DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	02/09/2026-02/18/2026*
	FEI NUMBER 3013189568

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jean G. Allaume, Vice President La Verne Manufacturing Operations

FIRM NAME	STREET ADDRESS
Gilead Sciences, Inc.	1800 Wheeler St
CITY, STATE, ZIP CODE, COUNTRY La Verne, CA 91750-5801	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer, Packer, and Labeler

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:

QUALITY SYSTEM

OBSERVATION 1

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

Specifically,

A. Your quality unit failed to ensure that the stability protocol Doc. No. (b) (4) or stability commitments for (b) (4) are being followed, in that, allows that all (b) (4) long-term stability studies (total of (b) (4) stability studies placed from 7/7/2020 to 10/5/2023, equivalent to (b) (4)) from (b) (4) climate chamber room ID # (b) (4) (located in room (b) (4) and dedicated to (b) (4)) at storage condition at (b) (4) ◦C and (b) (4)% RH to be transferred to retained sample room, in which there is no assurance or document to ensure if moved to sample retained room # (b) (4) with a temperature control at (b) (4) ◦C (most likely to be as per management) or sample retained room #(b) (4) (dedicated for (b) (4)) with a temperature control at (b) (4) ◦C. As per change control or assessment form FRM-12414 approved by QC and QA units on 3/21/2024, the samples were to be allocated in location (b) (4) (b) (4), asset (b) (4) in which is a(b) (4) room (temperature control at (b) (4) ◦C). Either of the retain sample rooms are not intended or qualified for the stability sample studies conditions. The quality unit did not provide any scientific rational for the use of the retained room when during this time there were (b) (4) qualified climate chambers available (i.e., ID # (b) (4) (b) (4)) at the site with long term conditions (i.e., (b) (4) ◦C and (b) (4)% RH).

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	Katherine E Jacobitz	Katherine E. Jacobitz, Supv. Sr Advisor	02/18/2026

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Furthermore, the sample were removed on ~~3/21/2026~~ 3/21/2024 Mod 2/18/2026 and return of the samples is not documented, no assess or change control generated and with no evidenced when they were returned to the (b) (4) climate chamber ID # (b) (4) . Therefore, there no assurance of total of days or weeks samples were out of the stability chambers and stability commitment conditions. In addition, the quality unit failed to have logbooks or any other alternate system for the stability chambers and retained rooms to identify the placing and retrieval of samples, by who, date and quantity. All these discrepancies are evident in the review of the deviation report # QE-216300 dated 3/26/2024, that on-demand calibration was requested due to temperature probe located in the room was not transmitting due to being affected for cleaning and maintenance performed under work-orders # 24LV267699 dated 3/21/2024 and work order # 24LV2271590 dated 3/26/2024.

In addition, the quality unit failed to generate an incident, investigation or deviation report for the stability samples impact, if any, for deviating as per product stability protocol, stability commitment, and as per stability control procedures # SOP-04778, Version 20, GMP Stability Study Execution, Effective date: 26 Nov 2025, specifically under section 4.6.2.2.

B. Established laboratory control mechanism is not followed. The quality and integrity of all QC samples cannot be assured due to a lack of appropriate access controls.

As per quality unit practice and control procedure # SOP-02319, Version 85, Sample Receipt Control and Management Procedures at Gilead La Verne, Effective Date: ~~16 Jan 2028~~ 16 Jan 2026; permits manufacturing personnel access to the QC Laboratory during non-operational hours to deliver samples and place them in the QC Laboratory and record in the Sample Receiving Log FRM-5407. However, this form does not document your actual practice which is to allow the manufacturing personnel into restricted QC access to samples contained in the unlocked refrigerator and/or freezer. Said practice does not ensure the quality of integrity of QC samples of refrigerator ID asset # (b) (4) and freezer asset # (b) (4) .

