DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/ Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	01/26/2026-02/03/2026
	FEI NUMBER 3004518843
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Vicky Xu, CEO	
FIRM NAME Chinese Peptide Company	STREET ADDRESS No. 69, 12 Street, Hangzhou Economic and Technological Development Zone
CITY, STATE, ZIP CODE, COUNTRY Hangzhou, Zhejiang, China 310018	TYPE ESTABLISHMENT INSPECTED Drug Substance 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

There is a lack of assurance that your drug substance (DS) manufacturing operations are appropriately designed to ensure the prevention of contamination of equipment or product by environmental and processing conditions that would be expected to have an adverse effect on product quality.

Specifically,

A. Your documented multiproduct manufacturing risk assessments, RA-2022-12 (version 6, approve date 20-JAN-2026) and RA-23004 (version 2, approve date 26-SEP-2025) are deficient. For example,

   i. The risk assessment failed to identify or appropriately evaluate the potential cross-contamination risks associated with (b) (4) processes performed in the DS manufacturing areas. Specifically, (b) (4) operations are performed during the (b) (4) of (b) (4) DS, including (b) (4) (b) (4) operations. These (b) (4) operations were performed without adequate protection of exposed product to the Grade D environment.

   ii. The risk assessment failed to evaluate potential contamination risks resulting from product spills and leakages occurring on non-product contact equipment surfaces or within surrounding and supporting manufacturing areas. On 27-JAN-2026, during observation of (b) (4) DS (b) (4) operation, leakage from (b) (4) was observed. No mitigation actions were taken immediately to ensure and demonstrate the removal and inactivation of the materials leaked onto the manufacturing floor.

   iii. Your cleaning validation (CV) risk assessment failed to consider manufacturing equipment's actual condition of use. For example, you consider the (b) (4) cover of (b) (4) Tank in the

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(b) (4) room (b) (4) not product contacting and therefore not requiring swabbing during CV. However, according to your manufacturing floor SME, the cover could contact the product during the transfer of the (b) (4)

B. Your cleaning validation and verification program for manufacturing process equipment is inadequate to prevent cross-contamination. For example,
   i. No data were generated to support the use of visual inspection on the cleanliness of the equipment, including (b) (4)
   ii. Swab sampling locations are not clearly defined for your cleaning validation studies.

C. Your firm lacks an established cleaning and sanitization program to prevent the introduction of microbial contamination into controlled DS manufacturing environments. In particular,
   i. Your disinfectant efficacy studies such as 96-1041R (version 0, approve date 13-AUG-2025), 96-0775R (version 0, approve date 13-MAY-2025), and 96-0991R (version 1, approve date 31-DEC-2025), do not adequately support the sanitization procedures for the antimicrobial and sporicidal effectiveness of the disinfectants and sporicidal agents for all representative manufacturing surfaces. For examples, materials of construction for (b) (4) interior surfaces and (b) (4) refrigerators, and unspecified (b) (4) were not included in the studies.
   ii. The cleaning and sanitization procedures for the Grade D areas of the DS manufacturing facility [SOP 10-0060 (version 40, effective date 31-DEC-2025)] lack sufficient details regarding wetted (contact) time to enable reproducibility. In addition, the SOP does not require documentation of the contact time in the cleaning logbooks during facility cleaning and sanitization.

D. During the walkthrough inspection of the drug substance manufacturing areas in your facility, the following deficiencies were observed:
   i. Multiple pieces of equipment are present during the (b) (4) operation stage of (b) (4) including (b) (4) The equipment remains in place during cleaning of the (b) (4) room after batch production. Consequently, there is no assurance that all areas are adequately cleaned and free of cross-contamination.

ii. (b) (4) particulates or stains were observed at the inside bottom surfaces of (b) (4) refrigerators (Equipment IDs: (b) (4) Additionally, cracks were observed in refrigerator ID (b) (4) These refrigerators are used to store (b) (4) (b) (4), including (b) (4)

iii. (b) (4) plates were observed positioned beneath the (b) (4) systems to distribute heavy loads. These plates created uneven surfaces in the vicinity of the (b) (4) system and could not be easily cleaned. There is no assurance that your current cleaning procedures are adequate to remove potential contaminants from under or around these plates.

E. (b) (4) systems used in the manufacturing of DS (b) (4) is not properly maintained to assure the (b) (4) is free of contamination. For example,

i. (b) (4) drainage was observed having slow moving or stagnant (b) (4) near the (b) (4) system and storage tanks. (b) (4) was observed discharging directly into the drainage near the (b) (4) storage tank. Black (mold like) stains were clearly visible where the (b) (4) pipe is located.

ii. Container used to (b) (4) was placed near proximity to the facility cleaning tools including brooms and cloth mops. The container had no lid and was placed on the floor upside down.

iii. Tubing is used to connect (b) (4) system with (b) (4) systems (b) (4) in the (b) (4) room (b) (4) It was observed to remain connected to the (b) (4) systems while the systems were not in use. According to your manufacturing floor SME the tubing is not routinely replaced. The requirement and procedure to rinse, clean, dry, and testing the tubing were not described in SOP 04-0569 (version 3, approve date 20-NOV-2023) and such actions were not documented.

OBSERVATION 2

Your firm has not established adequate procedural and technical controls to protect the electronic data acquisition systems used for the manufacture of (b) (4) DS in your manufacturing facility.

