DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA, 92612 (949)-608-2900	05/13/2026-05/20/2026
	FEI NUMBER 3000718309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Loubna(N.M.I)Kerkeb, President Bachem Americas

FIRM NAME	STREET ADDRESS
Bachem Americas, Inc.	1204 Park Center Drive, Vista
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vista, CA, 92081, USA	Active Pharmaceutical Ingredient (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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The Quality Unit failed to ensure that the drug substance was tested and released for distribution with appropriate laboratory determination of satisfactory conformance to final specifications prior to release.

Specifically, (b) (4) API Batch #(b) (4) (Manufacturing Date: (b) (4)), distributed on 22 Jun 20224, was released without meeting all required release testing specifications. The identification of (b) (4) analysis, performed as part of the release testing and governed by controlled procedure Doc.# STM-3-00034, Rev. 09, Analysis of (b) (4) Composition of (b) (4) Using (b) (4) Analyzer, Effective Date: 23 Oct 2017, was found to have yielded unreliable results. Specifically, no system suitability was performed as required by the procedure, and therefore the system suitability acceptance criterion was not met.

A re-injection of the chromatogram run was subsequently performed; however, the re-injection results were not used due to standard failure, resulting in the reporting of the original results without a completed system suitability. No deviation or investigation report was generated to document or address this failure. Furthermore, the analysis was reviewed and approved by QC personnel with the system suitability incorrectly documented as having been performed and the results recorded as within acceptance criteria, neither of which was accurate.

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The release testing results were subsequently included in the Certificate of Analysis (COA) and the batch was approved for release by the Quality Unit on 22 Jul 2024, despite the absence of a valid system suitability and without adequate scientific justification for the acceptance of the original results.

OBSERVATION 2

The written stability testing program is not consistently followed, evidencing a lack of adequate Quality Unit oversight over the stability testing process and its associated controls, thereby compromising the integrity and reliability of stability data generated for drug substances and intermediates.

Specifically,

A. The quality unit failed to ensure that stability chambers are secured, and access controlled. During the facility walkthrough conducted on 13 May 2026, the stability chambers were observed to be locked; however, they are not situated in a secure location, nor is access to them restricted. The stability chambers are located in an open area of the laboratory (Room 114), in proximity to the receiving area. As a result, all personnel granted access to the laboratory, including contractors and maintenance personnel, have direct and unrestricted contact with the stability chambers, creating the potential for unauthorized manipulation of the chambers and, consequently, compromising the integrity of the stability program. Furthermore, on 15 May 2026, a glass window replacement operation was performed in the laboratory. This practice further demonstrates the lack of adequate access controls surrounding the stability chambers and presents a risk to the integrity of ongoing stability studies.

B. The Quality Unit failed to ensure that stability samples were stored in a temperature-controlled or climate-controlled chamber for all studies and failed to follow controlled procedure Doc. SOP-3-00277, Rev. 29, Stability Program, Effective Date: 20 Oct 2025. Specifically, Section 9.3 of this procedure does not define ambient temperature storage conditions as distinct from room temperature storage conditions. It is the practice of the Quality Unit, as reflected in stability protocols # PROT-3-00554, (b) (4) (b) (4) (b) (4) and # (b) (4)-00710, (b) (4) (b) (4) to store stability samples at ambient

temperature in a locked cabinet within the QC Laboratory (Room 114 – Space (b) (4) Receiving Area). This area was found to be neither temperature-controlled nor subject to temperature monitoring or review. Furthermore, controlled procedure Doc. # SOP-3-00964, Rev. 09, (b) (4) Operation of (b) (4) Continuous Monitoring System, Effective Date: 27 Feb 2026, does not identify Room (b) (4) as a location requiring a critical deviation trigger for Controlled Temperature Units (CTUs) to be monitored and reviewed.

