DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51 Room 2269, Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	03/06/2023-03/17/2023
	FEI NUMBER 3013702557

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Wessman, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Alvotech Hf	Sæmundargata 15-19
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reykjavík, 102, Iceland	Drug Substance and Drug 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

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

Specifically

Your Quality Unit has not been effective in carrying-out its duties of ensuring that drug products are manufactured in accordance with current good manufacturing practices (cGMP) to ensure safety, efficacy, purity, and overall quality of drug substances (used to manufacture drug products) and drug products manufactured at your firm. This is demonstrated by observed deficiencies in your Quality Unit responsibilities related to controls on review of laboratory testing data, conducting investigations, and conducting activities per written procedures. The inspectional observations listed on this form document that your firm have not performed the adequate assessments/reviews to ensure the quality of drug substances and drug products manufactured and tested at your firm. For Example, but not limited to:

A. Quality Assurance is inadequate. For Example,

1. Process Performance Qualification (PPQ) Protocol Prot-0247 version 1.0 effective 31Jan2020 acceptance criteria require a minimum of (b)(4) consecutive batches during the PPQ campaign for the process validation run to be considered successful. Drug substance PPQ batches (b)(4) exhibited out-of-trend for aggregates due to the (b)(4) during (b)(4) operation. When batches (b)(4) were used in drug product PPQ campaign out-of-specifications (OOS) were observed for (b)(4) drug product PPQ batches that were attributable to the original out-of-trend results found in batches (b)(4) (b)(4) Quality assurance signed off on DSM DSP Process Performance Qualification Report: (b)(4) (b)(4) mg/mL (REP – 1015 version 1.0 effective date 07Sep2022)

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that (b) (4) manufacturing was successfully validated. The final disposition of batches (b) (4) was rejected.

2. PPQ Protocol for (b) (4) mg/ml and mg/ml: Prot-0253 version 1.0 superseded date: 23May2020 Table 1 lists the approach to drug product batch size and volumes with specific drug substance batches to be used in PPQ batches, which included drug substance batches . However, were not used in the drug product PPQ as per Table 1 in the Prot-0253. Quality assurance signed off on DPM; Process Performance Qualification (PPQ) Report (REP – 1090 version 1.0 effective date 29Jul2020) that drug product manufacturing was successfully validated.

3. QA approved change control CC-002073 to temporarily allow secondary packaging and labeling before drug substance release. Under the change control, drug product batches underwent secondary packaging and labeling from drug substance batches that had not been fully released. After the change control CC-002073 is closed, it is expected that the approach to continually manufacture drug product prior to drug substance release may continue as per Changes to SOP-1680 Continuous manufacturing of Drug Substance to Drug Product and onwards for further processing v2.0 effective 10 Mar 2023.

B. Supervisory oversight over quality/production unit operations and laboratory electronic system and data is deficient. For Example,

1. During our review of your Empower 3 chromatography software, interrupted sequences were observed, which generated "Data Incomplete" and "Bad Checksum" chromatographic data. At times, your firm's Quality Control Unit documented these interrupted injections as invalid assays, showing that no chromatogram had been generated, however, your Quality Unit was not aware that the software has the capability to verify the incomplete data and evaluate whether the sample did run, and if so, view the chromatogram. Furthermore, prior to the start of the current inspection your firm performed a review with respect to project integrity failures, detailed in technical report number REP-4262, titled "Additional Empower Project Audit Trail Review for Empower QC Projects", where interrupted sequences were identified, however, after this

assessment your firm continued not to be aware that the software has the capability to verify the data incomplete or bad checksum chromatograms. During our review of Empower 3 data, we reviewed electronic data for test samples, where interrupted injections were requested to be verified (brought back) and reviewed, if applicable. As a result, during review of such cases, the interrupted sample injections were not adequately documented to be performed in your invalid assay reports and/or master laboratory records (data packages), and evaluations were not performed to determine whether the interrupted test injections were within specification or out of specification, where applicable. Additionally, your firm has not demonstrated to understand the different types of communication errors and circumstances which may lead to a "Data incomplete" or "Bad Checksum" chromatography. This discrepancy in your firm's ability to review, document, and investigate all electronic data is a gap in your firm's Data Integrity Program.

