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	04/27/2026-04/30/2026
	FEI NUMBER 3015314582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Meng Zhang, Site Head

FIRM NAME	STREET ADDRESS
Jilin Asymchem Pharmaceuticals Co., Ltd.	No. 599, Xingqi Road, High-Tech Industrial Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dunhua, Jilin, 133700, China	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 I OBSERVED:

OBSERVATION 1

Written procedures for cleaning and calibration of equipment are not adequately described or fully followed.

Specifically,

A. The cleaning validation program does not include analytical verification for all equipment. For example, the cleaning validation conducted for (b) (4) drug substance did not include sampling or analytical verification of non-dedicated (b) (4) to validate the exclusion of this (b) (4) from sampling and ensure that the cleaning processes can achieve cleaning down to analytically acceptable levels. This (b) (4) is used in the (b) (4) step during the manufacture of the drug substance.

B. Equipment used during the manufacture of drug substances are not routinely calibrated to verify their performance. The (b) (4) related to at least (b) (4) used during the manufacture of (b) (4) intermediates and drug substances has not been recalibrated or verified since their qualification in 2019. (b) (4) is a defined parameter that is recorded in (b) (4) steps throughout the drug substance manufacturing process.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Joseph A Piechocki	Joseph A. Piechocki, Investigator	04/30/2026

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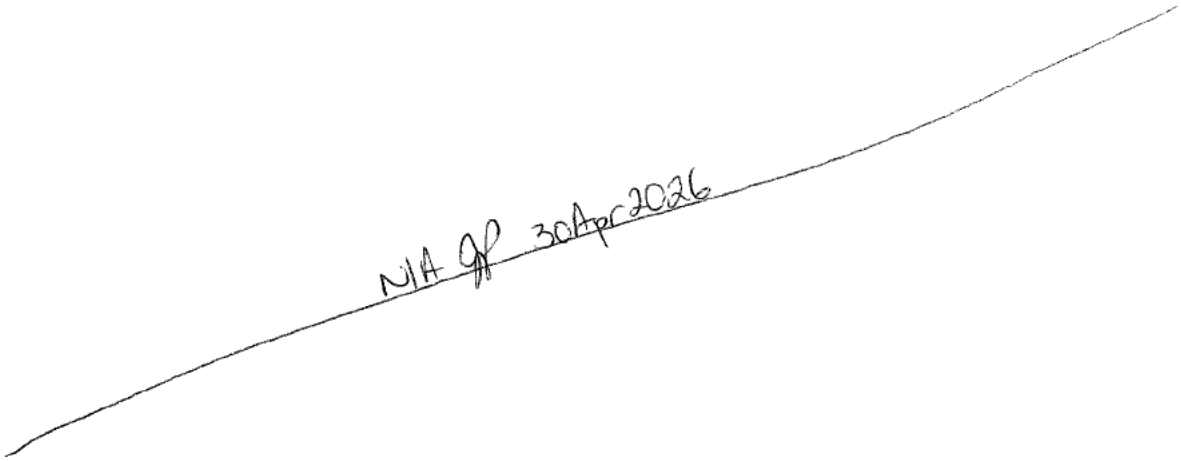
OBSERVATION 2

Process validation activities do not adequately demonstrate that the manufacturing process can reproducibly manufacture drug substance meeting predetermined quality attributes.

Specifically,

The homogeneity testing conducted during the initial process performance qualification (PPQ) of the drug substance (b) (4) assessed the material for assay, related substances, residual solvents, and water content. However, particle size distribution testing was not included as part of the homogeneity testing (including for the (b) (4) material), which is a quality attribute on the release specification.

Furthermore, a (b) (4) process was implemented for the drug substance due to downstream processing issues attributed to the particle size of the drug substance. The (b) (4) step for the (b) (4) of the drug substance was additionally changed to improve the particle size; however, the homogeneity assessment during the subsequent PPQ was not reperformed for particle size. In addition, homogeneity (including particle size) was conducted as part of the (b) (4) PPQ, however, this process is not identical to the original manufacturing process and therefore does not represent the homogeneity of a batch without (b) (4)



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	Joseph Piechocki	Joseph A. Piechocki, Investigator	04/30/2026