The following stability studies were found in the ambient uncontrolled temperature condition cabinet:

- Stability Protocol PROT-3-00554, (b) (4) (b) (4) (b) (4), Lot # (b) (4)
- Stability Protocol PROT-3-00554, (b) (4) (b) (4) (b) (4), Lot # (b) (4)
- Stability Protocol PROT-3-00554, (b) (4) (b) (4) (b) (4), Lot # (b) (4)
- Stability Protocol PROT-3-00710, (b) (4) (b) (4) (b) (4), Lot # (b) (4)
- Stability Protocol PROT-3-00395, (b) (4) (b) (4) Lot # (b) (4)

C. Your Quality failed to always ensure that at least one batch per year is introduced to the stability program as required by your controlled procedure Doc. SOP-3-00277, Rev. 29, Stability Program, Effective date: 20 Oct 2025; specifically, under section 9.4.3 Annual Stability Program. This discrepancy was evident in that (b) (4) API, Batch # (b) (4) (Manufacturing date: (b) (4) (b) (4), Analytical Release date: 22 Jun2024 and Commercially Release date: 6/13/2025), (b) (4) manufactured (b) (4) for FY2024, was not included in the stability program.

In addition, this discrepancy was documented in Deviation Report # DEV-011412, opened on 23 May 2025 (QA approved 05 Jun 2025). The deviation report attributed the error to SOP-3-00721, Rev. 11 (the previous stability procedure), stating that it "does not clearly define the requirement for at least one annual batch for the stability program." However, this requirement is explicitly stated under Section 8.8.2 of the same procedure, contradicting the stated root cause.

D. The Quality Unit failed to ensure that stability protocols are being followed, specifically with respect to the early removal of stability samples from climatic chambers and the timely completion of analytical testing consistent with established stability study intervals. These deficiencies are permitted under controlled procedure Doc. # SOP-3-00277, Rev. 29, Stability Program, Effective Date: 20 Oct 2025, and its predecessor, Doc. # SOP-3-00721, Rev. 12, Stability Program, Effective Date: 12 Mar 2025, as well as applicable product stability protocols. Specifically, SOP-3-00277 allows samples to be pulled early by (b) (4) prior to the (b) (4) interval, while SOP-3-00721 and the associated stability protocols permit early pulls of (b) (4) across any interval. Neither procedure discriminates by storage conditions (i.e., (b) (4)), and neither requires scientific justification or evaluation of how early sample removal may affect or impact study results, particularly during (b) (4) studies. Additionally, SOP-3-00277 provides an analytical completion window of up to (b) (4) after the pull-out date, rather than requiring completion within the defined stability interval, further compromising the integrity of the study timeline. Examples of early pull-out dates, late pull dates, and late interval completions were observed during the review of stability studies conducted for U.S. market products:

- Stability Protocol PROT-3-00314, (b) (4) API, Batch # (b) (4)
- Stability Protocol SLOT-3-00840, (b) (4) API, Batch # (b) (4)
- Stability Protocol SLOT-3-00902, (b) (4) API, Batch # (b) (4)
- Stability Protocol PROT-3-00554, (b) (4) (b) (4) (b) (4), Batch # (b) (4)
- Stability Protocol PROT-3-00710, (b) (4) (b) (4) (b) (4) Batch # (b) (4)

E. Your quality unit failed to ensure compliance with established stability procedures and stability protocols. Specifically, the quality unit failed to ensure that all required analytical testing intervals were performed as specified in the approved stability program. Missing analytical testing time points and/or intervals were identified across multiple stability studies mentioned in deviation reports, which

compromises the ability to establish or confirm the shelf life and storage conditions of the drug product.

