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	2/3/2025 - 2/7/2025
	FEI NUMBER 3002807778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jon Gabriel Noddeland

FIRM NAME	STREET ADDRESS
GE HealthCare	Lindesnesveien 208
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lindesnes, 4521, NORWAY	API 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

Deviation investigations are not conducted thoroughly to identify root cause(s) and insufficient CAPA actions were implemented to prevent reoccurrences.

Specifically, multiple deviation investigations were initiated for endotoxins detected in the API process intermediates, during the manufacturing of (b) (4) API (b) (4) Endotoxins were detected from multiple batches of API products manufactured between Feb 2022 to May-Sept 2024, initiating at least six (6) deviations. Each observed endotoxin event was investigated with deviation investigation, and CAPAs were identified or implemented. The investigations failed to identify the root cause(s) and source(s) of the observed endotoxins in the manufacturing process and implemented CAPA actions did not mitigate the endotoxin from the production process/equipment. CAPA actions identified from the investigation initiated for endotoxins detected on the latest (b) (4) API (b) (4) batches (May-Sept 2024), have not been implemented to date.

Between Feb 2022 to Sept 2024, following deviation investigations were initiated for endotoxins detected during the manufacturing of (b) (4) API (b) (4) product/intermediates:

- PR444720, initiated on 16Feb2022, impacting batch no. (b) (4)
- DEV-03494 (PR471820), initiated on Sept 2023, impacting batch no. (b) (4)
- DEV-03495 (PR472566), initiated on Oct 2023, impacting batch no. (b) (4)
- DEV-07580 (PR475000), initiated on Nov 2023, impacting batch no (b) (4)
- DEV-10764 (PR478137), initiated on Feb 2024, impacting batch no. (b) (4)
- DEV-13365, initiated for multiple batches: 02May2024 for batch# (b) (4) 21May24 for Batch# (b) (4); 04Jun24 for Batch# (b) (4); 20Aug24 for Batch# (b) (4); 10Sep24 for Batch# (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Junho Pak, Investigator	02/07/2025

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	2/3/2025 - 2/7/2025
	FEI NUMBER 3002807778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jon Gabriel Noddeland

FIRM NAME	STREET ADDRESS
GE HealthCare	Lindesnesveien 208
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lindesnes, 4521, NORWAY	API Manufacturer

OBSERVATION 2

Lack of appropriate controls to prevent contaminations of manufactured drug substances.

Specifically,

A. The exhaust from the dust collector used during the API filling operations are not filtered adequately, and not vented outside the production area. The blower unit for the dusk collector is located in the common production area and does not have an external exhaust vent. Additionally, the air filtration system within the blower unit does not adequately capture drug particles from the filling operations and the drug particles are exhausted inside the common production area. The blower/filtration unit was observed with coating of (b) (4) particles, resembling drug substances, and visible (b) (4) particles were observed in the surrounding manufacturing area. The blower unit is equipped with general particle filter and not a HEPA filtration system.

B. Manufactured product containers were not protected to prevent contamination and debris. The finished drug substance (API) containers staged for filling operations for [redacted] in Building (b) (4) were observed without protective covers (b) (4) There were no protective barriers over the open container tops, lined with (b) (4) bags, and the lined product containers were exposed to the room environment without any protection from falling debris or environmental contaminants. These open API product containers were observed in the filling room and the adjacent staging room and remained in this condition until the start of the filling operation (b) (4)

OBSERVATION 3

Annual product quality reviews were not conducted as per the written procedure.

Specifically, annual Product Quality Review (PQR) reports were not issued and approved within the timelines specified in the written procedure, SOP# LIU 0463, "Annual Evaluation of Product", version 7.0. As per the written procedure, PQR reports are to be reviewed and approved by (b) (4) (b) (4) All four APR reports I reviewed were approved and made

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Junho Pak, Investigator	02/07/2025

