DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	09/15/2025 - 09/19/2025
	FEI NUMBER 1000568184

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Olivia L. Blackwood, General Counsel and Company Secretary

FIRM NAME	STREET ADDRESS
A. Nelson & Co., Ltd.	5 Endeavour Way
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
London, Great Britain, SW19 8UH, United Kingdom	API and Homeopathic Drug Product 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

Failure to establish appropriate microbial specifications for homeopathic product, in accordance with accepted standards and consistent with the manufacturing process. Specifically,

A. Your firm failed to perform microbial testing on the (b) (4) finished liquid homeopathic products intended for (b) (4) prior to releasing them to the U.S. market. Additionally, your firm failed to conduct microbial testing on the bulk (b) (4) before releasing it for finished product packaging. Bulk (b) (4) is (b) (4) in-house (b) (4) and used as (b) (4) for some of these liquid homeopathic products.

Since 2023, your firm has distributed (b) (4) homeopathic liquid products into the U.S. market without adequate microbial testing, including but not limited to: Batch (b) (4) ml), Batch (b) (4) ml), Batch (b) (4) ml), Batch (b) (4) and Batch (b) (4)

USP General Chapter (b) (4) establishes specific microbiological acceptance criteria for non-sterile (b) (4) products, requiring a maximum limit of (b) (4) CFU/g or CFU/mL for the total aerobic microbial count and (b) (4) CFU/g or CFU/mL for the total yeast and mold count. The chapter also mandates the absence of E. coli (in (b) (4) g or (b) (4) mL) and Salmonella species (in (b) (4) g or (b) (4) mL) in these (b) (4) non sterile preparations. Therefore, your firm's failure to perform microbiological testing prevents verification that your (b) (4) homeopathic products meet appropriate microbiological standards and are free of objectionable microorganisms that could pose a risk to consumer health and safety.

B. Your firm failed to perform adequate risk assessments to support your microbial testing program for (b) (4)

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products. During the inspection, we observed that the firm relies on the supplier's Certificate of Analysis (CoA) for microbial test results of each batch of bulk (b) (4) received and only conducts microbial testing on these (b) (4) However, no documented rationale was provided to demonstrate that this testing approach provides adequate assurance of microbiological quality.

Furthermore, record review revealed that the firm tests only (b) (4) batch of finished (b) (4) for microbial contamination, rather than testing each individual batch. However, the firm's (b) (4) testing does not ensure that batches from each market are included. Our review of Form QR 036, "Production Laboratory Sample Record," covering (b) (4) to (b) (4) showed that none of the (b) (4) samples collected during (b) (4) sampling were intended for the U.S. market. As a result, the (b) (4) packaged for the U.S. market during this period were distributed without any microbiological testing. Since 2023, your firm has distributed (b) (4) batches of (b) (4) and (b) (4) batches of (b) (4) to the U.S. market without conducting adequate microbial testing. Examples include Batch (b) (4) Batch (b) (4) (b) (4) and Batch (b) (4)

OBSERVATION 2

Written records of investigations into unexplained discrepancies do not always include the conclusion and follow-up. Specifically,

Investigations initiated and performed by your Quality Unit in response to laboratory investigation reports (OOS) and Quality Incident Reports (QIR) for drug products, are not always comprehensive to determine all potential root causes. Additionally, Corrective and Preventive Actions (CAPAs) as a result of investigations are not always comprehensive to address root causes or adequately documented to have been performed. For Example,

A. The firm's out-of-specification (OOS) investigations for (b) (4) system failures consistently lack adequate documentation of definitive conclusions and systematic follow-up actions. For example:

-OOS 2025-032 (TAMC failure; ID Microbacterium phyllosphaerae), opened April 22, 2025: Investigation closed

with no definitive assignable cause identified. No CAPA was documented as a response.

-OOS 2024-099 (TAMC failure; ID Staphylococcus capitis), opened November 19, 2024: Investigation closed with no root cause identified, stating "Most probable root cause is due to sampling error". No CAPA was documented as a response. Investigation did not extend to batches manufactured using (b) (4) during that period.

-OOS 2024-058 (TAMC failure; ID Pseudomonas oryzihabitans), opened July 31, 2024: Investigation closed as inconclusive with no definitive root cause identified. Firm stated that "this is most likely a sampling error" and cited CAPA 447 as a corrective action, which was referenced in OOS 2024-054 and found to be ineffective. Investigation did not extend to batches manufactured using (b) (4) during that period.

-OOS 2024-054 (TAMC failure; ID Micrococcus luteus), opened July 25, 2024: Investigation closed as inconclusive with no definitive root cause identified despite mentioning two possible causes. CAPA 447, created in response to TOC OOS (OOS 2024-065, was referenced as a corrective action. Investigation did not extend to batches manufactured using (b) (4) during that period.

