DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	11/17/2025-11/25/2025* FEI NUMBER 1416980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacob A. Winchell, Site Director

FIRM NAME	STREET ADDRESS
Baxter Healthcare Corporation	25212 W Il Route 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Round Lake, IL 60073-9799	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 I OBSERVED:

OBSERVATION 1

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, your firm's environmental monitoring (EM) program for cross-contamination detection has significant limitations in scope and coverage. (b) (4) (b) (4), are manufactured at your facilities. However, there are no analytical methods for detection of (b) (4) from (b) (4) samples taken from (b) (4) areas. The current test method utilized only detects (b) (4) and fails to include (b) (4) manufactured in the same facility. From January 1, 2025, to November 20, 2025, alone, your firm tested at least (b) (4) EM samples, but only for the presence of (b) (4). Results for these were found to be false positives for the presence of (b) (4), and were then subjected to confirmatory testing, (b) (4) (b) (4) (Procedure RD-02-01-020, Document No. 1138932, Revision H) with a concentration limit of (b) (4) (b) (4) for (b) (4) detection.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shafiq Ahadi, Investigator X Shafiq Ahadi Investigator Signed By: 2000594974 Date Signed: 11-25-2025 14:42:02	11/25/2025

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A.

Risk assessments have failed to adequately evaluate cross-contamination risks in these laboratories where testing occurs for (b) (4) containing products, as follows:

The sterility laboratory, located within the (b) (4) building (b) (4) performs both internal and contracted sterility testing for both (b) (4) products.

The QC Microbiology Laboratory is located in the (b) (4) section of (b) (4) Building. This laboratory performs both internal and contracted testing, including environmental monitoring and solution bioburden testing, in the same laboratory where (b) (4) samples are also processed.

B.

The oversight by the Quality Control (QC) unit is deficient in that there is no written procedure defining the roles and responsibilities of QC and R&D, including QC's responsibility for reviewing, evaluating, and approving test results generated by R&D laboratories, who perform testing of commercial product. There are (b) (4) R&D personnel who currently execute and approve confirmatory testing for the detection of (b) (4) in environmental samples collected from (b) (4) your own GMP areas, as well those you collect from manufacturing suites of the co-located firm, who manufactures commercial drug product.

OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

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(b) (4) The software, (b) (4) that interfaces with the (b) (4) instrument (b) (4) (b) (4) in the R&D laboratory, for the performance of confirmatory testing of ‘ (b) (4) As A Referee Method For Medical Products Procedure RD-02-01-020” for the detection of (b) (4) ” in environmental samples, is deficient in that the raw data generated and captured can be modified and deleted without administrative-level permissions, audit trails, or electronic records documenting such modification. For example, on November 21, 2025, your R&D personnel demonstrated that the raw data generated from confirmation testing stored in computer folder (b) (4) can be potentially modified and deleted.

B. Data integrity gap assessment has not been performed to ensure adequate controls are in place to prevent unauthorized modification or deletion of raw data for the (b) (4) instrument (b) (4) - (b) (4) used to perform confirmatory testing.

C. There is no training provided to R&D personnel regarding the handling, storage, and archiving of raw data.

OBSERVATION 4

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically, QC analysts responsible for testing of environmental samples (EM) for the absence of (b) (4) are not trained by the quality team, resulting in inadequate oversight of personnel qualifications. For example, per the firm’s training procedure No. RD-03-01-019, Revision W, each analyst is required to complete, including but not limited to, (b) (4) containment training (Training Code: (b) (4) containment training (Training Code: (b) (4)), and good documentation training. QC analysts performing (b) (4) testing have not completed mandatory training requirements per the firm's training procedure (Document No. RD-03-01-019, Revision W).

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FIRM NAME Baxter Healthcare Corporation	STREET ADDRESS 25212 W Il Route 120
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OBSERVATION 5

Laboratory records do not include a description of the sample received for testing, the quantity of the sample and the date the sample was received for testing.

Specifically, your firm does not maintain adequate sample logs for environmental monitoring (EM) samples that failed the absence of (b) (4) test per (b) (4) for Determining the Absence of (b) (4) in Environmental Samples (Document no. RD-02-01-020, Revision S). For example, between January 1 and November 20, 2025, a total of (b) (4) EM samples failed the (b) (4) test for absence of (b) (4) However, there is no record of the receipt and tracking of these samples, which were subjected to (b) (4) Test Method (Procedure RD-02-01-020, Document No. 1138932, Revision H).

***DATES OF INSPECTION**

11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(Fri), 11/24/2025(Mon), 11/25/2025(Tue)

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."