DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Dr., Room 2037, Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/23/2026-07/03/2026
	FEI NUMBER 3003404148

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Pan Kai - President of Dosage Form Branch

FIRM NAME	STREET ADDRESS
Jiangsu Hengrui Pharmaceuticals Co., Ltd.	Dongjin Road, Port Industry Area, Economic & Tech Development Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lianyungang, Jiangsu 222069, China	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

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, written, followed, or including adequate validation of the aseptic process, Specifically,

A. Workshop (b) (4) manufactures (b) (4) (b) (4) Injection for the U.S. During review of the Workshop (b) (4) aseptic process simulation (APS) or media fill (MF) studies, the following was noted.

i. From 07/2025 to date, not all approved interventions were simulated during the (b) (4) fill line re-qualification. Specifically, from 07/2025, interventions are categorized by risk. However, you did not perform formal risk assessment to decide risk levels. (b) (4) of the total (b) (4) interventions are categorized as low risk; therefore, they are simulated only (b) (4) during the routine re-qualification. In addition, your analysis showed (b) (4) % to (b) (4) % of the approved interventions were not simulated in a total of (b) (4) MF studies from 07/2025 to date. You lack assurance your MFs were adequately performed to ensure product sterility.

ii. On 12/20/2025, during the aseptic filling of (b) (4) Injection (b) (4) Batch (b) (4) product), an unplanned intervention occurred that required the (b) (4) intervention to un-jam vials on the (b) (4) line. Deviation D2DR2025639M was initiated. However, this deviation has not been simulated to date in the subsequent MF study to ensure product sterility.

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iii. On 07/02/2026, review of the recent MF Batch (b) (4) videos showed operators did not observe the appropriate cleanroom behavior of using slow and deliberate motion while conducting filling activities. SOP GR-045, "Principles of Personnel Behaviors in Clean Room", section 7.10.2.1.1 states personnel should move slowly, and rapid movements or turn should be avoided.

B. During the inspection, we reviewed Workshop (b) (4) Airflow Visualization Study or smoke study dated 03/2026 and 06/2026. The incorrect smoke administration or poor aseptic practice were observed. Examples including but were not limited to the following:

i. Video #21 of static smoke test, "(b) (4) from filling area to (b) (4) area" is inadequate in that the smoke appeared blasting and was administered close to the (b) (4) and not from the HEPA filter location. It did not represent the actual HEPA airflow.

ii. Video #2 of inherent interference, "Stoppering" (b) (4) shows the dispensing of (b) (4) stoppers. We noted the operator held the stopper bag directly over the (b) (4) blocking HEPA first air to the (b) (4)

iii. Video #6 of corrective interference, "Crushed vials with (b) (4)" (b) (4) shows an operator's hand over adjacent open vials blocking clean first air to those vials. The impacted vials were not removed from use.

C. During the inspection, I (EL) conducted walkthrough inspections of the Workshop (b) (4) The following was noted.

i. On 06/29/2026, I observed the Workshop (b) (4) simulated aseptic filling using (b) (4) I saw scratches on the Grade A enclosure where sterile stoppers are retrieved and packaged. Additional scratches at different filling room Grade A locations were also identified by your firm. The damaged (b) (4) panels were replaced during the inspection. You do not know how long the scratches have been in your cleanroom.

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ii. On 07/01/2026, I inspected the Workshop (b) (4) filling room. I noted uneven caulking throughout the Grade A and Grade B areas. I also noted along the (b) (4) Grade A (b) (4) machine conveyor tracks and on the Grade A (b) (4) LAF for sterile material (b) (4) transfer, the (b) (4) (b) (4) tapes show deterioration or discoloration which appeared to be caused by flaking of the tape surface (b) (4) material. Locations of observed (b) (4) tape damage including, but were not limited to (b) (4) SOP EA-136, "Design, Installation and Acceptance Procedures of Clean Room", section 7.6.6 states the surfaces of the wall and ceilings in the cleanroom shall be smooth, eve, non-shedding, glare-free, and corrosion-resistant.

D. Loading patterns have not been established/validated for the proper placement of (b) (4) utensils and components in the (b) (4) #(b) (4) (Grade A) located in Workshop #(b) (4) to ensure proper air flow. These utensils and components are then transferred to the (b) (4) RABS unit. Additionally, smoke studies do not demonstrate unidirectional airflow for this (b) (4) located in the Grade B processing area.

E. Non-sterile (b) (4) is used for the internal cleaning of various tanks of the compounding system located in Workshop #(b) (4) for sterile drug products.