As per established controlled procedure Doc. # SOP-3-00277, Rev. 29, Stability Program, Effective Date: 20 Oct 2025, and its predecessor, Doc. # SOP-3-00721, Rev. 12, Stability Program, Effective Date: 12 Mar 2025, and the applicable stability protocols, all required analytical testing intervals must be performed at the designated time points to ensure product quality, safety, and efficacy throughout the proposed shelf life. However, during the review of stability records and stability study documentation, it was observed that required analytical time-point testing was not performed, was incomplete, or was not documented in accordance with the approved protocol requirements. These discrepancies are evident by the following deviation report generated due to missing stability interval points:

- DEV-008677, Product: (b) (4) API, Batch #(b) (4) interval
- DEV-009577, Product: (b) (4) API, Batch # (b) (4) (b) (4) and (b) (4) intervals
- DEV-009577, Product: (b) (4) API, Batch # (b) (4) (b) (4) interval
- DEV-009740, Product: (b) (4) API, Batch # (b) (4) (b) (4) interval
- DEV-010462, Product: (b) (4), Batch # (b) (4) (b) (4) interval
- DEV-011501, Product: (b) (4) API, Batch # (b) (4) (b) (4)
- DEV-012119, Product: (b) (4) Batch # (b) (4) (b) (4)
- DEV-012183, Product: (b) (4), Batch # (b) (4) (b) (4)

OBSERVATION 3

Your Quality unit failed to perform thorough and adequate laboratory investigations, to obtain appropriate root cause, extend to other batches and proposed adequate corrective /preventive actions. The deficiencies are evidenced as follows:

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A. Your Quality Unit failed to conduct a thorough assessment and established adequate root cause and corrective and preventive action (CAPA) to avoid re-occurrence. For example,

1. Investigation Report # OOS-2024-022, for Out-of-Specification (OOS) results obtained for the stability sample (b) (4) API, Batch #(b) (4) (b) (4) disclosed OOS results for the unspecified related substance (b) (4) 3.23% and (b) (4) 1.83%; Limit: NMT (b) (4) and purity (96.8%; Limit: NLT (b) (4) The root cause was attributed to laboratory error, specifically column degradation and/or sample preparation. It was determined that the analytical test would be repeated using a new column; however, all original system suitability acceptance criteria had been met, which does not support column degradation as a valid root cause.

   Furthermore, it is the firm's policy (b) (4) (b) (4) column, even for informational purposes, to demonstrate that column degradation was a contributing factor. The re-tested results were within specification, and the original OOS result was invalidated without adequate scientific justification. The root cause was not sufficiently challenged to ensure the validity of the conclusion. Additionally, no Corrective and Preventive Action (CAPA) was initiated to evaluate whether additional system suitability acceptance criteria are required to prevent recurrence.

   A similar deficiency was observed in Investigation Report # OOX-2025-004.

2. Investigation Report # OOS-2024-038, for Out-of-Specification (OOS) results obtained for the stability sample (b) (4) Batch #(b) (4) (b) (4) disclosed an OOS result for the (b) (4) Assay of (b) (4), with a result of 0.51 (b) (4) (b) (4) (Limit: NLT (b) (4)(b) (4) The root cause was attributed to laboratory error due to the sample not being fully dissolved. This conclusion was demonstrated by evaluating the sample (b) (4) (b) (4) (b) (4)— a practice not described or required by the analytical method, which raises concerns regarding the scientific validity of the root cause determination.

It was subsequently determined to repeat the analytical test, ensuring the sample mixture was fully dissolved, and the original OOS result was invalidated. However, no corrective action or CAPA was initiated as a result of this investigation. Furthermore, a second investigation related to the same incident was opened approximately one month later, as documented in Investigation Report # OOS-2024-0196, raising additional concerns regarding the adequacy and completeness of the original investigation.

3. Investigation Report # OOS-2025-0177, for Out-of-Specification (OOS) results obtained for (b) (4) API, Batch # (b) (4) disclosed an OOS result for the Related Substance test, with an unspecified impurity result of 0.12% (Limit: NMT (b) (4) The root cause was attributed to laboratory error due to contamination introduced during sample preparation. However, all completed checklists indicate that no abnormalities were observed during the sample preparation process, which directly contradicts the stated root cause of contamination.