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C. SOP-08627, Inspection of In-Process and Finished Product Vials at Gilead La Verne, v. 29.0, effective 28 Oct 2025, is inadequately written. For example, the procedure fails to describe the placement of rejected vials in (b) (4) bins designated for confirmed and non-confirmed defects, respectively, which was observed during the walkthrough of room (b) (4) on 13 FEB 2026. Furthermore, the quality unit stated that a non-confirmed vial, after review and approval by a second operator can be placed back onto the lot for it to be released to the market. The SOP-08627, Inspection of In-Process and Finished Product Vials, La Verne, v. 18, in effect 27 Jul 2022 to current version 29, describe reject placement and approved vials. This procedure applies to the inspection of In-Process and Finished Product Vials for (b) (4), such as (b) (4) lot (b) (4) manufactured (b) (4) exp (b) (4).

D. SOP-10934, Response to Critical Process Parameters for the Manufacturing GMP Utility Systems at Gilead La Verne, v. 9.0 effective 23 Sep 2024, lacks detail for the verification of items that require mandatory review and/or coverage. For example, the procedure states, "maintenance to walk through the critical utility areas at least (b) (4) to ensure they are continuing to operate as intended and show no signs and/or evidence of any abnormal conditions that could impact operations." During the walkthrough on 11 FEB 2026 of the (b) (4) (b) (4) # (b) (4) (asset ID: (b) (4)) (b) (4) sampling (b) (4) exhibited what appeared to be (b) (4) and not dispensing (b) (4) needed for sample collection, and a leak was observed. Furthermore, (b) (4) # (b) (4) (asset ID: (b) (4)) (b) (4) failed and a leak came out from the (b) (4). (b) (4) is distributed to (b) (4) and used for (b) (4) of process vessels, (b) (4) used to produce (b) (4). Version 6.0 to 9.0 of the SOP has been in place as of 17 MAY 2022 with revisions through current with the same practice.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

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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. Your Quality Unit failed to always ensure that the analytical testing which involves chromatographic data (i.e., HPLC and GC) for the (b) (4) intermediate ((b) (4)), finished product release, and stability studies meet the proper accuracy and reliability. This is evidenced in that the reproducibility tests (i.e., relative standard deviation percent, RSD %), as part of the system suitability and/or specifications do not always ensure the instrument performance throughout a chromatographic run. In addition, system suitability parameters—including tailing factor (T), theoretical plates (N), and resolutions (R), critical to ensuring accurate identification and quantification of analytes is only evaluated at the beginning of the run and not throughout a chromatographic run.

Example of this discrepancy is evident in the analytical testing of (b) (4) used for the release of the finished released product of (b) (4) , Batches # (b) (4) (Manufacturing date: (b) (4) (b) (4)), # (b) (4) (Manufacturing date: (b) (4)), and # (b) (4) (Manufacturing date: (b) (4)). In addition, to the (b) (4) , Batch # (b) (4) , and (b) (4) Intermediate Batches # (b) (4) , # (b) (4) , # (b) (4) ; used for the manufacturing of finished released product (b) (4) Batch # (b) (4) . Which used the following analytical chromatographic method control procedures: mtm 2/18/26

1. (b) (4) Assay – SOP # SDMTD-112, Version 46, Analysis of (b) (4) in (b) (4) Raw Material, (b) (4) Finished Product, (b) (4) , (b) (4) ((b) (4) to (b) (4)), and (b) (4) Intermediate by HPLC, Effective Date: 01 Aug 2025.
2. (b) (4) and (b) (4) Impurities – SOP # SDMTD-114, Version 38, (b) (4) in (b) (4) in Raw Material, (b) (4) and (b) (4) in (b) (4) Raw Material, and (b) (4) and (b) (4) in (b) (4) Finished Product and (b) (4) Determination by HPLC, Effective date: 03 Feb 2025.

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3. (b) (4) Assay – SOP # SDMTD-226, Version 25, Assay Determination of (b) (4) in (b) (4) Raw Material and (b) (4) - (b) (4) in (b) (4) (b) (4) and (b) (4) (b) (4), Effective Date: 19 Feb 2025.
4. (b) (4) Related Substance – SOP # SDMTD—291, Version 22, Determination of (b) (4) and Related Substance in (b) (4) (b) (4) (b) (4), and (b) (4) Raw Material, Effective Date: 06 Jun 2025.
5. (b) (4) Assay – SOP # SDMTD-259, Version 28, HPLC Protocol for (b) (4) in (b) (4) and (b) (4) Effective Date: 06 Aug 2024.
6. (b) (4) Residual Solvent – SOP # SDMTD-165, Version 25, Limit Test of (b) (4) in (b) (4) and Final Product by Gas Chromatography, Effective Date: 15 Aug 2024.