2. Once logging to the computer's Windows operation system, every analyst can access all the original electronic test data generated from standalone laboratory equipment systems, including those generated by other analysts, stored on the hard drive without restriction. In addition, approximately (b) (4) standalone laboratory systems are used by Research and Development analysts, with R&D folders/data unprotected and available to QC. Furthermore, analysts have the capability to move raw data between QC and R&D folders, and analysts are free to start, perform, and save testing in all folders, including R&D data folders. During the inspection, we observed a simulated UV-VIS test which confirmed the capability of the analyst to save the test data in the R&D data folder, which per your firm's current review procedure, is not noted to be reviewed by your QC reviewer. The ability for analysts to perform testing in non-QC data folders or older folders is a gap in your Data Integrity Program.

3. Per your firm's data review procedure, Quality Control (QC) personnel perform review of electronic test data for all analytical batch records using an approved review procedure and checklist for standalone equipment. This review process does not appear to be adequate, in that all potential data generated during that specific review period for that product are not reviewed. There is no adequate reconciliation of all generated electronic test data during the review process for standalone equipment.

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4. There is no adequate data integrity program in place to include a statistically sound comprehensive review of all electronic data by the Quality Assurance Unit for standalone and network systems, to ensure completeness, consistency, and accuracy of all chromatographic and non-chromatographic electronic data generated by the Quality Control Laboratory. Specifically, per your firm's procedure, only QC unit personnel perform review of electronic data. No electronic data is reviewed by the Quality Assurance unit, whether batch to batch, or an established time frame.

5. There is a lack of quality unit oversight over controlled documents. Your firm does not have a procedure which describes the type of records that can be discarded with or without prior approval/review from your Quality Assurance Unit. During our walkthrough of your firm's Quality Unit office area on 03/07/2023, we observed what appeared to be original cGMP records discarded by personnel in shred bins without adequate Quality Assurance oversight, including 2 training records with data and trainee signatures, but without QA signatures, original Master Batch Record and Master Laboratory Record pages, and discarded production labels. In addition, during the walkthrough, upon review of batch issuance procedures with a member of your Quality Assurance unit responsible for issuance of production and laboratory batch records, I observed too numerous to count/review records on the desktop recycle bin. There is no procedure which describes restrictions or usage of the desktop recycle bin in a cGMP environment.

6. Specifically, the Quality Unit lacks adequate control over the issuance of master manufacturing batch records purported to be controlled under SOP-0583, titled "Issuing of Batch Records", effective date 01/02/2022 and laboratory batch records (MLRs) purported to be controlled under SOP-0501, titled "Issuing and Archiving of Lab Records", effective date 06/16/2022 . During the inspection, it was observed that copies of official master manufacturing batch records for all drug substance and finished products manufactured at the firm are issued to non-QA personnel without adequately controlling each page. For example, copies of master batch records and master laboratory records are provided by a QA personnel to respective manufacturing and laboratory department personnel with only the issuers initials and date on the front page, leaving the additional pages uncontrolled.

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7. Established procedures within your firm's Quality unit are not always followed. Prior to the start of the current inspection, your firm identified the following deviations from written procedures: (1) (b) (4) CAPA trend report has not been completed for the (b) (4) of 2023 (DEV-002869) and (2) (b) (4) User Access Review and System audit trail review has not been completed (DEV-002821).

C. The established SOP for investigation of OOS, OOT and OOE results was not followed. For Example,

1. SOP-0259 (Handling of OOS, OOT and OOE Results, Version 11.0, Effective Date February 9, 2023) section 6.11.1.1 regarding the OOS due date extensions states that "Extensions can be granted, in exceptional cases, (b) (4) (b) (4) As of March 7, 2023, there were a total of 29 OOS in the years of 2022 and 2023; however, 19 out of these 29 OOS (65.5%) were extended (b) (4) (b) (4) The fact that 65.5% OOS were extended is not consistent with the SOP description that extensions are granted in exceptional cases.

2. The SOP-0259 section 6.11.6 states that "If the maximum number and/or duration of extensions is exceeded, a justification is required at the time the record goes overdue." The investigation of OOS-0053 (endotoxin OOS result for (b) (4) in (b) (4) (b) (4) manufacture) was extended (b) (4) times, which is the maximum number of extensions allowed in SOP-0259. The due date after the (b) (4) extension was December 30, 2022. However, on the record overdue date (i.e., December 30, 2022), the OOS remained open with no overdue justification provided.

