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	3/23/2026-4/2/2026* FEI NUMBER 1416980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ivan [NMI] Quadrio, Site Director, Associate Vice President of Engineering

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	Sterile Drug 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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm has documented recurring leaking unit defects in finished sterile drug products since at least 2023. Since January 2023, approximately 72 In-Process Retention investigations have been opened due to leaking bags or burst bags due to scrap alert being reached or AQL testing failures. In addition, your firm initiates a scrap alert for leaking units only once (b)(4) leaking units have been found during a production period, which is (b)(4) of production. The limit of (b)(4) units is based on historic process capabilities and was not determined based on criticality of the defect. In addition, you have received approximately 147 complaints related to leaking units since May 2023.

B. Your firm has repeatedly failed to take corrective actions to improve detectability of defects from the visual inspection process, leading to defects being found post inspection and in the market.

   a. Your firm has had leaking media fill units recovered in approximately 21 out of (b)(4) media fill runs performed since 2/7/2023. These units were initially deemed integral by your firm's 100% inspection process and were often identified as leaking post incubation and exhibiting turbidity. Your firm did not evaluate the effectiveness of the visual inspection process as a part of the investigations into these media fill leaking units.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Paranthaman SenthamaraiKannan, Investigator Robert J Ham, Investigator Supreet K Sran, Investigator Logan T Williams, Investigator	X Supreet K Sran Investigator Signed By: SUPREET K. SRAN - S Date Signed: 04-02-2026 16:07:50	4/2/2026

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b. Your firm received a verified complaint of cardboard particulate matter, which is extrinsic to your processes, in (b)(4) lot (b)(4) and determined that there was no impact to the batch and continued distribution. This particle was determined to be approximately 3.7mm at the longest dimension.

c. Your firm analyzed retention samples as a part of a complaint investigation for particulate matter in (b)(4) Lot (b)(4). The retain examination resulted in particulate matter being found and analyzed to be made of (b) (4) exhibiting oxidative degradation. This particle was determined to be approximately 2.6mm at the longest dimension.

C. Sterility testing failure investigations did not include thorough root cause analysis nor appropriate corrective and preventative actions to prevent recurrence. In November 2023, your firm recovered growth in product (b)(4) lot (b)(4) in an (b)(4) jar and investigated under PR2790565. Your firm determined the root cause to be due to the jar being non-integral prior to incubation with only a (b)(4) investigation performed and corrective actions were awareness training for the microbiologists and cleaning of the sterility incubator. No (b)(4) investigation was performed to include an evaluation of aseptic control during manufacturing. Your firm rejected this lot of (b)(4) Your firm recovered another sterility positive, investigated under PR3254160, in (b)(4) log (b)(4) on 7/24/2025. Your firm determined this root cause was the same as the 2023 sterility positive investigation, however, your firm determined that this should be classified as a "no test" and proceed with resampling and retesting. Your firm retested this product and reported a passing result for the sterility test and dispositioned the batch for release. The second investigation also contained only a (b)(4) investigation. No additional confirmation environmental monitoring testing was performed for the second sterility failure to determine a probable source of the contamination. Corrective actions for this sterility failure include requiring a (b)(4) verification of jar integrity prior to incubation.

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D. Your firm implemented no corrective actions and identified no probable root causes for recovery of 1 CFU of *Aspergillus fumigatus* in an active viable air sample in the grade A space for (b)(4) lot (b)(4) Additional environmental sampling and organism identification was not performed to determine a possible source of the organism. This batch was accepted for distribution based on this being an isolated event and all other results passing specification.

E. Bacterial endotoxin testing failure investigations did not include thorough root cause analysis and critical evidence was not retained. In July 2025, your firm recovered an endotoxin failure in (b)(4) batch (b)(4) with a mean endotoxin value of 5.5450 EU/mL, exceeding the limit of (b)(4), investigated under PR3250036. (b) (4) retest confirmed the failure with a mean result of 5.9349 EU/mL. However, the original sample unit/container was inadvertently discarded before investigational testing could be performed. The investigation states, "laboratory error could not be definitively concluded in the (b)(4) laboratory investigation in part because the original sample unit/container was not retained" and "the overall root cause investigation is inconclusive." Despite the inconclusive investigation, your firm classified this as "No, Laboratory Analysis/System" and released Sublot (b) (4) of the same batch (b)(4) for distribution while discarding Sublot (b) (4) "out of an abundance of caution." Corrective action was limited to "awareness training" for the analyst. The investigation also noted out-of-alert solution bioburden results and a "potential adverse trend detected for microbiological samples in the month of July," yet concluded manufacturing was "in a state of control" without through investigation.

