (b) (4) bulk batch customers of which (b) (4) is shipped to a United State customer. Since Zhejiang Huahai Pharmaceutical Co., Ltd. cannot trace back customer batch numbers there is no way of knowing of the traceability of each bulk batch manufactured product.

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	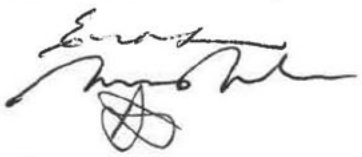	**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026

B. SMP-021.022, "OOS/OOT Investigation Management System", effective date: 01/15/2026, Step (b) (4) states that "results on the edge of the specification will be defined as OOT". However, (b) (4) batches of (b) (4) tablets, Batch No. (b) (4) (b) (4) reported (b) (4) Impurity results of (b) (4) ppm, respectively, against the specification of NMT (b) (4) ppm. The addition of the (b) (4) (b) (4) Impurity specification was added on November 13, 2025 under SCRF-25040. As such, only one timepoint of data was provided. The review of stability data noted that the mean (b) (4) Impurity from samples tested at timepoints ranging from (b) (4) (b) (4) had a mean (b) (4) Impurity of (b) (4) ppm. Batch No. (b) (4) (b) (4) were sampled at (b) (4) respectively. No investigation was performed to identify the root cause of the OOT results from the (b) (4) batches. I explained to the firm's management team that per their written procedure, an OOT investigation would be required. This was discussed with the firm's management team initially on 4/15/2026, was described in detail again to the firm on 04/16/2026, and it was indicated, on both occasions, that an investigation had yet to be carried out. However, on the last day of the inspection 4/24/2026, a OOT investigation was provided which indicated that the root cause of the OOT results was (b) (4) levels in (b) (4) When asked, your firm's management and QC personnel indicated that no analysis or retroactive review of (b) (4) content in (b) (4) had been performed and indicated that the investigation conclusions and subsequent CAPA were solutions to the hypothetical situation, of (b) (4) content in (b) (4) leading to the (b) (4) impurity in the (b) (4) OOT batches.

C. QA retention samples are handled by SMP-F-QC-010, "FDF Retention Sample Management Procedure", version: 07, effective date: 03/30/2026. Step (b) (4) states, "the reserve samples from representative sample lots selected by acceptable statistical procedures shall be visually examined (except special requirement from client) for appearance once per year for evidence of deterioration unless visual examination would affect the integrity of the reserve samples". On 04/20/2026, during an inspection of the QA retain sample storage, your firm's QA personnel explained that due to risk to product integrity, no annual product inspection is performed, instead

the external condition of the (b) (4) packaging container is assessed. After the intent of QA retention samples was explained to your firm's QA personnel and management team, it was explained that a misunderstanding occurred during review of the pertinent regulations, and as a result, samples were never inspected, due to a hesitancy to impacting the integrity of the non-sterile (b) (4) packaging container and equivalent data sourced from stability samples.

D. SMP-021.022, "OOS/OOT Investigation Management System", effective date: 01/15/2026, Step (b) (4) states that "results on the edge of the specification will be defined as OOT". However, (b) (4) batches of (b) (4) tablets, Batch No. (b) (4) (b) (4) reported (b) (4) Impurity results of (b) (4) ppm, respectively, against the specification of NMT (b) (4) ppm. The addition of the (b) (4) (b) (4) Impurity specification was added on November 13, 2025 under SCRF-25040. As such, only one timepoint of data was provided. The review of stability data noted that the mean (b) (4) Impurity from samples tested at timepoints ranging from (b) (4) (b) (4) had a mean (b) (4) Impurity of (b) (4) ppm. Batch No. (b) (4) (b) (4) were sampled at (b) (4) respectively. No investigation was performed to identify the root cause of the OOT results from the (b) (4) batches. I explained to the firm's management team that per their written procedure, an OOT investigation would be required. This was discussed with the firm's management team initially on 4/15/2026, was described in detail again to the firm on 04/16/2026, and it was indicated, on both occasions, that an investigation had yet to be carried out. However, on the last day of the inspection 4/24/2026, a OOT investigation was provided which indicated that the root cause of the OOT results was (b) (4) levels in (b) (4) When asked, your firm's management and QC personnel indicated that no analysis or retroactive review of (b) (4) content in (b) (4) had been performed and indicated that the investigation conclusions and subsequent CAPA were solutions to the hypothetical situation, of (b) (4) content in (b) (4) leading to the (b) (4) impurity in the (b) (4) OOT batches.

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E. QA retention samples are handled by SMP-F-QC-010, "FDF Retention Sample Management Procedure", version: 07, effective date: 03/30/2026. Step (b) (4) states, "the reserve samples from representative sample lots selected by acceptable statistical procedures shall be visually examined (except special requirement from client) for appearance once per year for evidence of deterioration unless visual examination would affect the integrity of the reserve samples". On 04/20/2026, during an inspection of the QA retain sample storage, your firm's QA personnel explained that due to risk to product integrity, no annual product inspection is performed, instead the external condition of the (b) (4) packaging container is assessed. After the intent of QA retention samples was explained to your firm's QA personnel and management team, it was explained that a misunderstanding occurred during review of the pertinent regulations, and as a result, samples were never inspected, due to a hesitancy to impacting the integrity of the non-sterile (b) (4) packaging container and equivalent data sourced from stability samples.

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	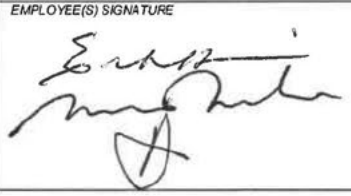	**Eileen A. Liu, Investigator** **Marcellinus D. Dordunoo, Investigator** **Dipesh K. Shah, Investigator**	04/24/2026