DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	4/30/2026-5/4/2026* FEI NUMBER 1000148174

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Frank Owen Griffin, General Manager

FIRM NAME	STREET ADDRESS
Element Materials Technology Boston - Acton Inc.	33 Nagog Park
CITY, STATE, ZIP CODE, COUNTRY Acton, MA 01720-3421	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory - Microbiology

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 OBSERVED:

OBSERVATION 1

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm's re-certification program for the sterility testing suite as governed by procedure SOP#: QC-0012 "Equipment Maintenance and Calibration", is deficient in that the program does not outline cleanroom re-certification requirements after preventative maintenance activities to the room and/or HVAC system. On April 10th, 2025, your HVAC contractor performed preventative maintenance of the sterility suite HVAC system. The sterility suite was not assessed/re-certified after the preventative maintenance to ensure that it was still operating in a state of control. On May 7th, 2025, your firm observed that the Magnehilic gauge of the ISO-5 BSC utilized to conduct drug product sterility testing, was out of range during logbook review. Your investigation determined that the cleanroom pressure differentials between the ISO-7 cleanroom and ISO-7 gowning room had reversed likely due to the preventative maintenance conducted in April 2025. SOP#: QC-0012 was not updated to require room recertification after preventative maintenance activities to prevent reoccurrence.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sean R Marcsisin, Investigator X Sean R Marcsisin Investigator Signed By: Sean R. Marcsisin -S Date Signed: 05-04-2026 14:49:29	5/4/2026

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Your firm's routine environmental monitoring program for the sterility testing suite as governed by procedure SOP#: P-0023 "Environmental Monitoring of the Sterility Suite Area Clean Rooms", is inadequate in that your alert and action limits specifications set for ISO-5 areas do not align with specifications determined in risk assessment Element-Acton-001 "Environmental Monitoring Plan and Risk Assessment for the Element-Acton Cleanroom Sterility Suite and Lab Clean BSCs at Acton, MA". For example, per Element-Acton-001, the action level specifications for surface sample environmental monitoring excursions in the ISO-5 classified biological safety cabinet (BSC) utilized to conduct sterility testing of drug products is to be (b)(4) CFU/(b)(4) plate. Procedure SOP#: P-0023 has an action excursion specification for the ISO-5 sterility testing BSC for surface samples as (b)(4) CFU/plate. Your firm lacks scientific justification for deviating from your risk assessment Element-Acton-001.

OBSERVATION 3
Buildings used in the processing of a drug product are not maintained in a good state of repair.

Specifically,

- Unknown white residue was observed on the front grate of the ISO-5 BSC utilized for drug product sterility testing.
- The white protective floor mat where carts utilized to stage sterility testing materials prior to entry into the cleanroom area was noted to be brown and appeared unclean.
- The mirror utilized to check gowning in the ISO-8 ante room had unknown brown material all along the edges of the mirror frame.
- What appeared to be adhesive tape was observed on the ISO-7 sterility suite gowning room wall adjacent to the material passthrough.
- Two ceiling tiles in the main laboratory area were discolored brown, indicating a prior leak.

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OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

The following inadequate investigations were noted during the inspection:

- OOS-OOT-2025-0144 was opened in June 2025 for fungal growth (*Irpex lacteus*) observed in the FTM negative control for the USP <71> sterility testing of samples under sample reference Lot# (b)(4). Your firm attributed the failed negative control to analyst testing error; however, your firm did not review your environmental monitoring program in an attempt to identify the source of the mold or how the mold ingressed into the sterility testing suite.

- OOS-OOT-2026-0124 was opened due to failed growth promotion testing of (b)(4) lot (b)(4). The phase 1 laboratory assessment was due April 24th, 2026. As of May 1st, 2026, the phase 1 laboratory assessment has not been initiated.

***DATES OF INSPECTION**

4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sean R Marcsisin, Investigator X Sean R Marcsisin Investigator Signed By: Sean R. Marcsisin -S Date Signed: 05-04-2026 14:49:29	5/4/2026

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 judgment, 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."