   The sample was re-tested (b) (4) and found to be within specification; consequently, the original OOS result was invalidated and replaced with passing results without adequate scientific justification. Furthermore, the corrective action proposed was to provide training to the analyst; however, the investigation checklist describes the analyst as experienced and fully trained, with no testing method deviations identified. The proposed corrective action is therefore inconsistent with the findings of the investigation and does not adequately address the root cause or prevent recurrence.

B. The Quality Unit failed to assess other batches during the investigation process that may have been impacted by the established root cause and conclusions. For example, Investigation Report # OOS-2024-038, for Out-of-Specification (OOS) results obtained for the stability sample (b) (4) (b) (4), Batch # (b) (4), (b) (4) disclosed an OOS result for the (b) (4) Assay of (b) (4), with a result of 0.51 (b) (4) (b) (4) (Limit: NLT (b) (4) (b) (4) The root cause was attributed to laboratory error due to the sample not being fully dissolved. However, otherbatches or samples processed concurrently were not re-evaluated using the (b) (4) method to confirm that the sample mixture was adequately dissolved, as was performed for the OOS batch. This re-evaluation was not conducted on the basis that the concurrent batch results were within

specification, which does not constitute adequate scientific justification for excluding those batches from the scope of the investigation, and ensures the reliability and accuracy of the results.

Furthermore, the documentation of batches involved, if any, is not required or documented as per the (b) (4) software used to generate and document investigations nor required as part of the controlled procedure Doc. No. SOP-3-00283, Rev. 19, Quality Control Procedure for Out of Specification Test Results, Effective date: 08 May 2026.

C. The Quality Unit failed to ensure that investigations are completed within the (b) (4) deadline established by controlled procedure Doc. # SOP-3-002863, Rev. 19, Quality Control Procedure for Out-of-Specification Test Results, Effective Date: 08 May 2026. Furthermore, no extensions were requested or justified as required by the same controlled procedure. Examples of this deficiency are evident in the following investigation reports:

- Investigation report OOS-2024-001 (opened: 13 Dec 2024 and closed: 28 Feb 2025), Total 77 days.
- Investigation report OOS-2024-011 (opened: 23 Apr 2024 and closed: 26 Jun 2024), Total 64 days.
- Investigation report OOX-2024-0196 (opened: 16 Nov 2024 and closed: 13 Jan 2025), Total 58 days.
- Investigation report OOX-2025-0189 (opened: 11 Nov 2025 and closed: 28 Feb 2026), Total 109 days.

D. The (b) (4) software system, used for generating and documenting investigation reports, does not require or capture documented evidence of analyst participation. Specifically, the system does not retain supporting documentation demonstrating that the analyst completed the investigation checklist or provided the required detailed responses. This gap allows investigation reports to be generated and finalized without verified analyst input or accountability.

Furthermore, controlled procedure Doc. # SOP-3-00283, Rev. 19, Quality Control Procedure for Out-of-Specification Test Results, Effective Date: 08 May 2026, does not establish a requirement for documented analyst participation in the investigation process, further contributing to this deficiency. This deficiency is evidenced across all investigation reports reviewed that were generated within the (b) (4) software system.

E. Your quality unit failed to follow its established control procedure Doc. # SOP-3-00283, Rev. 19, Quality Control Procedure for Out-of-Specification Test Results, Effective Date: 08 May 2026; specifically, under Section 11.2, Number of Repetitions, the procedure states that (b) (4) repetitions are to be performed, and for multiple determinations, all individual analyst results are relevant. For (b) (4) determinations (such as assay), (b) (4) individual determinations are carried out (with (b) (4) repetitions). However, during the review of the investigation report(s) evaluated, this practice was not executed.

