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	03/10,11,12,13, and 03/14/2025
	FEI NUMBER 3018262809

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Zhenzhong Lyu, Quality Manager

FIRM NAME	STREET ADDRESS
Merck Life Science Technologies (Nantong) Co. Ltd	No. 39 Jianggang Road NETDA
CITY, STATE, ZIP CODE, COUNTRY Nantong, Jiangsu, 226017, China	TYPE ESTABLISHMENT INSPECTED Excipients and 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

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

Specifically,

a) Since the year 2023 to 2025 [redacted (b) (4)] received customer complaints due to particulates contamination (3 batches) and presence of endotoxins (1 batch). The quality unit failed to conduct thorough investigations in all of the complaints reported; because, in none of them the root cause of the complaint was identified, the reserve/retention sample was evaluated, neither corrective actions nor preventive actions were established.
b) The current complaint SOP QM039, Complaint Management Procedure, version 8.0, effective date 10/28/2024 is deficient in requiring thorough investigations that could include the evaluation and/or testing of the reserve /retention samples in order to find the root cause.
c) The quality unit failed to identify the black foreign material found on the testing in [redacted (b) (4)] tank sample in order to determine the root cause regarding to the deviation record 4033841.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of products purporting to be non-sterile are not established.

Specifically, the quality unit fails to ensure that the laboratory samples to be tested for microbiological content and pathogens identification (e.g., [redacted (b) (4)] water, environmental monitoring, and [redacted (b) (4)] [redacted (b) (4)] products) are not jeopardized and/or microbiologically inactivated when they are transferred

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	03/14/2025

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from the microbiology laboratory to the inside of the testing rooms throughout (b) (4) that have (b) (4)

OBSERVATION 3

The written stability program fails to assure testing of the API products in the same container -closure system as that in which the products are marketed.

OBSERVATION 4

The amount of material taken from each container is not based upon appropriate criteria.

Specifically,

The quality unit fails to ensure that the amount of material taken for testing is based upon appropriate criteria such as criticality of the material, material variability, past history of the supplier, and the quantity needed for analysis.

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	José M. Cayuela	Jose M. Cayuela, Investigator	03/14/2025