DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 (b) (4)	6/8/2026 – 6/12/2026
	FEI NUMBER 3003802432

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Zhang Hanchang, General Manager

FIRM NAME	STREET ADDRESS
Qilu Pharmaceutical Co., Ltd. (High Tech Zone Site)	317 Xinluo Road High Tech Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jinan, Shandong, 250101 China	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.

OBSERVATION 1

Equipment used in the manufacturing of drug products has not been demonstrated to be suitable for its intended use.

Specifically, your firm failed to adequately qualify the operational parameters of critical manufacturing equipment to reflect actual routine production conditions. The (b) (4) for (b) (4) machine (b) (4) Equipment #(b) (4) used during (b) (4) processes, was qualified at operational ranges of (b) (4) However, a review of executed exhibit batch records indicates that production is executed at (b) (4) range of about is identified as a critical process parameter). Similarly, the (b) (4) rate for the same equipment was qualified at (b) (4) however, review of executed exhibit batch records revealed that during production it was executed at (b) (4)

OBSERVATION 2

Failure to establish and follow adequate written procedures for production and process controls designed to assure that drug products have the identity, strength, quality, and purity they purport to have.

Specifically,

A- No scientific or technical justification has been provided to support the wide operational ranges established on the Master Production Record. Furthermore, these ranges do not reflect actual or expected routine process conditions, as observed by differences between the proposed parameters and actual values observed in executed exhibit batch records.

B- Your firm's hold time validation studies are not representative of actual routine manufacturing operations and fail to evaluate the worst-case condition of bulk solutions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE)	DATE ISSUED
	TEKALIGN WONDIMU -S Digitally signed by TEKALIGN WONDIMU -S Date: 2026.06.11 20:58:41 -04'00'	Tekalign Wondimu, Investigator	6/12/2026

FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 (b) (4)	DATE(S) OF INSPECTION 6/8/2026 – 6/12/2026 FEI NUMBER 3003802432
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Zhang Hanchang, General Manager	
FIRM NAME Qilu Pharmaceutical Co., Ltd. (High Tech Zone Site)	STREET ADDRESS 317 Xinluo Road High Tech Zone
CITY, STATE, ZIP CODE, COUNTRY Jinan, Shandong, 250101 China	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

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OBSERVATION 3

Your firm failed to establish laboratory controls that include the use of reference standards having appropriate identity, strength, quality, and purity.

Specifically, working reference standards received from your Gongbei Research and Development (R&D) site are released for use based solely on accompanying Certificate of Analysis (CoA), without analyzing for identity and purity prior to use.

For example, in May 2026, you received (b) (4) vials of (b) (4) USP batch # (b) (4), from the Gongbei R&D site for use as working reference standard for (b) (4) Capsule assay testing. Quality Control records demonstrated that these reference standards were accepted and released for use based solely on accompanying certificate of analysis, without proper laboratory analyses.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (PRINT OR TYPE)	DATE ISSUED
	TEKALIGN WONDIMU -S Digitally signed by TEKALIGN WONDIMU -S Date: 2026.06.11 20:59:12 -04'00'	Tekalign Wondimu, Investigator	6/12/2026

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 judgement, 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."