It is firm practice to perform a (b) (4) test, that is, (b) (4) . The proposed (b) (4) or root cause does not confirm the alleged laboratory error; therefore, the required number of analysis repetitions must be performed to additionally ensure that results can be confirmed, rejected, or invalidated with statistical certainty, as required by the procedure. These discrepancies were observed in the following investigation reports, in which the (b) (4) or root causes attributed to laboratory error are not scientifically justified:

- Investigation report OOS-2024-022
- Investigation report OOS-2024-038
- Investigation report OOS-2024-019
- Investigation report OOX-2024-0196
- Investigation report OOX-2025-0044
- Investigation report OOX-2025-0177
- Investigation report OOX-2025-0210

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OBSERVATION 5

Reserve samples are not always handled appropriately and/or retained is representative or consistent of finished drug substance or (b) (4) configuration being distributed and/or marketed. These deficiencies are evidence of inadequate Quality Unit oversight of this process.

Specifically,

A. The Quality Unit failed to ensure that retained samples are properly stored and to follow controlled procedure Doc. # SOP-3-00275, Rev. 13, Intermediates and API Retain Sample, Effective Date: 28 Jan 2025, specifically Section 8.6.4 regarding storage conditions. It is the practice of the Quality Unit to store retained samples designated for room temperature conditions in a locked cabinet within the QC Laboratory (Room 114, Space (b) (4) – Receiving Area), a location that is neither temperature-controlled nor temperature-monitored.

   Furthermore, controlled procedure Doc. # SOP-3-00964, Rev. 09, (b) (4) Operation of (b) (4) Continuous Monitoring System, Effective Date: 27 Feb 2026, does not identify Room 114 as a location requiring a critical deviation trigger for Controlled Temperature Units (CTUs) to be monitored and reviewed.

   Additionally, during the QC Laboratory walkthrough conducted on 15 May 2026, two bottles identified as retained samples were found stored in Refrigerator ID #(b) (4) Shelf (b) (4) which was neither locked nor access-controlled. The retained sample bottles were identified as follows:

- (b) (4) (Code (b) (4), Batch # (b) (4) Retained Sample
- (b) (4) (Code (b) (4)), Batch # (b) (4), Retained Sample

B. The Quality Unit failed to consistently ensure that retained samples are stored in container/closure systems equivalent to those used for the storage and distribution of the bulk (b) (4) and drug substance, as required by controlled procedure Doc. # SOP-3-00275, Rev. 13, Intermediates and API Retain Sample, Effective Date: 28 Jan 2025, specifically Section 8.6.2.

The following deficiencies were observed:

(b) (4) (b) (4), **Batch #** (b) (4) The retained sample was found stored in a clear glass container; however, the production batch record indicates the (b) (4) was packaged in a plastic container. Furthermore, the Sample Amount Report, generated was not uploaded to the LIMS system by the Material Management Team and not available or to be found. Therefore, it was possible to verify the amount received or the container/closure system used.

(b) (4) (b) (4), **Batch #** (b) (4) (identified as (b) (4) : The retained sample was stored in a plastic container; however, the Sample Amount Report dated 05 May 2026 indicates the container is described as a "clear glass container (b) (4)." This is inconsistent with the production batch record, which specifies that the (b) (4) is packaged in a plastic container/closure system. This discrepancy was not identified by Material Management or QC personnel.

Furthermore, the Sample Amount Report for (b) (4) (b) (4) (b) (4), Batch # (b) (4) indicates that the container was sampled, weighed, and witnessed on 05 May 2026. However, as confirmed by the Production Manager, the container was actually sampled, weighed, and witnessed on 04 May 2026. The documentation was provided the following day by the Material Management Unit for signature, resulting in an inaccurate date recorded on the report. Therefore, the Quality Unit failed to ensure that processes and their associated documentation are executed and dated contemporaneously.

