DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Pharmaceutical Manufacturing Assessment 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	01/09 - 17/2025 FEI NUMBER 3003809840

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Cian O'Brien, Site Head - Sanofi Waterford, Ireland [redacted]

FIRM NAME	STREET ADDRESS
Genzyme Ireland Limited	Unit 701 IDA Industrial Park, Old Kilmeadon Rd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Waterford, Ireland X91 TP27	Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1: Procedures, process and testing designed to prevent microbial contamination of the drug product purporting to be sterile are not established. Specifically,

a. As observed on 16 January 2025 for assembly of the stoppering system to the [redacted] Fill Line [redacted] for [redacted] drug product manufacture Batch [redacted] you did not perform the [redacted] setup of the [redacted] in an aseptic manner. Specifically, you did not maintain sterility of the stoppering equipment [redacted] sterilized by [redacted] during [redacted] and instead you rely on sanitization of the [redacted] component contact equipment (e.g., [redacted] stopper bowl and [redacted] with [redacted] to render it ready for aseptic fill-finish.

You further failed to sanitize the [redacted] upon [redacted] into Grade A space from Grade C space for each [redacted] event. Additionally, you failed to conduct smoke studies for the stoppering system installation [redacted] interventions.

b. As observed on 13 January 2025 for the [redacted] setup of the [redacted] for [redacted] drug product batch [redacted] the following deficiencies were noted:

• An operator was observed using a sanitized [redacted] glove during assembly of the [redacted] sterilized [redacted] to the sanitized [redacted]

• During assembly of each of the sterile [redacted] to the [redacted] drug product [redacted] an operator was observed touching the connection interface, blocking first air (unidirectional laminar air flow) over the [redacted] with the sanitized [redacted] glove, with [redacted] and [redacted] touching the [redacted] glove.

• The [redacted] located directly over the oper [redacted] during manufacture is a sanitized surface, not sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Wayne Seifert Andrea Franco	Wayne Seifert, Senior Regulatory Specialist Andrea Franco, Pharmaceutical Scientist	01/17/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Cian O'Brien, Site Head - Sanofi Waterford, Ireland [redacted (b) (4)]

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You failed to maintain or provide manufacturing surfaces intended to be sterile in assurance of product sterility.

Observation 2: The [redacted (b) (4)] systems in support of [redacted (b) (4)] drug product manufacture are not adequately maintained. Specifically,

On 09 January 2025, the following was observed:

a. [redacted (b) (4)] on the floor at the [redacted (b) (4)] skid, below the [redacted (b) (4)] system.
b. A [redacted (b) (4)] leak at the [redacted (b) (4)] supply to the [redacted (b) (4)] analyzer.
c. [redacted (b) (4)] dripping from the multiple [redacted (b) (4)] distribution tank (Tank [redacted (b) (4)] from the manway.
d. [redacted (b) (4)] on the floor below the [redacted (b) (4)] below [redacted (b) (4)]

Observation 3: A standard operating procedure was not followed. Specifically,

a. According to QU-SOP-0056623, "Monitoring of [redacted (b) (4)] in the [redacted (b) (4)] Facilities and the Aseptic Processing Workshop", v4.0, Section 5.6, Tracking Out of Trends (OOT) for [redacted (b) (4)] the instruction is to record the OOT details in logbook [redacted (b) (4)] 000426. There was no logbook available for documenting the [redacted (b) (4)] OOTs and for trending.

b. According to QU-WIN-0034155, "Data Integrity", v13.0. Section 5.4, Logbook Reviews, upon completion of the final activity on the page, the page review must be conducted by an independent person. You failed to complete the page review for the following logbooks:

- Internal Sample Request Logbook ENV24000691
- Inspection Hood Measurement Logbook ENV240000545
- Cold Room Entry/Exit Logbook ENV240000825

Observation 4: Equipment used in the QC Microbiological Lab is not adequately maintained. Specifically,

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	[signature] Andrea Franco	Wayne Seifert, Senior Regulatory Specialist Andrea Franco, Pharmaceutical Scientist	01/17/2025

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On 15 January 2025, Laminar Flow Hood LAF [redacted] (b) (4) used in in-process control bioburden testing was observed with the [redacted] (b) (4) HEPA filter screen discolored, with the same observed for many other LAF units. You indicated the discoloration was rust. You failed to maintain the qualified state.

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SEE REVERSE OF THIS PAGE	Andrea Franco	Wayne Seifert, Senior Regulatory Specialist Andrea Franco, Pharmaceutical Scientist	01/17/2025