**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 4/13/2026-4/29/2026*<br>FEI NUMBER<br>3005644727 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jay George Kassir, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Samson Pharmaceuticals, Inc | 5635 Smithway St |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Commerce, CA 90040-1545 | 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:**
Quality System

## OBSERVATION 1

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

Specifically,

A. Your firm manufactured sterile (b) (4) solutions without performing particulate matter testing on finished products. On April 14, 2026, your quality management stated that the analysis was not performed in-house, nor was a contract laboratory utilized. For example, (b) (4) batches (b) (4), and (b) (4) did not have any particulate matter testing results included in the final batch records.

B. Your firm only recorded in-process visual inspection results with (b) (4) samples of (b) (4) checked (b) (4) by both production operators and quality assurance individuals according to SOP Number SP-QC-071, Quality Control Verification of (b) (4) Products, Revision Number A, dated March 18, 2026. As such, all batches (e.g. (b) (4), Lot# (b) (4)) recorded the in-process visual inspection results. There is no documented evidence, demonstrating that 100% inspection of a full batch has been conducted despite the requirement of visual inspection of each (b) (4) product for particles by this SOP.

C. Your firm has established a Finished Goods Final Inspection Report for AQL inspection of (b) (4), including criteria for critical, major, and minor defects; however, there was no documented evidence,

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demonstrating that ARL inspection was conducted during production. For example, the batches for (b) (4) (b) (4), Lot# (b) (4) and Lot# (b) (4) did not contain the Finish Goods Final Inspection Report.

D. No documented records demonstrated that your firm had qualified visual inspectors, nor had your firm established an SOP for their qualification.

Inadequate visual inspection and documentation of (b) (4) could result in unidentified defects in finished products. Your firm received a complaint regarding particulate matter observed in the (b) (4) (b) (4), Lot# (b) (4) on February 25, 2026.

E. Your firm used third party laboratories to perform chemical analysis of (b) (4) products under contract agreements that delineated duties. Qualification of these laboratories was deficient in that potential contractors were only required to complete and return a self-assessment form sent by Samson Pharmaceuticals; onsite visits or review of the contractors QMS was not performed.

F. No analytical method validation or verification of the test methods such as assay and impurity testing of (b) (4) were provided, reviewed and approved by your firm.

G. Your firm did not have a procedure that described the review and approval of test results submitted by your approved contract laboratories for (b) (4) .

(b) (4) batches of (b) (4) products have been released to market within expiry, including: (b) (4) batches ((b) (4) ) released in 2025, and (b) (4) ((b) (4) (b) (4) ) released in 2026.

**OBSERVATION 2**

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

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Specifically,

A. On August 12, 2025, mold was recovered from an ISO 5 active air sample labeled "(b) (4) Air" during the manufacture of (b) (4) Lot (b) (4) . Your firm failed to identify this organism to the genus or species level, as required by your in-house SOP for all organisms recovered from the cleanroom. Gram stains alone do not constitute microbial identification. Despite this unidentified contamination in the ISO 5 environment, the affected batch was released for distribution

B. On April 23, 2026, during observation of a simulated production run using (b) (4) , operators were observed repeatedly using tweezers to reposition bottles and caps within bowls, as well as tips on the production line. During these interventions, an operator extended his arms and gown beneath and over the tip bowl.

C. Your firm's process simulation (media fill) for its sterile (b) (4) filling operations does not challenge the worst-case commercial sublot quantity production. All media fill batches, including the most recent, Batch (b) (4) performed on April 8, 2026, were limited to (b) (4) units. A review of commercial batch records showed that sublots range from approximately (b) (4) to (b) (4) units.

D. Your firm failed to perform growth promotion testing on microbiological growth media, including (b) (4) used for your most recent media fill, Batch (b) (4) . Your firm discontinued in-house growth promotion testing of microbiological growth media and relies solely on vendor-supplied Certificates of Analysis (CoA) to confirm media suitability. This practice does not comply with your in-house procedure, SP-LP-095 “Growth Promotion Test” effective March 18, 2022, which requires growth promotion testing of media prior to release for use.

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**OBSERVATION 3**

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,

A. Environmental monitoring (EM) records for (b) (4) commercial batches and a media fill batch recovered personnel monitoring colony counts of (b) (4). The following instances were noted during the inspection:

(b) (4) **(Commercial Product)**

Batch (b) (4)

| Sublot | CFU Count | Source |
|---|---|---|
| (b) (4) | 9 CFU | (b) (4) |
| | 5 CFU | |
| | 1 CFU | |
| | 1 CFU | |
| | 1 CFU | |
| | 2 CFU / 2 CFU | |

Batch (b) (4)

| Sublot | CFU Count | Source |
|---|---|---|
| (b) (4) | 1 CFU | (b) (4) |

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| | | |
|---|---|---|
| (b) (4) | 1 CFU | (b) (4) |
| | 1 CFU | |
| | 1 CFU | |
| | 1 CFU | |

**Media Fill**

Batch (b) (4)

| CFU Count | Source | Note |
|---|---|---|
| 4 CFU | (b) (4) | Both counts attributed to the same production technician |
| 2 CFU | | Both counts attributed to the same production technician |

Your firm did not initiate out-of-specification (OOS) investigations into any of these microbial recoveries. Even when your EM batch record SP-LP-101-05.01 specification of "Microbial Test Results (b) (4) " was exceeded. The commercial batches and sublots were not quarantined or evaluated for potential impact to product sterility and were released for distribution.