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C. The Quality Unit failed to ensure that the retained sample storage chamber (b) (4) (b) (4) is secured and access-controlled. During the facility tour conducted on 13 May 2026, it was observed that the retained sample storage chamber was locked; however, it is not located in a secure area with restricted access. Specifically, the retained sample chamber is situated in an open area of the laboratory, Room 114, near the microbiology laboratory area, where all personnel granted access to the laboratory — including contractors and maintenance personnel have direct and unrestricted contact with the chamber. This lack of restricted access creates the potential for unauthorized manipulation of the retained sample storage chamber, which could compromise the integrity of the retained samples.

LABORATORY CONTROLS

OBSERVATION 5

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically, the Quality Unit failed to ensure that laboratory analytical instruments are properly qualified and/or calibrated, and that such qualifications and calibrations are reviewed prior to use to confirm that the instruments are suitable for their intended purpose. For example,

A. The Quality Unit failed to ensure that instruments are qualified, reviewed, and approved prior to use. This deficiency is evidenced by the (b) (4) (b) (4) (b) (4) (BIN # (b) (4), and (b) (4)), for which an Operational Qualification (OQ/PM) was performed on 17 Nov 2025; however, the qualification was not reviewed and approved by the Quality Engineering (QE) Unit until 11 Dec 2025. Despite the qualification remaining unreviewed and unapproved, Logbook # L24-488 indicates that the instrument was used on 21 Nov 2025, 22 Nov 2025, and 03 Dec 2025 — prior to being released or placed out-of-service by the Quality Engineering (QE) Unit.

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B. The (b) (4) Operational Qualification (OQ) of the Gas Chromatography (GC) system, performed by an outside contractor and reviewed and approved by the Quality Engineering (QE) Unit, failed to include the following required OQ components: FID detector linearity, (b) (4) , injector tower linearity, and (b) (4) injection linearity. This deficiency is evidenced by the OQ of the (b) (4) GC Model (b) (4) with (b) (4) Model (b) (4) (GC ID # (b) (4) and (b) (4) ID # (b) (4) dated 03 Dec 2025.

C. The Operational Qualification (OQ) for the (b) (4) FT-IR Spectrum (b) (4) Spectrophotometer (ID # (b) (4)) failed to include the (b) (4) module (b) (4) as part of the (b) (4) qualification. This instrument, used in conjunction with the (b) (4) module, is employed for identification (ID) testing of drug substances as part of release testing. Furthermore, the laboratory does not have an available certified (b) (4) reference standard, which is required for the OQ of the FT-IR (b) (4) module.

Additionally, controlled procedure Doc. # SOP-3-00606, Rev. 01, Operation, Calibration and Maintenance of the (b) (4) Spectrum (b) (4) FT-IR, Effective Date: 11 Apr 2017, does not include qualification requirements for the FT-IR (b) (4) module. This deficiency is evidenced by the OQ for the (b) (4) FT-IR Spectrum (b) (4) Spectrophotometer (ID # (b) (4) dated 03 Feb 2026. Evidence of instrument use, including use of the (b) (4) module for raw material identification testing, is documented in instrument Logbook # L24-192.

D. No Operational Qualification (OQ) has been performed for the (b) (4) Model (b) (4) (ID # (b) (4)), since the Installation Qualification/Operational Qualification (IQ/OQ) dated 15 Nov 2012. This instrument is used for (b) (4) determination as part of release testing of intermediates, in-process testing, raw materials, reference standards, and drug substances. Furthermore, (b) (4) OQ is required for this instrument as per controlled procedure Doc. # SOP-3-00593, Rev. 05, Operation and Maintenance of the (b) (4) and (b) (4) (b) (4) Effective Date: 16 May 2026, specifically under Section 11.

Additionally, the Performance Qualification (PQ) for the (b) (4) is currently conducted using (b) (4) replicates with an acceptance criterion of (b) (4) Relative Standard Deviation (RSD). This acceptance criterion is insufficiently stringent to ensure instrument accuracy and reliability. Notably, the instrument manufacturer's qualification acceptance criterion is NMT (b) (4) RSD, which is significantly more stringent than the criterion currently applied by the facility as part of the PQ.