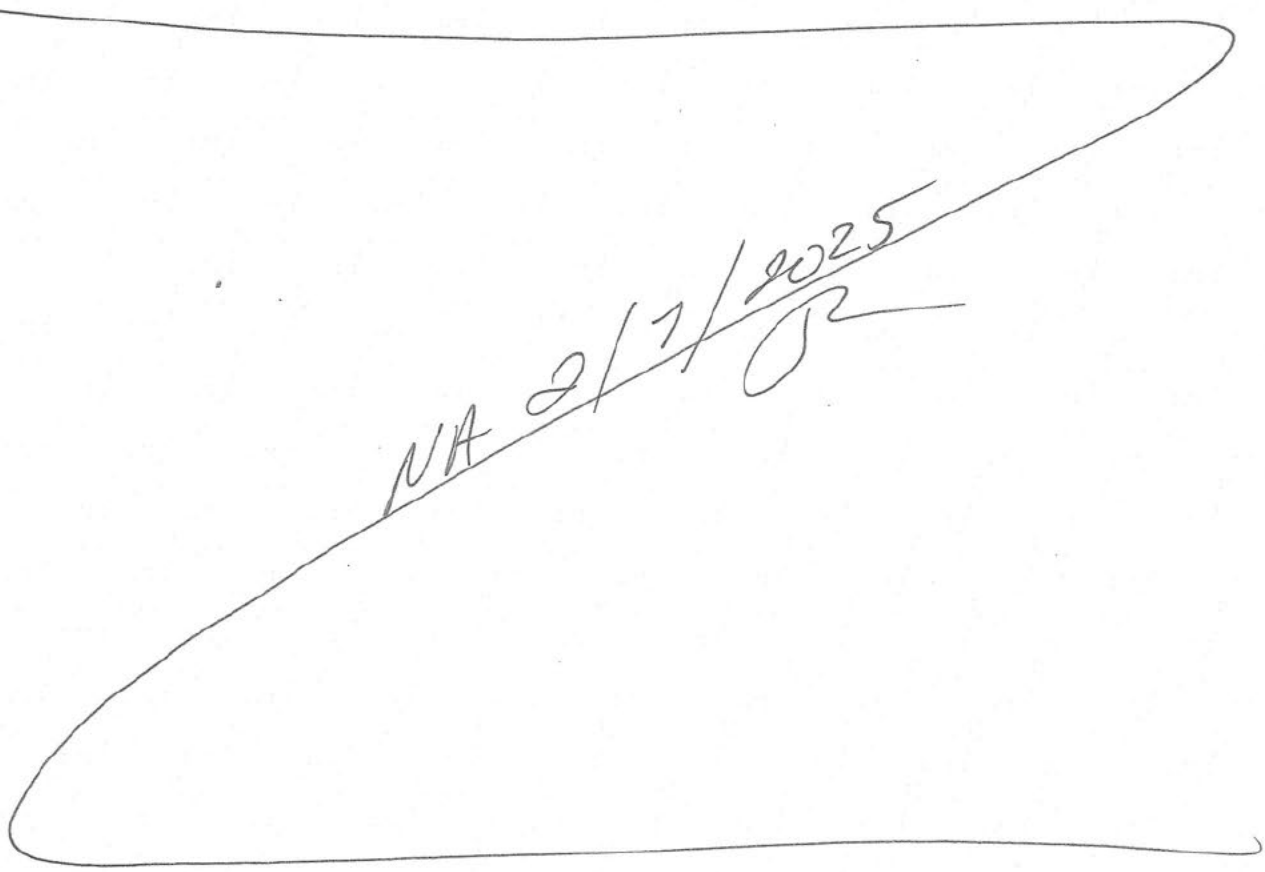
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857, CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	2/3/2025 - 2/7/2025
	FEI NUMBER 3002807778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jon Gabriel Noddeland

FIRM NAME	STREET ADDRESS
GE HealthCare	Lindesnesveien 208
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lindesnes, 4521, NORWAY	API Manufacturer

effective after the required approval date of (b) (4) and one of the PQR report (b) (4) (b) (4) PQR report) was not approved until (b) (4) after the required approval date. Additionally, there are no written requirements for the annual PQR reports to be approval by the top management for the site, and the Site Head did not sign/approve any of the four PQR reports I reviewed.



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Junho Pak, Investigator	02/07/2025

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."