

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 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	DATE(S) OF INSPECTION 11/03 - 11/2025
	FEI NUMBER 3002807485

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Elmar Zagler, Founder and Managing Director

FIRM NAME Loba biotech GmbH	STREET ADDRESS Fehrgasse 7
CITY, STATE AND ZIP CODE Fischamend, Austria, 2401	TYPE OF ESTABLISHMENT INSPECTED Drug Substance Manufacturer

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

Observation 1:

The Master Batch Record for (b) (4) does not reflect the manufacturing process. Specifically,

You failed to record process control activities during the manufacturing of DS Batch (b) (4)

(b) (4) The changes made for the process parameters for the preparation of (b) (4) used for the (b) (4) were not properly documented in the Master Batch Record for the specified batches. Batches (b) (4) were released. Quality assurance of the batch release process is deficient.

Observation 2:

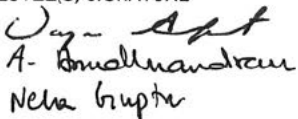
You failed to take adequate corrective action preventative action (CAPA) for a manufacturing system, resolution of an aberrant condition in a timely manner. Specifically,

On 3 October 2025, observed for the (b) (4) by system sight glass was a (b) (4) residue on the bottom product contact surface of the vessel. You identified on 2 October 2024 the observed attribute and initiated a CAPA 26 March 2025 for corrective action, with the (b) (4) residue an unresolved condition. You continue to manufacture under an aberrant state.

Observation 3:

Validations in support of (b) (4) drug substance manufacture are deficient. Specifically,

a. You (b) (4) sterilize the liquid anti-foam and inoculation media in (b) (4) manufacture by (b) (4) with the initial validation and reoccurring revalidation failing to provide a biological assessment (by biological indicator)

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of the sterilization process.

b. (b) (4) used in (b) (4) has a hold time of (b) (4) prior to (b) (4) with the hold time not validated from a microbiological control perspective.

c. Your cleaning efficacy study for cleaning/sanitization agents fails to assess all manufacturing facility substrates, facility isolates, and the cleaning/sanitization agents post opening at their expiry.

d. The (b) (4) on the (b) (4) used in (b) (4) sterilization of materials used in (b) (4) drug substance manufacture is replaced (b) (4) integrity tested, and (b) (4) sterilized/sanitized. There is no initial or reoccurring validation, physical/biological assessment for the (b) (4) sanitization/sterilization of the (b) (4) (b) (4)

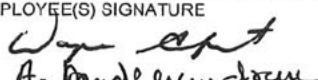
e. Your (b) (4) temperature validation studies for the GMP warehouses is a (b) (4) for each monitoring position and not for a period time and data scan rate that adequately assess the areas for 15 - 25°C temperature control.

Observation 4:

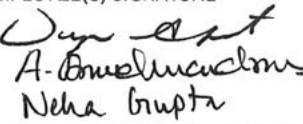
Equipment, facilities and a utility system in support of (b) (4) drug substance manufacture are not adequately maintained or are deficient in design. Specifically,

a. The (b) (4) material sampling area is a room, a corridor, Grade D space between the material receiving area and the GMP warehouse that includes (b) (4) sampling booths. There is no (b) (4) with the ceiling observed with gaps leading to interstitial space. (b) (4) Sampling Area (b) (4) was observed with a ceiling HEPA, light fixture seal dislodged from its mounting. The area is of inadequate design for raw material sampling.

b. You identified that your (b) (4) lines per manufactures recommendation should be replaced (b) (4) There is no procedure or other mechanism for the replacement of the (b) (4) lines and there is no procedure for inspection of the product contact surface at any time interval for deterioration.

