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	4/7/2026 – 4/15/2026 FEI NUMBER 3006689263
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Lu Yun, Vice President	
FIRM NAME Jiangsu Hengrui Pharmaceuticals	STREET ADDRESS No. 22 Jinqiao Road
CITY, STATE, ZIP CODE, COUNTRY Lianyungang Jiangsu 222069, China	TYPE ESTABLISHMENT INSPECTED API and sterile drug manufacture

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 did not include adequate validation of the sterilization process. Specifically,

A. Smoke studies

The review of the smoke study reports used to qualify the filling lines used in the aseptic filling of (b) (4) Injection and (b) (4) API stated no obvious turbulence or reflux was observed. The following uneven air currents were not identified or investigated:

1. Turbulence was noted in the following videos used to evaluate air flow currents in grade A areas:

Finished product line

- Dynamic Inside the dispensing machine
- Dynamic in the (b) (4)
- Dynamic in the (b) (4)
- (b) (4) and forcep in (b) (4) area
- (b) (4) and forcep in (b) (4) area
- (b) (4) transferring at (b) (4)

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- (b) (4) transferring at (b) (4)
- (b) (4) Sampling, (b) (4) cleaning
- (b) (4) Sampling, (b) (4) cleaning
- (b) (4) Stopper Area Static
- (b) (4) Stopper Area Static
- (b) (4) Remove the (b) (4) of the (b) (4)
- (b) (4) stopper

API filling line

- (b) (4) canisters transferring (b) (4)
- (b) (4) Reset (b) (4) probe
- (b) (4) Transferring
- (b) (4) Stopper

2. Lack of adequate smoke over (b) (4) activities being evaluated:

Finished product line

- (b) (4) and forcep in (b) (4) area
- (b) (4) Remove the (b) (4) of the (b) (4)
- (b) (4) Stopper

API filling line

- (b) (4) canisters transferring

3. The Smoke leaving the wand is not perpendicular:

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Finished product line

- (b)(4) and forcep in (b)(4) area
- (b)(4) Stopper Area Static Smoke
- (b)(4) Fallen vials on the (b)(4) belt

4. Obstruction in front of video camera so cannot evaluate

Finished product line

- (b)(4) Sampling, (b)(4) cleaning
- (b)(4) Sampling, (b)(4) cleaning

API filling line

- (b)(4) canisters transferring - (b)(4)

B. (b)(4) Validation

1. The positioning of the items is inconsistent between the minimum and maximum load patterns used to validate the (b)(4) The load patterns are used to sterilize equipment and gowning used in the manufacture of sterile (b)(4) API and (b)(4) Injection. For example, the (b)(4) stopper/utensil load pattern used in the manufacture of (b)(4) Injection:

(b)(4)

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(b) (4)

The aseptic filling of the (b) (4) Injection, (b) (4) mg, uses (b) (4) (b) (4) The load pattern used to sterilize these items is not documented. This results in the load pattern not being validated.

2. There are no detailed pictures for how to load the (b) (4) Details as to whether equipment is stacked or laid side by side are not given. For the load pattern used in the sterilization of the API equipment, (b) (4) are shown in the picture. How the equipment/tools are loaded into those (b) (4) is not provided.

3. Tools used inside the grade A aseptic filling line for finished product (b) (4) Injection, do not have a sterilized hold time. These items do not have a sterilized hold time. The tools are stored in the grade B area and are not part of the environmental monitoring or (b) (4) program. The tools currently in use were sterilized 09Oct2025.

4. Risk assessment for BI locations, to determine the hardest to reach locations for (b) (4) sterilization has not been performed. Procedures do not specify or document the exact location of the BI placement during validation. Only general locations are specified. For an example from the (b) (4) validations, see below:

(b) (4)

There is no assurance that the locations picked are the hardest to reach locations.

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C. Software Qualification:
Your firm failed to adequately qualify the RABs (b)(4) filling equipment, equipment # (b)(4) The OQ/PQ protocol, V-F-P 59 203P, is inadequate this protocol only tested the equipment's ability to reject overfills and underfills but failed to demonstrate the equipment's ability to accurately and consistently confirm fill weights within acceptable limits.

Additionally, the equipment lacks data storage capability, lacks in-process weight verification, and relies on operator transcription of displayed values without verification or electronic record retention.

No audit trail exists for this software, Siemens Version 1.0. No electronic data can be provided for conveyer speed, (b)(4) weight checks, line stops, or triggering of (b)(4) and no independent in-process checks are verified against the machine values.

(b)(4) Batch (b)(4) g, was manufactured on Feb 10, 2026, released on March 4, 2026, and shipped to the United States on (b)(4)

Observation 2
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

A. Visual Inspection
1. Your firm uses only one defect kit for operator training, ongoing requalification, and performance testing. This kit contains only one example of each defect type. Some of the defects have been in use for over four years, allowing operators to repeatedly view, and are tested on identical defects during each requalification cycle, allowing the same defects to be seen (b)(4) (b)(4) This practice does not adequately challenge operators to recognize defects they have not previously memorized. This practice also fails to demonstrate operators can identify

defects based on understanding characteristics rather than memorize specific defects in the one training/defect kit and does not represent the variably of defects that may occur in actual production.