F. (b) (4) have not been established/validated for the (b) (4) #(b) (4) used for terminally sterilizing drug products in Workshop #(b) (4) (b) (4) have not been established/validated for the (b) (4) #(b) (4) (b) (4) used for sterilizing glass vials for the aseptic (b) (4) drug products in Workshop #(b) (4)

Observation #2

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

We reviewed cleanroom disinfection and cleaning during the inspection. We noted the following.

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A. You conducted [redacted] (b) (4) to control microbiological contamination for all onsite workshops. Workshop [redacted] (b) (4) manufactures aseptically filled and, aseptically filled and [redacted] (b) (4) injectables for the U.S. market. We reviewed Workshop [redacted] (b) (4) validation and found the following.

i. No formal risk assessment was performed to determine the appropriate biological indicator (BI) and chemical indicator (CI) location.

ii. No precise descriptions but only general indicator locations were described in the validation study. An example of the location is: Test Point [redacted] (b) (4) Grade A), "Inside main equipment". It is not clear where exactly the BI and CI were placed on Test Point [redacted] (b) (4) during validation.

iii. BIs and CIs were placed in the open areas instead of in the most difficult to reach places during validation.

iv. A total of [redacted] (b) (4) monitoring locations were validated. However, your validation determined that only [redacted] (b) (4) locations should be tested during routine [redacted] (b) (4). You do not have scientific justification or data to support reduced monitoring.

B. [redacted] (b) (4) cloth wipes [redacted] (b) (4) are being used to clean classified cleanroom surfaces. Specifically, Grade A and Grade B wipes are [redacted] (b) (4) also wipes are replaced [redacted] (b) (4) However, you did not conduct any study to show the [redacted] (b) (4) sterilization process will not cause the cloth material to deteriorate and shed particles. Our review revealed that the cloth wipe issuance, [redacted] (b) (4) records are not traceable. Also, you do not have destruction records to show that wipes are not being recycled beyond the [redacted] (b) (4) use.

Observation #3

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

Your viable environmental monitoring (EM) results are not always reliable because the [redacted] (b) (4) plates incubation condition at [redacted] (b) (4) °C is not supported by your growth promotion test (GPT). Specifically, SOP

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QC-742, "Procedure for Surface Microbial Monitoring in Clen Areas", section 7.4.2 requires incubating all EM (b) (4) plates at (b) (4) °C for (b) (4) followed by (b) (4) °C for (b) (4) However, during GPT there is no (b) (4) °C incubation, the (b) (4) plates are only incubated at (b) (4) °C for not more than (b) (4) You do not have GP data to demonstrate the (b) (4) media can adequately support microbial growth at (b) (4) °C during EM.

Observation #4

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality, and purity of drug products. Specifically,

A review of the below deviation investigations noted the following:

A) DV#24520 was regarding the batch packaging record for (b) (4) Injection (b) (4) Vial) (b) (4) mL Batch# (b) (4) being drafted incorrectly. Incorrect items included the wrong expiration date, filling yield, and finished product yield. This record was reviewed by department head, effective department, and final approval was given by QA. These errors were attributed to the drafter (production) for this batch record.

B) DV#24304 occurred during the production of (b) (4) Injection (b) (4) mcg (b) (4) mL Batch# (b) (4) in Workshop # (b) (4) The "Batch Sterilization Record - (b) (4) Sterilization Cycle" page, finished product sampling, and retention records were not included in the batch record by the drafting personnel. A production employee made changes to the batch record during production and these changes were not approved by QA.

C) DV#12949 was regarding (b) (4) Injection (b) (4) bottle) (b) (4) mg (b) (4) mL Batch # (b) (4) in Workshop # (b) (4) This batch did not meet establish sterilization processing time limit specification for (b) (4) times for this TS drug product batch. Therefore, the batch received an extended sterilization cycle (normal cycle is (b) (4) and the extended cycle was (b) (4) Stability testing was performed on this batch for a six-month accelerated testing and long-term testing. After the accelerated stability testing results were obtained/approved, this batch was released for

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commercial distribution. A (b) (4) expiration date was assigned to this batch. QA approved the release of this batch.

D) DV#27544 occurred during the review of Batches #(b) (4) of (b) (4) Injection (b) (4) mg (b) (4) ml. The illuminance range documented in the batch records was (b) (4) and the correct illuminance range for visible inspection should be (b) (4) Per the investigation, the drafter of the batch record included the incorrect illuminance specification. This batch record was reviewed by the department head, effective department, and final approval was given by QA. Additionally, personnel in the visual inspection department identified the error in the illuminance draft and made corrections via strikethrough and signing but failed to promptly initiate a change for the rectification or notify QA.

E) DV#28434 occurred during the review of the batch packaging records for (b) (4) Injection (b) (4) ng (b) (4) mL Batch # (b) (4) An error was identified in the actual sampling quantity recorded in the visual inspection records. On-site QC had crossed out and revised the approved sampling quantity of (b) (4) units to (b) (4) units in the record. The correct quantity was (b) (4) units. QA did not approve this change.