F. Your firm failed to identify the root cause of (b)(4) contamination detected at sample site (b)(, entrance floor to the mixing tank room, in the non- (b)(4) facility on December 3, 2025 (NCR/SNCR PR#3360939). Although your firm separated the (b)(4) and non- (b)(4) manufacturing facilities in August 2024 to prevent cross-contamination, (b)(4) monitoring of site (b) (4) in the non- (b)(4) facility showed (b)(4) contamination while other monitoring locations tested negative. Your (b)(4) laboratory investigation validated the initial OOS results and continued the nonconformance investigation. Your firm's investigation

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did not identify a root cause; however, your firm implemented the use of dedicated (b)(4) in the (b)(4) building and is updating the laboratory investigation procedure despite the CAPA remaining open.

G. Your firm failed to thoroughly investigate and identify the root cause for contamination in non-(b)(4) facility. Sample site (b) (4) (hallway) in the non-(b)(4) facility tested positive during the week of August 17-24, 2025 (NCR/SNCR PR#3276947); however, the entrance door handle and the (b) (4) lobby floor were negative for (b)(4) during that period. Your firm identified the root cause as construction workers (b) (4) in for the morning shift, yet these workers neither entered the (b)(4) buildings prior to (b) (4) nor entered the hallway. Your firm's corrective actions included registering construction workers only in (b)(4) buildings and cleaning the exterior. Additionally, your firm's personnel monitoring for the non-(b)(4) building included only face shields and goggles of operators working inside production areas.

H. Your firm failed to implement corrective and preventative actions (CAPA, PR#3257234) for not collecting (b)(4) monitoring samples in non-(b)(4) facility locations. Your firm initiated three nonconformance investigations (NCR/SNCR PR#s 3313070, 3357344, and 3369775) in July 2025, October 2025, and January 2026, and CAPAs opened in July 2025 having July/August 2026 expiration date. Your firm did not implement corrective and preventative actions; however, manufacturing continued those days, and (b)(4) per batch/lot was tested before release.

I. Your firm's laboratory investigations into out-of-specification results are inadequate. Examples include but are not limited to:

a. PR 3389404 (Environmental Monitoring, Site A11, 12/10/2025): An environmental sample exceeded (b) (4) of the limit when tested on 12/10/2025 per method 11-25-80-1686 (effective 5/16/2025). Your firm did not open the investigation until 1/30/2026 (51 days

later) and canceled it on 2/10/2026, justifying cancellation by retroactively applying a method revision effective 1/26/2026 that changed the limit from (b)(4) The sample was out of limit under the method in effect at the time of testing.

b.PR 3009934 ((b)(4) RM lot (b)(4) , 5/13/2024): Raw material tested on (b)(4) showed (b)(4) ppm (b)(4) (limit: NMT (b)(4) ppm). Investigation was not opened until 9/11/2024 (four months later) and closed 9/13/2024 (two days later). Electronic chromatography data from the original testing on 5/13/2024 was not reviewed until 3/24/2025 and 3/26/2025, more than six months after the investigation was closed.

c.PR3291814 (Nicardipine batch (b)(4) UV ID failure, 9/17/2025): Final sample UV ID result was OOL with a (b)(4) difference for (b)(4) between sample and standard. The investigation concluded "no definitive cause could be determined during the investigation, but the most likely cause is instrument noise causing a false negative result." The investigation documented "the instrument has shown, historically, to have noise that can occur at this (b)(4) which causes false negative readings." Despite identifying a known instrument malfunction, your firm implemented no corrective action to repair or replace the instrument and it remains in use. The investigation concluded the batch would be released using (b)(4) resample results to disposition.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

A)Your firm routinely recovers biological indicators (BI) with positive growth during (b)(4)

(b)(4) qualification. Your firm is performing spore log reduction (SLR) calculations on biological indicators that mask potential (b)(4) issues. For example:

a. (b)(4) requalification QNC 24-42 on filling line (b)(4) performed on 9/25/2024 was issued as a "no test" due to insufficient BI population recovery of (b)(4), where the procedure requires at least (b)(4) population. The qualification shows multiple BI locations with positive growth of all (b)(4) replicates and many with (b)(4) replicates exhibiting growth. Even though this qualification resulted in a "no test", the qualification would be easier to achieve due to the low BI population, however this was not evaluated by the firm and a requalification was performed using new BIs.

b. (b)(4) requalification QNC 24-55 on filling line (b)(4) performed on 10/15/2024 as a follow up to the "no test" resulted in positive BI growth in 20 out of (b)(4) locations with three locations exhibiting growth in 4 out of (b)(4) replicate BI's. Your firm performed SLR calculations on these locations and determined that 6-log reduction was achieved and passed this qualification with no issues noted.

c (b)(4) requalification QRD 24-23 on filling line (b)(4) performed on 6/18/2024 resulted in positive BI growth in 18 out of (b)(4) locations with multiple locations exhibiting growth in 3 out of (b)(4) replicate BI's. Your firm passed this qualification with no issues noted.

d (b)(4) requalification QRN24-42 on filling line (b)(4) performed on 9/10/2024 resulted in positive BI growth in 11 out of (b)(4) locations with one location exhibiting growth in 4 out of (b)(4) replicate BI's. Your firm passed this qualification with no issues noted.

