

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product 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 I OBSERVED:
QUALITY SYSTEM**

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

- A) There is no documentation on the disposition status and reconciliation of approximately (b)(4) of rejected (b)(4) tablets, (b)(4) mg, Batch No. (b)(4) that have gone missing after being rejected on August 23, 2023, as part of Deviation DEV/NCR/23/0033, Deviation Initiation Date: June 19, 2023. Specifically, (b)(4) total containers, which consists of (b)(4) of Batch No. (b)(4) compressed tablets, had fallen on the floor from the (b)(4) during transfer from the hold area to Bottle packing line (b)(4). According to the final investigation report, the decision was made to destroy the entire batch due to the high number of rejects after tablet reinspection and probable impact on physical characteristics for all compressed tablets. According to the General Manager of Quality Assurance (QA), the rejected batch has not been disposed of as of the current inspection; this is approximately 23 months since the final investigation report was closed and approved by the QA and Production department in August 2023. However, only (b)(4) out of the (b)(4) total containers, which consists of (b)(4) out of the (b)(4) total rejected batch material, remained in the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

warehouse facility during my inspection walkthrough on August 08, 2025. The General Manager of QA and Senior General Manager of Operations stated that they were unable to explain the discrepancy and unable to account for the missing quantity of rejected compressed tablets for Batch No. (b)(4) which was initially intended for distribution to the U.S market.

B) OOS/IP/21/020 was initiated on March 30, 2021, due to (b)(4) Tablets USP, Batch No. (b)(4) Mfg. Date: 03/2021, Exp. Date: (b)(4) HPLC assay test not meeting specification limits for the (b)(4) stage. The batch was initially intended for the U.S market but ultimately rejected due to the following root cause: Operator potentially missing steps for (b)(4) and subsequently leading to inadequate (b)(4) According to the investigation report personnel interview section, it was understood that the (b)(4) step was possibly missed by the Operator due to assumption and the Executive (BMR Reviewer) being absent for verification. The investigation further stated that since the executed processing step is performed during (b)(4) the assumption/overlook tendency of the operator and unavailability of operator for missing the step is inferred to be inherent. However, there was no further assessment and preventive actions initiated to address the process and operational gaps that may continue to remain during critical manufacturing and packaging steps (especially during (b)(4))

C) OOS/QC/23/010 was initiated on April 28, 2023, due to (b)(4) Tablets USP (b)(4)mg, (b)(4)mg, (b)(4)mg, (b)(4)mg and (b)(4)mg /In-process, Batch No. (b)(4) having out-of-specification (OOS) (b)(4) results for the mean of individual assay: (b)(4)% (Specification: (b)(4)% for Sample Set (b)(4) Sample Set (b)(4) had passing results and no assignable root cause was identified for the Sample Set (b)(4) OOS results. As a preventive action, it was proposed to collect the (b)(4) content and assay samples at (b)(4) stage in (b)(4) vials (instead of (b)(4) vials) to eliminate error during (b)(4) weighing of sample vials. However, no further hypothesis testing, or detailed assessment was performed to evaluate the effects that

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-8 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

(b) (4) material may have on altering sample results before switching to the usage of (b) (4) vials. (b) (4)

(b) (4) Compressed tablets and finished product capsules are then packaged into (b) (4) bottles that are distributed to the U.S market. (b) (4) Tablets (b) (4)mg, final batch No. (b) (4) Mfg. Date: April 2023 was ultimately released to the U.S market based on passing (b) (4) of dosage unit results and Sample Set (b) (4) testing passing results in June 2023 (b) (4) Tablets within (b) (4) Bottles).

According to the Assistant General Manager of Quality Assurance, there is no documentation or record onsite for extractable and leachable studies being performed for (b) (4) bottle containers used for (b) (4) packaging of all tablets and capsules distributed to the U.S and other markets. During the current inspection, your firm was unable to provide any documentation of extractable and leachable studies performed for the (b) (4) containers (b) (4) for finished product tablet compression or capsule filling operations.

