DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DBM, 10903 New Hampshire Avenue; White Oak Building 22 Silver Spring, MD 20993 E-mail: CDER-OC-OMQ-International483Response@fda.hhs.gov	10/27,28,29, 30, and 10/31/2025 FEI NUMBER 3006532186

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Wang Liquan (also known as David Wang), General Manager/Site Head

FIRM NAME	STREET ADDRESS
Lonza Guangzhou Pharmaceutical Ltd.	68, Huangge Dadaobei
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Nansha District, Guangzhou Guangdong, 511455, CHINA	API Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of you0r 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

The responsibilities applicable to the quality unit are not fully followed.

Specifically,

a. Since the year 2023, approximately (b) (4) batches of (b) (4) API (code (b) (4) were released to the U.S. market without assurance that they had safety levels of (b) (4) impurities (e.g., (b) (4)

b. Since the year 2023, approximately (b) (4) batches of (b) (4) API (code (b) (4) were released to the U.S. market without assurance that they had safety levels of (b) (4) impurities (e.g., (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jose M. Cayuela	Jose M. Cayuela, Investigator	10/31/2025

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OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure to of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

The quality unit failed to provide adequate complaint investigations. For example,

a. The complaint investigation associated to the presence of black particles during the use of (b) (4) API, batch (b) (4) (code (b) (4) for drug product manufacturing failed to evaluate the reserve/retention samples and failed to require the black particles to the complainant to find the root cause. Neither the root cause was identified nor corrective and preventive actions were established. (b) (4) API batch (b) (4) was released for the U.S. market in (b) (4) (b) (4)

b. The complaint investigation associated to the presence of foreign matters during the use of (b) (4) API, batch (b) (4) (code (b) (4) for drug product manufacturing failed to evaluate the reserve/retention samples and failed to require the foreign matters to the complainant to find the root cause. Neither the root cause was identified nor corrective and preventive actions were established. (b) (4) API, batch (b) (4) (code (b) (4) was released for the U.S. market in (b) (4) (b) (4)

OBSERVATION 3

The quality system that approves contract laboratories to perform testing of (b) (4) impurities is deficient.

Specifically,

The quality unit fails to ensure that the contract laboratory used to perform testing of (b) (4) content in (b) (4) API (code (b) (4) has the capabilities, equipment, and the knowledge to perform the required testing in an accurate, precise, and reliable way.

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		Jose M. Cayuela, Investigator	10/31/2025