DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/27/2026-4/30/2026
	FEI NUMBER 3037143716

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amie Myers, VP of Operations

FIRM NAME	STREET ADDRESS
Microchem Laboratory	990 N Bowser Rd Ste 800
CITY, STATE, ZIP CODE, COUNTRY Richardson, TX 75081-2859	TYPE ESTABLISHMENT INSPECTED Contract Laboratory

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

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,
The Quality Unit failed to maintain adequate oversight of the Quality Management System (QMS), including the following:

a) Qualification Protocols
Failure to review and approve execution data, and associated documentation to confirm that acceptance criteria and all required activities were completed before implementation, as documented through a final report or formal authorization, including but not limited to:

- LD7047: (b) (4) Method created on Dec/01/2025, to support chemical assay testing of approximately (b) (4) samples, with the final report approved on April 29, 2026.

- DV1049: (b) (4) Media Validation/ Expiration to support the (b) (4) expiration dates of (b) (4) media used for microbial testing of approximately (b) (4) samples (lot (b) (4)) with the final report approved on April 28, 2026.

b) Out-of-Specification (OOS) Investigations
Failure of scientific rationale and evidence to support identification of root causes, and implementation of actions for OOS investigations, including but not limited to:

- 20251100SC002 (completed Nov/26/2025): No root cause identified; no rationale provided for

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Milton J De Jesus Tavarez, Investigator Jeffrey T Prosterman, Investigator X Milton J. De Jesus Digitally signed by Milton J. De Jesus Date: 2026.04.30 15:10:53 -05'00'	4/30/2026

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why the retest was considered valid.

- 202510OOSM003 & 202510OOSM004 (completed Dec/26/2025): Preservative system identified as root cause, but evaluation of other potential factors was not documented prior invalidating results.
- 20251200SC006 (completed Dec/2025): Root cause not finally established; a sequencing pattern ((b) (4) failing when run before (b) (4) samples) was identified but not investigated as a systemic issue.
- 20260100SC002 (completed Jan/14/2026): Investigation lacks justification for collecting a new sample rather than retesting the original.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a. The intermediate precision studies documented in the Method Verification Report for (b) (4) by HPLC (Method ID: LD7045, Effective date: 02/09/2026) and the Method Verification Report for (b) (4) by (b) (4) (Method ID: LD7023, Effective date: 12/30/2025) are deficient in that the results presented for Analyst II were performed on two separate dates and combined as a single dataset without adequate justification. Furthermore, a laboratory error was identified in each of the two analyses. These errors were not documented, investigated, or disclosed in the corresponding Method Verification Reports.

b. The Intermediate Precision study for Method Validation Report for (b) (4) by HPLC (Appendix I) (Method ID: LD7045, Effective date: 01/30/2026) had results which failed the specification. The test specification was changed, and a second test was performed. The results for the second preparation, passed the initial specification and were documented in the final report. The original failing results and the specification change were not included in the final

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report.

c. The accuracy studies for method validations, including but not limited to, (b) (4) (Method ID: LD7045, Effective date: 01/30/2026), (b) (4) (Method ID: LD7023, Effective date: 12/30/2025), and (b) (4) (Method ID: LD7047, Effective date: 04/29/2026), were performed with only (b) (4) for all concentration levels and without the use of a representative sample matrix.

d. The following analytical methods are not stability-indicating, including but not limited to: (b) (4) (Method ID: LD7045, Effective date: 01/30/2026), (b) (4) (Method ID: LD7023, Effective date: 12/30/2025), and (b) (4) (Method ID: LD7047, Effective date: 04/29/2026). The reviewed analytical methods did not include forced degradation studies necessary to demonstrate the ability of each method to accurately detect, separate, and quantify drug substance degradation products that may form over the shelf life of the drug product.

Method LD7047: (b) (4), method created on 12/01/2025 supported chemical assay testing of approximately (b) (4) samples. Method ID: LD7023: (b) (4), method created on 12/08/2025 supported chemical assay testing of approximately (b) (4) samples. Method ID: LD7045: (b) (4), method created on 11/06/2025 supported chemical assay testing of approximately (b) (4) samples.

X JEFFREY T. PROSTERMAN -S Digitally signed by JEFFREY T. PROSTERMAN -S Date: 2026.04.30 15:13:15 -05'00'

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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 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."