OBSERVATION 2

Written records of investigation of a drug complaint do not include the follow-up.

Specifically,

- A) Complaint #PC/NCR/FDF/23-020, was filed on October 5th, 2023 for (b) (4) (b) (4) tablets USP (b) (4) mg, due to the firm's customer receiving a complaint from

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE -E Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

the pharmacy that the tablets were disintegrating and found the tablets in the bottle to be crumbly, disintegrating, pitted, had dust in the in the bottles that came from the pill itself and did not have crisp markings on the tablet. The investigation report root cause analysis stated that: based on the investigation, it can be drawn that the tablets photographs of the control/reference sample resemble the tablet photographs of the complaint sample. The probability of generation of powder could be due to (b) (4) nature of the tablets. In addition, the subjected complaint was considered as 'Not Substantiated' and no corrective and/or preventive actions was initiated. However, there is no finished drug product release and stability specification established to determine the acceptability limit of (b) (4) tablets with chipped edges and disintegrating like physical characteristics. These physical characteristics was also observed during review of retain samples during the current inspection. According to the General Manager of Quality Assurance (QA), there was also no attempt made to request the original complainant sample for comparison purposes and further evaluation.

Furthermore, SOP QA084-02, Field Alert Report, Effective Date: December 31, 2022, states that: the following are some examples which need to be reported as a Field Alert Report (FAR): Crumbled, broken, disintegrated tablets found inside bottles...However, there is no documented explanation as to why there was no communication with the customer in regards to potentially filing a U.S FDA field alert report for the complaint as described in the procedure.

B) Complaint # PC/NCR/FDF/24-024 was initiated on May 10, 2024, for (b) (4) (b) (4) Tablets, (b) (4) mg, Batch No. (b) (4) due to customer finding medical grade piece of glove, which is/could be a finger part of the glove, upon opening the sealed bottle on April 23, 2024. It was determined that the glove might have torn during (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

activity prior to tablet inspection and then (b) (4) the tablets and filled in the (b) (4) CAPA/030/24 was initiated on June 24, 2024, to propose a new procedure: SOP PD289-00 Handling of Gloves in Manufacturing and Packing Area, Effective Date: October 03, 2024. However, the SOP does not include provisions for notifying the supervisor or documenting any potential future incidences concerning ripped pieces of gloves.

OBSERVATION 3

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

Specifically,

- A) Complaint investigations that are involved with field alert reporting activities are not logged into the Field Alert Report Log (Annexure I) for further follow-up and reference as per SOP QA084-02, Field Alert Report, Effective Date: December 31, 2022, requirement. This include the lack of documentation in the Field Alert Report Log for Complaint MC/036/20, Complaint Received on: December 04, 2020 by the customer for (b) (4) Tablets (b) (4) mg, Batch No. (b) (4) Manufacturing, Date: 01/2020, Exp. Date: (b) (4) due to pharmacist stating that one completed seal bottle had (b) (4) tablets under the strength of (b) (4) mg and (b) (4) tablet under the strength of (b) (4) mg, Initial FAR Date: December 08, 2020, Final FAR Date: December 08, 2020. According to General Manager of Quality Assurance (QA), this event was not logged to procedural unawareness by the QA department.
- B) The is no instrument usage log for Analytical Balance #PD/AWB/-06 used to routinely perform in-process analytical testing of compressed tablets of various drug products manufactured in Production Block (b) (4) In addition, the instrument usage log for friability test apparatus PD/FBL-01

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

has not been completed as per SOP PD240-02 Operation, Cleaning and Calibration of Friability Test Apparatus, Effective Date: October 28, 2023, section 6.2 Annexure II, Usage Log for Friability Test Apparatus (PD240-F02-01) requirement. According to General Manager of Quality Assurance (QA), this was due to procedural unawareness by operators and QA.

