DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Headquarters - White Oak CDER/OTS/OSIS/DNDSI 10903 New Hampshire Avenue Silver Spring, MD 20993; (301) 796-3865 Industry Information: www.fda.gov/oc/industry	4/13/2026 - 4/17/2026
	FEI NUMBER 3003037054

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sif Groth Ronn, Associate Vice President, Non-Clinical and Clinical Assay Sciences

FIRM NAME	STREET ADDRESS
Novo Nordisk	Novo Nordisk Park 1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
DK-2760, Malov, Denmark	Biopharmaceutical facility

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

The following objectionable conditions pertaining to method validation activities conducted in support of drug product (b) (4).

1) Not all method validation activities were documented in source records from study (b) (4). For instance, stability of (b) (4) in whole blood was evaluated after 1-hour, 2-hour, and 4-hour incubation periods at room temperature. However, source records have no time stamps to support the incubation time points. A similar finding was observed in the shipping and short-term stability experiments.

2) Existing standard operating procedures (SOPs) were not always followed during the conduct of method validation experiments. For instance,

2a. SOP Q053698, Section 9.8.2, states that only failed stability QCs should be included in subsequent confirmatory runs. Yet, confirmatory run 8 included a new full set of stability QCs instead of including only failing stability QCs from run 7.

2b. SOP Q053698, Section 5.1, states that an average percent relative error (%RE) should be calculated for each concentration (QC) level and used to accept or reject precision and accuracy (P&A) runs. Additionally, a P&A run should be rejected if the average %RE value exceeds 25% at LLOQ and ULOQ levels and 20% at all other QC levels. Yet, P&A run 9 was rejected based on visual assessment instead of a calculated average %RE value. At my request, average %RE values were calculated during the inspection, and it was discovered that run 9 was incorrectly rejected because the average %RE value was (b) (4) at all QC levels.

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	RUBEN C. AYALA -S Digitally signed by RUBEN C. AYALA -S Date: 2026.04.17 10:34:24 +02'00'	Ruben C. Ayala, PharmD, Lead Pharmacokineticist	04/17/2026