-OOS 2023-101 (TAMC failure; ID Staphylococcus warneri and Staphylococcus epidermidis), opened October 18, 2023: Investigation determined "Probable root cause is sample contamination by analyst during sampling." Analysts were reminded of aseptic sampling importance, but no CAPA was created to capture this corrective action. Investigation did not extend to batches manufactured using (b) (4) during that period.

-OOS 2022-049 (TAMC and Pseudomonas spp. failure) opened July 4, 2022: Investigation concluded "No clear root cause identified" and stated contamination during sampling was possible. The risk of microbial contamination as well as the changing procedures were re-explained to the analysts, but no CAPA was initiated to capture this corrective action.

These investigations involving various identified microorganisms were closed without establishing definitive root causes. This demonstrates a pattern of inadequate documentation where failures were frequently attributed to "sampling error" or "contamination during sampling" without implementing comprehensive corrective and preventive actions (CAPAs) to address the recurring issues.

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B. During the inspection, it was observed that your firm failed to adequately investigate quality incident report QIR-206, which was opened due to an import alert triggered by microbial contamination detected during FDA sampling (b) (4) The affected product was detected and denied entry into the US market. Per your investigation documented in QIR-219, you failed to extend the evaluation to retained samples collected for the same product (b) (4) despite the microbial failure occurring in this lot during FDA testing. Furthermore, the investigation failed to evaluate other batches that were packaged by (b) (4) on the same packaging line within the same time period as the affected batch, even though your Head of Quality confirmed that the packaging lines at (b) (4) are shared lines used to pack multiple different products. The failure to conduct a thorough investigation that includes evaluation of potentially affected batches and retained samples prevents your firm from determining the full scope of the problem and implementing appropriate corrective and preventive actions to prevent recurrence.

C. Your firm failed to adequately investigate environmental monitoring (EM) out-of-specification results and implement effective corrective and preventive actions. Multiple OOS investigations for environmental monitoring failures occurred in different areas of the facility throughout 2025, with your firm repeatedly concluding that no root cause could be identified and failing to initiate CAPAs to address underlying deficiencies such as cleaning procedures and sampling procedures.

Review of environmental monitoring trending reports for 2024 and 2023 revealed similar recurring deficiencies that had previously resulted in Quality Incident Report (QIR) 198 in 2024 and QIR 102 in 2023. Despite these formal quality incidents being initiated to address environmental monitoring issues, the corrective actions implemented appear to have been ineffective, as evidenced by the continued occurrence of similar EM failures in 2025. Eight OOS investigations were reviewed from 2025 (OOS-2025-014, 02/19/2025; OOS-2025-022, 03/18/2025; OOS-2025-040, 05/28/2025; OOS-2025-045, 06/16/2025; OOS-2025-048, 06/23/2025; OOS-2025-055, 08/06/2025; OOS-2025-057, 08/11/2025; and OOS-2025-064, 09/01/2025) involving environmental monitoring failures in critical manufacturing areas including the (b) (4) (b) (4) For all investigations, the firm's conclusion was that the results were probably due to high traffic areas, with no definitive root cause identified and no CAPAs implemented.

The firm's pattern of inadequate root cause investigations, failure to implement appropriate CAPAs, and

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ineffective resolution of previously identified environmental monitoring deficiencies demonstrates a systematic failure to maintain adequate environmental controls. This ongoing deficiency poses a significant risk of microbial contamination during the manufacture of finished drug products and indicates that the firm's quality system is not effectively preventing recurring environmental monitoring failures.

D. Your firm failed to implement adequate corrective and preventive actions (CAPA) following out-of-specification (OOS) investigations, despite identifying recurring root causes related to contamination and insufficient cleaning procedures. Two OOS investigations for refractive index testing revealed systematic deficiencies in the firm's corrective action process:

-OOS-2025-008, dated 02/14/2025, for (b) (4) ml (b) (4) involved a refractive index result of (b) (4) which exceeded the specification limit of (b) (4) The firm identified the root cause as contamination, cleaned the equipment, and retested with acceptable results. However, no CAPA was implemented, and no additional training was provided to the analyst.

-OOS-2025-009, dated 02/14/2025, for (b) (4) ml (b) (4) resulted in an OOS refractive index test. The firm again identified the root cause as insufficient cleaning and contamination. The equipment was cleaned, a (b) (4) check was performed, and retesting yielded acceptable results. Despite the recurring nature of the contamination issue, no CAPA was implemented, and no additional training was provided to the analyst.

Both investigations involved the same analyst and identified similar root causes related to cleaning and contamination issues. The firm's failure to implement CAPA, provide additional analyst training, or revise procedures represents an inadequate response that does not address the underlying systematic issues and increases the likelihood of recurring OOS events.

