DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857, CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	11/17/2025 - 11/21/2025
	FEI NUMBER 3008539577

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ronald Eulenberger, Managing Director

FIRM NAME	STREET ADDRESS
Wacker Biotech B.V.	Paalbergweg 2
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
1105 AG Amsterdam, Netherlands	Drug Substances 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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, sample containers used to collect endotoxin test samples, including finished drug substances, are not made of suitable materials to ensure reliable and accurate results. The firm uses sample containers made of (b) (4) to collect endotoxin samples for batch release testing and held up to (b) (4) prior to testing. No endotoxin recovery studies were performed to verify suitability of the sample containers, and to ensure (b) (4) container surfaces do not interfere with the endotoxins in the sample. Endotoxins (b) (4) are known to have affinity to adhere to (b) (4) materials, potentially resulting in false negative results.

OBSERVATION 2

Input to and output from the electronic records and data are not checked for accuracy.

Specifically, electronic test records from (b) (4) Integrity Test (b) (4) units are not reviewed or reconciled against the printed test reports and failed test results are not always identified or reported in the associated batch production records. Failed (b) (4) integrity test reports are not always printed or included in the associated batch production records and not reviewed to ensure compliance to written retesting requirements. The written test procedure allows maximum of (b) (4) integrity tests per (b) (4), including (b) (4) re-tests after initial failed test result.

Following failed (b) (4) reports obtained from the stored electronic data were observed to be missing from the production batch records for (b) (4) dug substances, Batch# (b) (4):

A. Initial failed (b) (4) results for (b) (4) on the drug substances (b) (4) Filling operation was not

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		Junho Pak Investigator	11/21/25

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included in the batch records

B. (b) (4) failed (b) (4) results during the (b) (4) step were not included in the batch records.

C. (b) (4) failed (b) (4) results during the (b) (4) step were not included in the batch records.

OBSERVATION 3

Laboratory testing procedures lack sufficient testing requirements to ensure accurate and scientifically sound determination of the test materials.

Specifically, there are no incubation time requirements listed in the written procedures to initiate the growth test for exposed biological indicators. Iincubation time requirements are not listed in the (b) (4) qualification protocol/report and exposed biological indicators were not placed on test for extended period of time. Biological indicators from (b) (4) qualification performed on (b) (4) were not placed on test until (b) (4), approximately (b) (4) later. (b) (4) is used to perform sterilization on production equipment components, including the (b) (4) assembly used during for the (b) (4) drug substance filling operation.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically, during the execution (b) (4) dug substances manufacturing, Batch# (b) (4) required pre-production environmental monitoring (EM) was not performed as specified in the procedure #SOP-XMS-8000.MF, including Airborne Viables and Non-Viable Particle monitoring of the production Laminar Flow Hood. Pre-production EM for the batch filling operation was performed during (b) (4) (b) (4) prior to drug substances filling operations. As stated in the written procedure, pre-production EM is required to be performed during (b) (4)

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OBSERVATION 5

Written procedures are not established for the cleaning and maintenance of equipment used in the manufacturing, processing, or holding of a drug product.

Specifically, equipment cleaning procedures do not include drying procedures or designated equipment holding area to prevent residual liquid solution (b) (4) from dripping into the classified production area. During the walkthrough of the production area, recently cleaned production (b) (4) tank (equipment# (b) (4) 1300) was observed dripping liquid into the classified area (Grade D), pooling under the equipment. This recently cleaned equipment was staged in the production corridor with the (b) (4) valve in open position to drain. Liquid (b) (4) in the classified area could potentially allow proliferation of microorganisms, including bacteria and mold.

N/A 11/21/25

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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."