OBSERVATON 2

Written records of OOS and deviation investigations do not always include the conclusions and follow-up and adequate root cause analysis.

Specifically,

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A. Root cause is not identified from OOS investigation to support implementation of potential corrective action(s) and/or preventive action(s) (CAPAs). For Example:

1. Increased [redacted] and increased drug substance (DS) levels were observed for [redacted] after using a [redacted] from a different vendor for [redacted] A total of 8 [redacted] DS batches were impacted by this change, out of which 4 DS batches had out of specification (OOS) [redacted] batch release results (OOS-0059, 00S-0061, 00S-0078). These OOS were closed without identification of a clear root cause to support implementation of potential CAPAs to ensure control of [redacted] levels in [redacted] batches.

2. In the transport validation study using [redacted] drug product (DP) batch [redacted] a particle was observed in one [redacted] during visual inspection of [redacted] after shipping simulations are undertaken (OOS-0080). The particle was identified as broken glass. The OOS investigation was extended [redacted] times, and root cause has not been identified to support implementation of any potential CAPAs.

3. An endotoxin result of < [redacted] EU/ml for drug substance [redacted] sample [redacted] was out of specification (NMT [redacted] EU/ml) (OOS-0083). During a phase I investigation, a retest was performed and the result was within specification (< [redacted] EU/ml), after which the [redacted] was used in further processing prior to identifying a root cause for the original result. The firm opened deviation DEV-002885 in response to not following SOP-0259.

B. Investigations initiated and performed by your Quality Unit in response to deviations are not always comprehensive with respect to root cause analysis. Additionally, Corrective Action/Preventive Action (CAPA's) as a result of investigations are not always comprehensive to address root causes documented to have been performed. For Example:

1. Deviation DEV-002302, dated 07/14/2022 was initiated due to endotoxin testing for [redacted] samples from 05/27/2022 for [redacted] not having been performed. Your firm's Investigation determined that the samples to be tested were mixed with samples that had already been tested, with root cause determined to be oversight and human error, in that the microbiology manager

missed an email notice within your firm's MODA software system which tracks sample testing. Upon further review, unrelated to this deviation, we observed that your firm had recently initiated CAPA-001881, dated 03/14/2022, in which SOP-0094, titled "Operation of Incubators", effective date 07/05/2022, was updated to segregate samples for incubation based on sample type and sample status. However, this CAPA and SOP-0094 was not mentioned in DEV-002303, and no consideration was given to the procedure as being a potential root cause for the deviation.

2. Deviation DEV-002636, dated 11/23/2022 was initiated due to EMS alarm management at your firm considered to be inadequate. Specifically, an example of the inadequacy of the EMS alarm management was observed during review of pressure differential alarms between Drug Product Manufacturing (DPM) Grade B and DPM Grade C areas on or around 04/11/2022, where on seven occasions, the pressure differential dropped below alarm limits, with three occasions into negative values, "suggesting that the Grade B area potentially encountered an influx of Grade C air". Immediate Actions documented within your deviation reads in part "as an interim action, immediate quality oversight will be required for alarms (air pressure reversal) in manufacturing areas" and "all area owners/alarm responders will notify QA if such an alarm happens and will determine if a deviation is needed". However, during our review of your DPM pressure alarm log for reporting period 12/15/2022 – 03/13/2023, we observed that pressure differential negative values were observed on at least two occasions, one on 12/21/2022 and another on 01/23/2023, with no notification provided by alarm owners to QA for determination if a deviation is needed. Additionally, there is no adequate justification why the immediate action only included notification of pressure differential alarms and not all EM alarms, when the deviation was initiated for inadequate alarm management for your firm's EMS system. Furthermore, the deviation was closed on 02/24/2023, with approximately six CAPA's initiated related to the deviation, ranging from updating current procedures for QA oversight over alarms to creating a procedure for QA oversight over alarm acknowledgment. As of the current inspection, your firm appears to have not performed any CAPA items detailed in approximately six different CAPA's related to DEV-002636.

3. Per deviation DEV-002123, dated 05/02/2022, your firm documented that equipment requalification activities had not been performed and were overdue for a total of (b) (4) freezers, refrigerators, cold storage rooms, controlled rate freezer and (b) (4) CAPA's initiated due to

this deviation do not appear to have been adequate in preventing similar incidents, as observed with no qualification performed for (b) (4) NVP equipment, detailed in Observation 8.