C) There is no documented rationale and quality risk assessment for assigning the same User ID and passwords shared amongst production block operators, supervisors, and managers for login into manufacturing equipment Human Machine Interface (HMI). For example, (b)(4) operators are provided with the supervisor level password for (b)(4) Equipment ID: PD (b)(4)01 and (b)(4) Equipment ID: PD (b)(4)02 as per SOP PD052-08 Operation of (b)(4) (Capacity (b)(4) Effective Date: November 24, 2023. This is despite the software vendor manual stating that supervisor level password prevents access to the program details, and it should be known only to the supervisor or in charge of the plant. The supervisor level user access allows for edits of the following data points:

- Process Time (total cycle time)
- (b)(4) Off time (time during which (b)(4) is switched off or during the time of (b)(4) is taking place).
- (b)(4) On and Off (time duration during which (b)(4)
- (b)(4) On and Off (time during which (b)(4)
- (b)(4) set point
- (b)(4) low and high limit
- (b)(4) setpoint.

The following additional manufacturing equipment Human Machine Interface (HMI) screens also have shared user IDs and passwords for Production Block (b)(4) in which operators are assigned supervisor level access:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE - 6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------



D) On August 06, 2025, I observed that the Packaging Supervisor was able to cut and delete logged software audit trail data and packaging batch data files within the Countec Data System Windows application account used for the (b)(4) Bottle Packing Line (b)(4) operations. The account login is also shared between operators and packaging supervisors. According to the IT Administrator, this was an oversight.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 4

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A) During the inspectional walkthrough on August 4th, 2025, visible (b)(4) stains were observed within (b)(4) PD (b)(4) 01 (b)(4) and behind the (b)(4) which remains open during (b)(4) operations for drug products intended for the U.S and other global markets. PD (b)(4) 01 was last used to manufacture (b)(4) (b)(4) tablets (b)(4) mg, (b)(4) mg, and (b)(4) mg, Batch No. (b)(4) prior to Product Changeover (Type-B) cleaning being completed on July 30, 2025. However, the following test results were reported after swab sampling performed as per the current inspection request for the same

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

8/4/2025-8/12/2025*

FEI NUMBER

3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME

Cohance Lifesciences Limited

STREET ADDRESS

A - 23a & A - 23b, C Lakshmi Plastics;
Ida Nacharam No 18 Road; Road No 18 - Ida
Nacharam

CITY, STATE, ZIP CODE, COUNTRY

Secunderabad, Telangana, 500076 India

TYPE ESTABLISHMENT INSPECTED

Finished Drug Product Manufacturer

equipment on August 4th, 2025:

[REDACTED] (b) (4)

An additional peak in the sample chromatograms for all (b) (4) swab sample locations was identified to be traces of (b) (4) which is a (b) (4) used in the (b) (4) treatment of (b) (4). The identified peak for (b) (4) had a higher area response compared to previously last manufactured product: (b) (4). For example:

Swab Analysis results for (b) (4) Duct (b) (4)

[REDACTED]

(b) (4) Tablets (b) (4) mg, was last manufactured on March 2025 using PD (b) (4) 01. (b) (4) additional drug product batches have been manufactured using the same equipment since then for the U.S and other global markets, including:

- (b) (4) Tablets (b) (4) mg and (b) (4) mg (USA), Batch No. (b) (4)

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Guerlain Ulysse, Investigator

DATE ISSUED

8/12/2025

Guerlain Ulysse
Investigator
Signed By: GUERLAIN E.
UCYSSE-8
Date Signed: 08-12-2025
22:49:46

