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	4/16/2026 – 4/24/2026 FEI NUMBER 3008316144
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Fred Lu, Head of Products Division (Vice President)	
FIRM NAME Jiangsu Hansoh Pharmaceutical Group Co. Ltd.	STREET ADDRESS No 5. Dongjin Road, Economic and Technical Development Zone
CITY, STATE, ZIP CODE, COUNTRY Lianyungang, Jiangsu 222069	TYPE ESTABLISHMENT INSPECTED Sterile drug manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observation 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the sterilization process. Specifically,

A. Scientific evidence could not be provided demonstrating the source of the smoke used during your air flow visualization studies is neutrally buoyant. During your review of smoke study videos in your aseptic filling lines in workshops (b) (4) as well as the (b) (4) line, the following discrepancies were noted:

1. The positioning of the (b) (4) ducts of the (b) (4) RABS in relation to the grade B area has the potential to short circuit the grade B air flow, causing an upward movement of air in the cleanroom. Smoke studies have not been performed in this area to demonstrate adequate airflow in aseptic filling lines workshops (b) (4)

2. Air flow videos are recorded with the smoke pointing directly upwards, not providing a uniform curtain of smoke in which to evaluate air currents.

SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator	SANDRA A. BOYD -S Digitally signed by SANDRA A. BOYD -S Date: 2026.04.24 03:54:45 -04'00'	4/24/2026

3. Turbulence was noted in various smoke study videos which were not assessed or addressed during the firm's review and approval.

4. Smoke is not present where activities are taking place. Additionally, rapid dissipation of smoke was noted which reduces the ability to detect eddy currents and adverse airflow.

5. When the RABS (b) (4) is (b) (4), first air does not reach the product contact surfaces.

B. Media fills are not representative of commercial manufacturing. Only the duration of an intervention is simulated in a media fill and not the physical activities. For example, C-VP-206-026000-2541 Validation Protocol of Media Fill for (b) (4) ml vial in workshop (b) (4) requires a (b) (4) simulation of maintenance in the filling line. On 17Oct2025, the maintenance personnel performed an activity inside the RABS for approximately (b) (4) then remained standing (b) (4) the RABS with the (b) (4) for the remaining (b) (4) The operator did not perform any additional activities during this time and was considered qualified by this media fill.

C. Your firm's (b) (4) decontamination validation for aseptic processing areas has not been adequately validated to demonstrate effective sterilization of all critical surfaces.
   1. Deficient (b) (4) design
      - Workshop (b) (4) were observed. (b) (4) (b) (4) Thus creating areas of occlusion not fully exposed to (b) (4)
      - Workshops (b) (4) do not (b) (4) observed were not (b) (4) Additionally, (b) (4) were not (b) (4) during (b) (4) process.
      - You have not evaluated the (b) (4) efficacy in (b) (4) areas of the (b) (4)

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2. Inadequate (b) (4) sterilization assurance
   - (b) (4) are (b) (4), prior to initial installation
   - There is no assurance that (b) (4) are completely and uniformly covered by the (b) (4) during routine decontamination cycles

3. Incomplete validation documentation
   - There is no list of equipment that remains in the room during (b) (4) cycle, in the validation protocol or in the report
   - There is no documentation on specific locations of BI and chemical indicators placement within the validation protocol and report

US marketed products manufactured in Workshop (b) (4) include (b) (4)
(b) (4)

D. There are no defined inherent or corrective interventions to be performed during a media fill in order to be qualified as an aseptic filling operator. For example, (b) (4) operators are documented as performing setup during commercial manufacturing. One operator performs the setup of the equipment, including aseptic connections, while the remaining operators assist by passing equipment to the main operator. In the batch record, there is no differentiation between the main operator and the support operators. Media fills are handled the same way with no way to determine who the

SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator	SB KB	4/24/2026

support operators were verses who performed the aseptic connection. This results in no assurance that an operator performing setup in commercial manufacturing previously performed a successful setup in a media fill.