2. Your defect library consists solely of photographs of the same defects contained in the single qualification kit. With some defects having been photographed and used for more than four years without rotation or addition of new examples, operators are repeatedly exposed to identical visual references rather than a representative range of potential defects.

3. Visual defects in your qualification program are no less than (b) (4) micrometers. This threshold may not adequately challenge operators to detect smaller, still significant, defects that could impact product quality. Your qualification program should include defects at or below the acceptance criteria to ensure operators can reliably detect rejectable defects. Specific particle defects included in the one defect/training kit include:

(b) (4)

4. Your firm removes labels from bottles during qualification testing, but does not have a system to ensure accurate identification of which vial number corresponds to which label, creating the potential for incorrect scoring of operator performance, inability to verify which specific defects were correctly or incorrectly identified, and compromised integrity of the qualification process.

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5. Requalification of visual inspectors is performed as a group rather than individually and does not replicate the exact manner in which batch release inspections are conducted. Group testing may allow operators to benefit from cues or behaviors of other operators which does not occur during routine individual inspection activities.

6. If a visual inspector fails requalification, your firm does not have a written procedure requiring the opening of a deviation or investigation. No process has been established to identify a root cause, assess whether previous batches inspected may have been inadequately inspected by the failed operator, and no requirement to implement a CAPA.

B. Aseptic Technique

The following inappropriate aseptic behaviors were noted during review of the smoke study and media fill videos associated with the aseptic filling of (b)(4) Injection:

1. Media fill (b)(4)
   - The operator shook the (b)(4) stopper bag over the stopper bowl, bypassing the (b)(4) (b)(4) when the stoppers failed discharge from the bag.
   - Operators are seen placing forceps and Tools are placed directly on equipment surfaces/floor of the (b)(4) RABs during
   - An operator was seen leaning on the table in the grade B area.
2. (b)(4) Reject the inverted vial on the vial transfer track (b)(4) the conveyer was not wiped down after being touched by the operator.

C. (b)(4) integrity testing

The firms (b)(4) integrity testing procedures are inadequate to ensure proper (b)(4) testing and maintenance.

1. During the inspection, we observed unlabeled (b)(4) in the (b)(4) room and the (b)(4) filling room in Workshop (b)(4) on April 7, 8, 13, 2026. (b)(4) installed in the (b)(4) are not labeled with installation date, (b)(4) serial numbers, or any identifying information.

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(b)(4) are also not clearly defined. The lack of labeling prevents verification that appropriate (b)(4) testing results are recorded.

2. On April 13, 2026, operators performed (b)(4) integrity testing with the time between a finished test of a (b)(4) and the start of a new (b)(4) test to be no less than (b)(4) However, the batch records show (b)(4) integrity testing time between finish of a test and start of a new test to be between (b)(4) Your firm them provided a video proving the operators could work even faster, completing the (b)(4) integrity test, and starting a test in less than (b)(4) During this evolution, operators were observed moving rapidly from (b)(4) to (b)(4) and not fully checking the (b)(4) for visual integrity.

3. Your SOP PO-59-223, SOP for Post of (b)(4) packaging, Revision 004, included no instructions for how to document and proceed with a failed (b)(4) integrity testing. The updated SOP, revision 005, effective April 13, 2026, instructs operators to replace a (b)(4) and record, if a (b)(4) integrity test fails. On April 13, 2026, one day after the SOP was updated, and the operators were signed off on the new SOP, (b)(4) failed in the (b)(4) room, Workshop (b)(4) during the pre-production integrity testing. Operators were instructed by the Production Workshop Director to retest the (b)(4) and proceeded to retest the failed (b)(4) contrary to the new SOP.

D. Interventions
Trending of interventions is not performed on the aseptic filling line for (b)(4) Injection.

Observation 3
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the to produce aseptic conditions. Specifically, discrepancies were noted during the review of the (b)(4) validation for the following areas:

A. API - (b)(4)
The (b)(4) cycle was observed taking place on the (b)(4) used in the aseptic filling of (b)(4) API on 13Apr2026. During this activity along with the review of the procedures associated with (b)(4) validation, the following discrepancies were noted:

- (b)(4) were observed (b)(4) or touching equipment during the (b)(4) cycle. (b)(4) are not put in place until after the (b)(4) is (b)(4)
- Various items were observed on the floor of the (b)(4) including (b)(4) packages, settle plates, active air equipment/lid, cleaning hose and tools. There is no evidence that (b)(4) penetrates these areas,
- The justification for BI location, as well as the (b)(4) validation, does not consider the ancillary equipment/supplies located inside the (b)(4) during validation.