X

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

- Mfg. Date: (b)(4) Status: Dispatched
(b)(4) Tablets (b)(4) mg and (b)(4) mg (USA), Batch No. (b)(4)
- Mfg. Date: (b)(4) Status: Dispatched
(b)(4) Tablets (b)(4) mg and (b)(4) mg (USA), Batch No. (b)(4)
- Mfg. Date: (b)(4) Status: Dispatched
(b)(4) Tablets (b)(4) mg and (b)(4) mg (USA), Batch No. (b)(4)
- Mfg. Date: (b)(4) Status: Dispatched
(b)(4) Tablets (b)(4) mg and (b)(4) mg (USA), Batch No. (b)(4)

This is despite the following product changeover cleaning steps being sign-off as completed and verified after production of (b)(4) Batch No. (b)(4)



B) During the inspectional walkthrough on August 4th, 2025, visible (b)(4) product residue was observed on the (b)(4) upper and outer surfaces, corner surface of the empty capsule reservoir, and outer surface of the empty capsules reservoir within Capsule filling machine (ID: PD/CFM-03). PD/CFM-03 was last used to manufacture (b)(4) capsules USP (b)(4) mg, Batch No. (b)(4) on July 22, 2025, prior to Product Changeover (Type B) cleaning being completed on July 24, 2025. However, the following test results were reported after swab sampling performed as per the current inspection request for the same equipment on August 4th, 2025:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

8/4/2025-8/12/2025*

FEI NUMBER

3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME

Cohance Lifesciences Limited

STREET ADDRESS

A - 23a & A - 23b, C Lakshmi Plastics;
Ida Nacharam No 18 Road; Road No 18 - Ida
Nacharam

CITY, STATE, ZIP CODE, COUNTRY

Secunderabad, Telangana, 500076 India

TYPE ESTABLISHMENT INSPECTED

Finished Drug Product Manufacturer

(b) (4)

This is despite the following product changeover cleaning steps being sign-off as completed and verified:

(b) (4)

C) On August 08, 2025, the following poor equipment conditions were observed for Compression Machine PD/TCM-03 located in Production Block (b) (4) and routinely used to compressed tablets for the U.S market:

- (b) (4) stains and spots observed on the (b) (4) and (b) (4)
- Visible dents on the (b) (4) of the (b) (4)
- Damaged/chipping (b) (4) parts for the (b) (4) In addition, (b) (4) (b) (4) stains were observed across the (b) (4)
- A shiny metal particle found on the (b) (4) of the compression machine.

The equipment was lasted to manufacture (b) (4) Tablets USP (b) (4) mg, Batch No. (b) (4)

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Guerlain Ulysse, Investigator

DATE ISSUED

8/12/2025

Guerlain Ulysse
Investigator
Signed By: GUERLAIN E.
UCYSSE-6
Date Signed: 08-12-2025
22:49:46

X

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

intended for the U.S market.

D) During my inspection walkthrough on August 04, 2025, I observed what appeared to be very visible inner stress cracks and scratches within the product-contact view glass of (b) (4) PD (b) (4) 01 bowl. PD (b) (4) 01 is routinely used for (b) (4) operations, (b) (4) for drug products distributed to the U.S and other global markets, including: (b) (4) Tablets (b) (4) and (b) (4) mg last manufactured on May 9th, 2025. There has been no incident report raised or maintenance check conducted for this matter until the current inspection.

E) During my inspection walkthrough on August 06, 2025, two visible large cracks was observed within the (b) (4) directly above the tablet and capsule (b) (4) of Tablets/Capsule Counting Machine ID: PD/TCC-03. According to the Packaging Supervisor, the cracks had recently occurred. However, there is no documentation of this incident, timeline of the occurrence, or maintenance check conducted for this matter until the current inspection.

