DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office One Montvale Ave CDER-OC-OMQ-International483Response@fda.hhs.gov	04/29/2026-05/08/2026 FEI NUMBER 3013702557
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ms. Lisa Graver, Chief Executive Officer	
FIRM NAME	STREET ADDRESS
Alvotech HF	Saemundargotu 15-19
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reykjavik, 102, Iceland	Biological Drug Substance/Product 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 WE OBSERVED:

OBSERVATION 1
Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, the quality unit failed to identify appropriate root causes and to implement corrections to reduce and adequately address the number of complaints for (b) (4) drug product, (b) (4) For example,

Since 2024, the site received approximately 845 complaints related to (b) (4) drug product batches distributed to the US. The complaint review indicated significant number (approximately 50%) of the complaints were related to (b) (4) malfunction such as (b) (4) (b) (4) as follows:

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Complaint Category	Before 01SEP2024	01SEP2024-04JUL2025	After 04JUL2025	Total number of complaints
(b) (4)				
Total	15	292	538	845

Following deficiencies were observed during complaint investigation review:

A. Consumer complaint COMP-2193 was reported for (b) (4) on 3/3/2026 for (b) (4) batch (b) (4). The firm manufactures bulk drug (b) (4) and sends to a third-party packing company to (b) (4) The contract packing company verified that assembly batches (b) (4) were used to pack batch (b) (4) The contract packing company reported during this complaint investigation, "***One incident occurred during the assembly process of batch*** (b) (4) ***but these had no impact on the complaint in question***". However, the details of this "*Incident*" were not shared by the contract packing company and the site failed to collect additional information about this incident if it might have caused the defect. The firm received twenty (20) complaints from this batch (b) (4) The complaints attributed to (b) (4) (b) (4) The site shipped approximately (b) (4) units of batch (b) (4) to the US in 2024.

B. Consumer complaint COMP-1579 was reported for (b) (4) on 7/7/2025 for (b) (4) batch (b) (4) The contract packing company reported during this complaint investigation, "***An incident has occurred during the packing process, which has no impact on the mentioned complaint***". However, the details of this "*Incident*" were not shared by the contract

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packing company and the site failed to collect additional information about this incident if it might have caused the defect. The firm received thirteen (13) (b) (4) complaints pertaining to this batch (b) (4) The site shipped approximately (b) (4) units of batch (b) (4) to the US in 2024.

C. The firm management stated the complaint sample receipt rate for the US complaints is approximately 5%. The site failed to take appropriate actions to ensure complaint samples are received once the patient reports that the complaint sample is available. For example, consumer complaint COMP-001633 was received on 8/1/2025 pertaining to (b) (4) batch (b) (4) for (b) (4) (b) (4) Review of the Complaint Intake Form (CMPLT-0008481) indicated the complaint sample was available. However, the firm did not make follow up 2nd or 3rd attempts (as indicated in Complaint Intake Form) to ensure the complaint sample is received for a thorough investigation. Additionally, the Complaint Intake Form used in complaint investigation is not filled completely with all required information and it is not approved by the personnel concerned. The firm management agreed that their complaint investigation is based on incomplete Complaint Intake Form.

D. Your risk assessments conducted as per deviations DEV-005067 and DEV-005068 for consumer complaints related to (b) (4) respectively are deficient. In both deviations, the site did not find any root cause for these defects (b) (4) (b) (4) The site categorized these defects as low risk to the patient, and no corrective actions were taken. However, in these investigations, the firm failed to thoroughly investigate why the (b) (4) is failing to perform as intended.