E. The sterilization processes used for equipment that comes into direct contact with your products have not been adequately validated. For example,

1. There are no specific details describing the placement of BIs during validation or assurance that the hardest to reach locations are monitored during (b) (4) load pattern validations. For example, a BI is only placed at the end of the (b) (4) hoses used during aseptic filling. The length of the hoses is not specified. These hoses can be recleaned and (b) (4) up to (b) (4) for (b) (4) A risk assessment wasn't performed to determine the current BI locations.

2. The firm sterilizes (b) (4) stoppers in bulk, prior to (b) (4) There is no assurance that the (b) (4) delivering sterilized stoppers to the (b) (4) area is sterilized during the (b) (4) process.

3. Load patterns procedures do not contain enough detail to ensure reproducibility. For example, there is no description of how tools are stored in the (b) (4) during (b) (4)

Observation 2
Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed.

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A. Reoccurring gram-negative recoveries in the grade B area surrounding the injectable manufacturing lines do not get investigated to determine the source. In 2025, the following gram-negative occurrences were reported:

Year	Workshop	Occurrences	Microbial name
		(b) (4)	

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Year	Workshop	Occurrences (b) (4)	Microbial name

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SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator	SB KAB	4/24/2026

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Year	Workshop	Occurrences (b) (4)	Microbial name
[redacted]			

B. Inadequate investigation into the (b) (4) reading. While observing filling of batch (b) (4) of (b) (4) Injection, USP, on 20Apr2026, I observed the (b) (4) governing the (b) (4) RABS to be (b) (4) at approximately 12:40pm, and took a photo of the (b) (4) I inquired about the status of the (b) (4) after 1:00pm. The firm initiated an investigation which determined the tube was cracked in the (b) (4) RABS which is connected to the (b) (4) The investigation stated the reading of the (b) (4) was within tolerance at 1:24pm (qualified range (b) (4) When I stated I observed the (b) (4) to be (b) (4) at 12:40pm, management stated this could be due to fluctuation. There was no evaluation as to whether a (b) (4) would fluctuate

SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator	SB KAB	4/24/2026

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with a cracked tube. The investigation did not address the discrepancy in the acceptable reading at 1:24pm.

C. Your firm's complaint investigations lack adequate depth and rigor as noted in the following deficiencies:

1. Investigations do not include a thorough evaluation of all possible factors in the manufacturing process that could have contributed to the complaint or defect. For example, complaint CP2500013, involving (b) (4) Injection USP, for loose caps, and leaking vials, failed to investigate capping speed.

2. Investigations fail to include examination and testing of retain samples when applicable to determine if the complaint represents a broader quality issue. For example, retain samples were not inspected during the investigations of the following complaints, CP2500039 involving (b) (4) Injection, CP250035 involving (b) (4) Injection, CP250001 involving (b) (4) Injection, and CP2500030 involving (b) (4) Injection, USP.

3. Quality does not perform an equipment and process review, but instead relies on Production to conduct their own review. Logs and raw data are consistently not reviewed to identify potential process deviations or equipment malfunctions. Quality defers production equipment and log review to the production department, and did not review raw data in complaint investigations CP2500039 involving (b) (4) Injection, CP250035 involving (b) (4) Injection, and CP250001 involving (b) (4) Injection.

4. Your firm did not perform a retrospective review for similar possibilities during the investigation of complaint CPC240024, involving a (b) (4) packaging artwork error of (b) (4)

SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator		4/24/2026

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Injection, USP, with the incorrect (b) (4) instructions. Additionally, the CAPA did not adequately address the root cause.

Observation 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

A. Inadequate aseptic technique was observed in the review of videos and while watching the aseptic filling of (b) (4) Injection in workshop (b) (4) on 20Apr2026. Discrepancies include:
   1. Operators block first air during the addition of stoppers. This was seen in workshops (b) (4) (b) (4) aseptic filling lines.