OBSERVATION 3

Quality of incoming (b) (4) stoppers is inadequate. Specifically,

After implementing multiple CAPAs at (b) (4) ((b) (4) stopper supplier) and Alvotech regarding procedural controls and defect characterization of incoming stopper quality, four (b) (4) lots (b) (4) from the last (b) (4) received lots still failed to meet Alvotech's tightened visual inspection criteria for acceptable (b) (4) stopper quality.

No in-house data was provided to demonstrate that the sampling plan to evaluate (b) (4) stopper quality is appropriate. (b) (4) stoppers arrive at the facility in (b) (4) bags with sampling performed (b) (4) (b) (4) bag.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in quality control records are instituted only by authorized personnel.

Specifically, GMP related computerized systems and equipment have not been validated/qualified to demonstrate the suitability of computer hardware and software to perform assigned tasks. For example:

A. Your firm maintains (b) (4) (b) (4) non-viable particle monitoring equipment used to perform and generate test data for non-viable particle (NVP) count used in environmental monitoring/cleanroom qualification activities in class B and class C areas in support of manufacturing operations. Subsequently, during our review of the (b) (4) equipment and firmware, it was observed that the firm was not aware of the equipment data storage

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capability and consequently does not review or backup the electronic data generated and stored on the equipment, only using printer printouts as primary data. Per your firm's management, the data capability storage for this equipment is up to (b) (4) tests, after which the data is overwritten with the most recent data. After our identification of this discrepancy during the inspection, your firm initiated a deviation investigation, where your firm temporarily discounted the use of the (b) (4) NVP counter equipment and printed out the electronic data for your review. Your preliminary review of this data during the inspection resulted in instances where some electronic data from the equipment does not appear to have affiliated data packages where testing was performed.

B. Your firm appears to have performed Performance Verification for Empower 3 software, however the verification does not evaluate the consistent performance of the software/equipment over a specified period and operating environment. For Example, during our review of your Empower 3 chromatography software, interrupted sequences were observed, which generated "Data Incomplete" and "Bad Check Sum" chromatographic data. Your firm has not demonstrated to fully understand the different types of communication errors and circumstances which may lead to a "Data incomplete" or " Bad Checksum" chromatography considering the relationship between the Empower application and database server, Empower RDS servers, internet connection, Empower LAC/Es, and the instruments connected to LAC/Es.

OBSERVATION 5

Container closure integrity assay validation is inadequate. Specifically,

The purpose of the container closure integrity assay is to detect a (b) (4) for microbial ingress. As per Container Closure Integrity Testing: SOP-1455 version 7.0 effective 25Jan2023 (b) (4) (b) (4) The maximum allowable OD limit was originally set to (b) (4) which was too low resulting in six out-of-specification (OOS) events. Each OOS event was determined by the Quality Unit to be not indicative of microbial ingress. The firm is proposing to widen the maximum allowable OD limit.

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OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed. Specifically,

Aseptic process simulation studies performed in the RABS are not fully representative of the conditions during routine aseptic filling operations of (b)(4) For instance, a (b)(4) intervention resulting in Dev-002366, along with (b)(4) interventions resulting in Dev-002383 and Dev 002164 were previously part of aseptic simulation studies, however, these interventions were removed from SOP-0434 DPM (b)(4) Line Interventions version 14.0. The interventions were not added back to the aseptic simulations even though they reoccurred.

Unidirectional air flow studies were not fully representative of routine Grade A operations as the smoke generator was not always placed near the HEPA filter. In addition, flow pattern videos do not always evaluate the interaction of the unidirectional airflow with the manufacturing operator when the operator is performing interventions.

There is no defined time limit from the end of RABS setup to the beginning of aseptic filling for routine drug product manufacturing or aseptic process simulations.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Specifically,

Your firm's Technical Summary Report for Disinfectant Qualification Studies (REP 2989, version 3.0 effective 26Jan2023) does not adequately support the sanitization procedures for the (b)(4) and (b)(4) effectiveness of the disinfectants and (b)(4) for all representative manufacturing surfaces in the Grade A RABS. For example, (b)(4) which can be used for (b)(4) successive drug product batches before replacing were not included in the studies.