E. The Operational Qualification (OQ) for the (b) (4) performed by an outside contractor, does not always qualify the instruments for their intended use. Specifically, the pump flow rate is qualified only within a range of (b) (4), and the injection volume is qualified only at (b) (4) precision with no established linear range. This deficiency is evidenced by the OQs for the following instruments:

- (b) (4), OQ dated 15 May 2026
- (b) (4) OQ dated 19 Sep 2025
- (b) (4) OQ dated 12 Mar 2026

Furthermore, the chromatographic parameters specified in the (b) (4) API release testing methods fall outside the qualified ranges of the instruments' use for the following test methods:

- STM-3-00049, Rev. 06, Assay, Purity and Related Substance Analysis of (b) (4) by (b) (4) Effective date 23 Mar 2023; specifically, under section 8.6 Equipment Setup, staes that flow rate is (b) (4) and injection volume is (b) (4)
- STM-3-00057, Rev. 03, Analysis of (b) (4) Related Substance by (b) (4) Chromatography (b) (4), Effective date 26 Apr 2021; specifically, under section 9.1 Equipment Setup, states that flow rate is (b) (4) and injection volume is (b) (4)
- STM-3-00034, Rev. 09, Analysis of (b) (4) Composition of (b) (4) Using (b) (4) Analyzer, Effective date 23 Oct 2017; specifically, under section 9.2.4 Equipment Setup, states that injection volume is (b) (4)

This deficiency is evidenced in the analytical batch records for (b) (4) API Batch # (b) (4) (Manufacturing Date: (b) (4)) and Batch # (b) (4) (Manufacturing Date: (b) (4)).

OBSERVATION 6

The established laboratory controls are inadequate, as they do not include scientifically sound and appropriate test procedures sufficient to ensure that they conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your Quality unit failed to ensure that all reference standards are properly labeled, and/or identified as per controlled procedure Doc. # SOP-3-00717, Rev. 10, Quality Control Reference Material Program, Effective date: 18 Feb 2025; specifically, under section 8.2.3, which state that reference standard labels are to contain: Assigned ID number, storage condition, lot number and applicable expiration date or re-teste date.

The following reference standards, used for the testing of raw materials, in-process samples, intermediates, and drug substance, were selected at (b) (4) It was observed that these standards were labeled only with an assigned ID number, with no storage conditions or expiration/retest date indicated:

- (b) (4) ID # (b) (4) , Lot (b) (4)
- (b) (4) , ID # (b) (4) , Lot (b)
- (b) (4) , ID # (b) (4) , Lot (b) (4)
- (b) (4) ID # (b) (4) , Lot (b) (4)
- (b) (4) ID # (b) (4) , Lot (b)

B. The quality unit failed to always use certified reference standards (RS) to ensure the accuracy and reliability of analytical testing. It is the quality unit's practice and policy to use uncertified reference standards for qualitative testing (e.g., identification tests, system suitability for HPLC

normalization runs, IPC runs, etc.). However, as per controlled procedure Doc. # SOP-3-00717, Rev. 10, Quality Control Reference Material Program, Effective Date: 18 Feb 2025, specifically under Section 8.0, the procedure states that reference standards used for analysis include Compendial (i.e., USP, Ph. Eur., NIST, etc.), In-House RS (Qualitative or Quantitative RS), Non-Compendial, and Customer-Provided standards. Per this section, all types of reference standards are required to be certified, identified, and/or accompanied by their respective Certificate of Analysis (COA). This requirement is not exclusive to quantitative RS and applies equally to qualitative RS.

In addition, under section 8.5.2 Qualitative In-House RS of this procedure states that (b) (4) unless it is required by material label. However, this practice does not ensure the Qualitative RS still meets its approved quality attributes over time and remains suitable for testing use and its regulatory purpose.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 7

Firm failed to establish and implement controls to prevent mix-ups of material from one dedicated area to another.

