DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov CVM-483-Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/24/2025-02/28/2025, 03/03/2025
	FEI NUMBER 3008617115

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Yao Ligao, Director of the Board

FIRM NAME	STREET ADDRESS
Zhejiang Guobang Pharmaceutical Co., Ltd.	No. 6 Weiwu Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Shaoxing, Zhejiang Province, 312300, P.R. China	Active Pharmaceutical Ingredient 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) (WE) OBSERVED:

OBSERVATION 1

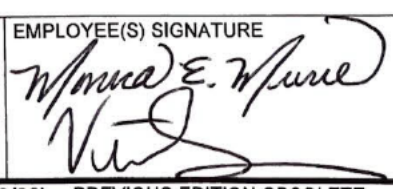
Laboratory controls lack scientifically justified and appropriate specifications and test procedures necessary to ensure that components meet established standards for identity, quality, and purity.

Specifically, (b) (4) water is utilized in the critical cleaning of equipment in classified rooms during the manufacturing processes of your drug substances. (b) (4) water was also used as a component in the manufacturing of drug substances including, but not limited to, (b) (4) Batch (b) (4) released and shipped to the US market.

A. USP compendial methods recognize that scientific standards for culturing (b) (4) water samples include sample sizes of up to (b) (4) mL for (b) (4) Your firm has not justified that the (b) (4) mL sample of (b) (4) water currently tested for microbial monitoring of (b) (4) sampling locations is appropriate to derive statistically valid colony counts at your site. Additionally, your firm has not validated that a (b) (4) mL sample taken for (b) (4) adequately captures all microbial colonies present in the larger (b) (4) mL sample collected at each (b) (4) water (b) (4)

B. Your firm has failed to detect and enumerate microorganisms that have been released by potential biofilms within your (b) (4) water system to evaluate the overall state of control of the (b) (4) water system. Current method validation studies do not include additional organisms typically isolated from the (b) (4) water system (house isolates) since your firm does not identify the normal microbiome.

C. Your firm's (b) (4) water specification is not scientifically justified to exclude objectionable microorganisms from the (b) (4) water samples cultured during the tests for Total Aerobic Microbial Count (TAMC) and Total Bacteria, Molds and Yeasts Count (TYMC). The microbial specifications for (b) (4) water include "Total Viable Count <= (b) (4) cfu/mL", "Total Aerobic Microbial Count <= (b) (4) cfu/mL", "Total Bacteria, Molds and Yeasts

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Monica E. Murie, Investigator Victoria Spivak, Investigator	03/03/2025

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Count <=(b)(4) cfu/mL", and "Specified Microorganisms: Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus should be(b)(4) per(b)(4) mL of water sample". Your firm has failed to speciate recoveries found on TAMC and TYMC(b)(4) to determine if the specified objectionable microorganisms or other pathogenic bacteria are present in your(b)(4) water system below alert and action limits.

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	Monica E. Murie Victoria Spivak	Monica E. Murie, Investigator Victoria Spivak, Investigator	03/03/2025

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."