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	06/22/2026-07/16/2026
	FEI NUMBER 3007373503

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Pan Kai - President of Dosage Form Branch	
FIRM NAME Jiangsu Hengrui Pharmaceuticals Co., Ltd.	STREET ADDRESS 38 Huanghe Road, Economic and Technological Development Zone
CITY, STATE, ZIP CODE, COUNTRY Lianyungang, Jiangsu 222047, China	TYPE ESTABLISHMENT INSPECTED 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 sterilization process.

Specifically,

Workshop (b) (4) ceased manufacturing of U.S. products in (b) (4) and was decommissioned in (b) (4) However, (b) (4) Injection batches within expiry are still in the U.S. market.

Your correction to the prior Warning Letter (WL) regarding Workshop (b) (4) was inadequate. Specifically, review of airflow visualization study (AVS) revealed there was a failure to provide an accurate airflow pattern presentation of Workshop (b) (4) under both static and dynamic conditions.

A. "Transfer of (b) (4) " studies show the LAF (b) (4) internal and external airflow during (b) (4) movement in the Grade B area.

- In each of the "External Airflow" and "Internal Airflow" video, a smoke generator was strapped to the opening end of the LAF (b) (4) The smoke did not represent the actual Grade B cleanroom HEPA airflow as the actual airflow came from the ceiling HEPA filters. Also, the smoke velocity

SEE REVERSE OF THIS PAGE	Marvin D. Jones - Investigator Eileen A. Liu - Dedicated Drug Cadre	DATE ISSUED 07/16/2026

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appeared high and having a "jetting" effect. As a result, the smoke was being forced or blasted into the air stream instead of being carried by the actual Grade B HEPA airflow.

- There was no smoke coverage inside the (b) (4) during "Internal Airflow" study. The above study was to show that the Grade A (b) (4) internal airflow remained positive and laminar during (b) (4) movement. Without smoke coverage, the airflow inside the LAF (b) (4) cannot be visualized and assessed.

Observation #2

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 reports/investigations noted the following:

A) D1DR2025127C - dynamic environmental monitoring records were missing for (b) (4) Injection (USP) Batch #(b) (4) and (b) (4) Injection (USP) Batch #(b) (4) both products were manufactured in Workshop #(b) (4) Batch #(b) (4) was missing one filling record (two pages) which documented such information as product name, batch number, petri dish information, name of tester, time, sampling location, and test results. Batch #(b) (4) was missing one filling record (two pages) which documented product name, batch number, petri dish information, name of tester, time, sampling location, test results. This deviation refers to the loss of completed original records of personnel surface viable sampling records. The firm's investigational root cause was that the procedure "QC-775 030 Environmental Monitoring Procedure for Clean Area" did not specifically detail/describe the transfer of completed environmental monitoring records between production/QC departments. These original environmental records were never located which demonstrates a lack of control for critical original records.

B) D1DR2025174M – (b) (4) Injection (b) (4) mg Batch #(b) (4) was drafted incorrectly. Incorrect items included the theoretical volume, theoretical weight, the actual amount of (b) (4) added, the wrong expiration date, filling yield, and finished product yield. These records were reviewed by

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department head, effective department, and final approval was given by QA. These errors were attributed to the drafter (production) for these batch records.

C) D1DR2025190M - During review of the batch production records of (b) (4) Injection for Batches #(b) (4) in Workshop #(b) (4) numerous drafting errors were noted in the records upon review of completed batches. Errors discovered were such as; incorrect (b) (4) weight used to (b) (4) (b) (4) incorrect (b) (4) integrity test standard, incorrect calculation error of total preparation sampling volume, incorrect filling balance rate, incorrect product name entry error in (b) (4) (b) (4) integrity test. These records were reviewed by department heads, effective departments, and final approval was given by QA. These errors were attributed to the drafter (production) for these batch records.

D) D1DR2025317M – the electronic batch record for (b) (4) Injection Batch #(b) (4) was drafted incorrectly regarding the sampling of intermediates in the batch record lacked the microbial limit sampling before (b) (4) the methods/descriptions related to the laminar flow (b) (4) and the (b) (4) (b) (4) This batch record was reviewed by department head, effective department, and final approval was given by QA. These errors were attributed to the drafter (production) for these batch records.

Observation #3

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

Specifically,

A) A review of (b) (4) Injection (b) (4) mg Batch #(b) (4) with expiration date (b) (4) manufactured in Workshop #(b) (4) noted various critical processing range limits are not specified in the batch record, such as; (b) (4) Additionally, several critical processing parameters are not document with actual values (check mark only) and values that are recorded are inaccurate because no acceptable processing ranges are documented in the batch record.

B) A review of (b) (4) Injection (b) (4) mg/mL Batch #(b) (4) with expiration date (b) (4) manufactured in Workshop #(b) (4) noted various critical processing range limits are not specified in the batch record, such as;

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(b) (4) Additionally, several critical processing parameters are not document with actual values (check mark only).

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