On 5/5/2026, the firm's VP Quality confirmed that the site did not submit any BPDR for the mal functioning (b) (4)

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, in the video for airflow visualization studies of the aseptic (b) (4) filling line used to produce all drug products (VALQ - 8900 - L3-2b, performed on August 15th, 2023), the qualification of the (b) (4) (b) (4) intervention to add unopened stopped bags showed that airflow from the (b) (4) filling unit into the stopper loading station causes a void over the unopened stopper bags, preventing first-pass airflow from reaching the bags while the (b) (4) The stopper bags are not further disinfected before they are opened to (b) (4)

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically, requalification for employees performing 100% visual inspection for particulates on (b) (4) (b) (4) is performed (b) (4) after each employee has completed inspection of (b) (4) despite the fact that the employees will inspect up to (b) (4) during (b) (4) There has been no initial or requalification after (b) (4) inspection to demonstrate that the employees can perform the operation adequately (b) (4)

OBSERVATION 4

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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, deviation investigations pertaining to above-action excursions, including observed objectionable microorganisms in (b) (4) system were not thoroughly investigated to include the risk assessment extended to the batches manufactured that time. For example:

A. A holistic deviation investigation, DEV-005216 was initiated to investigate multiple incidents (during (b) (4)), when above action limit results were observed pertaining to (b) (4) testing for bioburden at sampling location (b) (4) area (room ID: (b) (4) in drug substance manufacturing facility (b) (4) This investigation was initiated in response to the (b) (4) samples collected from the (b) (4) room on (b) (4) when total viable count of (b) (4) CFU (b) (4) mL was observed for (b) (4) Bioburden test against the Action Limit of ≥(b) (4) CFU/(b) (4) mL. In (b) (4) (b) (4) room, the site recovered two objectionable microorganisms Ralstonia insidiosa and Ralstonia pickettii in addition to other organisms including Herbaspirillum aquaticum / huttiense, Methylobacterium aquaticum, Rhodotorula mucilaginosa, and Sphingomonas parapaucimobilis / yabuuchiae. During the investigation, the firm identified (b) (4) loop serving (b) (4) as the most probable source of contamination. The firm's impact assessment is deficient as the scope of the risk assessment was not extended to (b) (4) batch (b) (4) of (b) (4) ROW markets) and (b) (4) batches (b) (4) of (b) (4) manufactured during that time. Other incidents when the site observed above action (b) (4) bioburden results including objectionable organisms in (b) (4) room (room ID: (b) (4) include the sampling that was performed on (b) (4) (DEV-004932) and (b) (4) (DEV-005916).

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B. Deviation investigation DEV-005188 was initiated when above-action bioburden test results were observed for the (b) (4) samples collected on (b) (4) from (b) (4) loop (sampling location: (b) (4) For this location, the site observed total viable count of (b) (4) CFU/(b) (4) mL against the Action Limit of ≥(b) (4) CFU/(b) (4) mL. The organism identified in this excursion was gram negative Methylobacterium radiotolerans. The (b) (4) loop for (b) (4) (b) (4) was identified as a probable root cause for this deviation as well. This deviation impacted (b) (4) drug substance manufacturing areas (b) (4) However, the firm's impact assessment was deficient as the scope of the risk assessment was not extended to the batches manufactured in (b) (4) areas. In addition to the batches (b) (4) discussed in bullet point 4A) manufactured in (b) (4) area; the site manufactured (b) (4) batches (b) (4) (b) (4) in (b) (4) manufacturing area. Drug substance (b) (4) ROW markets.

Other deviation investigations that were not conducted thoroughly include DEV-005067 and DEV-005068 and are discussed in **Observation 1D**.

OBSERVATION 5

The responsibilities and procedures applicable to the quality unit are not fully followed.

Specifically, the quality unit failed to ensure environmental monitoring trend reports are generated as required under SOP-0509, Trending of environmental monitoring data. For example,

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Environmental monitoring and (b) (4) Trend Review Reports pertaining to drug product and drug substance manufacturing areas were not generated, reviewed, and approved from (b) (4) (b) (4)

The firm's Contamination Control Program (SOP-1858) requires Contamination Control Board (CCB) members to meet (b) (4) to discuss EM results and trends and to take appropriate actions. Review of the CCB meeting minutes for (b) (4) indicated that the CCB discussed various EM Trends; however, this deficiency i.e., creation, reviewing, and approval of trend reports was not part of the Contamincation Control Board meeting agenda.

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