DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/15, 18-22, 25/2024
	FEI NUMBER 3002807751

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mai-Britt Hammer Frost Thomasen, Corporate Vice President - Purification Plants

FIRM NAME	STREET ADDRESS
Novo Nordisk A/S	Hallas Alle 1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kalundborg Sjalland 4400 DK	Drug Substance Manufacturing Site

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

OBSERVATION 1

The routine sample volume that is used to test for appropriate standards of quality and purity of the (b) (4) water for (b) (4) DS manufacturing is insufficient to be representative of the capacity of the water systems (b) (4) and (b) (4).

OBSERVATION 2

Insufficient information has been provided to demonstrate that the (b) (4) water and (b) (4) water used for (b) (4) drug substance (DS) purification is adequately controlled for total microbial counts and objectionable organisms in water systems (b) (4)

OBSERVATION 3

Drug Substance manufacturing and processing unit operations that have been observed to be performed for (b) (4) (b) (4) DS at the Novo Nordisk A/S drug substance manufacturing facility (FEI: 3002807751) are not included in the (b) (4) submission to the Agency for review. For example,

a. The equipment ((b) (4) and (b) (4) process steps that are used to (b) (4) in recovery in (b) (4) are not described in the (b) (4)

b. Critical process parameters, in-process controls, and results to support routine (b) (4) of (b) (4) DS are not adequately described in the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Lindsey J. Brown -S; Maxwell Korang Yeboah -S; Zachary J. Kraus -S; Ralph M. Bernstein -S	Lindsey Brown, Senior Microbiologist Ralph M. Bernstein, Biologist Maxwell Korang-Yeboah, Senior Staff Fellow Zachary Kraus, Senior Research Scientist	03/25/2024

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OBSERVATION 4

Master production and control records lack complete manufacturing and control instructions. Specifically, critical details regarding (b) (4) DS unit operations are not described in Master or Executed Batch Production records.

OBSERVATION 5

The validation of the (b) (4) DS manufacturing process, including a full description of the validation data for critical process parameters and in-process controls in support of routine production have not been appropriately documented in the (b) (4)

OBSERVATION 6

Written procedures used in the manufacture, processing, or packing that are designed to assure identity, strength, quality, and purity of the drug substance are inadequate. Specifically, SOP Q0800455 "Behaviour in API production facilities and Sourcing warehousing facilities" ver. 1.0 does not include a description of behavior for product contact material to minimize the risk of contamination to the DS.

OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, changes to the (b) (4) DS production schedule were made without quality oversight.

OBSERVATION 8

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that production cultures conform to appropriate standards of identity, strength, quality, and purity. Specifically, a (b) (4) microliter sample is used to assess microbial contamination within a (b) (4) (b) (4) tank.

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