Specifically, during walkthrough of the facility on 05/13/2026, we discovered a drum (Drum# (b) (4) of approved and released raw material (b) (4)) Lot# (b) (4) that was incorrectly located in the firm's outdoor Hazardous Waste collection area on the (b) (4) corner of Building (b) (4) We observed the (b) (4) drum was exposed to the outdoor and in direct sunlight co-mingled with other drums and containers awaiting disposal.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA, 92612 (949)-608-2900	05/13/2026-05/20/2026
	FEI NUMBER 3000718309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Loubna(N.M.I)Kerkeb, President Bachem Americas

FIRM NAME	STREET ADDRESS
Bachem Americas, Inc.	1204 Park Center Drive, Vista
CITY, STATE, ZIP CODE, COUNTRY Vista, CA, 92081, USA	TYPE ESTABLISHMENT INSPECTED Active Pharmaceutical Ingredient (API) Manufacturer

After informing Site QA Director and Site Leader of our discovery on 05/13/2026, we were informed in a meeting the next morning that the (b) (4) drum would be quarantined and eventually disposed of or destroyed.

However, during a later walkthrough of the building(b) (4) facility on 05/14/2026 we observed production in-progress of Project (b) (4) on the (b) (4) floor of Room (b) (4) utilizing a drum of raw material (b) (4) The (b) (4) drum was later confirmed to be Drum# (b) (4) which we were informed was no longer in approved status and should not have been acceptable for use by production.

OBSERVATION 8

Repeat Observation

Your firm failed to properly maintain buildings and facilities used in the manufacture of (b) (4) and API in clean and controlled conditions.

Specifically,

A. Production room 303 (b) (4) doors opens directly the outdoor adjacent to the firm's hazardous waste collection area without adequate controls, presenting a significant risk of environmental contamination to the manufacturing area.
B. The main (b) (4) door Room 303 exhibited visible gaps, light infiltration through the door frame, and accumulation of dust and debris on the adjacent interior floor, indicating a failure to maintain adequate environmental separation and cleanliness in manufacturing areas.
C. At the time of inspection, Production Room 303 contained stored materials arranged in piles, which is not an acceptable practice for a designated production area.
D. The flying insect light trap (#(b) (4) in Production Room 303 was observed to be non-functional.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA, 92612 (949)-608-2900	05/13/2026-05/20/2026
	FEI NUMBER 3000718309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Loubna(N.M.I)Kerkeb, President Bachem Americas

FIRM NAME	STREET ADDRESS
Bachem Americas, Inc.	1204 Park Center Drive, Vista
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E. Windows in production room 303 were covered with paper material to prevent dust ingress; however, the coverings were observed to be torn and separated from the window frame on multiple sides.

F. During the May 13, 2026, walkthrough, hazardous waste, raw materials, and corrosive substances were observed stored outdoors without protection or proper segregation throughout the facility.

JOEY V. QUITANIA -S
Digitally signed by JOEY V. QUITANIA -S
Date: 2026.05.20 16:58:13 -07'00'

Joey Quitania (Sr. CSO)

TAREQ W. HADDAD -S
Digitally signed by TAREQ W. HADDAD -S
Date: 2026.05.20 16:59:25 -07'00'

Tareq Haddad, CSO

Miguel A. Martinez -S
Digitally signed by Miguel A. Martinez -S
Date: 2026.05.20 17:00:28 -07'00'

Miguel A. Martinez, Chemist

KAMYL Y. GUZMAN MORALES -S
Digitally signed by KAMYL Y. GUZMAN MORALES -S
Date: 2026.05.20 17:01:40 -07'00'

Kamyl GuzmanMorales, Chemist

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Navneet Kaur -S Digitally signed by Navneet Kaur -S Date: 2026.05.20 16:57:10 -07'00'	Navneet Kaur, CSO	05/20/2026

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."