DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Phone #: 240-402-2900 Email: CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/02/2026 - 02/06/2026
	FEI NUMBER 3026587575

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Suresh D. Sorathiya, Managing Director

FIRM NAME	STREET ADDRESS
SNJ Labs Private Ltd.	Plot No 5 to 16,Survey No 137, Kotda Sangani, Padavala
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Rajkot, Gujarat, 360024, India	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Failure of your quality unit to ensure that critical deviations are investigated and resolved.

a. Your firm had four OOS results for the (b) (4) content in the finished active pharmaceutical ingredient (API) (b) (4) from April-September 2024. Root causes identified included loose wire connections to the (b) (4) instrument, black coating on the (b) (4) poor (b) (4) performance, and instrument malfunction. However, no preventive maintenance was performed on the instrument since 2020. Your firm retested the samples and invalidated the original OOS results (OOS/24/001 (b) (4) %], OOS/24/006 (b) (4) %], OOS/24/007 (b) (4) %] and OOS/24/010 (b) (4) %]; specification limit: (b) (4) %). Your firm's corrective actions and preventive actions to the assignable root cause were inadequate and that resulted in repeated sample failures. During April-September 2024, your firm analyzed and released (b) (4) finished API batches from Plant (b) (4) and (b) (4) batches of (b) (4) from Plant (b) (4) without performing any risk assessments.

b. Your firm did not thoroughly investigate the OOS (OOS/24/005) results for (b) (4) assay by HPLC in (b) (4) API intended for the US market. The assay results were (b) (4) % (first replicate) and (b) (4) % (second replicate); specification limit: (b) (4) % to (b) (4) % w/w. The identified root cause was due to a (b) (4) failure at (b) (4) in the HPLC system; however, the chromatographic data acquisition was documented at (b) (4) The investigation did not verify these details or conduct further investigation for an assignable root cause. Your firm invalidated the initial OOS results, retested the samples with passing results, and implemented no preventive actions.

OBSERVATION 2
Your firm failed to use validated and stability-indicating test procedures.

Your firm failed to use validated, stability-indicating methods to test active pharmaceutical ingredients (API) (b) (4) (b) (4) intended for the US market when assigning retest dates of (b) (4) The analytical method used for

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testing stability samples is not stability indicating and cannot identify degradation products. Furthermore, your firm started stress studies for (b) (4) API on (b) (4) intended for the US market, however your firm is currently assigning a (b) (4) retest date to this product. Your firm manufactured (b) (4) batches of (b) (4) and (b) (4) batches of (b) (4) in 2025.

OBSERVATION 3

Your firm failed to exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data and failure to have adequate controls to prevent omission of data.

a. The finished product testing data for (b) (4) intended for the US market using stand-alone instruments, atomic absorption spectrophotometer AAS (SNJ/QC/AAS/37), UV/VIS Spectrophotomer (SNJ/QC/UV/39), and voltameter (SNJ/QC/VM/15) in the computer "C or E" drive were backed up to (b) (4) external hard drives (b) (4) (b) (4) according to your IT administrator. Analysts have unrestricted privileges to cut, copy, paste, delete and rename data files on computer hard drives and there is no assurance that data are original/unaltered before backup. Your firm has the capability to save HPLC data on the server, however, your firm has not conducted gap assessments for GMP data files saved on computers connected to stand-alone instruments.

b. Your firm's analysts have privileges of changing date and time settings on computers attached to the atomic absorption spectrophotometer and UV-Vis spectrophotometer.

c. Your firm failed to validate the Excel software used for laboratory data calculations. Your QC Manager confirmed this on February 4, 2026. The results calculated for (b) (4) assay for (b) (4) finished product batch (b) (4) using Excel software were not available during the inspection and your QC manager stated that your firm's practice is to perform calculations using the software, take a printout without saving or locking the files for review.

OBSERVATION 4

Failure to properly maintain buildings and facilities used in the manufacture of API.

Your firm failed to maintain facility and equipment in clean status for manufacturing and processing of (b) (4) (b) (4) (Plant (b) (4) and (b) (4) API (Plant (b) (4)

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a. Clean room [redacted] Plant [redacted] showed [redacted] material spots on the ceiling (approximately [redacted] above the [redacted] Floors had stains and peeling seals between the floor and wall behind the [redacted] Room corners near the ceiling showed dust-like material and cracks on February 2, 2026. The [redacted] cleaning record showed that the room was last cleaned on [redacted] and there was no documentation on the logbook for [redacted] cleaning of ceiling.

b. Clean room [redacted] Plant [redacted] used for [redacted] API [redacted] was not in clean condition on February 2, 2026. Floors showed [redacted] liquid like substance leaking from [redacted] of [redacted] materials scattered on the floor next to [redacted] and [redacted] liquid stains on floors and walls. The [redacted] cleaning record showed that the room was cleaned on [redacted] equipment [redacted] inside room [redacted] showed apparent [redacted] deposits throughout, despite cleaning logs showing the last cleaning on [redacted]

c. [redacted] contained [redacted] inside despite status boards showing "cleaned" on February 2, 2026. Equipment cleaning logs indicated that cleaning was performed on [redacted]

d. Clean room [redacted] area in Plant [redacted] showed [redacted] deposits on the floor, [redacted] runover stains on walls, rusted [redacted] pipelines, rust like deposits on the [redacted] to the [redacted] and [redacted] stains on the [redacted] of the [redacted] on February 4, 2026. [redacted] API is exposed in this room before loading and unloading from the [redacted]

OBSERVATION 5
Failure to have adequate written procedures for the sampling of raw materials.

Your firm has inadequately written SOPs for raw material sample collection and in-process control samples that fail to provide sufficient instructions for QC personnel and operators. SOP QCG/006-05 (Sampling of Raw materials and packing materials) lacks detailed information on how to collect samples from raw material bags. SOP PDG/032-02 (SOP for sampling procedure of in-process and intermediate sample) does not provide adequate details for collecting in-process samples for [redacted]

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OBSERVATION 6

Failure to follow and document laboratory controls at the time of performance and failure to document and explain any departures from laboratory procedures.

a. Your QC microbiology laboratory analysts failed to document original inoculation counts in growth promotion testing (GPT) data sheets for (b) (4) media for (b) (4) Vendor lot (b) (4) in house lot (b) (4) Additionally, growth promotion results for (b) (4) media (b) (4) media (b) (4) vendor lot (b) (4) in house lot (b) (4) were documented as "positive" on (b) (4) exceeding the ≤ (b) (4) timeframe specified in SOP QMG/009-03 "SOP for procedure of Media efficacy testing-growth promotion and inhibitory property test."

b. Your QC microbiology laboratory analysts confirmed on February 4, 2026, that growth promotion testing (GPT) was not performed for (b) (4) (lot (b) (4) and (b) (4) (vendor lot (b) (4) lots that were received and currently used for microbiological testing of finished products, environmental monitoring and water testing. Furthermore, your QC Manager confirmed that method verification was not performed for growth promotion studies.

c. Your firm failed to initiate laboratory incidents when analysts did not correctly follow HPLC processing methods to analyze (b) (4) assay data for (b) (4) API intended for the US market by HPLC. Additionally, your firm has not established an auto-integration processing method for analyzing HPLC chromatography data for (b) (4) intended for the US market.

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