DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 404-253-1161 Industry Information: www fda.gov/oc/industry	07/06-13/2023
	FEI NUMBER 1000158576

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Leonardo Costa Siqueira, Corporate Vice President - API

FIRM NAME	STREET ADDRESS
Novo Nordisk Pharmaceutical Industries LP	3612 Powhatan Rd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Clayton, NC 27527-9217	API 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 (I) (WE) OBSERVED:

OBSERVATION 1

There is a failure to thoroughly investigate the cause of any unexplained discrepancy.
Specifically, your firm has identified objectionable organisms during in-process testing of intermediate Semaglutide active pharmaceutical ingredient (API) on at least three occasions for batches manufactured in the Recovery area between February and June 2023, to include:

February 2023
- Batch (b) (4) , Serratia marcescens
- Batch (b) (4) , Acinetobacter guillouiae, Serratia marcescens, Enterococcus casseliflavus
- Batch (b) (4) , Enterobacter asburiae

March 2023
- Batch (b) (4) , Enterobacter asburiae, Enterobacter bugandensis
- Batch (b) (4) Enterobacter asburiae, Enterobacter bugandensis
- Batch (b) (4) , Enterobacter species

June 2023
- Batch (b) (4) , Citrobacter freundii

Deviations DV0134891 and DV0138159 were completed to address the February and March occurrences, respectfully; however, an additional occurrence was identified for batch (b) (4) manufactured in June 2023. Deviation DV0143695 was initiated on July 5, 2023 to investigate the June 2023 event, and is currently open. The initial two deviations to date have been ineffective in determining the source and corrective actions are inadequate. Addtional batches of intermediate Semaglutide active pharmaceutical ingredient were also manufactured during this time frame, for the purposes of process validation and further manufacture.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Brittny C. Cargo -S Digitally signed by Brittny C. Cargo -S Date: 2023.07.13 14:47:52 -04'00' Seneca D. Toms -S Digitally signed by Seneca D. Toms -S Date: 2023.07.13 14:47:13 -04'00'	Brittny C. Cargo, Investigator Seneca D. Toms, Investigator	07/13/2023

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OBSERVATION 2

Microbial controls are deficient in that:

- Microbial limits have not been established for in-process API material, which have had microbes identified during the recovery phase.

- (b) (4) used for production is not required to be evaluated for absence of objectionable organisms unless total microbial counts exceed (b) (4).

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		Brittny C. Cargo, Investigator Seneca D. Toms, Investigator	07/13/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."