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c. Observed in the (b) (4) material receiving area was multiple doors with inadequate door seals with one door leading to the outside. A ceiling tile was observed removed leading to interstitial space. d. Observed in Area (b) (4) was (b) (4) with the (b) (4) (b) (4) in an unclean state. The associated area for the (b) (4) leading to the outside was in an unclean state. A similar situation, but to a lesser extent was observed for the (b) (4) manufacturing area. For the specified areas, you fail to have a procedure for good housekeeping. Observation 5: A standard operating procedure is not available or is deficient in support of (b) (4) drug substance manufacture. Specifically, a. On 06 November 2025, observed for the simulated fill of (b) (4) drug substance was the fill technicians gloved hands resting on the laminar flow clean bench, a sanitized surface. You identified that the fill technician sanitized gloved hands should not touch the work surface during manufacturing, with the good aseptic practice instructed during training. SOP-07-0024, Working in Laminar Flow Workbenches, v00, Effective 11 February 2025 is silent for said requirement. b. On 06 November 2025, observed for the simulated fill of (b) (4) drug substance was personnel environmental monitoring that included finger dabs from each gloved hand, with only a slight touch of each finger to the media plate. Job aid, JA-06-0004, Environmental Monitoring in LAFS, Rev 02, Effective date 21 April 2025 is silent for rolling each finger across the media that provides an optimum assessment of glove quality, bioburden. c. On 27 November 2024, a tolerance limit violation event (TLV 2024/003) was identified, associated with the preparation of a sample solution a day before for RP-HPLC analysis for (b) (4) resulting in the out of specification results. There is no time specified in the HPLC (b) (4) identity_purity analysis protocol for the sample solution preparation prior to performing the analysis. d. You indicate that (b) (4) would include (b) (4) The			
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requirement is not specified by any procedure.

e. For (b) (4) manufacture, you fail to have a procedure, documentation for line clearance.

f. SOP-01-0004, Deviation Management, Rev 04, Effective date 30 October 2025 does not describe the closing process for an open deviation. The responsible personnel and the criterion for closing a deviation opened for a GMP-relevant event in a timely manner are unknown.

g. Trend analyses of invalid test results were not performed in a timely manner. There is no standard operating procedure to provide instructions to perform routine trend analyses and to take appropriate actions in mitigation of an invalid test result.

h. SOP-02-0003, Training, Rev 01, Effective date 03 November 2025 fails to provide a description for a change that requires a face-to face retraining within (b) (4). The retraining process of an employee in a uniform and timely manner is unknown.

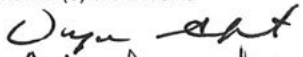
i. The duration for the preparation of drug substance (DS) bottles for shipment, removal of the DS bottles from the storage freezer until loading in the conditioned shipping container is not specified in SOP-07-0070, Packaging of (b) (4) DS bottles for shipping, Rev 00, Effective date 14 May 2025 and Operation Instructions No. : 503/020, Rev 00, Effective date 15 October 2024. Preparation of the DS bottles for shipment is not controlled.

Observation 6:

Quality oversight of deviation management is inadequate. Specifically,

a. You failed to open a deviation for the lack of documentation for (b) (4) in the master batch record for Batch (b) (4) according to your SOP-01-0004 Deviation Management, Rev 04, Effective date 30 October 2025.

b. Deviations occurred due to different root-causes for a recipe used in (b) (4) manufacture for (b) (4) classified as an 'umbrella deviation' in deviation # AB 862/357-recipes (b) (4). You classify frequently occurring

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deviations within a short time-period with the same or very similar trigger (root cause) under a 'umbrella deviation' according to SOP-01-0004, Deviation Management, Rev 04, Effective date 30 October 2025. Deviation Management SOP-01-0004 was not followed to categorize deviation events, perform root-cause analyses and establish CAPAs.

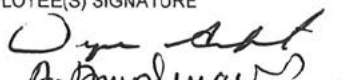
Observation 7:

Supervisory oversight on the training of the employees is inadequate. Specifically,

a. Investigations of the out of specification results (OOS-2025-065 and OOS-2025-076) led to critical changes for the preparation of (b) (4) for (b) (4) limit of the (b) (4) components and (b) (4) range. No re-training is documented for the operators who prepared the (b) (4) after the changes were introduced in the process.

b. On 27 March 2025, an invalid test investigation (ITI2025/045) was performed for using an unqualified HPLC (LQE0314), for which a barrier sign label (b) (4) was placed but not clearly visible to prevent using the instrument. No retraining was documented for the operator who ran the HPLC, without checking the qualification/validated state of the equipment. Any additional step taken to block the use of the unqualified equipment is unknown.

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