E. The firm demonstrated recurring issues with line clearance and line setup operations, specifically related to establishing correct expiration dates prior to manufacturing and entering accurate expiration dating on machines. These deficiencies resulted in incorrect expiration dates being printed on finished products, which at times required the firm to rework labeling or justify using incorrect labeling.

Multiple Quality Incident Reports were reviewed demonstrating this recurring pattern: QIR-229, 07/31/2025;

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QIR-231, 08/22/2025; QIR-222, 05/15/2025; QIR-217, 04/22/2025; QIR-202, 12/11/2024; QIR-177, 08/21/2024; QIR-176, 08/19/2024; QIR-173, 07/30/2024; and QIR-162, 05/20/2024. The recurring deficiencies observed include expiration date calculation errors such as confusion between using filling dates versus bulk manufacture dates and incorrect shelf-life assignments; line clearance failures including complete absence of clearance procedures and cartons with previous product information remaining on equipment; machine setup and data entry errors involving incorrect expiration dates programmed into printing equipment and wrong batch numbers entered into systems. These incidents involved various products across different markets including Netherlands, Germany, US, and France, indicating the recurring nature of the deficiency spans multiple product lines and manufacturing operations.

The firm's trending system appears inadequate as it focuses on individual products rather than the type of deficiency, thereby masking the recurring nature of these expiration dating setup errors. Despite repeated occurrences of similar root causes related to unclear procedures for selecting appropriate bulk manufacturing dates and insufficient line clearance verification, the firm continues to experience these recurring failures, suggesting that implemented corrective actions have been ineffective in preventing recurrence.

F. Your firm conducted a recall of a homeopathic drug product from the US market, documented in Quality Investigation Report (QIR) 210 dated (b) (4) The recall was initiated because (b) (4) (b) (4) ml product (batch number (b) (4) was packaged in (b) (4) cartons incorrectly labeled as (b) (4) (b) (4) ml. While the (b) (4) packaging bottles were correctly labeled, the (b) (4) packaging cartons contained wrong product identification. Your firm's investigation revealed that additional units with the same packaging error were present at the US distributor's warehouse, prompting a complete recall of all affected products. Despite conducting this investigation, your firm failed to identify the root cause of the packaging mix-up. The corrective and preventive actions implemented were inadequate and consisted only of customer service training and updating the mock recall form to include a comprehensive process flow. These actions do not address the fundamental packaging control deficiencies that led to the recall. Most significantly, your firm's investigation resulted in no improvements to line setup procedures or clearance operations, which are critical control points for preventing product mix-ups during packaging operations.

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OBSERVATION 3

Document control procedures under Quality Unit oversight are inadequate. Specifically,

During our walkthrough on September 15, 2025, we observed discarded cGMP records in your outside trash bins, QC laboratory waste bins, and QA office shred bins which appear to be cGMP-controlled records. Your document control procedures do not detail record discard and/or shredding operations and which records are permitted to be discarded. The firm's current document control procedures fail to establish adequate protocols for the proper disposal of cGMP records, including criteria for determining which records may be discarded and appropriate disposal methods for different types of controlled records. Examples of these improperly discarded records observed during our walkthrough are listed below.

A. Records found in outside trash bins are as follows:

-Finished Product Specification (FPS) form for batch (b) (4) printed in error and discarded without proper documentation.

-Master Manufacturing Record for (b) (4) ml (b) (4) campaign, signed by QA but listing incorrect product (should have been (b) (4) ml), discarded without proper documentation.

-Refractive index test form, printed in error and discarded without proper documentation.

-Finished Product Specification (FPS) forms for (b) (4) (b) (4) duplicate copies discarded without proper documentation.

-Finished Product Specification (FPS) form for (b) (4) batch number (b) (4) duplicate copy discarded without proper documentation.

-FTIR analysis form for (b) (4) batch (b) (4) duplicate copy with handwritten batch number (b) (4) signed and dated by QA, discarded without proper documentation or authorization.

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B. Records found in QC Laboratory Waste Bin are as follows:

-Completed (b) (4) reagent preparation form dated 09/10/25 with unacceptable pH results, discarded without proper documentation (no laboratory incident report filed) when reagent was re-prepared on 09/11/25.

-Handwritten sticky note questioning significant difference between firm's test results (b) (4) %) and manufacturer's COA (b) (4) %) for (b) (4) against specification of ≤(b) (4)%, with response "No, we have enough work". No OOT investigation was initiated.

-Handwritten note containing (b) (4) results dated 04/09/2024, resulting in non-contemporaneous recording of data.

-Handwritten note containing (b) (4) test results for (b) (4) batch (b) (4) dated 04/18/2024, resulting in non-contemporaneous recording of data.