B)Your firm's (b)(4) validation BI locations are not based on data but only a theoretical risk associated with the location. Your firm did not utilize tools such as temperature mapping, humidity mapping, airflow pattern studies, or chemical sensors to determine worst-case locations for BI placement. In addition, these '(b)(4)' like filling machines were designed in 1989 and

include many hard to reach locations which likely present as occluded surfaces.

C)Your firm does not trend critical interventions for routinely performed aseptic manipulations during production for use in media fill process simulations. For example, Your firm routinely opens (b)(4) during media fills but during production up to (b)(4) can be opened depending on the batch size. Clearing (b) (4) jams is routinely performed (b)(4) during media fills, however, this practice is performed up to (b)(4) times during routine production. Fixing film tears occurs (b)(4) during media fills but has occurred at least (b)(4) during (b)(4) in actual production since the last inspection.

D)Clearing of (b) (4) jams is not always performed with a tool and (b) (4) jams are routinely cleared by using the (b)(4) gloves directly. Removal of (b) (4) jams directly with (b)(4) (b) (4) (b) (4) is likely to cause contact with secondary product contact surfaces as well as the port track that carries ports from the port (b)(4) to the (b)(4).

E)Environmental monitoring of the grade A space in the (b)(4) filling machines only includes (b)(4), continuous non-viable particle probes and one continuous viable probe during production. Your firm does not sample any grade A surfaces, such as the (b) (4), or the filling nozzle during batch sampling.

F)Your firm has performed air flow studies on only one (b)(4) fill machine in the last 10 years. Multiple turbulent zones over critical surfaces were reported in your firm's evaluation of the airflow study report including the (b) (4)(b)(4) area and around (b) (4) forming and filling. Your firm has (b)(4) total (b)(4) filling machines in use.

OBSERVATION 3

The statistical quality control criteria fail to include appropriate acceptance levels and rejection levels.

Specifically,

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Multiple visual inspection methods have been implemented without adequately qualifying inspection sensitivity, defect detectability, or comparability between methods. For example,

a) Your firm's 100% visual inspection process only requires (b)(4) of defects to be found during inspector qualification without adequate justification, this includes defects that could result in leaking units. In addition, several defects that can result in leaking units such as (b)(4) and various port/closure defects, are not included in the challenge (b)(4). Partially (b) (4) and damaged (b) (4) are also not represented defects during qualification.

b) Particle defects included in the qualification (b)(4) are between (b)(4)- per (b)(4) chart (approximately (b)(4) microns) for colored, white, or metallic particles. Fiber defects are approximately (b)(4) long in the qualification (b)(4) Clear particles are approximately (b)(4) per (b)(4) chart (approximately (b)(4) microns). These sizes are not based on inspection threshold studies and are gross particle defects which are readily discernable without additional lighting or inspection techniques.

c) Your firm has only performed threshold studies to generate probability of detection curves and reject zones across the visual range of defects for your AQL visual inspection process which employes a (b)(4) inspection (b)(4) against a (b)(4) background. Your firm's 100% visual inspection process is a (b)(4) inspection (b)(4) against the same background. No equivalency or threshold study was performed for the 100% visual inspection process.

d) Your firm's 100% visual inspection process speed of (b)(4) is based on machine fill speed requirements and not inspection capabilities at that speed. In addition, during qualifications your firm requires a false reject rate of (b)(4) however, during routine production false reject rates of greater than (b)(4) are routinely observed. These false rejects are then placed back onto the line with the good population after evaluation by a Supply Handler

(Manufacturing personnel).

e) Your firm's qualification (b)(4) is comprised of (b)(4) bag size and does not include (b)(4) for the larger, (b)(4) bags. Your firm's risk assessment for developing a qualification (b)(4) determined that even though there is more solution in a (b)(4) bag, the (b)(4) bag is more difficult to inspect due to label obscuring area.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

Your firm supplies HEPA air to the (b)(4) filling equipment at the (b)(4) of the (b)(4) through production completion. In an idle, non-production, state your firm does not protect or maintain the Grade A space from ingress of less than Grade A air quality. In addition, pressure differentials are monitored only during production and decontamination cycles.