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OBSERVATION 8

Equipment used in testing and holding operations in support of drug substances and drug products is not of appropriate design, of adequate size, and suitably located to facilitate operations for its intended use.

Specifically,

A. Your firm maintains (b) (4) non-viable particle monitoring equipment used to perform and generate test data for non-viable particle (NVP) count used in environmental monitoring/cleanroom qualification activities in class B and class C areas in support of manufacturing operations. The qualification of this equipment has not been performed, with at least one equipment in usage since the year 2018. As a result, the Quality Unit has not demonstrated the suitability of the equipment to perform assigned tasks and has not reviewed the electronic data since the implementation of these equipment.

B. Per deviation DEV-002123, dated 05/02/2022, your firm documented that equipment requalification activities had not been performed and were overdue for a total of (b) (4) freezers, refrigerators, cold storage rooms, controlled rate freezer and (b) (4) The identified equipment were/are used for storage of samples for testing, tested samples, raw materials, reagents, reference materials, reference samples, stability samples (ongoing stability samples) in support testing operations, and bioburden reduction in support of continuous chromatography and viral inactivation (CC & VI) and (b) (4) for (b) (4) products (b) (4) manufacturing operations. There is no adequate justification for having missed equipment requalification activities, with some equipment overdue by more than 2 years. In addition, CAPA's initiated due to this deviation do not appear to have been comprehensive and adequate in preventing similar incidents, as observed with no qualification performed for (b) (4) NVP equipment, detailed above.

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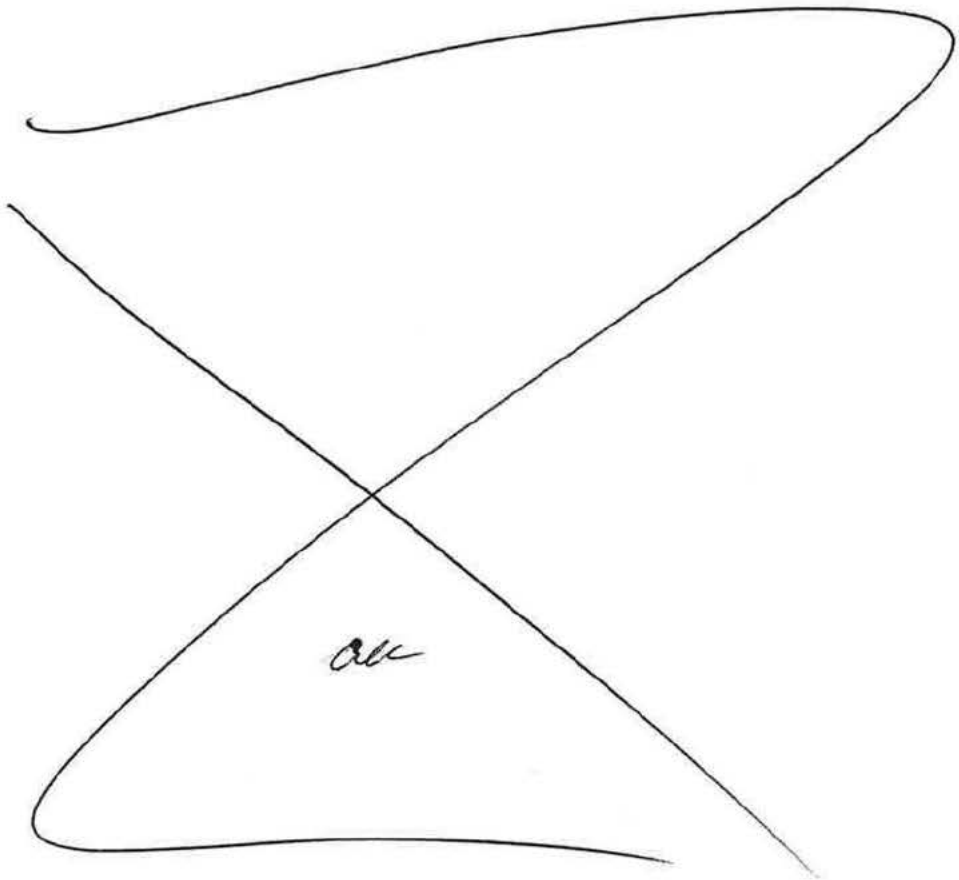

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