OBSERVATION 3

Reserve drug product samples are not representative of each lot or batch of drug product and retained and stored under conditions consistent with product labeling.

Specifically, retain samples for the US market were found stored in (b) (4) bins with (b) (4) covers. In some instances, samples were additionally wrapped in (b) (4) bags and/or sealed in (b) (4) bags, with some samples double-wrapped. However, these additional protective components added to the product and/or primary/ secondary packaging closure system do not represent the product and container closure system as marketed or received by consumers. This practice is inconsistent across all products and container closure and is not required or specified in the firm's control procedure Doc. No. SOP-08511, Version 54, Reserve/Retain Sample Collection and Retention Procedure at Gilead LA Verne, Effective Date: 20 Aug 2025. The current practice of adding extra protection to the products/containers closure may delay or mask any deterioration that would otherwise be detected during annual visual inspections.

Examples of this discrepancies were observed for the following finished products:

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- (b) (4), Batch # (b) (4) Exp. Date: (b) (4)
- (b) (4) ((b) (4)) (b) (4) Pellets, (b) (4), Batch # (b) (4), Exp. Date: (b) (4)
- (b) (4) ((b) (4)) Tablets (b) (4) / (b) (4), Batch # (b) (4), Exp. Date: (b) (4)
- (b) (4) ((b) (4)) Tablets, (b) (4), Batch # (b) (4), Exp. Date: (b) (4)
- (b) (4) ((b) (4)) Tablets, (b) (4) / (b) (4), Batch # (b) (4), Exp. Date: (b) (4)
- (b) (4) ((b) (4)) Tablets, (b) (4) / (b) (4) / (b) (4), Batch # (b) (4), Exp. Date: (b) (4)

OBSERVATION 4

Test procedures relative to appropriate laboratory testing for sterility are not followed.

Specifically,

1. The firm's analyst was observed to not performing adequate procedural step for bacterial endotoxin testing according to document number SDMTD-510 of (b) (4) sample preparation on February 13th, 2026, to ensure testing does not yield false negative results.
   a. During bacterial endotoxin testing for samples of (b) (4) taken on February 13, 2026, a total of (b) (4) samples were tested. The analyst attempted to (b) (4) each sample by placing each test tube on a (b) (4) for (b) (4); however, the majority, if not all (b) (4) samples were not properly (b) (4) to establish proper (b) (4) formation throughout the test tube to ensure uniformity, homogeneity, and prevention of endotoxin adsorption. This occurred due to each test tube being overfilled. The (b) (4)

samples consisted of various sample (b) (4) including (b) (4) (b) (4) from (b) (4) and (b) (4) The firm generates (b) (4) for (b) (4) formulation, cleaning for (b) (4) holding tanks, as well as cleaning of dedicated (b) (4) for (b) (4).

OBSERVATION 5

Established sampling plans are not followed.

Specifically,

1. The firm's Standard Operating Procedure SOP-10912, revision 19.0, for Sampling and Monitoring of (b) (4) Systems specified that no (b) (4) is required for (b) (4) in controlled areas. However, during the investigation of quality event QE-174808 (exceeded bioburden alert and action limit), the interview section noted that most samplers (b) (4) the (b) (4), (b) (4) prior to sample collection. SOP-10912 was not sufficiently clear to ensure that (b) (4), except for (b) (4), are not to be (b) (4). The current version 31.0 of SOP-10912 still contains the same language as revision 19.0.
    a. During a conversation with the firm, the firm could not determine the definition of "required" and whether (b) (4) require (b) (4), or not. However, the firm stated that samples should not include (b) (4) of the (b) (4) in order to maintain consistency with actual manufacturing conditions, where production personnel do not (b) (4) the (b) (4) prior to use.
    b. According to SOP-10912, multiple sample (b) (4) are designated as (b) (4) operation specifically (b) (4) which are used for (b) (4) formulation, cleaning for (b) (4) holding tanks, as well as cleaning of dedicated (b) (4) for (b) (4).

