DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	07/27/2026-08/05/2026
	FEI NUMBER: 1000623515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sunil Kumar Singh, Chief Quality and Compliance Officer

FIRM NAME	STREET ADDRESS
Cohance Lifesciences Limited	Plot Nos 262-271, Ida Pashamylaram
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sangareddy, Telangana, 502307, India	API Intermediate/API/Finished 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:

OBSERVATION 1

Analytical methods used for testing are not always validated, the suitability of compendial methods is not always verified under actual conditions of use, and system suitability testing is not always conducted prior to sample analysis to demonstrate that the analytical system is performing as intended.

Specifically,

A) Your firm failed to validate in-house laboratory test methods used across all stages of the manufacturing processes for Active Pharmaceutical Ingredients (APIs) and finished drug product. Approximately, (b) (4) in-house methods out of (b) (4) total analytical methods used for analysis of (b) (4) API, and (b) (4) methods are not validated. These unvalidated analytical methods are used for the analytical testing of raw materials, key starting materials, in-process, intermediate, API, and finished drug products and your firm has not demonstrated that they consistently produce results that are accurate, precise, specific, linear, and reproducible across their intended ranges.

These unvalidated methods include, but are not limited to, purity and identification by Gas Chromatography (GC) and High-Performance Liquid Chromatography (HPLC), (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Zachary L. Stamm, DDC Investigator Alan A. Rivera, DDC Investigator	08/05/2026

(b) (4)
impurities testing, and (b) (4)

B) Your firm also failed to perform method verification for all USP methods used to test KSMs and raw materials used in the manufacturing of APIs, as well as (b) (4) API used in the manufacture of (b) (4) finished drug product, with approximately (b) (4) USP methods lacking documented verification. One of these unverified USP methods (Identification Infrared Adsorption, USP <197>) is used as a stability testing method of (b) (4) API and two (Identification by IR USP <197> and Optical rotation USP <178>) are used as stability testing methods of (b) (4) API.

Since August 2024, your firm has manufactured approximately (b) (4) lots for the U.S. market, including (b) (4) lots of (b) (4) API, and (b) (4) lots of (b) (4) finished drug product. All lots were tested using unvalidated in-house methods and unverified USP methods, were distributed into U.S. commerce, and remain within their expiration dates.

C) Your firm does not perform system suitability testing for your in-house purity by GC analytical method for (b) (4) raw material, used in the manufacture of (b) (4) finished drug product. Your firm's current Standard Test Procedure (STP-QC-03-2217-01-R00, approved May 22, 2021), Section 6, limits the injection procedure to one (1) reference sample injection and two (2) sample injections and analytical results are considered acceptable if the retention time of the reference sample is "similar" to that of the sample. This practice does not provide adequate assurance that the chromatographic system is performing within appropriate parameters, including tailing factor, theoretical plates, resolution, relative retention time, and/or RSD of replicate injections at the time of analysis. Furthermore, your firm has no documented procedure defining what constitutes an acceptable percentage variance from the retention time (RT) specified in the STP.

For example, this deficiency was evidenced during the inspection of your Quality Control (QC) Laboratory at the API site on July 29, 2026:

1. On July 27, 2025, (b) (4) (Batch (b) (4) was tested for purity by GC and yielded a retention time of (b) (4) Your STP-QC-03-2217-01-R00 specifies that the average percent area of (b) (4) should be reported at a retention time of (b) (4) (b) (4) this represents a deviation of (b) (4) or (b) (4) from the established STP retention time. The result was approved by QC on July 28th, 2025.

2. On March 14, 2025, (b) (4) (Batch (b) (4) was tested for purity by GC and yielded a retention time of (b) (4); this represents a deviation of (b) (4), or (b) (4) from the established STP retention time (b) (4) The result was approved by QC on March 15, 2025.

   (b) (4) (Batch (b) (4) was used in the manufacture of (b) (4) lots of (b) (4) (b) (4) finished drug product, which were distributed into U.S. commerce and remain within their expiration dates.

OBSERVATION 2

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

Your firm's Phase II investigation, OOS/FP/24/302-01, initiated March 29, 2024, into three Out-of-Specification (OOS) batches of (b) (4) USP API (Code: (b) (4) failed to extend to other API products that may have been associated with the specific failure.

Your firm identified that (b) (4) API batches (b) (4) were OOS for Related Substances by HPLC. Your firm's Phase II investigation determined the root cause to be the raw material (b) (4), raw material code (b) (4), manufactured by (b) (4). Your firm documented the receipt of (b) (4) batches of this raw material (Batches (b) (4) (b) (4) totaling (b) (4) However, your firm's investigation failed to determine whether these batches of (b) (4) were used in the manufacture of other API products.

OBSERVATION 3

Written procedures are not established and followed for the evaluation of all changes that could affect the production and control of the intermediate or API, and the potential impact of proposed changes on the quality of the intermediate or API is not adequately evaluated.

Specifically,

Your firm's change control procedure, titled "Handling of Change Control Note in QualZen Module of ZenVector Application for PSA", COR-CQA-GSOP-022, Revision 00, effective March 18, 2026, does not require the Cross-Functional Team Review document their Impact Assessment Methodology, and there are no minimum content requirements defined for major change risk/impact assessments.

The following change controls do not document what items were assessed by each department as part of the change control approval process:

- PRO/CCA/24/3163, Initiated April 13, 2024: (b) (4) transfer to Unit (b) (4)
- PRO/CCA/24/3159, Initiated April 10, 2024: Reprocessing of (b) (4) OOS batches using an R&D-provided procedure
- PCC/PSA/MNT/2025/005, Initiated December 12, 2025: Replacement of HMI and installation of (b) (4) in (b) (4) system

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OBSERVATION 4

Written procedures for laboratory testing do not include adequate controls to ensure the correct carrier gas is used during gas chromatography (GC) analytical testing, and there is no documented verification that the correct gas is in use prior to, during, or after analysis.

Specifically,

Your firm does not have written procedures or controls in place to ensure the correct carrier gas (nitrogen or helium) is used during analysis of API or drug products by gas chromatography.

In both QC laboratories for the API and finished dosage facilities, the gases are connected to the GC equipment via (b) (4)

Additionally, your firm does not document verification that the correct carrier gas is selected and used. Your firm has not demonstrated that the use of the correct gas can be determined from analytical results.

OBSERVATION 5

Materials are not handled and stored in a manner to prevent degradation, contamination, and cross-contamination.

Specifically,

On July 31, 2026, we observed that the (b) (4) access point for the delivery of (b) (4) to the API manufacturing facility, located (b) (4) of the facility, was unlocked and open. Your firm's procedure titled, Cleaning & Handling of Hose fo(b) (4) SOP-MNT-03-0073, Effective Date January 7, 2026, did not require that this access point be closed and locked to prevent potential contamination at the time of this inspection

The (b) (4) delivered at this access point serves as (b) (4) for your firm's (b) (4) system, which is used in the manufacturing of drug substance intermediates and drug substances.