   2. An operator was seen having to lean his upper body inside the RABS unit to retrieve and return forceps in workshop (b) (4)

   3. Reaching over (b) (4) vials during the execution of an intervention. The affected vials were not removed.

B. The firm's visual inspection qualification program is inadequate to demonstrate that inspectors can reliably detect all defect types in sterile injectable products.
   1. Your visual inspection qualification program lacks adequate Quality Unit over-site and control. Production personnel maintain qualification kits, administer qualification tests, make pass/fail determination with only a Quality review of the bottle condition. This arrangement fails to ensure the proper administration of qualification tests according to a written procedure as well as fails to ensure objective evaluation of inspector performance.

2. Your firm's (b)(4) mL liquid visual inspection qualification kit lacks documented verification of the actual particle sizes present in the qualification vials. For example, vial (b)(4) is labeled as containing a (b)(4) particle of (b)(4) um, but visual observation indicated the particle is significantly larger. Your firm has not provided microscopic measurements, or objective evidence confirming the actual size of particles in any qualification vial. Inspectors can not be properly assessed on their ability to detect particles at specified size limits when the actual particle sizes are unknown.

3. Your firm's (b)(4) visual inspection qualification kit, (b)(4) mL, is inadequate because it does not include representative range of foreign particulate matter types and sizes that could reasonably occur during manufacturing operations. The kit only contains (b)(4) um fiber for (b)(4) products, which fails to challenge the inspector's ability to detect other common defects, such as glass particles, or fibers, of varying sizes and colors.

4. The (b)(4) mL liquid visual inspection qualification kit does not contain turbid samples, white spots/particles, or colored particles.

5. Your (b)(4) visual inspection qualification program uses only (b)(4) mL vials for inspector qualification, while your commercial production includes vial sizes ranging from (b)(4) mL to (b)(4) mL. This single-size approach fails to adequately qualify inspectors to detect defects across the range of container sizes and fill volumes used in production, as detection difficulty varies with container geometry, fill volume, and viewing angles.

6. Complaint photos depicting particulate matter are not incorporated into training or qualification kits, preventing inspectors from learning to recognize real world defects

7. A (b) (4) item qualification kit is made prior to qualify personnel performing visual inspection in the laboratory (release testing). The (b) (4) foreign object defects in this kit are randomly selected from other defect kits, resulting in a qualification kit containing liquid vials of different sizes (b) (4) (b) (4) This kit is not reflective of how product is tested in the laboratory during release. Additional deficiencies include:
   - The qualification kit always contains (b) (4) defects.
   - After documenting the status of the container being inspected, the analyst peels off the sticker revealing the original vial number and documents that number on the form. All good vials are identified with a prefix of (b) (4)
   - When the proctor confirms the correct identification of the defect is not documented.

C. Interventions are not trended based on the location of where the intervention takes place, or whether the intervention was a (b) (4) or a (b) (4) intervention. This affects the accuracy of the media fills and results in all activities potentially not being reflected in the smoke studies.

D. Your firm failed to establish and maintain adequate documentation for (b) (4) installed in the (b) (4) during aseptic filling operations. For example:
   - You do not record nor track manufacturer serial numbers or lot numbers on the (b) (4)
   - You have not established a (b) (4) lifestyle program where you track (b) (4) manufacture's expiration dates

Observation 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, the following discrepancies were noted during review of the environmental monitoring program:

A. Not all (b) (4) used during aseptic filling of injectable products are sampled at the end of the batch. C-VP-206-71000-2617 Risk Assessment of Environmental Control in Workshop (b) (4) specifies sampling of (b) (4) to monitor after batch manufacturing. This results in (b) (4) being monitored (b) (4) This assessment was not based on an evaluation of where interventions take place. Similar risk assessments resulted in (b) (4) in (b) (4) regardless of whether they were used during aseptic filling.