OBSERVATION 5

Deviations from written production and process control procedures are not recorded.

Specifically,

Your firm failed to initiate a deviation investigation when the manufacturing team lead found that a stock label was not placed inside a pouch prior to entering the fill room (Class C), as required by SOP "Preparation for filling, Document No. FILL-016." During a customer complaint investigation (Complaint number: 5351394; NCR/SNCR PR#3069496) for particulate matter (PM) in (b)(4) solution

(product code (b)(4) lot (b)(4) the team lead stated that labels may not be consistently brought into the fill rooms with a pouch. Cardboard from the film stock label was identified as the probable root cause of the PM.

OBSERVATION 6

Employees are not given training in the particular operations they perform as part of their function.

Specifically,

Your firm failed to adequately train and qualify laboratory personnel adequately for monitoring absence of (b)(4) in non- (b)(4) manufacturing facilities. During qualification, the analysts were trained to (b)(4), while the limit for (b)(4) detection is (b)(4) ppb. Analysts were qualified if sample preparations exceeded (b)(4) ppb. Qualifying analysts at higher (b)(4) concentrations does not ensure they can efficiently (b)(4) the much lower concentrations required for environmental monitoring to prevent cross-contamination. Your firm did not conduct a study to determine the lowest concentration analysts can efficiently (b)(4) for (b)(4) Additionally, analysts were qualified for (b)(4) sampling using (b) (4) and (b) (4) surfaces.

OBSERVATION 7

Established specifications, standards, sampling plans, test procedures and laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

a. Your laboratory analysts failed to follow the written procedures for microbiological testing of (b)(4) samples. Per SOP "Microbiological /Pyrogen testing of the plant water

system, Document No: RD-02-02-005", the (b)(4) must be placed on (b)(4) media plate by a (b)(4) to prevent (b) (4) trapped between the (b) (4) and (b)(4) However, on March 25, 2026, many (b) (4) sample (b) (4) had (b) (4) trapped, cut edges, and folded edges that did not contact the plates for the accurate enumeration of microbes.

b. Your microbiology laboratory analyst failed to contemporaneously sign the endotoxin test record for (b)(4) samples when the test was completed on March 31, 2026.

OBSERVATION 8

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm failed to validate disinfection studies to clean and remove (b)(4) drug residue ((b)(4) and (b)(4)) from various surfaces in the non- (b)(4) manufacturing facility. Your firm lacked a rationale for selecting only (b) (4) surfaces for cleaning validation studies and did not evaluate hard-to-clean surfaces.

OBSERVATION 9

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

Your firm routinely tests environmental monitoring samples beyond validated stability timeframes, potentially resulting in degraded samples, false negative results, and undetected cross-contamination. Your firm established sample stability per validation protocol PRO RD 02-02 (Evaluation of the

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Absence of (b)(4) Samples and Standards Beyond (b)(4), approved 3/14/2003), which demonstrated environmental swab samples are stable for (b)(4) at room temperature and (b)(4) when refrigerated or frozen. Your firm's procedure RD-02-01-020 (Swab Procedure for Absence of (b)(4) Environmental Samples, Effective Date: 24-Jan-2026) states in Section 7.2.2.G: "Samples are good for (b)(4) at room temperature (b)(4) refrigerated or frozen." Despite this validated stability limit and procedural requirement, your firm tests samples weeks after collection. Examples include but are not limited to:

a) Electronic Laboratory Notebook (ELN) experiment 20260317-133 documents Baxter environmental samples collected from 2/27/2026 through 3/17/2026 were stored at (b)(4) and analyzed beginning 3/17/2026. The earliest samples (collected 2/27/2026) were tested (b)(4) hours) after collection, exceeding validated frozen stability by (b)(4) days).

b) ELN experiment 20260218-103 documents Baxter environmental samples collected from 2/11/2026 through 2/17/2026 were stored at (b) (4) and analyzed beginning 2/18/2026. The earliest samples (collected 2/11/2026) were tested (b)(4) hours) after collection, exceeding validated frozen stability by (b)(4) days).

c) ELN experiment 20260212-102 documents Baxter environmental samples collected from 2/4/2026 through 2/11/2026 were stored at (b) (4) and analyzed beginning 2/12/2026. The earliest samples (collected 2/4/2026) were tested (b)(4) hours) after collection, exceeding validated frozen stability by (b)(4) days).

***DATES OF INSPECTION**
3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri), 3/30/2026(Mon), 3/31/2026(Tue), 4/01/2026(Wed), 4/02/2026(Thu)

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Investigator
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DATE ISSUED
4/2/2026

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."