OBSERVATION 5

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A) Your firm's cleaning validation revised Protocol No. ECV/VP/008-05, MACO Establishment Protocol, Effective Date: January 25, 2019, established (b) (4) (Total Score: (b) (4) as the worst-case product to the conduct cleaning validation study for all non-dedicated equipment product contact surfaces used to product U.S and non-U.S marketed

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

finished drug products. This was based on a total score and assessment done for toxicity, solubility and hardest to clean considerations. However, there is no documented scientific justification as to why (b) (4) tablets (Total Score: (b) (4)) was instead selected to perform the cleaning validation study and 2023 recleaning validation study for all equipment product contact surfaces, given the following total scores reported in the protocol as per the table below:

Total score based on Toxicity, Solubility, and Hardest to clean considerations:



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	<small>Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-8 Date Signed: 09-12-2025 22:49:46</small> X _____	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
		FEI NUMBER 3008768274
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations		
FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam	
CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer	

During the inspection, the Assistant General Manager of Quality Assurance (QA) stated that (b)(4) tablets, Total Score: (b)(4) was mistakenly chosen instead of the actual previously identified hardest-to-clean product (b)(4) Total Score: (b)(4) to conduct the cleaning validation study due to (b)(4) having the lowest maximum carry-over (MACO) limit.

B) Since the 2018 cleaning validation, there has been no further evaluation and cleaning validation study for more than (b)(4) newly introduced finished drug products to assess overall toxicity, Solubility, and Hardest to clean considerations for shared non-dedicated equipment surfaces, including: (b)(4)

In addition, your firm has performed a single cleaning verification study for certain finished drug products dating back to 2015, without any written justification on the frequency, timeline, drug product selection, and selection of only some hardest-to-clean areas for swab analysis versus all hardest-to-clean areas reviewed during visual inspection.

C) There is no documented scientific rationale and quality risk assessment for having one cleaning validation study representative for all finished drug product profiles. The 2018 cleaning validation study protocol and report did not assess the differences in physical properties and manufacturing processes for various types of drug products, including: capsules (b)(4) (b)(4) and compressed tablets (b)(4) Tablets was instead selected as the sole drug product to conduct the cleaning validation study.

D) SOP PD291-01, Operation and Cleaning of Tablet Compression Machine, Effective Date: March 13, 2025, instructs operators to solely use (b)(4) and a (b)(4) cloth for cleaning surfaces of the (b)(4) and table compression machine surface. However, (b)(4) was not assessed as part of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

the original cleaning validation study and sampling plan. Only (b) (4) was evaluated for (b) (4) residue for all surfaces. According to the Production Manager, the firm has decided to use (b) (4) as part of their routine cleaning operations instead of (b) (4) to prevent rusting of equipment surfaces. He stated the (b) (4) was not evaluated as part of the cleaning validation program due to an oversight.

E) During my inspection walkthrough on August 04, 2025, I observed an unidentified (b) (4) bowl stored within Module (b) (4) area, Production Block (b) (4) last used to manufacture (b) (4) tablets (b) (4) mg, (b) (4) mg, and (b) (4) mg, Batch No. (b) (4). According to the Production Manager, the (b) (4) bowl is not used in the production of (b) (4) and is instead used as part of the (b) (4) Equipment ID: PD (b) (4) -04. (b) (4) Equipment ID: PD (b) (4) 04 was last documented as being used in (b) (4) area (b) (4) for manufacturing operations involving (b) (4) Tablets, USP (b) (4) mg, (b) (4) mg, and (b) (4) mg, Batch No. (b) (4) on July 27, 2025. However, the Production Manager and Senior General Manager of Operations, was unable to explain and provided documentation for why, how, and when the (b) (4) was placed in the different drug production area for a different product.

F) On August 06, 2025, (b) (4) ID: PD (b) (4) 1 was observed to be unplugged/ disconnected and stationed on the production floor with other equipment parts. According to General Manager (GM) of QA, the (b) (4) is disconnected after batch production involving (b) (4) tablets USP (b) (4) mg, (b) (4) mg, and (b) (4) mg. (b) (4) ID: PD (b) (4) 1 was last used on June 12, 2025, for Batch No. (b) (4). It was also previously used on May 31, 2025, to produce Batch No. (b) (4). The batch record instructions require the operator to maintain the (b) (4) at a (b) (4) between (b) (4) (b) (4). However, there is no procedure to verify the functionality of the (b) (4) after reconnection and before usage for batch production operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSSE-8 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

LABORATORY CONTROLS SYSTEM

OBSERVATION 6

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established.

