DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/9/2026-2/20/2026*
	FEI NUMBER 3017473850

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lyndon R. Leitner, CEO

FIRM NAME	STREET ADDRESS
Staska Pharmaceuticals, Inc.	742 Evergreen Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bennet, NE 68317-2365	Outsourcing Facility

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 whether or not the batch has been already distributed.

Specifically,

Your procedures do not require investigation when Acceptable Quality Limit (AQL) sampling fails after 100% visual inspection.

On July 10, 2025, during visual inspection of Ascorbic Acid Preservative Free Injection batch SP2500050, (batch size: (b) (4) units), your initial 100% visual inspection rejected 80 critical, 49 major, and 12 minor defects. Subsequent AQL sampling identified 5 major defects, exceeding your acceptance criterion of (b) (4) major defects, and the AQL failed.

Your Quality Unit approved proceeding to (b) (4) visual inspection without initiating an investigation to determine why the initial 100% visual inspection failed to detect the 5 major defects found during AQL sampling, without documenting the rationale for this decision, and without evaluating whether other batches may be similarly affected. After (b) (4) visual inspection and tightened AQL sampling (which passed), the batch was released.

Your procedure PRD07 "Visual Inspection", Revision 00, Effective Date 09/09/2025, does not require investigation of AQL failure before proceeding to (b) (4) re-inspection.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm lacks adequate controls to ensure the integrity and reliability of analytical data generated by High-Performance Liquid Chromatography (HPLC) systems used for release testing of sterile drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Chad W Rice, Investigator Carl A Huffman, Investigator X Chad W Rice Investigator Signed By: 2002111256 Date Signed: 02-20-2026 09:03:19	2/20/2026

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A. Your firm does not have a written procedure requiring review of electronic raw data, audit trails, and system-generated records from HPLC analyses prior to batch release. Your Quality Control (QC) pharmacist reviews only printed reports and manually verifies calculations, but does not review:

- Electronic raw chromatograms
- Integration events and manual integrations
- Injection sequences and any deleted or repeated injections
- Audit trails showing user activities, including data modifications or deletions
- Metadata (e.g., user IDs, system configuration changes)

Your firm's current practice of reviewing only printed summaries and recalculating results does not fulfill the Quality Unit's responsibility to ensure the reliability of analytical data used for batch disposition decisions. For example, the batch record for Ascorbic Acid Preserved, Batch SP26003, manufactured on (b) (4) and tested by HPLC on January 20, 2026, contains only a printed HPLC summary report with no documentation of electronic data review, audit trail verification, or confirmation that all injections performed are included in the reported results.

B. One chemist performs the majority of HPLC analyses for product release testing without independent verification of the electronic data by the Quality Unit. This practice does not provide adequate oversight to detect:

- Unauthorized reintegration of peaks
- Deletion of failed injections or out-of-specification (OOS) results
- Selective reporting of data
- Manipulation of integration parameters to achieve passing results
- System suitability failures that were not investigated

Without comprehensive review of electronic data and audit trails, there is no assurance that reported test results are complete, accurate, and free from unauthorized manipulation.

C. (b) (4) employees authorized to perform HPLC analyses have administrative user roles in the (b) (4) chromatography data system. Administrative privileges in (b) (4) allow these users to:

- Modify integration parameters after data acquisition
- Reprocess chromatographic data
- Modify or disable audit trail settings
- Change system configuration and methods

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- Adding and removing users

Analysts who generate analytical data should not have administrative privileges that permit modification or deletion of that data without independent oversight and detection.

OBSERVATION 3

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

Specifically,

A. Non-Viable Particle Monitoring Probe Orientation

On February 12, 2026, during the production of Glutathione (Preserved), Batch SP26012, the orientation of the non-viable particle counter probe was not directed into the flow of air in the monitored location. The probe was positioned (b) (4) rather than in-line with the (b) (4) laminar airflow, preventing representative sampling of the ISO 5 environment where aseptic manipulations occur.

Your firm cannot demonstrate that the orientation and placement of the probe provides a meaningful sample of the critical aseptic processing area.

B. Environmental Monitoring Equipment Obstructing First-Pass Air

Your firm's procedures for environmental monitoring during production operations do not ensure that monitoring equipment is positioned to avoid compromising unidirectional airflow in the ISO 5 critical zone.

Specifically, your procedure MIC01 "Viable Environmental and Personnel Monitoring", Revision 00, Effective Date 10/17/2025, does not provide specific instructions for the placement of settle plates and non-viable particle monitoring equipment within the ISO 5 (b) (4) laminar airflow hoods to ensure they do not interfere with unidirectional airflow over the critical aseptic processing area. Section 8.3 of MIC01 states only: "After reaching the respective sampling location, place the settle plate in the defined sampling location as per the lay out." The procedure does not specify that settle plates and monitoring equipment must be positioned to avoid obstructing first-pass air over exposed sterile product, containers, and closures, nor does it prohibit placement directly in the path of unidirectional airflow where aseptic manipulations occur.

MIC01-FRM01, Layout, Sampling Schedule, and Justification of Sampling Points for Environmental Monitoring (Attachment to MIC01-00), identifies settle plate sampling locations (SP(b)(4) through SP(b)(4) for various laminar airflow hoods but does not provide specific positioning instructions within each hood to prevent airflow obstruction during aseptic operations.

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For example, on February 12, 2026, during the production of Glutathione (Preserved), Batch SP26012, in (b) (4) laminar airflow hood PD-LF008, where HEPA-filtered air flows (b) (4) , both the settle plate and non-viable particle counter probe were observed positioned at (b) (4) of the ISO 5 area, (b) (4) to the HEPA filter face. This placement positioned (b) (4) monitoring devices (b) (4) and the aseptic processing area where vials were being filled, stoppered, and crimped. As stoppered vials were transferred (b) (4) across the work surface during production, they passed through the zone where first-pass HEPA-filtered air was obstructed by the settle plate and particle counter probe.

This placement practice:

- Obstructs unidirectional airflow over exposed sterile product, containers, and closures during production
- Creates a potential zone of turbulence or stagnant air in the critical aseptic processing area
- Demonstrates that your environmental monitoring procedures, as written and executed, interfere with the maintenance of ISO 5 air quality during routine operations

Your firm cannot demonstrate that environmental monitoring is conducted in a manner that does not disrupt the unidirectional airflow necessary to protect sterile product from contamination.

***DATES OF INSPECTION**
2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/20/2026(Fri)

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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."