OBSERVATION 6

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Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, as per firms quality units practice, control document SDMTD-025, Version 101, Sampling Procedure at Gilead La Verne, Effective Date: ~~16 Jun 2026~~ 16 Jun 2026, and control procedure control procedure Doc. No. SOP-08511, Version 54, Reserve/Retain Sample Collection and Retention Procedure at Gilead LA Verne, Effective Date: 20 Aug 2025; (b) (4) of (b) (4) ((b) (4) (b) (4)), containing (b) (4) (with one (b) (4) each) and (b) (4) vials identified as (b) (4) are collected and stored as part of the reserve or retained sample. In addition, any complaints or future investigation regarding product integrity will use the (b) (4) vials for testing. However, the annual inspection review is only performed to the (b) (4) and does not consider in the evaluation the visual inspection the (b) (4) vial for any evidence of product deterioration. This discrepancy is evidenced under the Annual Product Inspection at Gilead La Verne form # FRM-02365 for (b) (4) performed to (b) (4) batches reporting period 08/31/24 to 08/30/2025.

MMM 2/18/26

PRODUCTION SYSTEM

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically, your firm's quality unit failed to reject inadequate airflow visualization studies that were supposed to demonstrate proper particle control dynamics. For example:

A. Your firm's 2024 Airflow Visualization Study for the aseptic filling process area of filler line (b) (4) does not show the full range of airflow. The smoke study video in the final report of year 2024, "LV-RQR-A-2011-0005 Airflow Visualization Study - Video 1 – Product Pathway (Filler (b) (4) and (b) (4) (File # REC-97652), shows the turntable where depyrogenated vials accumulate but does not show the nozzles or manifolds where smoke is released. The video fails to demonstrate that smoke was introduced into the chamber perpendicularly to air flow. Although your firm had unedited

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video showing the full setup and smoke introduction orientation, this footage was not included in the final video. The quality unit nevertheless approved the final smoke study video as adequate.

B. Your firm's Airflow Visualization Study for the aseptic processing area of filler line (b)(4) does not always demonstrate proper particle control dynamics for entire activity steps. In the 2024 video "LV-RQR-A-2011-0005 Airflow Visualization Study - Video 2 – Filler (b) (4): Inherent Interventions" (File # REC-97815), intervention of removal of primary (b) (4) cover for stopper station did not demonstrate removal of (b) (4) covers from (b) (4), unlike the 2022 smoke study video. However, the quality unit approved the final smoke study video as adequate.

C. Your firm's Airflow Visualization Study for the aseptic processing area of filler line (b)(4) does not consistently show smoke covering critical areas where activities occur. In the 2024 video "LV-RQR-A-2011-0005 Airflow Visualization Study - Video 2 – Filler (b) (4): Inherent Interventions" (File # REC-97815), the operator connects a stopper bag to the (b) (4) to transfer stoppers into the (b) (4), but smoke did not cover the (b) (4) to demonstrate proper particle control dynamics where activities occur. Similarly, in the 2025 video " LV-RQR-A-2011-0006 Airflow Visualization Study - Video 3 - Capper (b) (4) and Product Path" (File# REC-123708), smoke did not cover the component during a mechanical component change. In contrast, the 2022 smoke study video showed smoke covering critical activity areas and demonstrated proper particle control dynamics. Despite these deficiencies, the quality unit approved the 2024 and 2025 videos as adequate.

***DATES OF INSPECTION**

2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/13/2026(Fri), 2/17/2026(Tue), 2/18/2026(Wed)

YouKeun Kim, Investigator
Bryan L. Mcluskin, Investigator
Miguel A. Martinez, Chemist
Elvis Patel, Microbiologist
PEARL C. OKURUGBO, INVESTIGATOR
Carolina D Vasquez, Investigator

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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."

2/18/2026.

2/18/2026

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