DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	02/23/2026-02/27/2026
	FEI NUMBER 3002807711

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark McQuillan, Managing Director

FIRM NAME	STREET ADDRESS
Nicobrand Limited	189 Castleraine Road, Coleraine County
CITY, STATE, ZIP CODE, COUNTRY Londonderry BT51 3RP United Kingdom	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Drug substances do not bear a retest/expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality, and purity at the time of use.

Specifically, you test assay and chromatographic purity of (b) (4) (USP) in (b) (4) according to a common HPLC test method as included into you testing instructions FP0001 Revision 25 (for (b) (4) (b) (4) . You have validated this test method according to the validation report, Development and Validation of a High-Performance Liquid Chromatography Assay and Impurity Identification Method for (b) (4) dated 11/30/2004. This HPLC test method is not stability indicating method such that you have not conducted force degradation study for (b) (4) You routinely use this non-stability indicating method to analyze long term and accelerated stability samples for (b) (4) for the US market.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components of in-process materials, and drug substances conform to appropriate standards of identity, strength, quality and purity.

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	RAJIV R. SRIVASTAVA -S Digitally signed by RAJIV R. SRIVASTAVA -S Date: 2026.02.27 16:57:11 Z	Rajiv R Srivastava, CSO	02/27/2026

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Specifically, your firm failed to monitor the (b) (4) Water Plant system to ensure that it consistently produces (b) (4) water that, at a minimum, meets the USP monograph for (b) (4) water at the point of use (POU). Your (b) (4) Water Plant is under Stage (b) (4) Performance Qualification. The water quality monitoring for POU (b) (4) does not represent the water quality used for the manufacturing of (b) (4) in (b) (4) ID # (b) (4) (in (b) (4) Production Room (b) (4) The POU (b) (4) uses ~ (b) (4) of (b) (4) hose to connect to the user point of (b) (4) ID # (b) (4) (in (b) (4) Production Room (b) (4) The water sampling does not include at least (b) (4) of hose that is part of the water distribution line to the (b) (4) ID # (b) (4) Your production manager (b) (6) stated that (b) (4) is the only possible closest point to the (b) (4) ID # (b) (4) (in (b) (4) Production Room (b) (4) for water sampling.

OBSERVATION 3

The process validation for (b) (4) is not adequate.

Specifically, you manufacture (b) (4) for the US market according to the Batch Processing Record (b) (4) Effective date 12/5/2025. You validated the manufacturing process as per the Process and Cleaning Validation Protocol for (b) (4) USP (b) (4) Production Process (b) (4) (Effective date 9/15/2006). The corresponding report dated 11/15/2006 confirmed that the batch is packaged in (b) drums. You did not validate the process for (b) (4) such that you collected samples from (b) (4) drums for full testing. No additional testing was done for the batch (either in the IBC or in the drums) to assure the batch (b) (4)

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

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A. On 14/10/2024, you recorded non-conformance, LIR/OOS/002/24 for (b) (4) (b) (4) for unspecified impurity by HPLC. The sample is tested in duplicate sample preparations and result is reported for the average of the two tests. The OOS result was recorded for Batch No. (b) (4) (Mfg. date 4/9/2024 Expiry date (b) (4) for unspecified impurity (b) (4) % (at RRT ~(b) (4) against the Specification ≤(b) (4) % for Test 2 sample. The Test 1 sample did not have this unspecified impurity at the respective RRT.

Your Phase I preliminary investigation did not find any root cause. The Phase I diagnostic test was unable to reproduce the initial OOS Test 2 sample peak. Based on this finding, you determined that the "peak" observed in the initial Test 2 sample was not as a result of impurity in the sample, but due to a transient HPLC issue (Instrument issue). In the same sequence you also tested (b) (4) Batch No. (b) (4) (Mfg. date 3/26/2024 Expiry date (b) (4) You reported the initial test results for (b) (4) except that for (b) (4), you excluded the peak at RRT (b) (4) (unspecified impurity (b) (4) %).

B. On 5/29/2024, you recorded non-conformance, LIR/OOS/004/24 for (b) (4) (b) (4) for unspecified impurity by HPLC. The sample is tested in duplicate sample preparation and result is reported for the average of the two tests. The OOS result was recorded for Batch No. (b) (4) (Mfg. date 3/28/2024 Expiry date (b) (4) for unspecified impurity (b) (4) % (at RRT ~(b) (4) against the Specification ≤(b) (4) % for Test 1 sample. The Test 2 sample did not have this unspecified impurity at the respective RRT.

Your Phase I preliminary investigation did not find any root cause. The Phase I diagnostic test was unable to reproduce the initial OOS Test 1 sample peak. Based on this finding, you determined that the "peak" observed in the initial Test 1 sample was not as a result of impurity in the sample, but dues to a transient HPLC issue. You also noted in your investigation, "*** it is impossible to determine the cause***". You reported the initial test result but excluded the peak at RRT (b) (4)

You analyzed implicated (b) (4) Batch No. (b) (4) in a sequence that included (b) (4)

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batches: (b) (4) in that order.

C. On 12/7/2023, you recorded a major deviation, D23/011 for your (b) (4) water system. The (b) (4) water system consists of (b) (4) points of use (POU) with respective sampling points, (b) (4). The water was sampled on 11/30/2023 and deviation was recorded for sampling point (b) (4) for a TOC result of (b) (4) ppm which was above USP Specification of ≤(b) ppm. The user point, (b) (4) serves to the (b) (4) ID # (b) (4) (in (b) (4) Production Room (b) where you manufacture (b) (4) for the US market. Your procedure (b) (4) Water Loop and Mains (b) (4) Water Sampling Schedule 2023 Revision 00 (Effective date 1/12/2023) confirmed that you sample the user points (b) (4) You resampled the user points on 12/7/2023 and the TOC for all the user points met the specifications.

Your investigation did not find any root cause. You concluded that the initial OOS for the TOC at (b) (4) user point was most likely caused due to the airborne contamination during the initial sampling (on 11/30/2023) from (b) (4) You derived this conclusion based on the facts that, except the TOC of (b) (4) the water quality on 11/30/2023 comply with the USP including, meeting the conductivity and microbial specification.

Your conclusion about the water quality on 11/30/2023 based on the test of resampling on 12/7/2023 is not fully justified for reasons including but not limited to; the water sampled on 12/7/2023 does not represent the water that was sampled on 11/30/2023, the (b) (4) conductivity does not represent conductivity of the water for user point (b) (4) (b) (4) prior to reaching to the (b) (4) conductivity meter. In addition, as per your process chemist (b) (6) ~(b) (4) of (b) (4) hose is used to connect the (b) (4) POU to the (b) (4) ID # (b) (4) and your (b) (4) (b) (4) of the (b) (4) Sterilization unit was due for replacement on 11/22/2023 after meeting the (b) (4) usage.

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Between 11/30/2023 and 12/7/2023, you have manufactured (b) (4) (b) (4) batches) for the US market.

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