Observation #5

The quality control unit lacks responsibility and authority to fully investigate errors that have occurred.

Specifically, a review of (b) (4) Injection Batch # (b) (4) noted that a Red Alert Alarm occurred for the (b) (4) monitoring Point # (b) (4) However, this alarm was not documented in the filling section of the batch record and no corrective action were documented.

Observation #6

The master production and control records are deficient in that they do not include complete manufacturing instructions and specifications. Specifically,

A review of representative batch records for U.S. drug products (b) (4) (b) (4) mg/vial Batch # (b) (4) and (b) (4) Injection (b) (4) mg (b) (4) mL Batch # (b) (4) noted various critical

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processing range limits are not specified in the batch record, such as; (b) (4) (b) (4) Additionally, several critical processing parameters are not document with actual values (check mark only) and values that are recorded are inaccurate regarding acceptable processing range limits.

Observation #7

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

A. There is a lack of justification for not testing retain samples for customer complaint of foreign material in drug product. Specifically, you learned of complaint CR2025057D on 05-10-2025 regarding foreign material (particles) in 3 vials of (b) (4) Injection (b) (4) (b) (4) Batch (b) (4) (Exp. (b) (4) A Field Alert Report (FAR) 25001D2 was submitted on 05/14/2025. Your investigation concluded Batch (b) (4) met all specified quality standards. You did not test retain samples during FAR investigation. A final FAR was submitted on 06/18/2025. However, on 06/23/2026, more than a year after the final FAR and during the current inspection, you decided to visually inspect (b) (4) retain samples for foreign particles. You lacked adequate justification for not conducting testing to rule out microbial contamination in a timely manner to ensure product quality and patient safety.

B. Deviation D2DR2026218M was initiated on 05/28/2026 for the manufacturing of (b) (4) Injection (b) (4) U.S. Batch (b) (4) exceeding specified compounding time of ≤ (b) (4) due to issues in the (b) (4) system during (b) (4) The actual compounding time for Batch (b) (4) was (b) (4) which including the approximate (b) (4) wait time for analysis of the (b) (4) additional in-process samples. You did not have or include formal hold-time studies, historical data, or stability data to ensure the extra hold-time would not have negative impact to product quality. Nonetheless, your investigation deemed the above batch acceptable. Batch (b) (4) was released on 06/26/2026 (Exp. (b) (4) and shipped to the U.S. market on (b) (4)

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Observation #8

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

A. Your bacterial endotoxins test results by gel clot method for (b) (4) are not always reliable in that the validated test method is not followed to include the product positive control (PPC) in each test sample. The PPC is to ensure appropriate detection for the presence of interference factor that may result in false negative endotoxin results. You reported no out of limit (OOL) (b) (4) bacterial endotoxin results from 08/2023 to date. However, without including the PPC in your (b) (4) endotoxin tests you cannot rule out false negative endotoxin results did not occur.

B. Your firm uses (b) (4) stoppers in the manufacturing of U.S. (b) (4) Injection. During the inspection, we reviewed the endotoxin and bioburden test method validations for the release of incoming (b) (4) stoppers. We found the test method validations inadequate for the following.

   i. You failed to spike (b) (4) stoppers with appropriate level of endotoxin to demonstrate your extraction and test method can successfully extract and recover endotoxins adhered to the (b) (4) stoppers.

   ii. You failed to spike (b) (4) stoppers with bacteria cfu to demonstrate your extraction and test method can successfully extract and recover bacterial contamination adhered to the (b) (4) stoppers.

There has been no failure in endotoxin and bioburden test results for incoming (b) (4) stoppers. You cannot rule out contamination if test procedures used are not scientifically sound.

Observation #9

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Equipment used for the manufacturing of drug products are not properly identified to facilitate operations for its intended use. Specifically,

A) On 6/25/2026, I inspected the (b) (4) system in Workshop # (b) (4) which provides (b) (4) to the (b) (4) system for the manufacturing of sterile (b) (4) drug products. I observed that the piping of these (b) (4) systems were not properly identified and the process flow of the (b) (4) was not identified in several areas of these systems. I observed one leak and two dead legs in the (b) (4) system. Additionally, there was a lack of proper lighting in these areas to ensure proper inspection of these systems.

B) On 6/25/2026, I inspected the (b) (4) system in Workshop # (b) (4) which provides (b) (4) to the (b) (4) system for the manufacturing of the terminally sterilized drug products. I observed that the piping of these (b) (4) systems were not properly identified and the process flow of the (b) (4) was not identified in several areas of these systems. I observed one leak and two dead legs in the (b) (4) system.

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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."