B. Finished product - (b)(4) RABs

- The validation (V-F-P 59 242C) of the (b)(4) filling area, containing the (b)(4) RABs used in the aseptic filling of (b)(4) Injection as well as the (b)(4) procedure followed prior to routine production, does not specify whether or not the (b)(4) RABs (b)(4) during (b)(4) A risk assessment located in the validation states if the equipment (b)(4) the (b)(4) cannot reach all area during sterilization, resulting in insufficient sterilization effect.
- The routine (b)(4) procedure (PO-59 008), performed NLT (b)(4) for the filling room as well as the area outside of the API (b)(4) (grade A/B area), does not specify the placement or location of chemical indicators.
- A (b)(4) cycle for the grade A/B areas is only required if the HVAC stops running for more than (b)(4) (b)(4)

Observation 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Environmental Monitoring

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1. Adequate risk assessment could not be provided for changing viable surface monitoring from (b) (4) to (b) (4) for the (b) (4) These (b) (4) located in the (b) (4) RABs, are used to handle settle plates during environmental monitoring.
2. Recovery studies have not been performed that show using one swab (b) (4) of a (b) (4) (b) (4) gives adequate recovery.

Observation 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

The following discrepancies were noted during review of the aseptic filling lines for the following:

(b) (4) API (b) (4)

1. On April 9, 2026, I observed your firm failed to maintain equipment in a clean and orderly manner. The (b) (4) Sterile (b) (4) equipment (b) (4) was found to have the following deficiencies:

   Deep scratches and gouges on interior surfaces including:
   - (b) (4) worktable inside the (b) (4)
   - Floor surfaces inside the (b) (4)
   - Several broken (b) (4) on the (b) (4)

2. The (b) (4) in the (b) (4) cannot be emptied into the canister without crossing first air above the (b) (4) This (b) (4) is refilled approximately (b) (4) times during the aseptic filling of (b) (4) API (b) (4) This was observed during the simulated fill performed on 14Apr2026, and during the smoke studies.

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Batch (b)(4) of sterile drug substance (b)(4) manufactured in this (b)(4) on November 19, 2025, was used for production of the sterile finished product (b)(4) (b)(4) Injection, Batch (b)(4) released on March 4, 2026, and shipped to the United States on (b)(4)

(b)(4) Injection (b)(4) RABs)

1. Deep scratches and gouges were observed on the interior surface where the (b)(4) is placed. This is the area where sterile stoppers travel prior to being installed.

2. The (b)(4) blocks first air during the addition of (b)(4) stoppers.

3. Scientific justification could not be provided for delaying alarms for (b)(4) in critical areas (between the filling room (grade B) and the capping room (grade C) for pressure differential excursions. This delay is based on the air exchange in the grade D area. Pressure differentials are measured (b)(4) between these rooms while pressure differentials inside the (b)(4) RABs between these two areas (grade A to grade B with grade A air supply) is only measured (b)(4)

Observation 6

Written procedures for cleaning and maintenance fail to include assignment of responsibility, description in sufficient detail of methods, equipment and materials used and description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance.

The following discrepancies were noted during the review of cleaning activities which took place in the filling room on 8Apr2026.

1. Mop heads cannot be completely submerged in the cleaning bucket. The mop heads are used to clean the ceilings, walls, and floors of the API refining room and the finished product filling

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room, directly outside of the Grade A areas. I observed the operator submerging the mop head repeatedly, at different angles, attempting to submerge the entire mop head prior to cleaning.

2. Cleaning of the grade B room did not follow the sequence of cleaning listed in PO-59 006, i.e. ceiling, walls, equipment surface, floor.

Observation 7

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

Your firm failed to ensure adequate oversight during the installation of a (b) (4) valve within a Grade A aseptic processing environment RABS equipment #(b) (4) on April 8, 2026. Quality Assurance personnel were observed to be positioned away from the operation with obstructed views, preventing verification that aseptic techniques and environmental controls were maintained during this critical installation. Your SOPs ICC-A-206, Rev 006, In process Control of Aseptic (b) (4) Filling, and IC-A-207, Rev006, In-Process checks for (b) (4) (b) (4) is not sufficient to ensure aseptic processing evolutions are adequately observed by QA.

Observation 8

The TLC test method for determining (b) (4) degradation impurities used during stability has not been proven to be stability indicating.

Observation 9

The (b) (4) method (b) (4) used to test (b) (4) has not been proven to be better than or equal the to the USP method. The firm's procedure does not include a (b) (4) (b) (4) On 7Apr2026, I observed (b) (4) with their edges peeling off the (b) (4)

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API OBSERVATIONS

Observation 10

There is a failure to maintain equipment in a clean and orderly manner to prevent contamination that could alter the quality of the drug substance.

On April 7, 2026, during a walkthrough of the packaging area of Workshop (b) (4) particles were observed on the surface of the (b) (4) equipment # (b) (4) and under the (b) (4) equipment # (b) (4) This (b) (4) and the room were signed off as "cleaned" on April 7, 2026.
Your firm's testing identified the particles as (b) (4)
This room, and (b) (4) equipment are not dedicated, and are used for:

- (b) (4) packaging of (b) (4) API for the US market
- (b) (4) packaging of excipient (b) (4) for the domestic market
- (b) (4) packaging of the excipient (b) (4) for the US market

Observation 11

The (b) (4) method used during the assay testing of (b) (4) has not been proven to be stability indicating.

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