B. Due to space constraints, no environmental monitoring (non-viable particles, viable air, settle plates) is performed where (b) (4) stopper addition takes place. Only particle counting is executed in the (b) (4) hood (b) (4) area where operator passes (b) (4) stopper bags to stopper bowl areas). No activities are performed in this area during monitoring.

Observation 5

Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Discrepancies were noted during the cleaning performed on 20Apr2026 in workshop (b) (4) after the manufacture of (b) (4) Injection-USP including:

A. Operators were seen kneeling on the (b) (4) as well as reaching over and leaning on equipment during cleaning.
B. Using the same cloth to clean numerous pieces of equipment, including cleaning the lower parts of the (b) (4) RABS followed by cleaning the inside of (b) (4) RABS (b) (4)
C. Only the forceps used during setup or the removal of a stuck stopper are (b) (4) All (b) (4) remaining forceps, including those used in the removal of fallen/jammed vials are not (b) (4) These forceps remain on the aseptic filling lines

indefinitely. These forceps are not documented as being present during the (b) (4) cycle. This accounts for (b) forceps inside the grade A area in workshop (b) (4) (b) (4) line.

D. There is no data in support of spraying of the (b) (4) RABS (b) (4) with (b) (4) prior to (b) (4) disinfects the entire surface of the (b) (4) Review of media fill videos showed an operator using as few as (b) (4) squirts to disinfect a RABS (b) (4)

Observation 6

Routine calibration, inspection, checking of automatic, mechanical, electronic equipment is not performed according to a written program designed to assure proper performance. The following discrepancies were noted during the review of the (b) (4) weight check systems on aseptic filling lines in workshops (b) (4)

A. Workshop (b) (4) The weight checks performed on the (b) (4) balances prior to use, do not bracket the amount being weighed. The balances are verified using a (b) (4) g weight while the approximate mass of the items being weighed is approximately (b) (4) and (b) (4) g (empty and filled vial). No manual weight checks are performed throughout filling. This system is used in the aseptic filling (b) (4) Injection.

B. The ability of the system to reject over filled and under filled vials is not confirmed prior to start of manufacturing. The vials used during the functionality check, performed (b) (4) are not weighed out to confirm rejects near the upper and lower weight limits. The Validation Manager confirmed the low weight vials are made by (b) (4) (b) (4) and that they (b) (4) to the designated overfill vial so the vials are

obviously over and under filled during the functionality check performed in workshops (b) (4) and (b) (4) This affects (b) (4) Injection (b) (4) and (b) (4) mg/vial and (b) (4) Injection, USP (b) (4)

C. Although required by procedure, no (b) (4) checks have been performed on the (b) (4) balances used to perform (b) (4) weight checks in the (b) (4) workshop. No manual weight checks are performed during manufacturing.

Observation 7

Control procedures are not established that describe in process controls which validate the performance of those manufacturing processes that may be responsible for causing variably in the characteristics of in-process materials and the drug product.

A. Your firm failed to validate the in-process inspection method to evaluate (b) (4) of aseptically (b) (4) Injection.

(b) (4)

- Currently you use (b) (4) but provided no documented evidence that this method has been validated for accuracy, precision, or reproducibility.
- There is no documented acceptance criteria for (b) (4)
- There is no documented training program for personnel performing (b) (4) inspections, including no visual training aids or competency assessments to ensure consistent (b) (4) technique.

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B. The method used to test the sterility of (b) (4) used during (b) (4) interventions, P-QS-MA-900017-A01 Operating Procedure for Inspection of (b) (4) has not been validated.

C. Reconciliation of injections is not performed on the chromatograms generated using OpenLab 2.4 software.

SEE REVERSE OF THIS PAGE	Sandra A Boyd, Investigator Karen A Briggs, Investigator	SANDRA A. BOYD -S Digitally signed by SANDRA A. BOYD -S Date: 2026.04.24 03:56:01 -04'00'	4/24/2026

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."