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Specifically,

A. Partial performance qualification (PQ) of the (b) (4) system was conducted after the drug substance Process Performance Qualification (PPQ) batches were manufactured and tested for release. Critical functions such as user permission and system administrative permission settings, user's ability to delete data and methods, data storage, and audit trail were not fully validated until the PQ was approved on 03-OCT-2021.

B. The (b) (4) analytical method used to measure (b) (4) content for the release testing of PPQ batches was not verified prior to use for such testing. No system suitability information was generated for the (b) (4) testing. The use of unverified method for PPQ batch release testing provides no assurance that the test results are accurate or reliable.

C. Excel templates are used to calculate quality control (QC) analytical testing results. The calculation results are not retained in the electronic form and cannot be traced to the analyst who performs the calculation. The printed copy cannot be traced to the time of calculation, and the signature cannot be verified or reviewed.

D. During walkthroughs of manufacturing areas, a use of (b) (4) timers (b) (4) (b) (4) to record time in batch record was observed. There are no instructions in batch record or operating procedures to use the (b) (4) timers to measure and record time in batch records. Timers used to record time in the batch records or test record in the manufacturing areas and QC laboratory are not initially qualified, and (b) (4) drifts are allowed.

E. During a walkthrough of the reference standard storage room (b) (4) an employee was observed to make an incorrect entry to the reference standard freezer Instrument/Equipment Log, ID 2009102704. Specifically, incorrect date was entered in the Instrument/Equipment Log 'date end', which was immediately overwritten to indicate the correct date. SOP 01-0004 Record Control Procedure, rev.27, date effective: 16-JAN-2026 instructs employees to "cross out the erroneous item by drawing a straight single line through the item, to keep the original content legible. Correct

clearly near the item, and make a remark about the correction reason, with signature and date of the correction."

F. Unique user account and password were not set up for the analysts who use the Sartorius electronic balance in the QC lab to conduct QC testing.

G. Procedures and technical controls are not established to effectively control and detect unauthorized use of analytical samples and reference standards, creating opportunities for selective reporting or unauthorized testing.

H. (b) (4) check of (b) (4) user account information (conducted (b) (4) by IT personnel [SOP 04-0842 (version 2, approve date 25-JUL-2024) does not detect user account changes that occur during (b) (4) allowing potential unauthorized access or privilege changes to go undetected for up to (b) (4)

I. The snapshot function is enabled for (b) (4) Analysts can process analytical runs using this function before the run or the sequence is completed, allowing potential manipulation of integration parameters, reprocessing of data, or aborting unfavorable results before final results are recorded in the official record.

OBSERVATION 3

Your firm lacks adequate assurance that the critical process equipment, used for the manufacturing of (b) (4) DS, is maintained in a validated state.

Specifically,

A. You failed to perform proper PQ studies for the (b) (4) Specifically,
   i. No (b) (4) was conducted.

ii. (b) (4) range/limits were not supported by data.

iii. (b) (4) limits provided in the (b) (4) were not the same as the limits provided in the equipment qualifications.

iv. You failed to demonstrate that (b) (4) was qualified and challenged under the worst-case conditions.

OBSERVATION 4

Your firm failed to prepare batch production records to include complete information relating to the accomplishment of each significant step in the manufacture of the batch, for each batch of (b) (4) DS.

Specifically,

A. Your manufacturing floor SME stated that after addition of (b) (4) starting material, (b) (4) is used to (b) (4) (Equipment ID (b) (4) via (b) (4) (b) (4) However, such step was not documented in the executed batch records including PPQ batches and recent batch records including Batch (b) (4)

B. During a mock run of the (b) (4) procedure per MBR (b) (4) an operator (b) (4) which was used to (b) (4) . (b) (4) is not specified in the manufacturing procedures or batch manufacturing records (e.g., Section 5.3.1.2 (b) (4) of the MBR). Your manufacturing floor SME stated that the (b) (4) step is routinely performed during manufacturing process. However, it is not specified and not documented in the batch records.

OBSERVATION 5

Standard operating procedures or work instructions are not followed or are inadequate.

Specifically,

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A. During a QC laboratory walkthrough, data processing for (b) (4) using SOP 50-1033 Standard Test Procedure for Related Substance and Assay Determination of (b) (4) by HPLC, rev. 3, date effective: 30-OCT-2025, was observed. Reference standard samples and the product test samples were processed differently resulting in different peaks being integrated. The SOP 50-1033 does not specify that the reference standard and the test samples should be processed to assure consistent integration.

B. During a walkthrough of the (b) (4) Room (b) (4) a (b) (4) sampling procedure was observed. A portion of (b) (4) was collected and transferred to a test tube using a sampling tool. The quantity of (b) (4) for in-process testing during (b) (4) is not specified in the SOP 50-0050 or batch records and was not confirmed during sampling.

C. During an in-process (b) (4) test in the (b) (4) Room (b) (4) an operator did not perform an inspection of (b) (4) used for in-process testing (b) (4) as required per SOP 50-0050 (b) (4) Testing, rev.7, date effective 31-MAY-2021. SOP 50-0050 states (b) (4) (b) (4)

D. No risk assessment or gap analysis was performed to waive the requirement for method verification for appearance testing.

E. Time observed on select devices (e.g., computers, (b) (4) systems, balances) in the manufacturing areas was different. SOP 07-0023 Standard Operating Procedure for Time Calibration, rev. 6, date effective 31-MAY-2024, requires (b) (4) calibration of "instruments and meters that are not connected to the NTP time server."

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