

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov		01/19-27/2026*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER	
Ms. Vesna Kapelj, Chief Technical Operations Officer		3004497364	
FIRM NAME	STREET ADDRESS		
Centrient Pharmaceuticals India Private Limited	Bhai Mohan Singh Nagar,		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Toansa, Punjab 144 533 India	API 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

Failure to clean equipment and utensils to prevent contamination or carry-over of a material that would alter the quality of the intermediates and Active Pharmaceutical Ingredient beyond the official or other established specifications.

Specifically,

The (b) (4) non-dedicated (b) (4) used at the (b) (4) stages of APIs manufacturing have not been appropriately cleaned since their installation 27+ years ago. For example,

A. On 19 and 20 January 2026, we observed thick build-up of (b) (4) materials of (b) (4) (b) (4) on the (b) (4) Ducts of (b) (4) IDs: (b) (4) (b) (4) located in your (b) (4) facility – Site (b) (4) These non-dedicated (b) (4) are used in the manufacturing of (b) (4) APIs. During the inspection, these (b) (4) were in use for (b) (4) manufacturing of (b) (4) since October 2025 with no batch-to-batch cleaning performed in between batches. These equipment were awaiting (b) (4) cleaning cycle of (b) (4)

On 20-Jan-2026, your firm collected swab samples to conduct protocol (GD.004426) based evaluation to determine the risk for the potential carryover and cross-contamination of APIs from the areas of (b) (4)

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Duct of (b) (4) and tested swabs for active and degradant materials by HPLC while the equipment was in (b) (4) manufacturing for (b) (4). The swab samples showed failing test results for most of the sampling locations as follows:

Table 1

(b) (4)

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01/27/2026

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Note: The above swab sample results are indicative of only approximately 5% of the actual results considering the swab stick could not adsorb/retain large amount of (b) (4) materials that was present on the (b) (4) surface area that was swabbed for each swab sample.

In addition to (b) (4) API peaks, the swab samples showed numerous unknown peaks randomly eluting at different retention times in all swab samples tested by HPLC. These unknown peaks were not identified and accounted for in the above table. There is a potential that the unknown peaks could be degradants relating to (b) (4) APIs.

On 20-Jan-2026, your firm collected most of the (b) (4) materials from (b) (4) duct of (b) (4) post collection of the swab samples. The reported quantities collected were (b) (4). These significantly large amount of (b) (4) materials were present in the (b) (4) bowl which may potentially cause cross-contamination between different drug substances that are (b) (4) using these non-dedicated (b) (4).

B. Procedures used in the collection and analyses of swab samples are deficient. For example,

1. Your procedure for equipment cleaning is deficient in that there is no requirement for Batch-to-Batch cleaning. On 20-Jan-2026, we observed thick deposition of (b) (4) material throughout (b) (4) IDs: (b) (4). According to section (b) (4) of your cleaning procedure SOP.003095 (b) (4) cleaning of equipment is performed at the frequency of (b) (4) for (b) (4) (b) (4) API. However, your firm changed (b) (4) cleaning to (b) (4) while no Batch-to-Batch cleaning is performed. There was no justification provided for extending the duration of (b) (4) cleaning.

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2. Your STP (AM.001019) is deficient in that there is no mention of swab blank solution preparation. In the absence of swab blank solution preparation procedure, your QC Analysts were testing swab diluent which does not include new swab stick which is treated similar to swab sample test solution preparation.

3. Your equipment cleaning validation (SOP.000300) and test (AM.001019) procedures does not specify the type of swab stick that should be used for the collection and testing of swab samples. On 20-Jan-2025, your production operator collected swab samples for chemical analyses using sterile cotton swab stick. This swab stick was unable to absorb (b) (4) material due to narrow tip. Additionally, your production operator swabbed by holding a swab stick in perpendicular position which exposed minimum area of the swab tip causing least adsorption of residual materials on swab stick. Moreover, your operator was leaving a wide gap while swabbing in vertical and horizontal directions leaving some areas not swabbed. There is a potential that the results reported in Table 1 could be several times higher than the reported causing cross-contamination and risk to the product quality and patient health.