B. Your firm released a batch with OOS result without scientific justification and investigation. Your contract testing laboratory reported an OOS result for the assay of (b) (4) , Lot# (b) (4) (b) (4), dated September 12, 2025. (b) (4) was tested three times, with one result failing

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the USP specification ((b) (4) - (b) (4), and other two failing the internal specification ((b) (4) % - (b) (4) %). No documented OOS investigation is available, and your firm has released this batch for distribution.

**OBSERVATION 4**

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

Your SOP no. SP-QA-050, "Vendor Qualification" described, in part, the requirements for qualifying material suppliers of (b) (4) used in (b) (4) . The procedure did not specify the number of lots and the tests required to qualify the vendor. The reliability of the material's COA was not established and monitored on a continuing basis.

Facilities and Equipment System

**OBSERVATION 5**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. Your cleanroom at 5635 Smithway Street was constructed and qualified in August 2022 by a third-party contractor. Their qualification was limited to physical parameters including particle counts, HEPA identification, filter scan and leak test, air balance and velocity, and room pressure. No viable (active air, surface, or personnel monitoring) EM qualification was performed. Your firm substituted routine (at

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rest) production environmental monitoring data from the first commercial batch ((b) (4) ) in place of a dedicated performance qualification study.

B. Your firm failed to establish documented alert and action levels for environmental monitoring parameters, including viable air, surface, and personnel monitoring sampling. A review of SOP SP-LP-101, "Environmental Monitoring of Cleanroom" effective December 19, 2025, and SOP SP-LP-106, "Alert, Action, and Out-of-Specification Investigation for Microbiology" effective April 1, 2026, revealed that neither procedure specifies alert or action levels to initiate out-of-specification (OOS) investigations.

C. Neither viable air samples nor non-viable particulate (NVP) samples were collected in the immediate vicinity of the critical filling zone. Production technicians position the microbial air sampler and non-viable particulate analyzer (b) (4) (b) (4) during production. The current setup does not allow the sampling devices to be positioned (b) (4) of the critical filling area, as required by SOP SP-LP-101, "Environmental Monitoring of Cleanroom", effective December 19, 2025.

D. Environmental monitoring for air sampling did not follow established procedures. On April 13, 2026, it was observed that the active air sampling plates for media fill (Lot No. (b) (4) ) showed no surface impressions. These plates had completed the required incubation period and were reviewed by the responsible operator. The operator stated that active air sampling was conducted at up to (b) (4) (b) (4) However, according to SOP No. SP-LP-101, Environmental Monitoring for Cleanroom and Personnel, Revision B (effective December 19, 2025), your firm required collection of (b) (4) for active air sampling during environmental monitoring of (b) (4) production.

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**OBSERVATION 6**

The calibration of instruments is not done at suitable intervals in accordance with an established written program.

Specifically,

There was no performance verification during the use of the in-line (b) (4) (s/n: (b) (4) ) and (b) (4) (P/N: s/n: (b) (4) -(b) (4)); the systems were calibrated (b) (4) by an outside contractor. The units were used to monitor (b) (4) used in the manufacture of (b) (4) .

Laboratory System

**OBSERVATION 7**

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

There was no written stability program for (b) (4) although units were manufactured between 2015 and 2025. A stability study for the (b) (4) product was reported on 11/01/23 but (b) (4) were assayed per the respective USP methods which were not validated as stability indicating methods.

**OBSERVATION 8**

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The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit.

Specifically,

1) Your firm used (b) (4) as an active ingredient in (b) (4) but there was no procedure that required impurity testing for (b) (4) .

2) Your SOP no. SP-QC-016, "Receipt, Sampling and Testing of Raw Materials" described the receipt, sampling, testing, and disposition of raw materials. The procedure required identification analysis but there was no requirement for periodic full testing of incoming API raw materials such as (b) (4) used in (b) (4) .

***DATES OF INSPECTION**

4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri), 4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed)

X Taichun Qin
Investigator
Signed By: 2001324646
Date Signed: 04-29-2026 11:46:58

X Walden H Lee
Chemist/Biologist
Signed By: 1300071161
Date Signed: 04-29-2026 11:47:43

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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."