Specifically,

A) The (b) (4) analytical method for (b) (4) Tablets USP (b) (4) mg, (b) (4) mg, (b) (4) mg, (b) (4) mg, and (b) (4) mg, which is routinely used for in-process testing, has not been evaluated for accuracy, sensitivity, specificity and reproducibility according to the Assistant General Manager of QA. This includes that lack of evaluation for the (b) (4) sample preparation procedure and suitability of sample mass differences. For example:

(b) (4) testing protocol for (b) (4) Tablets USP (b) (4) mg, (b) (4) mg, (b) (4) mg and (b) (4) mg /In-process instructs Quality Assurance (QA) personnel to collect (b) (4) of the finished product individual dosage form. For (b) (4) Tablets USP (b) (4) mg, (b) (4) Batch No. (b) (4) this equates to a sample size quantity specification of: (b) (4) mg to (b) (4) mg. According to the Assistant QA Manager, there is no study available for establishing the lower and higher range of the sample size allowed to be taken by QA for (b) (4) testing. In addition, the following out-of-specification (OOS) results were reported since June 2021 and were attributed to probable sampling errors:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

Unique Identifier	Batch Number	Product Name and Strength	Date opened	Date closed	Detailed Reason	Category
OOS/QC/23/010	(b) (4)	(b) (4) Tablets USP (b) (4) mg, (b) (4) mg, (b) (4) mg, (b) (4) mg and (b) (4) mg / Inprocess	(b) (4)	(b) (4)	No assignable cause was identified. Probable root cause: Error during (b) (4) weighing of sample vials.	Valid
OOS/QC/22/018	(b) (4)	(b) (4) tablets USP (b) (4) mg, (b) (4) and (b) (4) mg / Inprocess	(b) (4)	(b) (4)	No root cause was identified. Probable root cause: improper makeup volume of during sample solution preparation	Invalid
OOS/IP/21/033	(b) (4)	(b) (4) Tablets USP (b) (4) mg, (b) (4) mg, (b) (4) mg, (b) (4) mg &	(b) (4)	(b) (4)	No root cause was identified. Probable	Valid

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-6 Date Signed: 09-12-2025 22:49:46 X	DATE ISSUED 8/12/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 8/4/2025-8/12/2025*
	FEI NUMBER 3008768274

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanagala Sudhakar Reddy, Senior General Manager of Operations

FIRM NAME Cohance Lifesciences Limited	STREET ADDRESS A - 23a & A - 23b, C Lakshmi Plastics; Ida Nacharam No 18 Road; Road No 18 - Ida Nacharam
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Secunderabad, Telangana, 500076 India	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer
-------------------------------------------------------------------------	--------------------------------------------------------------------

		(b) (4) mg / Inprocess			root cause: Sampling error i.e human inaccuracy in sampling.	
--	--	---------------------------	--	--	-----------------------------------------------------------------------------	--

B) The (b) (4) analytical test method for (b) (4) Tablets USP (b) (4) mg, (b) (4) mg, (b) (4) mg and (b) (4) mg has not been evaluated for robustness despite differences in assay sample preparation steps for release and stability testing versus (b) (4) testing.

***DATES OF INSPECTION**
8/04/2025(Mon), 8/05/2025(Tue), 8/06/2025(Wed), 8/07/2025(Thu), 8/08/2025(Fri), 8/11/2025(Mon), 8/12/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Guerlain Ulysse, Investigator	Guerlain Ulysse Investigator Signed By: GUERLAIN E. UCYSSE-E Date Signed: 08-12-2025 22:49:46 X	DATE ISSUED 8/12/2025