C. On 20-Jan-2026, during the walkthrough inspection of your manufacturing facility, Site (b) (4), I observed that the equipment is not properly cleaned, even though the status indicated that it was cleaned and ready to use. The following are the examples, but the deficiencies are not limited to:

- i. I observed visible (b) (4) residues on the surface of the (b) (4) of a cleaned (b) (4), ID # (b) (4) 308, which is used in the manufacturing of (b) (4) API, indicating inadequate cleaning procedures that create substantial risk for cross-contamination or carry over. According to the logbook and the cleaning records, (b) (4) was completed on 18-Jan-2026; however, the presence of visible residues demonstrated that the cleaning procedure was ineffective in achieving the required cleanliness for pharmaceutical manufacturing equipment used in multi-product operations. The previous product manufactured

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on the (b) (4) was (b) (4) product (b) (4). Upon request, your firm conducted a swab analysis and reported the presence of (b) (4) API, confirming that cleaning procedures failed to adequately remove residual product from the equipment surfaces. The last batch of (b) (4) API was manufactured on 06-Oct-2025. Following this, your firm conducted (b) (4) cycles on (b) (4).

- ii. I observed (b) (4) residual material inside a cleaned (b) (4), ID #301, which is used in the manufacturing of (b) (4) API, indicating inadequate cleaning procedures that create substantial risk for cross-contamination or carryover. According to the logbook and the cleaning records, (b) (4) was completed on 19-Jan-2026, and the equipment was marked as ready to use. However, the presence of visible residues demonstrated that the cleaning procedure was ineffective in achieving the required cleanliness for pharmaceutical manufacturing equipment used in multi-product operations. The previous product manufactured in the (b) (4) was a (b) (4) product, (b) (4). Upon request, your firm collected samples from the (b) (4). The approximate weight of the residual material was (b) (4). IR spectrophotometric analysis revealed the presence of (b) (4) API. HPLC analysis also confirmed the presence of (b) (4). The last batch of (b) (4) was manufactured on 07-Oct-2025. Following this, your firm conducted (b) (4) cycles on (b) (4). The presence of (b) (4) API confirmed that cleaning procedures failed to adequately remove residual product from the equipment surfaces.

OBSERVATION 2

Failure of production operations to prevent contamination of intermediate and API by other materials.

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Specifically,

A. Your firm utilizes (b) (4) 101, for the manufacturing of (b) (4) (b) (4). During the walkthrough inspection on 19-Jan-2026, we observed several floating foreign materials that appeared to be (b) (4) pieces inside the (b) (4). At the time of my observation, (b) (4) 101 contained (b) (4) in (b) (4) water ready for the next batch, with visible (b) (4) contamination present in the manufacturing environment. Further review of the manufacturing process confirmed that these (b) (4) pieces originate from the (b) (4) bags holding (b) (4) (b) (4) during the (b) (4) process into (b) (4) 101. According to the firm, the last time the (b) (4) were changed was on 4-Oct-2025, and your firm has manufactured approximately (b) (4) batches since then, indicating that this (b) (4) contamination issue has potentially affected (b) (4) of (b) (4) batches without proper identification or corrective action to address the contamination source. The (b) (4) during the manufacturing process utilizes only (b) (4), which may be inadequate to remove all (b) (4) particles depending on their size distribution, creating substantial risk that (b) (4) contamination could pass through the (b) (4) system and be incorporated into the finished (b) (4) API.

B. During the walkthrough inspection of Site (b) (4) I observed that the (b) (4) ID # (b) (4) 302, used in the manufacture of (b) (4) API, was found to contain numerous scratches due to mechanical wear and tear in the product contact areas. Upon request, the (b) (4) was operated for approximately two (2) minutes, during which (b) (4) particles were visibly generated within the equipment, demonstrating active contamination of the manufacturing environment with (b) (4) debris that could be incorporated into the API during processing operations. I observed the same condition, visible scratches on the inner surface of (b) (4) ID # (b) (4) 301. This condition demonstrates inadequate preventive maintenance and poses a risk of (b) (4) contamination to the API. The use of equipment in

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this degraded state may adversely affect the quality of the drug substance. On 27-Jan-2026, your firm informed us that approximately (b) (4) had been shaved off from the inner surface of the (b) (4) ID # (b) (4) 302 based on the preliminary investigation.

OBSERVATION 3

Failure to have the procedures and processes necessary to ensure the API and intermediates manufactured at your facility meet established specifications for quality and purity.

Specifically,

Your firm's procedure *SOP No. 001480: SOP for Environmental Monitoring of (b) (4) Content, Revision No. 12, Effective Date: 07/09/2025*, is deficient. Your firm failed to monitor critical entry points; outside/exterior door handles from the external environment into the manufacturing facilities.

(This is repeat observation from June-July 2022 inspection)

***DATES OF INSPECTION**

01/19/2026(Mon), 01/20/2026(Tue), 01/21/2026(Wed), 01/22/2026(Thu), 01/23/2026(Fri), 01/27/2026(Mon)

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