DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main St., Suite 7200 Dallas, TX 75202 214-253-5200 Industry Information: www.fda.gov/oc/industry	03/2-6/2026
	FEI NUMBER 1628757

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Edward J. Vilt, Site Director

FIRM NAME	STREET ADDRESS
Aurorium LLC	500 North 9th St.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Midlothian, TX 76065	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 (I) (WE) OBSERVED:

The following observations pertain to the manufacture of active pharmaceutical ingredients, including (b) (4) (b) (4) , USP. Approximately (b) (4) batches of (b) (4) , USP were made from (b) (4) .

OBSERVATION 1

Failure to properly maintain buildings, facilities and equipment used in the manufacture of active pharmaceutical ingredients (API).

Specifically,

a) During our walk-through of the manufacturing facility on March 2 and 3, 2026, we noted there were areas of the building that had excessive corrosion, water leaking from equipment, and deterioration of walls and floors. Examples include the following.

- We observed water leaking from a pipe that went from the (b) (4) to the (b) (4) ((b) (4) (b) (4)
- The platform where the (b) (4) is located is deteriorating and has excessive corrosion.
- The wall between the (b) (4) room and production has water damage and is warped and the panels are separating. On the side in the (b) (4) room there is exposed insulation from a large hole in the corner of the room near the (b) (4) and (b) (4) tanks.
- We observed a leak on the (b) (4) unit and the metal support for the skid had excessive corrosion.
- There were remnants of an old platform on the (b) (4) platform area (b) (4) where the concrete had broken into pieces.
- There is water leaking from the exhaust for the dryer.

b) On March 3, 2026, we observed the presence of a clear tape placed around a phalange connection on the (b) (4)

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	Margaret M. Annes	Margaret M. Annes, Sr. CSO Ronda Loyd-Jones, Branch Chief	03/06/2026

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(b) (4) . The system is under (b) (4) can enter the system. The (b) (4) system (b) (4) (b) (4)

c) Tank (b) (4) used to store (b) (4) from the (b) (4) that will be (b) (4) tanks is not completely covered and is open to the environment.

OBSERVATION 2

Failure to investigate all out of specification test results.

Specifically, a review of (b) (4) test results from March 2024 to February 2026 revealed four (4) instances where your firm received an out of specification test result for endotoxins. Your firm has no documentation to show that these out of specification test results were investigated nor did you perform any product impact assessment. Per MIDL-SOP-307 (b) (4), effective January 1, 2024, the specification for endotoxin is (b) (4) EU/mL.

- Sample from (b) (4) system collected 05/29/2024 - test result was 0.430 EU/mL
- Sample from (b) (4) system collected 09/25/2024 - test result was 1.508 EU/mL
- Sample from (b) (4) system – QC Laboratory collected 09/25/2024 - test result was 0.439 EU/mL
- Sample from (b) (4) system – QC Laboratory collected 03/31/2025 - test result was 17.589 EU/mL
- Sample from (b) (4) system collected 05/27/2025 - test result was 0.418 EU/mL

In addition, several of the lab reports for the testing of the (b) (4) indicate that the sample for endotoxin testing was received outside of the recommended temperature range. The laboratory report does not state the temperature the samples were received at nor does it state what the recommended temperature range is. There is no evaluation of this issue to determine if it has any impact on testing of the (b) (4) to receive accurate results.

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OBSERVATION 3

Failure of the Quality Unit to fulfill its oversight responsibilities.

Specifically,

a) CAPAs are not fully documented in accordance with your established procedure entitled Corrective and Preventative Actions (MIDL-SOP-124) effective January 1, 2024; they also are not closed out in a timely manner. For example:

• CP25-014 (initiated 8/15/2025), CP25-010 (initiated 7/01/2025), CP25-019 (initiated 11/17/2025), CP24-12 (initiated 10/11/2024), and CP24-13 (initiated 9/24/204), either lack or have insufficient documentation of an effectiveness check.
• CP24-12, CP24-13 and CP25-019 have not been finalized and signed off as completed or reviewed by quality.

b) Your firm does not have written procedures for the issuance, use and reconciliation of loose-leaf forms used for documentation of manufacturing (e.g. batch record) and laboratory testing. Examples of these forms include:

• All forms and documents that are part of the batch record
• Form 239A Reagent/Solution Preparation Log
• Form 120A Label Control Form
• Form 121A Label Issuance
• Form 112B (b) (4) Pre-Shipment Review Log
• Form 133D Total Unacceptable (b) (4) Count

c) There is a failure to review and approve all quality-related documents. The analytical testing lab books (data collection form) used for testing of (b) (4) , USP (API) are not controlled documents. The documents are not assigned numbers or revisions nor have they been reviewed and approved by the Quality Unit. These forms include the following:

• USP/FCC/JP Chemistry Testing of (b) (4)

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- USP/FCC/EP/JP Loss on Drying of (b) (4)
- USP/FCC/EP/JP Equivalent (b) (4) Test for (b) (4)
- (b) (4) and Morphology

d) Your firm has no written SOP governing the circumstances that would warrant the creation of a work order to ensure that all maintenance of equipment is reported. For example, on March 3, 2026, we observed the presence of a clear tape placed around a phalange connection on the (b) (4). No work order has been initiated to fix the issue and your firm has no documentation to show how long the tape has been on the equipment and who made the decision to do so.

e) There is a failure of the Quality Unit to appropriately review all (b) (4) test results.

- There is no documented Quality Unit review of the results from August 2025 to present.
- From March 2024 to February 2026 there were four (4) instances of out of specification results for endotoxin that were not investigated however, the Quality Unit documented that the results were reviewed.

OBSERVATION 4

Your firm failed to conduct an annual product quality review of your API.

During the current inspection of your facility we observed that you had not conducted your 2024 annual product quality review for your API (b) (4), USP. On August 6, 2025, your firm initiated a deviation report however, no content was provided in the report explaining why the 2024 review had not been completed or when it would be finalized. The deviation is still open.

OBSERVATION 5

Failure to perform testing of the (b) (4) used in production and in the QC Laboratory.

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Specifically, your firm could not provide test results for the (b) (4) for the (b) (4) of (b) (4) and (b) (4). MIDL-SOP-307 (b) (4), effective January 1, 2024 requires (b) (4) testing of the (b) (4) for (b) (4), endotoxin, and microbial (standard plate count and pseudomonas).

In addition, your firm has no documentation and/or procedure to show exactly where the samples are being taken by your 3rd party contractor. The laboratory results simply state (b) (4), "Lab" and "Production".

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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."

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