-Incomplete identification test form for raw material during training (not completed due to unavailable reagent), discarded without proper documentation.

C. Records found in QA Shred Bin are as follows:

-Duplicate manufacturing batch record page for line clearance and batch set up checks for (b) (4) (b) (4) batch (b) (4) discarded without proper documentation.

-Blank and incomplete Finished Product Specification Forms printed in duplicate for four batches, discarded without proper documentation.

-Various finished product stability test forms (b) (4) (density, (b) (4) TLC, identification) issued 08/21/2025 but not used, discarded without proper documentation or explanation when replacement forms were issued 08/26/2025 and executed.

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OBSERVATION 4

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically,

A. During our inspection, we observed that your firm has on numerous occasions extended product shelf life without supporting stability data. For example, your firm extended the shelf life for homeopathic drug product US (b) (4) ml batch number (b) (4) originally expiring (b) (4) This batch was manufactured around August 2024 and shipped to the US market. Due to excess unsold inventory at the distributor, your firm initiated Planned Process Deviation (PPD) (b) (4) dated (b) (4) to extend the shelf life from (b) (4) to (b) (4) Your firm completed relabeling with a new batch number (b) (4) and new expiration date of (b) (4) with the repackaged batch awaiting QA review at the time of our inspection. We observed similar shelf-life extension practices during our review of QIR-177, dated (b) (4) for (b) (4) batch number (b) (4) and QIR-229, dated (b) (4) for (b) (4) batch number (b) (4)

B. Your firm packages a variety of (b) (4) homeopathic drug products after receiving bulk product from contract manufacturers. While your firm performed a risk assessment dated May 12, 2025, to identify potential risks associated with qualification, packaging processes, and their impact on product quality, patient safety, and regulatory compliance, your firm has not performed process validation studies for these packaging operations as of the current inspection. Process validation studies are necessary to demonstrate that the packaging operations consistently produce products meeting predetermined specifications and quality attributes. Your firm's own risk assessment identified multiple potential issues during packaging operations that require validation, including incorrect packaging components such as (b) (4) or labels, incorrect weight of (b) (4) within containers, seal integrity for lids, cross contamination from packaging materials, environment, or handling, errors in line clearance procedures leading to product mix-ups, incorrect, missing, or misprinted labeling, packaging integrity and defects, equipment malfunctions, and inadequate equipment cleaning and maintenance. During the current inspection, multiple deviations were observed involving incorrect labeling and expiration dating on packaging labels,

demonstrating that the packaging process is not adequately controlled.

C. During our walkthrough on September 15, 2025, we observed finished product in unsecured waste bins awaiting pickup by your city waste service provider. Specifically, (b) (4) Lot (b) (4) EXP (b) (4) along with product cartons were found in this unsecured waste bin. While your firm maintains a second locked waste bin designated for discarded finished products, this secured bin was observed to be at maximum capacity at the time of our inspection. Additionally, your firm does not maintain adequate written procedures for disposal of finished products.

OBSERVATION 5

Complaint investigations under Quality Unit oversight are inadequate. Specifically,

A. Your firm failed to conduct adequate investigations for complaints involving the same product and similar adverse events. Three complaints were received for (b) (4) reporting similar burning sensations:

-CCPF-41394, dated 08/26/2024, for (b) (4) batch number (b) (4) with a complaint that "(b) (4) felt like burning sensation."

-CCPF-41415, dated 10/04/2024, for (b) (4) batch number (b) (4) with a complaint that the product "made (b) (4) burn."

-CCPF-41432, dated 11/01/2024, for (b) (4) with a complaint that the product "burned (b) (4) (b) (4) "

Despite having batch numbers available for two of the complaints, the firm did not perform any testing on retain samples. The firm's conclusion that there was "no trend for this issue" was inaccurate, as all three complaints involved the same product and similar burning sensations in the (b) (4) area, with the pattern established since the first complaint on 08/26/2024.

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B. Per your firm's complaint procedure, complaint investigations should be completed within (b) (4) and if not, extensions should be documented and justified. During the inspection, the following complaints were observed to still be open with no extensions taken:

-CCPF-41525, dated 06/25/2025, for (b) (4) regarding a complaint of (b) (4) burning due to the product (b) (4) overdue).

-CCPF-41485, dated 04/08/2025, for (b) (4) regarding a complaint of allergic reaction due to the product (b) (4) overdue).

-CCPF-41499, dated 05/13/2025, for (b) (4) ml regarding a complaint that the product resulted in customer (b) (4) overdue).

-CCPF-41526, dated 07/01/2025, for (b) (4) ml regarding a complaint that the product caused a (b) (4) (b) (4) overdue).

-CCPF-41572, dated 08/13/2025, for (b) (4) regarding a complaint of (b) (4) (b) (4) overdue).

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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."